Resource Utilization and Costs of Care for Treatment of Chronic Headache

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Structured Abstract

Objective. To identify and summarize evidence from empirical studies relating to the cost of care and the economic impact of chronic headache.

Search strategy. We used a strategy combining the MeSH term "headache" (exploded) with terms and text words pertaining to cost and resource utilization to search the MEDLINE, HealthStar, and CINAHL databases for relevant studies published between January 1966 and December 1996. Other computerized bibliographic databases, textbooks, and experts were also utilized.

Selection criteria. We considered full reports of original empirical research, published in English, which concerned an adult (non-pediatric) subject population suffering from primary headache (i.e., not traumatic, post-lumbar puncture, or other secondary headaches), reported data relevant to the economic impact of chronic headache on medical resource utilization or work loss, and met minimal methodological criteria related to the validity of cost or utilization measures.

Data collection and analysis. From studies of patients with primary headache, data were collected on: rates and predictors of headache-related and total health care provider consultation, emergency department utilization, hospitalization, prescription and non-prescription drug use, and work loss and disability. Data were annualized when necessary to make results of different studies more comparable.

Main results. Of over 400 citations identified, 126 appeared to meet screening criteria, and 35 met all criteria and were included in this review. While between 56% and 91% of chronic headache sufferers seek the care of a health care provider, only one-third report having received a diagnosis of their condition. While most patients with migraine consult a health care provider at some point, most do not continue to seek medical care. Relatively fewer patients with tension-type headache seek medical care. A small sub-population of chronic headache sufferers accounts for a high proportion of provider consultations, emergency department visits, and prescription drug claims. The vast majority of headache sufferers have used drugs to treat their headaches at some time. Non-prescription drugs are used more often than prescription drugs. Patients with more severe headache symptoms are both more likely to consult a health care provider about their headaches and more likely to use prescription medications. Use of prescription drugs for headache increases with age and is higher among women than men. About two-thirds of patients who try prescription medications do not continue to use them, citing the availability of effective non-prescription drugs, unwanted side-effects, and inadequate relief among the reasons for discontinuing prescription drug use. Rates of absenteeism due to headache of 2 to 4.3 days per year were reported in employee and community studies, while higher rates, ranging from 14.3 to 61 days per year, were observed in two studies conducted in clinical settings. These average

figures obscure the fact that while many to most patients miss no days of work or school, a relatively small proportion of subjects accounts for many missed days. While headache does cause a large number of absences from work, it appears that many headache sufferers stay on the job, functioning with significantly reduced effectiveness, when they have a headache.

Conclusions. Chronic headache sufferers represent a diverse population which is difficult to study. Population-based studies suggest that many headache sufferers do not seek medical care for their headaches and do not use prescription drugs to treat them. Studies conducted among headache patients in clinical settings suggest that these patients have more severe headache symptoms, use more prescriptions drugs, and are heavier users of medical resources. Data from both types of studies must be considered if the comprehensive cost of chronic headache is to be estimated.

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Resource Utilization and Costs of Care for Treatment of Chronic Headache

Summary

Overview

Reliable, comprehensive, and generalizable information on the cost of headache has multiple important uses: for gauging the overall economic burden of headache in comparison with other problems; for use in cost-effectiveness analyses of preventive and therapeutic interventions; and for informing the development of clinical practice guidelines. Unfortunately, chronic pain syndromes such as headache are difficult to quantify in economic terms. Even with recent advances in the classification of headache syndromes, patients with chronic headaches remain difficult to diagnose, and data on the prevalence of the various types of headache are still lacking. Economic analysis of chronic headache is further complicated by the fact that many sufferers treat their headaches with over-the-counter medications and do not seek medical care.

For this report we surveyed the published literature on the cost of headache and summarized the key findings from papers reporting primary data that appeared to be both relevant and of adequate quality. Our intent was to address this key question: What are the direct medical and non-medical costs, as well as the indirect costs, associated with chronic headache care? For the purposes of this report, "chronic headache" includes migraine, tension-type headache, cluster headache, and mixed migraine and tension-type headache.

Methodology

This review is based on a comprehensive search of the literature involving multiple, parallel strategies. The primary strategy involved a computerized search of the MEDLINE, HealthStar, and CINAHL databases for relevant studies published between January 1966 and December 1996, using a strategy combining the MeSH term "headache" (exploded) with terms and text words pertaining to cost and utilization. Other computerized bibliographic searches and databases, review articles textbooks, and experts were also utilized.

A total of 400 citations were identified from the primary search, and 24 citations were identified from other sources. These citations were then screened and included for further review if they were:

(1) Published in English;

(2) Full reports of original research (i.e., *not* a letter, editorial, case report, review, or abstract);

(3) About an adult (non-pediatric) subject population; and

(4) About a subject population suffering from primary headache (i.e., not traumatic, post-lumbar puncture, or other secondary headaches).

Of the 424 citations screened according to the above criteria, 127 (30%) were included for further review. We were not able to obtain a copy of one of these articles. The remaining 126 were read in full and subjected to an additional review of their content and methods. In order to be included at this stage, articles were required to:

(1) Meet the above screening criteria;

(2) Contain material relevant to the economic impact of chronic headache on medical resource utilization or work loss;

(3) Meet minimal methodological criteria related to the validity of cost or utilization measures.

Thirty-five of the 126 articles reviewed met these criteria. Data from the included articles were abstracted onto specially designed data collection forms.

The studies reviewed in this report used a variety of methods for gathering cost and utilization data. In some cases, epidemiological methods were used to assess utilization in a defined population. Other studies used before-after measures to determine the impact of an intervention on utilization or cost outcomes. While there have been numerous methodological standards published for evaluating the quality of cost-effectiveness or other economic analyses of clinical practices, we were not able to identify any widely accepted or particularly useful scales for grading the broad variety of studies included in this report; thus, we did not formally grade the quality of the evidence provided by the studies. We have, however, commented on the quality of this evidence in the text of the report and have also attempted to describe the potential biases of individual studies and the direction of these biases.

Findings

Utilization of Health Care Resources

Health Care Provider Consultation

Among people with migraine headache, health care provider consultation rates ranged between 56%-91% in eight studies. Consultation rates for tension-type headache were generally lower, ranging from 16% to 71%.

The severity of headache appears to play a role in health care provider consultation; patients with more severe attacks are more likely to seek care from a provider, while patients who have never consulted a physician about their headaches report that their symptoms are not severe enough to warrant such a consultation and/or that they are able to treat their headaches satisfactorily with non-prescription medications.

Chronic headache sufferers who seek medical advice do not necessarily continue to consult a health care provider. In one interview survey, of 81% of migraine sufferers who had sought care at any time previously, only 36% were receiving care at the time of the survey; similarly, of the 71% of tension-type headache sufferers who had ever sought care, only 28% were still receiving care. Some respondents listed as their primary reasons for not continuing care the availability of non-prescription medications and the fact that they were not having headaches of sufficient frequency or severity to warrant continuing in care. More than 50%, however, said that they did not return because they were unhappy with their health care providers or had experienced negative side-effects with their medications.

As a group, patients with migraine have higher rates of health care provider consultation than does the general population. Furthermore, among migraineurs, a small number of patients have particularly high consultation rates. In one study, most migraineurs averaged 1-4 physician visits per year, while 7.6% of the subjects made more than 12 visits per year to primary care and specialty physicians for the care of their headaches.

Predictors of Receiving a Headache Diagnosis

Community-based studies suggest that a large number of people who satisfy widely accepted diagnostic criteria for migraine or tension-type headache never receive a diagnosis of their condition from a physician. Predictors associated with receiving a physician diagnosis of migraine include household income, sex, and older age. Among patients found to meet the International

Headache Society (IHS) criteria for migraine, a physician diagnosis is more likely for persons whose household incomes are higher and for women.

Use of the Emergency Department (ED) for the Treatment of Migraine

Studies providing data on the use of the ED for the treatment of chronic headache show wide variation in ED utilization. While one study reported that a high percentage (48%) of migraine patients surveyed had visited the emergency department for treatment of an acute attack of migraine in the previous 12 months, other studies reviewed reported lower rates of ED use, ranging from 3% to 20% of migraineurs over periods of time ranging from 6 months to lifetime.

Prescription drug users had the highest lifetime rates of ED utilization (33% for men and 27% for women), and non-prescription drug users the lowest (one-third of the prescription drug user rates). Those migraineurs using no medications reported intermediate rates of ED utilization (20% for men and 15% for women). The investigators were not able to identify whether the high rate of ED use among prescription drug users was due to the severity of the subjects' headaches, medication failure, or side-effects associated with their medication.

A substantial proportion of migraineurs present to the ED without having taken medication to treat their headaches. Medication failure is noted by another large proportion.

Hospitalization

Between 6% and 11% of patients with migraine reported being hospitalized for treatment of their headaches at some point in their lifetime. Migraineurs have overall hospitalization rates nearly twice as high as those in a non-migraine comparison group.

Pharmaceutical Use

The discussion below focuses on the types of medications used by headache sufferers and the patterns with which they are used, rather than on summary measures of the economic cost of pharmaceutical use. Data on the average wholesale price of drugs are readily available from other sources.

Chronic headache sufferers have several options for the pharmacological treatment of their headaches: prescription versus non-prescription treatment and treatment for prevention versus treatment for the relief of acute episodes. Almost all headache sufferers report having used some sort of pharmaceutical agent to treat their headaches at some time. Overall rates of medication use are reported to be near 95%.

Prescription vs. Non-Prescription Drug Use

All the studies reviewed showed that non-prescription drugs are used more often than prescription drugs. Several clinical factors seem to be related to the use or non-use of prescription medications. Among patients with severe headache, those with migraine are more likely to use prescription drugs. Patients with higher headache-related disability, more frequent attacks, headache associated with vomiting, and migraine with aura were all more likely to use prescription medications. Use of prescription drugs increases with age and is higher among women than men; however, it is not related to income level or insurance coverage.

Black migraineurs had a much lower rate of prescription drug use than whites; however, blacks had a slightly higher rate of non-prescription drug use than whites.

In addition, it appears that about two-thirds of patients who try prescription medications do not continue to use them, citing the availability of effective non-prescription drugs, unwanted side-effects, and inadequate relief among reasons for discontinuing prescription drugs.

Use of Preventive Medications

Patients with recurrent headache may be treated with acute or preventive medication or with some combination of the two. It appears from four studies, however, that preventive drug treatments are used by only 3%-13% of migraineurs.

Frequency of Medication Use for Treatment of Acute Headache

Patterns of use of medication for acute headache episodes vary widely from patient to patient. In several studies, a small minority of headache sufferers were particularly heavy users. Factors associated with heavy use included increasing age and higher frequency of headaches.

Effect of Sumatriptan on Drug and Health Care Resources Utilization

Medication use can have an impact on other health service utilization. Two studies found similar decreases in health care provider (physician and emergency department) utilization in migraineurs after the introduction of the anti-migraine drug sumatriptan. Pharmaceutical costs were increased significantly in one study, but not available in the other. The routine use of sumatriptan in clinical practice may have a significant impact on practice patterns and the utilization of health care resources, but the precise nature and magnitude of this impact are as yet uncertain.

Non-Pharmacological Therapy

Several studies have attempted to estimate the economic impact of behavioral therapy for chronic headache. One study described a very large reduction in self-reported medical costs among patients undergoing relaxation and biofeedback training. Costs considered included medication, visits to family physicians and neurologists, hospital costs, and costs for alternative treatments such as acupuncture and chiropractic. Other studies have described the duration of patient-therapist contact as a proxy for costs in comparisons of home- versus clinic-based training in relaxation and biofeedback or relaxation and/or cognitive therapy. Because no differences have been observed in the efficacy of the less intensive (and less costly) home-based training and more traditional office-based treatment, researchers have concluded that the home-based treatments may be more cost-effective.

Work Loss

Unlike the costs described in previous sections which result in direct expenditures, work loss due to headache is an indirect cost. A dollar figure for lost productivity can be estimated from rates of absenteeism or reduced effectiveness.

Studies describing rates of absenteeism have been conducted in the workplace, community, and clinical settings. Rates of absenteeism due to headache of 2 to 4.3 days per year were reported in employee and community studies, while higher rates, ranging from 14.3 to 61 days per year, were observed in two studies conducted in clinical settings. These average figures obscure the fact that while many to most patients miss no days of work or school, a relatively small proportion of subjects accounts for many missed days.

While headache does cause a large number of absences from work, it appears that many headache sufferers stay on the job, functioning with significantly reduced effectiveness, when they have a headache. Most subjects reported a slight to moderate effect of migraine on their work; men and women experience similar reductions in effectiveness with their headaches. Studies have found no differences in the frequency of missed work days by race, but black women and men were less likely to report reduced efficiency at work than either whites or Asian-Americans.

There have been few efforts to estimate the economic impact of this lost productivity. The cost of errors or inaccuracies in work performed during a headache attack may never be known.

Future Research

Most studies of the cost of care for headache, and of the clinical management of headache, pertain to migraine; the costs of tension-type, cluster, and other chronic primary headache disorders remain to be estimated. Low rates of recognition and diagnosis of chronic headache conditions and the large proportion of chronic headache sufferers who receive no treatment or who self-treat with over-the-counter medications make it difficult to estimate the scope of chronic headache in economic or human terms. Epidemiological data collection methods have identified and begun to quantify this problem. In clinical and administrative data, ascertainment of chronic headache is also difficult, as there is evidence of under-diagnosis, and, furthermore, administrative coding methods do not correspond with current headache disease classification systems. Until these and other problems can be resolved, it will remain difficult to estimate the aggregate economic burden of headache or to estimate the costs of headache for cost-effectiveness analysis or cost-benefit analysis.

Large gaps exist in the literature. We do not, for example, know the average number of health care provider visits it takes to reach a diagnosis of chronic headache, how many and what kinds of tests are performed to make a diagnosis, what kinds of treatment options patients are offered, or how many medications are tried before relief is obtained or the patient gives up treatment. We need to better understand why patients with chronic headache are admitted to the hospital and what is done for them while they are there. We also do not know all there is to know about the impact of chronic headache on work—whether chronic headache prevents people from obtaining or retaining jobs or has an effect on their ability to advance in their job. We must also determine from whose perspective the economic impact of headache should be viewed. Insurers, for example, may not have an interest in work loss or absenteeism. Employers may be concerned about medical costs and work loss but not the impact on family life or social role functioning.

Finally, several studies have documented the magnitude of work loss and reduced productivity due to headache. While the mean number of days absent from work annually appears to vary roughly from about 2 to 14 for chronic headache sufferers, there has been little systematic effort to translate these missed days into corresponding estimates of economic loss from either the societal or individual perspective. Also requiring much more study is the impact on productivity of headaches that impair worker performance, but do not lead to work loss days.

We find that each paper reviewed here provides some useful information about the economic cost of headache. But no study attempts to estimate the *total* cost for a nationally representative population of sufferers. To produce reliable, comprehensive, and generalizable estimates of the economic cost of headache, good quality resource utilization information from multiple, complementary data sources almost certainly will be required. An analytical framework for identifying the required data elements and carrying out the calculations can be built around standard economic models of disease cost.

Technical Review

Introduction

Calculating the costs of chronic diseases poses many difficulties for the health services researcher. Individuals with diseases such as diabetes, hypertension, or lung disease often have comorbid conditions which require treatment and which produce costs of care that are hard to distinguish from the costs associated with the main condition in question. Chronic pain syndromes such as headache and low back pain are even more difficult to quantify in economic terms. Even with recent advances in the classification of headache syndromes, patients with chronic headaches remain difficult to diagnose, and data on the prevalence of the various types of headache are still lacking. Economic analysis of chronic headache is made more difficult by the fact that many sufferers treat their headaches with over-the-counter medications and do not seek medical care.

For the purposes of this report, "chronic headache" includes migraine, tension-type headache, cluster headache, and mixed migraine and tension-type headache. Most studies of the cost of care for headache, and of the clinical management of headache, pertain to migraine. This may be due, in part, to the investment of pharmaceutical companies in drugs to treat migraine, which is a relatively well-defined and prevalent headache syndrome.

Ideally, an analysis of the cost of headache would include direct medical and non-medical expenses, as well as indirect costs. Our search of the literature yielded information on rates of health care provider consultation, hospitalization, and use of the emergency department services. We also found some data on pharmaceutical use and the cost-effectiveness of non-pharmacological treatments. In addition, there is a small body of literature on work loss and absenteeism due to headache.

However, large gaps exist in the literature. We do not, for example, know the average number of health care provider visits it takes to reach a diagnosis of chronic headache, how many and what kinds of tests are performed to make a diagnosis, what kinds of treatment options patients are offered, or how many medications are tried before relief is obtained or the patient gives up treatment. We need to better understand why patients with chronic headache are admitted to the hospital and what is done for them while they are there. We also do not know all there is to know about the impact of chronic headache on work—whether chronic headache prevents people from obtaining or retaining jobs or has an effect on their ability to advance in their job. We must also determine from whose perspective the economic impact of headache should be viewed. Insurers, for example, may not have an interest in work loss or absenteeism. Employers may be concerned about medical costs and work loss but not the impact on family life or social role functioning.

Until these and other questions can be answered, it will remain difficult to estimate the aggregate economic burden of headache or to estimate the costs of headache for cost-effectiveness analysis or cost-benefit analysis. In the closing section of this report, we present a more detailed discussion of the information and analytical strategies required for a more comprehensive analysis of the cost of headache.

We have chosen not to review papers on the prevalence of chronic headache, as good summaries of this literature have already been

published (Kroenke and Mangelsdorff, 1989; Linet, Celentano, and Stewart, 1991; Lipton, Stewart, Celentano, et al., 1992; Stang, Sternfeld, and Sidney, 1996; Stewart, Lipton and Liberman, 1996; Winnem, 1992).

Methodology

This review is based on a comprehensive search of the literature involving multiple, parallel strategies. The primary strategy involved computerized searches of the MEDLINE, HealthStar, and CINAHL databases for relevant studies published between January 1966 and December 1996. The original search strategy (Appendix A) was designed to identify articles relating to the cost of care and the economic impact of chronic headache. We initially ran this search to capture articles published through December 1996 and entered into MEDLINE, HealthStar, or CINAHL before the end of January 1997. We later extended this search to identify articles that had been published before the end of 1996, but entered into the databases *after* January 1997. We also revised the original search by including the MeSH terms "drug utilization" and "drug utilization review" and the "utilization" subheading (used as a floating subheading) (Appendix B).

As part of the overall evidence report project, separate computerized searches of MEDLINE were performed to identify studies concerning the diagnosis and treatment of chronic headache and review articles on these topics, and reviewers of all this literature were instructed to be vigilant for studies appropriate for this report. We also reviewed a Cochrane Collaboration database of pain trials for relevant literature. Finally, a small number of papers were identified through a formal process of reviewing the reference sections of relevant articles (reviews and original research reports) and through recommendations from experts and reviewers. A total of 424 citations were identified and screened. Table 1 provides a detailed breakdown of these citations by source.

The titles and abstracts of the 424 citations identified through these means were then screened. Articles were included for further review if they were:

(1) Published in English;

(2) Full reports of original research (i.e., *not* a letter, editorial, case report, review, or abstract);

(3) About an adult (non-pediatric) subject population; and

(4) About a subject population suffering from primary headache (i.e., not traumatic, post-lumbar puncture, or other secondary headaches).

Of the 424 citations screened according to the above criteria, 127 (30%) were included for further review. We were not able to obtain a copy of one of these articles (Cull, Wells, and Miocevich, 1992). The remaining 126 were read in full and subjected to an additional review of their content and methods. In order to be included at this stage, articles were required to:

(1) Meet the above screening criteria;

(2) Contain material relevant to the economic impact of chronic headache on medical resource utilization or work loss;

(3) Meet minimal methodological criteria related to the validity of cost or utilization measures.

Thirty-five of the 126 articles reviewed met these criteria. Reasons for excluding the remaining 91 articles are provided in Appendix C. Data from the included articles were abstracted onto specially designed data collection forms (Appendix D). Studies which addressed more than one measure of utilization were analyzed wherever applicable.

Table 1: Literature search yield broken down by source*

Source	Original cost search strategy	Original strategy, post-1/97 entry	Revised strategy (incorporating new terms)	Totals
Database:				
MEDLINE	247	17	76	340
HealthStar	30	5	6	41
CINAHL	6	0	13	19
Subtotal:				**400**
Other sources:				
Treatment search				11
Diagnostic search				4
Review article search				1
Cochrane database of pain trials				0
Other (peer reviewers, review article citations, etc.)				8
Subtotal:				**24**
Total:				**424**

* Totals given for each source exclude articles also identified through the sources listed above it or (in the case of the multiple searches of MEDLINE, HealthStar, and CINAHL) to the left of it in this table.

The studies reviewed in this report used a variety of methods for gathering cost and utilization data. In some cases, epidemiological methods were used to assess utilization in a defined population. Other studies used before-after measures to determine the impact of an intervention on utilization or cost outcomes. While there have been numerous methodological standards published for evaluating the quality of cost-effectiveness or other economic analyses of clinical practices (Drummond, Richardson, O'Brien, et al., 1997; Siegel, Weinstein, Russell, et al., 1996), we were not able to identify any widely accepted or particularly useful scales for grading the broad variety of studies included in this report; thus, we did not formally grade the quality of the evidence provided by the studies. We have, however, commented on the quality of this evidence in the text of the report and have also attempted to describe the potential biases of individual studies and the direction of these biases. In four cases, articles with major methodological flaws threatening the validity of the cost or utilization data reported were excluded from consideration; these cases are described in Appendix C.

Results

Utilization of Health Care Resources

Health Care Provider Consultation

A large percentage of people with chronic headache seek the advice of a health care provider at some point in their lives. Eight of the studies reviewed reported consultation rates which ranged between 56%-91% for migraine headache (Clouse and Osterhaus, 1994; Edmeads, Findlay, Tugwell, et al., 1993; Green, 1977; Linet, Stewart, Celentano, et al., 1989; Osterhaus, Gutterman, and Plachetka, 1992; Rasmussen, Jensen, and Olesen, 1992; Stang and Osterhaus, 1993; van Roijen, Essink-Bot, Koopmanschap, et al., 1995). Consultation rates for tension-type headache were generally lower, ranging from 16% to 71% (Edmeads, Findlay, Tugwell, et al., 1993; Rasmussen, Jensen, and Olesen, 1992). Health care provider consultation rates for all eight studies reviewed are provided in Table 2. The relevant studies are summarized in Evidence Table 1.

The severity of headache appears to play a role in health care provider consultation. Rasmussen, Jensen, and Olesen (1992) reported that patients with more severe attacks were more likely to seek care from a provider. Patients interviewed by Edmeads, Findlay, Tugwell, et al. (1993) who had never consulted a physician about their headaches stated that their symptoms were not severe enough to warrant such a consultation and/or that they were able to treat their headaches satisfactorily with non-prescription medications.

Chronic headache sufferers who seek medical advice do not necessarily continue to consult a health care provider. Edmeads, Findlay, Tugwell, et al. (1993) found in an interview survey that of the 81% of migraine sufferers who had sought care at any time previously, only 36% were receiving care at the time of the survey; similarly, of the 71% of tension-type headache sufferers who had ever sought care, only 28% were still receiving care. Some respondents listed as their primary reasons for not continuing care the availability of non-prescription medications and the fact that they were not having headaches of sufficient frequency or severity to warrant continuing in care. More than 50%, however, said that they did not return because they were unhappy with their health care providers or had experienced negative side-effects with their medications.

As a group, patients with migraine have higher rates of health care provider consultation than does the general population. Clouse and Osterhaus (1994) reported the results of a study in which a sample of 1,336 migraineurs were matched with a comparison group of 1,336 non-migraineurs for age, sex, duration of enrollment, and subscriber/ dependent status in a United Health Care Corporation-affiliated health plan. Migraineurs had much higher rates of resource utilization and costs in every category measured. In the 18-month study period, migraineurs made 2,616 migraine-related physician visits and 19,971 non-migraine-related physician visits; non-migraineurs made a total of 13,072 physician visits in the same time period.

Among migraineurs, a small number of patients have particularly high consultation rates. Osterhaus, Gutterman, and Plachetka (1992) reported that although most migraineurs in their study averaged 1-4 physician visits per year, 7.6% of the subjects made more than 12 visits per year to primary care and specialty physicians for the care of their headaches.

Predictors of Receiving a Headache Diagnosis

Community-based studies suggest that a large number of people who satisfy widely accepted diagnostic criteria for migraine or tension-type headache never receive a diagnosis of their condition from a physician. Celentano, Stewart, Lipton, et al. (1992) and Lipton and Stewart (1993) analyzed the results of a survey of the general U.S. population in which subjects were asked a series of questions, the answers to which would allow the researchers to classify the subjects' headaches according to the International Headache Society (IHS) criteria for migraine or chronic tension-type headache (Headache Classification Committee of the International Headache Society, 1988). Celentano, Stewart, Lipton, et al. (1992) reported that only 29.7% of males and 41.6% of females meeting the IHS criteria for migraine reported having received a diagnosis of migraine from a physician.

Table 2: Health care provider consultation rates for headache

Study	Setting	Headache type	Demographic group	Consultation rate*	Time period
Clouse and Osterhaus, 1994	managed care primary care	migraine	all	90%	18 mo
Osterhaus, Gutterman, and Plachetka, 1992	specialty clinic	migraine	all	91%	12 mo
Mounstephen and Harrison, 1995	employee	migraine	all	58%	lifetime
				19.4%	12 mo
Green, 1977	community	migraine	female	74%	lifetime
			male	66%	
Linet, Stewart, Celentano, et al., 1989	community	migraine	female	28%	lifetime
			male	15%	
Stang and Osterhaus, 1993	community	migraine	female	85%	lifetime
			male	77%	
Edmeads, Findlay, Tugwell, et al., 1993 (interview survey)	community	migraine	all	81%	lifetime
		tension-type	all	71%	
Edmeads, Findlay, Tugwell, et al., 1993 (prevalence study)	community	migraine	all	64%	lifetime
		tension-type	all	45%	
Rasmussen, Jensen, and Olesen, 1992	community	migraine	all	56%	lifetime
		tension-type	all	16%	
van Roijen, Essink-Bot, Koopmanschap, et al., 1995	community	migraine or migraine + tension-type	all	70%	lifetime

* Consultation rate is the percentage of symptomatic patients seeking the care of a primary care or specialist health care provider in an office-based practice, not in an emergency department or inpatient setting.

Lipton and Stewart (1993) examined predictors associated with receiving a physician diagnosis of migraine in this same group of patients. The strongest predictor of physician diagnosis was household income. Among patients found to meet the IHS criteria for migraine, a physician diagnosis was 40% more likely for persons whose household incomes were $45,000 or more per year than for persons in households with an average income of less than $10,000 per year. Another strong predictor of physician diagnosis was female sex. Women were 40% more likely than men to be diagnosed with migraine. Increasing age was also a factor.

Use of the Emergency Department (ED) for the Treatment of Migraine

Studies providing data on the use of the ED for the treatment of chronic headache are summarized in Evidence Table 2. One of these studies (Osterhaus, Gutterman, and Plachetka, 1992) reported that a high percentage (48%) of migraine patients surveyed had visited the emergency department for treatment of an acute attack of migraine in the previous 12 months. Furthermore, 15% of the study's subjects accounted for 60% of all emergency department visits. Patients for this study were recruited from a group of migraine patients who had previously participated in clinical trials of migraine medication. It is possible that this population suffers from more frequent and/or more severe headaches than do other migraineurs and, consequently, that they visit the ED more frequently. The other studies reviewed reported lower rates of ED use, ranging from 3%-20% of migraineurs over periods of time ranging from 6 months to lifetime (see Table 3).

One study (Celentano, Stewart, Lipton, et al., 1992) reported that the probability of ED use among migraineurs varied according to whether patients used prescription medication, non-prescription medication, or no medication. Prescription drug users had the highest lifetime rates of ED utilization (33% for men and 27% for women), and non-prescription drug users the lowest (one-third of the prescription drug user rates). Those migraineurs using no medications reported intermediate rates of ED utilization (20% for men and 15% for women). The investigators were not able to identify whether the high rate of ED use among prescription drug users was due to the severity of the subjects' headaches, medication failure, or side-effects associated with their medication.

The studies summarized in Table 3 all reported rates of ED use by migraineurs, but did not provide many details of how ED services were used. Two other studies provided slightly more information. Kaa, Carlson, and Osterhaus (1995) studied consecutive migraine patients presenting to the walk-in ED at the Group Health Cooperative Central Hospital in Seattle. Of 16,755 total patient visits to the ED, 323 (1.9%) were for migraine. These 323 visits were made by 152 patients; 36% of patients made repeat visits. Though the authors did not state the precise reasons these patients went to the ED for treatment of their headaches, they do report the most common symptoms given on presentation. Headache was reported by 98.8% of patients, nausea by 47.4%, photophobia by 31.6%, and vomiting by 28.2%. Most migraineurs (62.2%) had taken medication to treat their headaches before presenting at the ED (24%, over-the-counter analgesics; 19%, narcotic analgesics; 13%, ergots; and 12%, Midrin®). The median time spent in the ED was one hour, and no diagnostic tests were performed in 95% of visits. Most patients received meperidine injections with promethazine or hydroxyzine; antiemetics alone were given at 51.7% of visits; and antihistamines at 38.4% of visits. In 64% of ED visits for migraine, the encounter was completed with no arrangement for follow-up or referral; 34% of visits ended with instructions for the patient to follow-up

Table 3: Emergency department (ED) use for acute headache among migraineurs

Study	Setting	Headache type	Demographic group	Patients seen in ED (%)	Time period
Clouse and Osterhaus, 1994	managed care, primary care	migraine	all	18%	18 mo
Edmeads, Findlay, Tugwell, et al., 1993	community	migraine	all	14%	lifetime
Michel, Pariente, Duru, et al., 1996	community	migraine	all	5%	6 mo
Osterhaus, Gutterman, and Plachetka, 1992	specialty clinic	migraine	all	48%	12 mo
Celentano, Stewart, Lipton, et al., 1992	community	migraine	male	13%	lifetime
			female	20%	
Linet, Stewart, Celentano, et al., 1989	community	migraine	male	5%	12 mo
			female	3%	

with their primary care physician; at 2% of visits patients were referred to specialists; and one patient was admitted to the hospital.

Salomone, Thomas, Althoff, et al. (1994) reviewed the records of patients presenting to the ED at Truman Medical Center in Kansas City. Of 132,653 total ED visits, 2,540 (1.9%) were for headache, and of these, 13.3% were specifically for migraine. After verification of coding, the study population included 185 patients with 339 visits. Repeat visits were made by 39% of patients. Three or more visits were made by 21 patients, accounting for 42.5% of all visits. Only 1.5% of emergency department visits were described as being for "first" headache and 3.2% were for "worst" headache. Of the patients studied, 54.6% reported that they had not taken any medication before coming to the ED. Prophylactic medications were used by 17.3% of patients who made only one visit to the emergency department, 58.1% of those who made two visits, and 76.2% of those who made three or more visits. At 19 visits, patients reported that their medications had been ineffective, and at eight visits they reported that they had run out of medication. Medication was administered in the ED in 82.3% of visits and provided complete or considerable relief in 64.5% of those cases.

Hospitalization

Hospitalization rates were reported in five of the papers reviewed (Table 4; see also Evidence Table 3). Between 6% and 11% of patients with migraine reported hospitalization for treatment of their headaches at some point in their lifetime (Clouse and Osterhaus, 1994; Michel, Pariente, Duru, et al., 1996; Osterhaus, Gutterman, and Plachetka, 1992; Stang and Osterhaus, 1993). Clouse and Osterhaus (1994) reported that migraineurs had overall hospitalization rates nearly twice as high as those in a non-migraine comparison group.

Table 4: Hospitalization rates for treatment of headache

Study	Headache type	Demographic group	Rate of hospitalization (for headache)	Time period
Clouse and Osterhaus, 1994	migraine	all	10.6%	18 mo
Michel, Pariente, Duru, et al., 1996	migraine	all	7%	6 mo
Osterhaus, Gutterman, and Plachetka, 1992	migraine	all	7.0%	12 mo
Stang and Osterhaus, 1993	migraine	female	8.4%	lifetime
		male	6.2%	
Rasmussen, Jensen, and Olesen, 1992	migraine or tension-type	all	2.0%	lifetime

Pharmaceutical Use

The discussion below focuses on the types of medications used by headache sufferers and the patterns with which they are used, rather than on summary measures of the economic cost of pharmaceutical use. Data on the average wholesale price of drugs are readily available from other sources (Medical Economics Company, 1996).

Chronic headache sufferers have several options for the pharmacological treatment of their headaches: prescription versus non-prescription treatment and treatment for prevention versus treatment for the relief of acute episodes. Almost all headache sufferers report having used some sort of pharmaceutical agent to treat their headaches at some time. Overall rates of medication use are reported to be near 95% (Lipton and Stewart, 1993; Kryst and Scherl, 1994).

The studies reviewed for this section of the report are described in Evidence Table 4.

Prescription vs. Non-Prescription Drug Use

All the studies reviewed showed higher rates of non-prescription than prescription drug use (Table 5). Several clinical factors seem to be related to the use or non-use of prescription medications. Individuals experiencing severe headaches are more likely to consult a health care provider (Rasmussen, Jensen, and Olesen, 1992) and thus more likely to obtain prescription medication. Among patients with severe headache, those with migraine are more likely to use prescription drugs. Celentano, Stewart, Lipton, et al. (1992) found that, of a group of patients who reported "severe headache," but who did not meet the IHS criteria for migraine according to a self-report questionnaire, 15.7% of men and 22.1% of women reported prescription medication use; of patients with severe headache who did meet the diagnostic criteria for migraine, 28.3% of men and 40.1% of women used prescription drugs. The same study found that patients with higher headache-related disability, more frequent attacks, headache associated with vomiting, and migraine with aura were all more likely to use prescription medications.

Some patient-centered factors may also influence the likelihood of the use of prescription medication. Use of prescription drugs appears to increase with age. In a survey of young headache sufferers, Linet, Stewart, Celentano, et al. (1989) found that the rate of prescription drug use doubled from 8.8% in

Table 5: Use of prescription and non-prescription drugs for headache

Study	Headache type	Demographic group	Patients using non-prescription drugs for headache*	Patients using prescription drugs for headache*	Time period
Celentano, Stewart, Lipton, et al., 1992	severe headache (not migraine)	men	74.6%	15.7%	not specified ("current usual treat-ment")
		women	62.5%	22.1%	
	migraine	men	-	28.3%	
		women	-	40.1%	
Clarke, MacMillan, Sondhi, et al., 1996	migraine	all	78%	28%	3 mo
Edmeads, Findlay, Tugwell, et al., 1993	migraine	all	91%	44%	ever
	tension-type		90%	24%	
Kryst and Scherl, 1994†	severe headache (migrainous or non-migrainous) among patients using medications	50%	42.7%	1 year	
	disabling headache (migrainous or non-migrainous)		45.3%	-	
Linet, Stewart, Celentano, et al. (1989)	migraine	men			1 year
		age 12-17	-	8.8%	
		age 18-23	-	16.2%	
		age 24-29	-	18.0%	
		women			
		age 12-17	-	10.9%	
		age 18-29	-	16.8%	
Lipton and Stewart, 1993	migraine	men	66.9%	28.3%	not specified
		women	56.8%	40.1%	
Mounstephen and Harrison, 1995	migraine	all	-	10%	1 year

* Percentages of non-prescription and prescription drug use represent either the type of medication used at the time of the study by the subject or the most frequently used type of medication over the lifetime of the subject depending upon the study.

† Data reported on all patients using some type of medication in the last year; 7.3% of respondents used both prescription and non-prescription medications to treat their headaches.

boys 12 to 17 years old to 18% in men 24 to 29 years old. A similar pattern was noted among women. Celentano, Stewart, Lipton, et al. (1992) also found that the use of prescription medications was greater in older age groups, increasing from 26% among men under 30 years of age to 38.6% among men between the ages of 50 and 59. Prescription drug use was also found to be higher among women than men (Celentano, Stewart, Lipton, et al., 1992; Linet, Stewart, Celentano, et al., 1989; Lipton and Stewart, 1993).

Kryst and Scherl (1994) reported that respondents to the Kentucky Health Survey who said that their headaches interfered with their family life were more likely to use prescription medications. The same study found that the use of prescription medications was not related to income level or insurance coverage. Similarly, Celentano, Stewart, Lipton, et al. (1992) reported that migraineurs with incomes less than $20,000 per year were less likely, but not significantly so, to use prescription medications than those with higher incomes.

Celentano, Stewart, Lipton, et al. (1992) examined differences in medication use by race and reported that black migraineurs had a much lower rate of prescription drug use than whites: 14% versus 29% among men, and 30% versus 40% among women. However, blacks had a slightly higher rate of non-prescription drug use than whites: 71% versus 67% among men, and 61% versus 57% among women. Black women were less likely than white women or women of other racial groups to use prescription medications or any medications at all.

A surprising number of patients with apparently troublesome headache symptoms do not use prescription drugs. Lipton and Stewart (1993) found in a survey that 43% of men and 34% of women with three or more headaches per week did not use prescription medication. Similarly, 61% of men and 47% of women who reported moderate to severe disability due to headache did not use prescription medications. Kryst and Scherl (1994) found that 45.3% of subjects who described their headaches as disabling took only non-prescription medications.

In addition, it appears that many patients who try prescription medications do not continue to use them. Edmeads, Findlay, Tugwell, et al. (1993) found in their interview survey that 62% of headache sufferers who had seen a physician for the treatment of headache had been given a prescription. However, only 34% of these patients were still taking their prescription medication at the time of the survey. The reasons cited by patients for discontinuing their medication were as follows: 53% felt that they could get adequate relief with non-prescription medication; 26% experienced unwanted side-effects of their prescription medication, felt that the relief it provided was inadequate, or were concerned about taking a prescription medication; and 21% stated that their headaches did not bother them, had resolved, or were of insufficient frequency or severity to require prescription medication. The same study reported that physicians recommended non-prescription medications for 50% of their patients and that 25% of these patients had discontinued taking their non-prescription medications.

Use of Preventive Medications

Patients with recurrent headache may be treated with acute or preventive medication or with some combination of the two. It appears, however, that preventive drug treatments are used by only a small percentage of patients (Table 6). It is unclear whether the patients in these studies had never been offered preventive therapy or had tried it and found it ineffective.

Frequency of Medication Use for Treatment of Acute Headache

Headache sufferers who use medications (prescription or non-prescription) to treat

acute episodes of headache appear to use these medications intensively. Edmeads, Findlay, Tugwell, et al. (1993) reported that the migraine and tension-type headache sufferers in their prevalence study used medication an average of three times per week. Medications were used more than once per week by 20% of migraine sufferers and 17% of tension headache sufferers. Micieli, Frediani, Cavallini, et al. (1995) reported that 5.3% of their study population consumed more than one analgesic compound per day for headache relief. Additionally, 12.7% reported daily use of analgesics, 46.6% reported weekly use, 28% reported monthly use, and 7.5% denied using any analgesics. Chronic tension-type headache patients had a greater tendency toward daily use.

Von Korff, Galer, and Stang (1995) reported a detailed study of the frequency of medication use among patients treated for headache in a managed care setting. Subjects were recruited from patients making visits to primary care providers at Group Health of Puget Sound. Headache diagnoses among the population studied included migraine or migraine plus tension-type headache (57.4%), tension-type headache only (30.1%), and other headache diagnoses (12.5%). Frequent medication use (defined as more than 14 days per month) was observed in 18.4% of patients using prescription drugs and 20.1% using non-prescription drugs. The authors found that non-prescription medications were slightly more frequently used at the baseline interview than in the 1-year and 2-year follow-up periods. The overall use of prescription medications declined between the baseline and 1-year follow-up and remained stable between years 1 and 2. In a multivariable model, increasing age and higher frequency of headaches were found to be independent predictors of frequent analgesic use.

Ottervanger, Valkenburg, Grobbee, et al. (1996) examined the use of sumatriptan by patients of general practitioners in the Netherlands. Most of the 952 patients in the study (75%) took sumatriptan 1-10 times per month. However, 4% of patients took sumatriptan daily or more than 10 times per week and were considered to be overusers. Most overusers were men, and most of them reported a poor efficacy for sumatriptan. Frequency of use of sumatriptan was not related to age. Gaist, Hallas, Sindrup, et al. (1996) described the use of sumatriptan in Denmark using a population-based prescription database. Of 2,878 patients

Table 6: Use of preventive medications for headache

Study	Headache type	Patients reporting use of preventive medications for headache	Drug
Clarke, MacMillan, Sondhi, et al., 1996	migraine	5%	propranolol, pizotifen
Edmeads, Findlay, Tugwell, et al., 1993	migraine	5%	not specified
	tension-type	2%	not specified
Mounstephen and Harrison, 1995	migraine	13%	not specified
Rasmussen, Jensen, and Olesen, 1992	migraine	4%	beta blockers
		3%	clonidine

receiving sumatriptan, 1,283 (45%) redeemed only one prescription during the 27-month study period. Twenty percent of the total sumatriptan use was accounted for by the heaviest 1% of users. Heavy sumatriptan users were also the highest consumers of opiates and ergot alkaloids.

The heavy utilization of pharmaceuticals by chronic headache sufferers can also be stated in economic terms. Clouse and Osterhaus (1994) compared the medical and pharmacy claims of 1,336 migraine patients and 1,336 non-migraine patients receiving care at a United Health Care Corporation affiliated health plan. In the 18-month study period, the migraine group averaged 21 pharmacy claims per patient, whereas the non-migraine group averaged 7 claims per patient. The health plan paid out $495,542 in pharmacy claims for the migraine group and $177,774 for the non-migraine group.

Effect of Sumatriptan on Drug and Health Care Resources Utilization

The majority of studies reviewed for this report were performed before the introduction of the anti-migraine drug sumatriptan in 1993. The routine use of sumatriptan in clinical practice may have a significant impact on practice patterns and the utilization of health care resources, but the precise nature and magnitude of this impact are as of yet uncertain.

Litaker, Solomon, and Genzen (1996) compared the utilization of services and costs of care in a group of 104 migraineurs for 18 months before and after they began regular use of sumatriptan. The mean number of physician visits for migraine (excluding initial consultation) decreased significantly from two visits before sumatriptan to one visit after its introduction. The authors measured the costs of care in terms of both professional and institutional costs (the cost of sumatriptan was not included in the analysis) and concluded that there was a 40% reduction on overall costs after the introduction of sumatriptan.

Cohen, Beall, Miller, et al. (1996) examined the effect of sumatriptan use on resource utilization in a group-model health maintenance organization. Subjects were allowed to self-treat an unlimited number of migraine attacks with subcutaneous sumatriptan in a 12-month period. The authors compared the number of physician visits, emergency department visits, diagnostic imaging studies, and prescription services in the 12 months preceding the study and the 6 months following the start of sumatriptan treatment. The number of physician and emergency department visits decreased significantly, while the number of prescription services increased significantly. The number of diagnostic imaging studies performed was low during the pre-treatment period and remained unchanged after the introduction of sumatriptan.

Although some types of resource use and associated costs may decrease with wider use of sumatriptan, there is a potential for increases in resource use and costs in other areas. It is conceivable, for example, that the availability of sumatriptan in EDs may encourage more patients with migraine to seek treatment at these facilities for acute episodes of headache. Similarly, publicity about sumatriptan may encourage more migraineurs to consult health care providers to obtain a prescription. Further research will be needed to determine the precise impact of sumatriptan on practice patterns, resource utilization, and costs of care.

Non-Pharmacological Therapy

The literature review identified three studies of the cost-effectiveness of non-pharmacological treatments for chronic headache (Attanasio, Andrasik, and Blanchard, 1987; Blanchard, Andrasik, Appelbaum, et al., 1985; Blanchard, Jaccard, Andrasik, et al., 1985). These studies are summarized in Evidence Table 5. All three were conducted by the same research group.

Blanchard, Jaccard, Andrasik, et al. (1985) described a very large reduction in medical costs among patients undergoing relaxation and biofeedback training. Costs considered included medication, visits to family physicians and neurologists, hospital costs, and costs for alternative treatments such as acupuncture and chiropractic. A total of 73 patients were randomized into one of three treatment arms, and pre- and post-treatment cost data were collected and compared. The authors reported a reduction in medical expenses from $955 in the 2 years pre-treatment to $52 in the 2 years post-treatment.

There were a number of methodological problems with this study. The investigators did not describe the patient population, the method in which patients were recruited, or the inclusion/exclusion criteria used. Also, medical cost data were obtained from 45 of 73 patients in the pre-treatment study group and from 20 of 73 in the post-treatment group, but it was unclear how many (if any) patients provided both pre- and post-treatment data. Finally, all cost data were self-reported based on patients' personal expense and tax records, introducing possible recall bias. The authors acknowledged the limitations of the study, but still concluded that the non-pharmacological therapy used was able to greatly reduce costs.

In another paper, Blanchard, Andrasik, Appelbaum, et al. (1985) compared what they termed the "cost-effectiveness" of two types of non-pharmacological therapy; however, no comprehensive cost assessment was employed. The duration of patient-therapist contact was used as a proxy for cost, and cost-effectiveness was calculated as the percentage improvement in the headaches divided by the total time the patient was in contact with a therapist. Patients with tension-type, migraine, or combined migraine and tension-type headaches kept a diary on the characteristics of their headaches for a 4-week baseline period prior to treatment. Patients were matched into dyads based on their headache characteristics and demographic characteristics and then randomly assigned to clinic-based or home-based relaxation and biofeedback training. One month after training, they were reassessed for changes in the number, frequency, duration, and severity of their headaches, as well as the number and types of medications used to treat them. The authors concluded that home-based relaxation and biofeedback training was significantly more cost-effective than the office-based approach which involved more contact with the therapist. No long term follow-up was done to see if treatment had lasting effects.

In a slightly later study from the same group of investigators, Attanasio, Andrasik, and Blanchard (1987) randomized 25 tension-type headache patients to one of three treatment groups after a four-week baseline assessment of their headache activity. The authors saw no significant difference in the effect of treatment on cost-effectiveness for patients receiving office-based cognitive and relaxation therapy, home-based cognitive therapy alone, or home-based relaxation therapy alone. The small sample size of this study may have prevented the authors from identifying what may be small differences in the effectiveness of these treatment modalities.

Work Loss

Consultation with a health care provider, the use of emergency and in-patient hospital services, and the use of pharmacological and non-pharmacological treatments all result in direct medical costs. Work loss due to headache, on the other hand, is an indirect cost. It is difficult to place a dollar value on activities not performed because a person was unproductive or bedridden due to headache. Ordinarily, researchers classify a study subject's job title and assign an average wage for that job, then divide the subject's salary by the number of days absent from work to reach

a dollar figure representing work loss. Most of the studies reviewed in this report stopped short of this step and simply quantified rates of absenteeism and (in some cases) reduced effectiveness (see Evidence Table 6 for descriptions of all the included studies). Without further information it is very difficult to understand the full impact of chronic headache on job performance and productivity.

Table 7 summarizes data from the included studies on mean days of work lost per year due to headache. Jones and Harrop (1980) surveyed employees of General Foods, Ltd. in the United Kingdom returning to work after an absence due to headache. In the 8-month study period, 98 employees reported 281 absences from work due to headache, with an average rate of absence of 4.3 days per year.

In another survey of a working population, Clarke, MacMillan, Sondhi, et al. (1996) examined employees of the Royal Hull Hospital in the United Kingdom. They found an average of two absences from work per year due to migraine. This rate of absence, if extrapolated to all migraine sufferers working in the National Health Service (NHS) in the U.K., would equate to approximately 20% of all the sick days taken per year by NHS employees. In addition, the Royal Hull Hospital employees reported an average of 15.5 days per year spent at work with a headache, 12.4 of these days with migraine.

Table 7: Mean days of work lost per year due to headache

Study	Country	Headache type	Population	Days of work lost (annualized)
Clarke, MacMillan, Sondhi, et al., 1996	U.K.	migraine	employee	2.0
Green, 1977	U.K.	migraine	community	4.0
Jones and Harrop, 1980	U.K.	migraine	employee	4.3
Osterhaus, Gutterman, and Plachetka, 1992	U.S.	migraine	specialty clinic	14.3
Stang and Osterhaus, 1993	U.S.	migraine	community	4.0*
van Roijen, Essink-Bot, Koopmanschap, et al., 1995	Netherlands	migraine or migraine + tension-type	community	3.9 (women) 1.0 (men)
Newland, Illis, Robinson, et al., 1978	U.K.	migraine or non-migraine headache	community	3.7 (men only)
Micieli, Frediani, Cavallini, et al., 1995	Italy	episodic headache (migraine, cluster, or tension-type)	specialty clinic	61.2
		chronic tension-type		44.4
		migraine + tension-type		28.8

* Restricted activity days, including bedridden days.

At a reported effectiveness of 56% while working with migraine, this equates to another 5.5 days of absence per year.

In a community-based survey of the Dutch population by van Roijen, Essink-Bot, Koopmanschap, et al. (1995), 10% of female and 2% of male migraineurs reported absence from work due to headache in a 2-week period. On the basis of these 2-week figures, female migraineurs averaged 3.9 days/year absent from work due to headache; males averaged 1.0 days/year. However, these figures only apply to the small percentage of migraineurs who reported any work loss. In this same population of migraineurs, 25% reported that they should have worked additional hours at their jobs to make up for lost productivity due to the effects of migraines suffered during working hours. Women reported that they had lost 23 hours of productivity due to migraine in 1 year; men lost 19 hours. Women estimated that they worked at 73% effectiveness during a migraine attack; men at 69% effectiveness.

A similar rate of work loss due to migraine was reported by Stang and Osterhaus (1993) based on data from the National Health Interview Study. In this study, a random sample of the U.S. population was asked a variety of questions about migraine headache. Those with migraine reported an average of 4 days per year spent in bed with a headache. This study also reported an additional 1.8 days of restricted activity for every day spent in bed. The authors calculated that there are 9,008,418 adults over age 18 with migraine in the United States, with the result that 36,033,672 work days per year are lost in the United States due to migraine.

Stewart, Lipton, and Simon (1996) reported the results of a follow-up survey to the American Migraine Study. In this second survey of respondents age 18 years or older with at least a 1-year history of migraine, they examined work loss due to migraine and effectiveness at work during migraine attacks. Respondents were asked to provide information on only their most severe headaches. The authors calculated Lost Work Day Equivalents (LWDEs) based on the number of days actually absent due to migraine and the number of days spent at work during a migraine attack. For days spent at work during an attack, the subjects' reported effectiveness while at work was taken into account. The average number of LWDEs was not reported, but investigators found that fewer than half of the migraine sufferers accounted for over 90% of LWDEs. Among women, the best predictor of higher LWDEs was the duration of migraine; among men, it was severity of the migraine attack.

In a population-based survey of adults in Southampton, England, Newland, Illis, Robinson, et al. (1978) identified subjects with headache, also recording whether patients typically had any of three symptoms of migraine: unilateral distribution, warning, and nausea. Among the 2,066 respondents, 686 men and 917 women reported some type of headache in the previous year. Work loss averaged 3.7 days in the previous year among the 655 men for whom work loss data were available. No work loss occurred in the 192 men who reported no migraine features with their headaches. No data on work loss were reported for women.

In a study of migraineurs who had been previously enrolled in clinical trials, Osterhaus, Gutterman, and Plachetka (1992) reported a higher average rate of work loss. In this study, 501 of 648 respondents were employed. About half of the employed respondents reported any absence from work due to headache: 29 of 56 (52%) men and 250 of 445 (56%) women. The average number of missed work days per *year* for these men and women were 30 and 25.2 days, respectively. However, if the number of absences were averaged over the entire population of employed respondents, the rate would drop to 15.5 days per year for men and 14.2 days per year for women.

Micieli, Frediani, Cavallini, et al. (1995) looked at work loss in a group of patients recruited from two specialty headache clinics in Italy. This study found a higher rate of absence among these clinic patients than either Osterhaus, Gutterman and Plachetka (1992), in a similar clinic population, or others in studies of the general population. Furthermore, 58.5% of migraine patients and 70.6% of tension-type headache patients in this study reported that headaches suffered during work were completely debilitating.

Other researchers report work loss in a slightly different way. Rasmussen, Jensen, and Olesen (1992) surveyed people living in western Copenhagen County (Denmark). They found that 43% of employed migraineurs reported at least one absence from work per year due to migraine. Of this same subset, 91% were absent less than 7 days/year while 9% were absent between 7-14 days/year. Of those with tension-type headache, 12% were absent at least once because of headache and 16% were out for more than 14 days.

Breslau and Davis (1993) also reported data on migraine and work loss. This study examined the relationship between migraine, physical health, and mental health in a sample of 1,200 persons, ages 21-30, enrolled in a southwest Michigan health maintenance organization. One of the outcomes reported by the authors was that subjects who suffered from migraine had greater limitations in activity due to their health and greater absence from work in the month previous to the study than did controls (30.9% of migraineurs versus 18.7% of controls).

Edmeads, Findlay, Tugwell, et al. (1993) reported on a population-based survey of Canadian headache sufferers. Subjects reported that 11% of their migraines caused them to leave or be absent from work. However, this study did not report the average number of days of absence from work. Celentano, Stewart, Lipton, et al. (1992) studied the amount of disability caused by headache. Among women, 11.2% reported no disability due to migraine, 50.8% mild disability, and 36.9% moderate/severe disability. In men 15.3% reported no disability, 53.0% mild disability, and 30.7% moderate/severe disability. In this case, moderate to severe disability was characterized as requiring bed rest, absence from work, and an inability to perform routine daily activities.

Linet, Stewart, Celentano, et al. (1989) asked subjects 12 to 29 years old identified by a telephone survey in Washington County, MD, how often they missed work or school because of headache. Cases were based upon Ad Hoc criteria for migraine determined in a telephone interview. For days when they had headaches, 85.9% of women and 91.7% of men reported that they would not be absent from work or school, 10.2% of women and 6.1% of men said that they would be absent half of the day, and 3.7% of women and 1.8% of men said they would be absent all day.

These data are quite different from those reported by Stewart, Lipton, and Liberman (1996), who sampled residents of Baltimore County, MD, ages 18 to 65, using random digit dialing. Among subjects meeting IHS criteria for migraine, 33% of women and 44% of men said they would not be absent from work due to headache, 31% of women and 31% of men would rarely be absent, 16% of women and 11% of men would be absent less than half of the day, and 20% of women and 15% of men say they would be absent more than half of the day. It is evident that the populations identified in these two studies were different; the differences may be due to differences in age or in diagnostic criteria.

Although Kryst and Scherl (1994) did not report days of absence or disability due to headache, 37.9% of respondents with migraine in the Kentucky Health Survey said that headaches affected their attendance at work or school.

Mounstephen and Harrison (1995) surveyed employees of a chemical manufacturing and research firm in the United Kingdom regarding the duration and frequency of their migraine headaches. Most subjects reported a slight to moderate effect of migraine on their work. Headache-related absence was reported by 24.2% of migraineurs. Based on the responses of 62 migraineurs these authors calculated that women would experience an average of 144 hours of migraine symptoms per year. For men this number was estimated to be 44 hours per year. It could be expected that a significant number of these migraine headache affected hours would occur at work. However, the authors did not collect specific information on work loss due to migraine.

One study examined the effect of race on absence from work and disability. Stewart, Lipton, and Liberman (1996) found no differences in the frequency of missed work days by race. However, they did report that black women and men were less likely to report reduced efficiency at work than either whites or Asian-Americans. They also reported that men and women experience similar reductions in effectiveness with their headaches. No reduction in effectiveness was reported by 9% of women and 11% of men, a less than 25% reduction was reported by 22% of women and 23% of men, a 25-49% reduction in 35% of women and 37% of men, a 50-74% reduction by 17% of women and 13% of men, and a 75% or greater reduction by 17% of women and 17% of men. Clarke, MacMillan, Sondhi, et al. (1996) reported that subjects estimated that they worked only 56% as effectively when they were suffering from migraine headache.

While headache does cause a large number of absences from work, it appears that many headache sufferers stay on the job, functioning with significantly reduced effectiveness, when they have a headache. Days of work lost vary remarkably among different countries; cultural differences, rather than biological differences, may explain some between-country differences in work loss. There have been few efforts to estimate the economic effect of this lost productivity. The price of errors or inaccuracies in work performed during a headache attack may never be known.

Conclusions

Despite the fact that large numbers of Americans suffer from chronic headache, little research has been done to assess how this condition affects the utilization of health care resources, quality of life, and personal productivity. The published studies provide only a glimpse of some resource utilization and economic issues related to chronic headache, usually migraine. Characterizing patients with chronic headache is problematic, even with the aid of the IHS diagnostic classification, and study populations may still exhibit remarkable diversity. Interpreting the generalizability of the results reported in clinical studies is difficult.

Perhaps the most striking finding highlighted by the studies reviewed in this report is the low rate of health care provider diagnosis of chronic headache conditions. While between 56% and 91% of chronic headache sufferers seek the care of a health care provider, only one-third report having received a diagnosis of their condition. The literature reviewed did not address the number of provider visits required or the number and type of tests utilized to make the diagnosis. Those who never receive a definitive diagnosis for their headache symptoms will most likely continue to seek answers from a health care provider and try to find relief from non-prescription medications. Access to and knowledge of the health care system probably play an important role in receiving a diagnosis. While it is likely true that those people with the most severe and frequent

headaches have a better chance of receiving a diagnosis, it is also likely that there are many more people with moderately disabling headaches who could benefit from medical treatment.

Whether or not an individual with chronic headache receives a specific diagnosis of migraine, tension-type headache, or some other syndrome, such an individual tends to be a frequent user of health care resources such as provider office visits, emergency department visits, inpatient admission, and pharmaceutical therapies. Another issue not addressed by the literature is identification of patterns with which these resources are used. For example, we do not know if people who regularly see their health care provider also use the emergency department for care or if the emergency department is more likely to be used by those who have no other regular source of care. Also, we do not know why people with chronic headache are hospitalized, or if there are common treatment protocols used for patients hospitalized for headache.

Some patients with chronic headache have a high number of contacts with the medical establishment. Osterhaus, Gutterman, and Plachetka (1992) reported that 7.6% of the subjects in their study made 12 or more visits to a physician per year for the care of their headaches. The reasons why some patients have such a high number of visits has not been studied. Some patients may be receiving in-office treatment for acute headache attacks; others may be seeking reassurance that their headache symptoms are not caused by some other life-threatening illness; still others may be experiencing unwanted side-effects of medications and searching for satisfactory pain relief.

On the other hand, many individuals with chronic headache pain never seek the care of a doctor, or after some period of time become discouraged with the ability of organized medicine to provide relief. This causes them to discontinue their care and, most likely, their access to prescription medications. The reasons why people with chronic headache discontinue care have not been thoroughly examined. Edmeads, Findlay, Tugwell, et al. (1993) began to elucidate some aspects of this question. Some patients feel that their headaches are not severe or frequent enough to warrant medical attention; others were unhappy with the care their physician provided, experienced negative side-effects of prescription medications, or had found over-the-counter medications which were able to treat their headaches.

This not infrequent rejection of regular medical care should not be interpreted as a savings in health care costs. Although satisfactory studies have not been done, it is possible that individuals who do not receive regular medical care for their headaches may suffer negative consequences of self-medication such as rebound headaches, or may be less productive in the home or work place because they lack regular medical monitoring of their condition.

Most individuals with chronic headache rarely or never use the emergency department for the treatment of their headaches. Similarly, few are ever hospitalized. However, a small but notable percentage of patients—probably between 5% and 20%—do use these resources. We do not know the precise reasons for these encounters or whether they are medically necessary.

Probably related to the large percentage of undiagnosed headache sufferers is the large number of people who rely on non-prescription medications to treat their symptoms. While this may not be related to a lack of ongoing medical care in all cases, it is likely that there is some relationship. Some chronic headache sufferers may believe that their symptoms are not frequent or severe enough to warrant the use of prescription medication, and others may have experienced unwanted side-effects. Nevertheless, there are probably many who would benefit from

prescription medication. Also, there is the finding of Edmeads, Findlay, Tugwell, et al. (1993) that 10% of their survey population were using prescription medications to treat their headaches without the supervision of a physician.

Another point underscored by the studies reviewed for this report was the low number of patients using preventive drug treatment for their headaches. It might be the case that patients had not been offered preventive medications, had not tolerated them, or that their providers were not aware of the availability of these medications. A major area that has not been addressed in the literature is the description of the treatment received by chronic headache patients when they see a health care provider. It appears that some patients become discouraged by the lack of a diagnosis, medications which do not adequately relieve their symptoms, or by the side-effects of medications. The type of patient education these individuals receive and the prognoses they are given are unknown.

Also unclear is what emphasis, if any, is placed on non-pharmacological therapies such as biofeedback, cognitive therapy, and stress management or alternative therapies including acupuncture, hypnosis, spinal manipulation, and massage. Although there is very little published literature on the costs of non-pharmacological therapy, this alternative to drug-based management of chronic headache may be a useful and cost-effective tool in the treatment of this patient population.

Finally, several studies have documented the magnitude of work loss and reduced productivity due to headache. While the mean number of days absent from work annually appears to vary roughly from about 2 to 14 for chronic headache sufferers, there has been little systematic effort to translate these missed days into corresponding estimates of economic loss from either the societal or individual perspective. Also requiring much more study is the impact on productivity of headaches that impair worker performance, but do not lead to work loss days.

Future Research

Reliable, comprehensive, and generalizable information on the cost of headache has multiple important uses: for gauging the overall economic burden of headache in comparison with other problems; for use in cost-effectiveness analyses of preventive and therapeutic interventions; and for informing the development of clinical practice guidelines. For this report we surveyed the published literature on the cost of headache and summarized the key findings from papers reporting primary data that appeared to be both relevant and of adequate quality. We find that each paper reviewed here provides some useful information about the economic cost of headache. But no study attempts to estimate the *total* cost for a nationally representative population of sufferers.

Coming closest to offering a comprehensive assessment of the resource use implications of headache are the analyses by Osterhaus, Gutterman, and Plachetka (1992); Stang and Osterhaus (1993); and Clouse and Osterhaus (1994). But these studies focus on migraine only, so that the costs of tension-type, cluster, and other chronic primary headache disorders remain to be estimated. And there are other, more specific limitations to the three studies. The first studied a population (migraineurs in specialty clinics who had participated in clinical trials) that is arguably not nationally representative of headache sufferers. The second was not able to sort out emergency room use. The third could not examine work loss. None of these studies could present data on non-prescription drug use and none could report on non-pharmacological therapy. None of this is intended as a criticism of these studies, which were well-executed and limited primarily by

the nature of the available data. Rather, it is to set the stage for arguing that to produce reliable, comprehensive, and generalizable estimates of the economic cost of headache, good quality resource utilization information from multiple, complementary data sources almost certainly will be required.

In this concluding section, we present an analytical framework for identifying the required data elements and carrying out the calculations. This framework is built around standard economic models of disease cost. For each parameter or variable in the cost models, the questions of interest then become: What type of data is required? Where can it be found? How difficult, or expensive, will it be to acquire? Thus, we first present the framework and then briefly discuss potential data sources.

Analytical Framework

At least two important definitional issues must be addressed at the outset. Since costs will vary both by type of headache and the demographic and clinical makeup of the study population, estimates of total costs should be derived as the sum of costs across headache and patient types. This, in turn, requires operational definitions for *headache types* and *patient types*. For concreteness, we illustrate below.

Headache Types

Let the general term "headache" be further classified now into three categories: migraine headache (subdivided into "migraine" and "migraine variants"), tension-type headache, and other unspecified headaches.

In terms of the *International Classification of Diseases, 9th Revision, Clinical Modification* (ICD-9-CM) codes (U.S. Department of Health and Human Services, 1994), these three categories can be defined as follows:

Migraine:

346.0 Classical Migraine
- with focal neurological phenomena
- with aura

346.1 Common Migraine
- atypical
- sick headache

346.8 Other Migraine
- hemiplegic
- opthalmoplegic

346.9 Other migraine, unspecified

Migraine Variants:

346.2 Variants of Migraine
- cluster
- histamine
- Horton's neuralgia
- neuralgia (ciliary, migrainous)

Tension Headache:

307.81 Tension Headache (Psychalgia)

Other, Unspecified Headache:

784.0 Headache
- facial pain
- pain in head NOS
- excludes atypical face pain, migraine, tension headache

Patient Types

It is generally accepted that headache costs will vary by age and sex, and they may also vary by race and geographic region. Fundamentally, this is because the direct medical costs associated with headache will depend heavily on the individual's frequency of headaches (by type); underlying health status (including comorbidities); overall economic status, which directly influences financial access to care; and proclivity to use medical care (controlling for financial access). Similarly, the indirect (work loss) costs of headache will be a function of the individual's labor force participation and relative wages. Since the patient's health status, overall

economic status, proclivity to use medical care, and labor market earnings are all strongly correlated with age, sex, and race, these demographic variables may usefully serve to define our patient types. It is reasonable to suggest, but requires further scrutiny to conclude, that headache costs will vary geographically (all else equal) because of variations in provider practice styles.

Cost Models

Establishing the unit of analysis: Cost per episode vs. cost per period. Headache exhibits characteristics of both a *chronic* and an *acute* disease. In the course of a given year, an individual may suffer recurrent attacks of sharp, but time-limited pain. In direct response to some of these acute events, the individual may seek medical care or miss time from work or be less productive on the job. For other acute headache events, the individual may not seek medical care as such, but find other means of coping (including just "watchful waiting"). Moreover, in anticipation of such acute events, the individual may purchase medications or spend time and money seeking preventive care, e.g., behavioral therapy.

Thus, it is no simple matter to derive an operational definition of the headache "episode," nor to capture all of the direct and indirect costs associated with any such episode. In the discussion that follows, an episode refers basically to the acute, time-limited pain event referred to above, but with recognition that its precise moments of onset and termination will likely not be discernible in any economic or clinical data base accessible to investigators. However, one may be able to make rough inferences about the occurrence rates for headache episodes for specific types of patients from two types of available information: (1) claims data reporting the direct medical costs for headache, and (2) survey data yielding reported rates of acute events.

Because new headache guidelines, or cost-effectiveness analyses generally, may alter the cost associated with headache by altering the frequency and/or intensity of episodes, we first present a cost model below (the detailed model) that specifically includes episode rates, by patient type. But because the available data may or may not prove adequate to support an episode-level model, we next present an alternative formulation (the aggregated model). For either model, the summary outcome of interest is *total headache-related cost per year*, computed as the sum of total direct and total indirect cost per year.

Both models focus on headache-specific costs, while holding all other health-related costs in the background. The alternative "all-cost" approach—in which the total health-related costs for headache sufferers are compared with the total health-related costs for a "comparison sample" of otherwise similar individuals—is not pursued here. Defining and then finding appropriate comparison samples are both formidable tasks in the present context. Rather, we assume that headache-related costs can be parsed out or extracted directly, and to a satisfactory degree, from the combination of data sets (based variously on insurance claims records, patient surveys, and relevant published literature) to be discussed subsequently.

Detailed model. In the notation that follows, the parameter j refers to headache type, i refers to patient type, and h indexes the number of (acute) episodes per year. Headache cost may then be computed as follows:

$$C(\text{Direct})_{ij} = \Sigma_h \, p(X_{ijh}) \, X_{ijh} \bullet \{p_{ij}(y|x) \, [C_{ij}(Y) + C_{ij}(Z_1)] + [1-p_{ij}(y|x)] \, C_{ij}(Z_2)\}$$

$$C(\text{Indirect})_{ij} = \Sigma_h \, p(X_{ijh}) \, X_{ijh} \bullet \{p_{ij}(wl|x) \, WL_{ij} \, (Wg_i) + p_{ij}(pe|x) \, [(1-PE_{ij}) \, DD_{ij} \, (Wg_i)]\}$$

$C(\text{Total})_{ij} = C(\text{Direct})_{ij} + C(\text{Indirect})_{ij}$.

If there are N_{ij} individuals of patient type i meeting the criteria for headache type j, then total cost per year is

$C(\text{Total}) = \Sigma_i \Sigma_j N_{ij} C(\text{Total})_{ij}$,

where

(1) X_{ijh} denotes h headaches of type j for a patient of type i per year

(2) $p(X_{ijh})$ is the probability of exactly X_{ijh}

(3) $p_{ij}(y|x)$ is the probability of a claims-generating encounter, given a headache episode of type j for a patient of type i

(4) $C_{ij}(Y)$ is the average claims-based cost per episode, given j and i

(5) $C_{ij}(Z_1)$ is the average cost of resources consumed as part of claims-based encounter but not included in claims

(6) $C_{ij}(Z_2)$ is the average cost of non-claims-based treatment per episode

(7) $p_{ij}(wl|x)$ is the probability of any work loss days, given a headache episode

(8) WL_{ij} is the average work loss days per episode, given any work loss days

(9) Wg_i is the average daily wage rate for patient type i

(10) $p_{ij}(pe|x)$ is the probability of partial effectiveness at work, given an episode

(11) PE_{ij} is the average partial effectiveness at work, given an episode

(12) DD_{ij} is the average number of days of partial effectiveness at work per episode.

Note that depending on the form of the data, one might make use of the following simplifying relationship:

$\Sigma_h p(X_{ijh}) X_{ijh} = X(\text{Mean})_{ij}$, where

(13) $X(\text{Mean})_{ij}$ is the average number of headache episodes per year, given i and j.

Aggregated model. Suppose now that we cannot adequately ascertain headache frequency at the individual level, or that direct costs are deemed to be so non-linearly related to the occurrence of episodes that the functional form of the model above appears unrealistic. Then one could adopt the following type of specification:

$C(\text{Direct})_{ij} = C_{Tij}(Y) + C_{Tij}(Z_1) + C_{Tij}(Z_2)$

$C(\text{Indirect})_{ij} = WL_{Tij}(Wg_i)$
$+ [1\text{-}PE(\text{Mean})_{ij}] DD_{Tij}(Wg_i)$,

where

(14) C_{Tij} is the total annual claims-based cost for headache type j for a patient of type i

(15) $C_{Tij}(Z_1)$ is the total annual cost for resources consumed in claims-based encounters but not included in claims, given i and j

(16) $C_{Tij}(Z_2)$ is the total annual cost for non-claims-based treatment of headache, given i and j

(17) WL_{Tij} is the total work loss days due to headache per year, given i and j

(18) DD_{Tij} is the total disability (but not work loss) days per year due to headache, given i and j

(19) $PE(\text{Mean})_{ij}$ is the average value of partial effectiveness for disability-affected days on the job, given i and j.

With either the detailed or the aggregated model, a diverse array of data would be needed for estimating the parameters defined above. We conclude with a brief review of potential data sources and a preliminary assessment of the extent to which they would

be adequate in concert to support new, comprehensive estimates of the cost of headache.

Potential Data Sources

Insurance Claims Records

With claims data, one can track the health care utilization and cost over time of a well-defined sample of individuals. For each recorded encounter, data are generally available on the reason for visit or admission, the individual's clinical status *as captured by ICD-9-CM codes*, medical procedures performed as captured in Current Procedural Terminology (CPT™) codes (American Medical Association, 1998), and demographic descriptors.

A strength of such data is that, in theory, they reflect a reliably recorded history of events from which medical care resource consumption can be directly inferred. Two acknowledged limitations, however, are that data will be available for covered services only, and detailed clinical data on the patient, as found in the medical record, will not generally be available. Thus, for the headache sufferer, if non-pharmacological treatments are not among the services covered by the insurance plan (as is typically the case), claims data can reveal nothing about their utilization. In addition, work loss and other measures of non-medically related cost due to headache (e.g., caregiver hours devoted to the migraine sufferer) will not be found in claims data. Finally, measures of the economic opportunity cost of services are generally not reported directly in claims data, but must be inferred through the application of cost-to-charge ratio techniques and other approaches; see Lave, Anderson, Brailer, et al. (1994) for an overview of how claims data have been used recently for estimating the cost of health services.

Currently, claims data may be obtained from several sources:

Data pooled across employer-based health plans. A prime example is the commercially available MEDSTAT MarketScan® database (MarketScan® Databases [computerized database], 1998), which compiles the claims of approximately 7 million individuals enrolled in benefit programs sponsored by large employers located throughout the U.S. Not all benefit plans offer the same degree of covered services; so outpatient prescriptions may be covered under one plan but not another. In general, these data reflect the utilization of acute care services by privately insured middle-income families of working age. Since chronic headache does not discriminate by income group and is probably most prevalent among persons age 25-55, databases like MarketScan® would appear to be potentially important sources of cost information.

Medicare and Medicaid. The Medicare data set is compiled and maintained by the Health Care Financing Administration (HCFA). Medicare data include claims for inpatient and outpatient services provided to patients age 65 and over and to disabled persons under age 65. These data are of generally good quality, but lack information on outpatient prescription drugs and long-term care services. As noted above, chronic headache (while found among those over age 65) is most prevalent in the non-elderly.

The Medicaid data set is also compiled and maintained by HCFA, but is limited in some important respects. By construction, only Medicaid eligibles are followed, thus generally limiting the focus to lower income persons. Since eligibility varies across states and any individual's own eligibility within a given state may also vary year by year, obtaining reliable and comparable longitudinal data is problematic. Moreover, there is still considerable variation across states in the quantity and quality of the claims data reported to HCFA.

Thus, while each of these well-known data sources may be of some use in estimating the direct medical cost of headache, there are substantial limitations. It may be the case, however, that a careful analysis of appropriate subsets of Medicaid claims can yield sound observations of resource use for lower income persons; this would serve to complement the analyses from datasets like MarketScan®, where the focus is necessarily on families above the poverty line.

Medical care organizations (MCOs). Yet to be exploited in a large-scale way are claims and clinical data collected routinely by health maintenance organizations and other MCOs which act as both provider and insurer for well-defined patient populations. Ideally, such data would come from relatively large MCOs, providing comprehensive services to many thousands of persons at a diverse set of geographic sites.

Survey Data

An important advantage of collecting utilization and cost information through patient surveys is that, in principle, a comprehensive accounting of the resource impact of disease can be obtained. Questions can be tailored to suit the particular disease under examination, and statistically representative samples of persons can be interviewed. An important limitation, however, is that self-reported information is almost always at some risk to recall bias; ideally, such data would be validated by selectively comparing survey responses with clinical and administrative data.

For studying headache costs in the U.S., at least three surveys appear to hold considerable promise: (1) the American Migraine Study (Celentano, Stewart, Lipton, et al., 1992), (2) the Baltimore County Prevalence Study (Stewart, Lipton, and Liberman, 1996), and (3) the Baltimore County Diary (and Telephone) Study (also Stewart, Lipton, and Liberman, 1996).

- The American Migraine Study was conducted in 1989 on a national probability sample of migraine patients aged 12-80 years; see Lipton and Stewart (1993); Celentano, Stewart, Lipton, et al. (1992); and Linet, Stewart, Celentano, et al. (1989). Migraine diagnosis was validated using International Headache Society criteria. This survey contains more than 60 questions covering severity and type of symptoms, resource utilization, willingness to pay for care, insurance, and occupation. One limitation is that only persons with relatively severe migraine were included.
- The Baltimore County Project was conducted in 1993-1994 and limited to persons residing in that part of Maryland (Stewart, Lipton, and Liberman, 1996). The project was conducted in several phases, beginning with a telephone survey of 13,000 persons to determine the prevalence of headache (not necessarily migraine). The screening instrument used did not include questions related to headache costs. In the second phase, respondents reporting signs and symptoms of migraine were asked to undergo confirmatory medical examinations. In a third phase, a sample of 260 persons with a clinically confirmed diagnosis of migraine participated in a 3-month diary study. The daily entries focused on the presence or absence of a headache during the 24-hour period, symptoms and severity of the headache, types of medications taken, whether hours at work were lost, and percentage effectiveness at work. The first phase of this project yielded data with better diagnostic accuracy than the American Migraine Study, with 97% sensitivity and 86% specificity.

A limitation of both the American Migraine and the Baltimore County studies is their exclusive focus on migraine headache. But they well illustrate the potential for

survey data to fill in the gaps left by claims data and our third source of cost information, the published literature.

Published Literature

Although most of the studies we identified in the published literature individually yield useful information, in sum they do not provide adequate data for the analyst to construct a reliable, comprehensive, and generalizable picture of the cost of headache. Nonetheless, the published literature should still be regarded as a potentially important source of data for headache cost analyses. Excellent studies will no doubt continue to be published, providing results that may usefully be incorporated into future primary cost analyses.

Mapping Cost Model Variables to Potential Data Sources

To see how claims and survey data might be used in implementing the detailed and aggregated headache cost models presented above, see Table 8. For each variable or parameter, we indicate whether relevant data appear to be available from MEDSTAT, the American Migraine Study, or the various phases of the Baltimore County Project.

We tentatively conclude that if these data sources were used in concert, all components of our cost models could be estimated—at least for migraine headache. Producing comparable cost estimates for tension-type and other headache types remains a major challenge. But the way forward in all cases will almost certainly call for creative efforts to combine data from a variety of sources.

Table 8: Availability of information for headache cost models

Variable or Parameter	MEDSTAT MarketScan®	American Migraine	Baltimore County Study		
			Telephone Survey	Medical Examination	Diary
1) # of headaches, type of headache, type of patient		X	X		X
2) probability of 1)		X	X		
3) probability of a claims producing encounter for patient and headache type		X		X	
4) average claims-based cost/encounter	X				
5) average cost of resources consumed as part of claims-based encounter but not included in claims	X	X		X	X
6) average cost of non-claims-based treatment per headache		X	X	X	X
7) probability of work loss day		X	X		
8) work loss days per headache		X			
9) daily wage average		X			
10) probability of patient effectiveness during headache		X	X		X
11) average patient effectiveness/day		X	X		X
12) average number of days of partial effectiveness		X			
13) average number of headaches/year		X			
14) total annual claims-based cost for headache type and patient type	X	X		X	
15) total annual cost for resources consumed in claims-based encounters but not counted in claims	X	X		X	
16) total annual cost for non-claims-based treatment for headache		X		X	

Variable or Parameter	MEDSTAT MarketScan®	American Migraine	Baltimore County Study		
			Telephone Survey	Medical Examination	Diary
17) total work loss days due to headache		X			
18) total disability but not work loss days per year due to headache		X			
19) average value of partial effectiveness on disability days		X			
Patient type (i)	X	X	X		
Headache type (j)	X	X	X		

References

Adelman JU, Vonseggern R. Cost considerations in headache treatment. 1. Prophylactic migraine treatment. Headache 1995;35(8):479-87.

Akpek S, Arac M, Atilla S, Onal B, Yucel C, Isik S. Cost-effectiveness of computed tomography in the evaluation of patients with headache. Headache 1995;35(4):228-30.

American Medical Association. CPT™ '98: Physicians' Current Procedural Terminology. Chicago, IL: American Medical Association, 1998.

Appleby J. Data briefing. Migraine. Health Serv J 1996;106(5498):34-5.

Attanasio V, Andrasik F, Blanchard EB. Cognitive therapy and relaxation training in muscle contraction headache: efficacy and cost-effectiveness. Headache 1987;27(5):254-60.

Baker HL Jr. Cranial CT in the investigation of headache: cost-effectiveness for brain tumors. J Neuroradiol 1983;10(2):112-6.

Beaty ET, Haynes SN. Behavioral intervention with muscle-contraction headache: a review. Psychosom Med 1979;41(2):165-80.

Becker L, Green L, Beaufait D, Kirk J, Froom J, Freeman W. Detection of intracranial tumors, subarachnoid hemorrhages, and subdural hematomas in primary care patients: a report from ASPN, Part 2. J Fam Pract 1993a;37(2):135-41.

Becker L, Green L, Beaufait D, Kirk J, Froom J, Freeman W. Use of CT scans for the investigation of headache: a report from ASPN, Part 1. J Fam Pract 1993b;37(2):129-34.

Becker L, Iverson D, Reed F, Calonge N, Miller RS, Freeman W. Patients with new headache in primary care: a report from ASPN. J Fam Pract 1988;27(1):41-7.

Becker WJ, Riess CM, Hoag J. Effectiveness of subcutaneous dihydroergotamine by home injection for migraine. Headache 1996;36(3):144-8.

Blanchard EB, Andrasik F, Appelbaum KA, Evans DD, Jurish SE, Teders SJ, Rodichok LD, Barron KD. The efficacy and cost-effectiveness of minimal-therapist-contact, non-drug treatments of chronic migraine and tension headache. Headache 1985;25(4):214-20.

Blanchard EB, Jaccard J, Andrasik F, Guarnieri P, Jurish SE. Reduction in headache patients' medical expenses associated with biofeedback and relaxation treatments. Biofeedback Self Regul 1985;10(1):63-8.

Breslau N, Davis GC. Migraine, physical health and psychiatric disorder: a prospective epidemiologic study in young adults. J Psychiatr Res 1993;27(2):211-21.

Broadhead WE, Larson DB, Yarnall KS, Blazer DG, Tse CK. Tricyclic antidepressant prescribing for nonpsychiatric disorders. An analysis based on data from the 1985 National Ambulatory Medical Care Survey. J Fam Pract 1991;33(1):24-32.

Burke EJ, Andrasik F. Home- vs. clinic-based biofeedback treatment for pediatric migraine: results of treatment through one-year follow-up. Headache 1989;29(7):434-40.

Business & Health. Special report. Controlling headache costs. Bus Health 1992;6-30.

Cady RK, Shealy CN. Recent advances in migraine management. J Fam Pract 1993;36(1):85-91.

Carrera GF, Gerson DE, Schnur J, McNeil BJ. Computed tomography of the brain in patients with headache or temporal lobe epilepsy: findings and cost-effectiveness. J Comput Assist Tomogr 1977;1(2):200-3.

Celentano DD, Linet MS, Stewart WF. Gender differences in the experience of headache. Soc Sci Med 1990;30(12):1289-95.

Celentano DD, Stewart WF, Lipton RB, Reed ML. Medication use and disability among migraineurs: a national probability sample survey. Headache 1992;32(5):223-8.

Clarke CE, MacMillan L, Sondhi S, Wells NE. Economic and social impact of migraine. Q J Med 1996;89(1):77-84.

Clouse JC, Osterhaus JT. Healthcare resource use and costs associated with migraine in a managed healthcare setting. Ann Pharmacother 1994;28(5):659-64.

Cohen JA, Beall DG, Miller DW, Beck A, Pait G, Clements BD. Subcutaneous sumatriptan for the treatment of migraine: humanistic, economic, and clinical consequences. Fam Med 1996;28(3):171-7.

Cull RE, Wells NEJ, Miocevich ML. The economic cost of migraine. Brit J Econ 1992;2:103-15.

Cypress BK. Headache as the reason for office visits, National Ambulatory Medical Care Survey: United States, 1977-78. Adv Data 1981 Jan 7;(67):1-6.

Dahlöf CG. Health-related quality of life under six months' treatment of migraine—an open clinic-based longitudinal study. Cephalalgia 1995;15(5):414-22.

Davey PJ, Leeder SR. The cost of migraine: more than just a headache? Pharmacoeconomics 1992;2(1):5-7.

de Lissovoy G, Lazarus SS. The economic cost of migraine. Present state of knowledge. Neurology 1994;44(6 Suppl 4):S56-62.

Demaerel P, Boelaert I, Wilms G, Baert AL. The role of cranial computed tomography in the diagnostic work-up of headache. Headache 1996;36(6):347-8.

Diamond S, Medina JL. Headaches. Clin Symp 1989;41(1):2-31.

Drummond MF, Richardson WS, O'Brien BJ, Levine M, Heyland D. Users' guides to the medical literature. XIII. How to use an article on economic analysis of clinical practice. A. Are the results of the study valid? JAMA 1997;277(19);1522-7.

Dumas MD, Pexman JH, Kreeft JH. Computed tomography evaluation of patients with chronic headache. Can Med Assoc J 1994;151(10):1447-52.

Edmeads J, Findlay H, Tugwell P, Pryse-Phillips W, Nelson RF, Murray TJ. Impact of migraine and tension-type headache on life-style, consulting behaviour, and medication use: a Canadian population survey. Can J Neurol Sci 1993;20(2):131-7.

Feczko JM. Cost of sumatriptan. Lancet 1992;340(8813):243.

Friedman H, Taub HA. Brief psychological training procedures in migraine treatment. Am J Clin Hypn 1984;26(3):187-200.

Frolund F, Frolund C. Pain in general practice. Pain as a cause of patient-doctor contact. Scand J Prim Health Care 1986;4(2):97-100.

Furlong S, Pryse-Phillips W, Crowley M, Turner CJ. Prescribing practices for the management of headache in Newfoundland and Labrador. Headache 1996;36(9):542-6.

Futterman R, Hill J. Evaluation of a benefits modification for the treatment of migraine headaches among members of a managed care organization. AHSR FHSR Annu Meet Abstr Book [no date];13:142.

Gaist D, Hallas J, Sindrup SH, Gram LF. Is overuse of sumatriptan a problem? A population-based study. Eur J Clin Pharmacol 1996;50(3):161-5.

Ganiats TG, Carson RT, Hamm R, Spann SJ, Hagen MD, Cantor SB. Population-based discounting of future health outcomes. AHSR FHSR Annu Meet Abstr Book 1994;11:53.

Ginsberg G, Israeli A, Cohen A, Stessman J. Factors predicting emergency room utilization in a 70-year-old population. Isr J Med Sci 1996;32(8):649-64.

Green JE. A survey of migraine in England, 1975-1976. Headache 1977;17:67-68.

Greiner DL, Addy SN. Sumatriptan use in a large group-model health maintenance organization. Am J Health Syst Pharm 1996;53(6):633-8.

Hackett G. Management of migraine. Practitioner 1994;238(1535):130-6.

Headache Classification Committee of the International Headache Society. Classification and diagnostic criteria for headache disorders, cranial neuralgias and facial pain. Cephalalgia 1988;8(Suppl 7):1-96.

Hoffert MJ. Treatment of migraine: a new era. Am Fam Physician 1994 Feb 1915;49(3):633-8, 643-4.

Holroyd KA, Penzien DB. Pharmacological versus non-pharmacological prophylaxis of recurrent migraine headache: a meta-analytic review of clinical trials. Pain 1990;42(1):1-13.

Hopkins A. The epidemiology of headache and migraine, and its meaning for neurological services. Schweiz Med Wochenschr 1996;126(4):128-35.

Hopkins A. Lessons for neurologists from the United Kingdom Third National Morbidity Survey. J Neurol Neurosurg Psychiatry 1989;52(4):430-3.

Hudzinski L, Zebrick L. Bruxism 1995. Headache Quarterly 1996;7(1):48-53.

Ilacqua GE. Migraine headaches: coping efficacy of guided imagery training. Headache 1994;34(2):99-102.

Jhingran P, Cady RK, Rubino J, Miller D, Grice RB, Gutterman DL. Improvements in health-related quality of life with sumatriptan treatment for migraine. J Fam Pract 1996;42(1):36-42.

Jones A, Harrop C. Study of migraine and the treatment of acute attacks in industry. J Int Med Res 1980;8(5):321-5.

Kaa KA, Carlson JA, Osterhaus JT. Emergency department resource use by patients with migraine and asthma in a health maintenance organization. Ann Pharmacother 1995;29(3):251-6.

Kahn CE Jr, Sanders GD, Lyons EA, Kostelic JK, MacEwan DW, Gordon WL. Computed tomography for nontraumatic headache: current utilization and cost-effectiveness. Can Assoc Radiol J 1993;44(3):189-93.

Kent J. The treatment of chronic benign pain syndrome in capitated health care. Manag Care Q 1996;4(2):77-83.

Klapper JA. Toward a standard drug formulary for the treatment of headache. Headache 1995;35(4):225-7.

Knaus WA, Davis DO. Utilization and cost-effectiveness of cranial computed tomography at a university hospital. J Comput Assist Tomogr 1978;2(2):209-14.

Knaus WA, Wagner DP, Davis DO. CT for headache: cost/benefit for subarachnoid hemorrhage. Am J Roentgenol 1981;136(3):537-42.

Kozma CM, Mauch RP, Reeder CE, Lawrence BJ. A literature review comparing the economic, clinical, and humanistic attributes of dihydroergotamine and sumatriptan. Clin Ther 1994;16(6):1037-51.

Kozma CM, Reeder CE. Comparison of the economic, clinical, and humanistic attributes of dihydroergotamine and sumatriptan. Clin Ther 1995;17(2):315-9; discussion 314.

Kroenke K, Mangelsdorff AD. Common symptoms in ambulatory care: incidence, evaluation, therapy, and outcome. Am J Med 1989;86(3):262-6.

Kryst S, Scherl E. A population-based survey of the social and personal impact of headache. Headache 1994;34(6):344-50.

The Lancet. Sumatriptan, serotonin, migraine, and money. Lancet 1992;339(8786):151-2.

Larson EB, Omenn GS, Lewis H. Diagnostic evaluation of headache. Impact of computerized tomography and cost-effectiveness. JAMA 1980;243(4):359-62.

Lave JR, Pashos CL, Anderson GF, Brailer D, Bubolz T, Conrad D, Freund DA, Fox SH, Keeler E, Lipscomb J, et al. Costing medical care: using Medicare administrative data. Med Care 1994;32(7 Suppl):JS77-89.

Linet MS, Celentano DD, Stewart WF. Headache characteristics associated with physician consultation: a population-based survey. Am J Prev Med 1991;7(1):40-6.

Linet MS, Stewart WF, Celentano DD, Ziegler D, Sprecher M. An epidemiologic study of headache among adolescents and young adults. JAMA 1989;261(15):2211-6.

Lipton RB, Amatniek JC, Ferrari MD, Gross M. Migraine. Identifying and removing barriers to care. Neurology 1994;44(6 Suppl 4):S63-8.

Lipton RB, Stewart WF. Migraine in the United States: a review of epidemiology and health care use. Neurology 1993;43(6 Suppl 3):S6-10.

Lipton RB, Stewart WF, Celentano DD, Reed ML. Undiagnosed migraine headaches. A comparison of symptom-based and reported physician diagnosis. Arch Intern Med 1992;152(6):1273-8.

Lipton RB, Stewart WF, Von Korff M. The burden of migraine. A review of cost to society. Pharmacoeconomics 1994;6(3):215-21.

Lipton RB, Stewart WF, Von Korff M. Migraine impact and functional disability. Cephalalgia 1995;15(Suppl 15):4-9.

Litaker DG, Solomon GD, Genzen JR. Impact of sumatriptan on clinic utilization and costs of care in migraineurs. Headache 1996;36(9):538-41.

Luciani RJ, Osterhaus JT, Gutterman DL. Patient preferences for migraine therapy: subcutaneous sumatriptan compared with other medications. J Fam Pract 1995;41(2):147-52.

MarketScan® Databases [computerized database]. Ann Arbor MI: The MEDSTAT Group, 1998.

Mayou R, Seagroatt V, Goldacre M. Use of psychiatric services by patients in a general hospital. BMJ 1991;303(6809):1029-32.

McGrath PJ, Humphreys P, Keene D, Goodman JT, Lascelles MA, Cunningham SJ, Firestone P. The efficacy and efficiency of a self-administered treatment for adolescent migraine. Pain 1992;49(3):321-4.

Medical Economics Company. Drug topics redbook. Oradell, New Jersey: Medical Economics Co., 1996.

Michel P, Pariente P, Duru G, Dreyfus JP, Chabriat H, Henry P, Dreyfus JP. MIG ACCESS: a

population-based, nationwide, comparative survey of access to care in migraine in France. Cephalalgia 1996;16(1):50-5.

Micieli G, Frediani F, Cavallini A, Rossi F, Bussone G, Merli S, Nappi G. Quantification of headache disability: a diagnostic-based approach. Headache 1995;35(3):131-7.

Mitchell CS, Osborn RE, Grosskreutz SR. Computed tomography in the headache patient: is routine evaluation really necessary? Headache 1993;33(2):82-6.

Mounstephen AH, Harrison RK. A study of migraine and its effects in a working population. Occup Med 1995;45(6):311-7.

Murray WJ. Evaluation of aspirin in treatment of headache. Clin Pharmacol Ther 1963;5(1):21-25.

Newland CA, Illis LS, Robinson PK, Batchelor BG, Waters WE. A survey of headache in an English city. Res Clin Stud Headache 1978;5:1-20.

Nuechterlein KH, Holroyd JC. Biofeedback in the treatment of tension headache. Current status. Arch Gen Psychiatry 1980;37(8):866-73.

Osterhaus JT, Gutterman DL, Plachetka JR. Healthcare resource and lost labour costs of migraine headache in the US. Pharmacoeconomics 1992;2(1):67-76.

Ottervanger JP, Valkenburg HA, Grobbee DE, Stricker BH. Pattern of sumatriptan use and overuse in general practice. Eur J Clin Pharmacol 1996;50(5):353-5.

Pascual J, Polo JM, Berciano J. Serious migraine: a study of some epidemiological aspects. Headache 1990;30(8):481-4.

Peters BH, Fraim CJ, Masel BE. Comparison of 650 mg aspirin and 1,000 mg acetaminophen with each other, and with placebo in moderately severe headache. Am J Med 1983;74(6A):36-42.

Rapoport AM. Recurrent migraine: cost-effective care. Neurology 1994;44(5 Suppl 3):S25-8.

Rasmussen BK, Jensen R, Olesen J. Impact of headache on sickness absence and utilisation of medical services: a Danish population study. J Epidemiol Community Health 1992;46(4):443-6.

Richardson GM, McGrath PJ. Cognitive-behavioral therapy for migraine headaches: a minimal-therapist-contact approach versus a clinic-based approach. Headache 1989;29(6):352-7.

Robinson RG. Pain relief for headaches. Is self-medication a problem? Can Fam Physician 1993;39:867-8, 871-2.

Saadah HA. Abortive headache therapy with intramuscular dihydroergotamine. Headache 1992;32(1):18-20.

Sage MR, Wilson BC, Benness GT. Changes in neurological practice in South Australia after the introduction of computerized tomography. Med J Aust 1980;1(4):163-5.

Salomone JA 3rd, Thomas RW, Althoff JR, Watson WA. An evaluation of the role of the ED in the management of migraine headaches. Am J Emerg Med 1994;12(2):134-7.

Sands GH, Mulloy K, Goldstein J, Munoz E. Prospective payment experience with DRGs in headache patients. Headache 1990;30(3):157-9.

Scarani G, Beghi E, Tognoni G. Pharmacological treatment of primary headache: analysis of current practice from a drug utilization study. Headache 1987;27(6):345-50.

Siegel JE, Weinstein MC, Russell LB, Gold MR. Recommendations for reporting cost-effectiveness analyses. JAMA 1996;276(16):1339-41.

Silberstein SD, Lipton RB. Headache epidemiology. Emphasis on migraine. Neurol Clin 1996;14(2):421-34.

Silvestrini M, Bernardi G. Computed tomography in the routine evaluation of headache. Headache 1994;34(3):176.

Sinclair DE, Kovacs G, Hillis M. Cranial CT scans—emergency department utilization. J Emerg Med 1993;11(5):643-6.

Solomon GD. Quality-of-life assessment in patients with headache. Pharmacoeconomics 1994;6(1):34-41.

Spencer DC, Daugird AJ. The nature and content of telephone prescribing habits in a community practice. Fam Med 1990;22(3):205-9.

Stang PE, Osterhaus JT. Impact of migraine in the United States: data from the National Health Interview Survey. Headache 1993;33(1):29-35.

Stang PE, Osterhaus JT, Celentano DD. Migraine. Patterns of healthcare use. Neurology 1994;44(6 Suppl 4):S47-55.

Stang P, Sternfeld B, Sidney S. Migraine headache in a prepaid health plan: ascertainment, demographics,

physiological, and behavioral factors. Headache 1996;36(2):69-76.

Stang PE, Von Korff M. The diagnosis of headache in primary care: factors in the agreement of clinical and standardized diagnoses. Headache 1994a;34(3):138-42.

Stang PE, Von Korff M. The stability of reported headache symptoms over time. In: Olesen J, editor. Headache classification and epidemiology. New York: Raven Press, 1994b: 45-9.

Steiner TJ. Long-term cost-benefit assessment of anti-migraine drugs. Cephalalgia 1995;15(Suppl 15):37-40.

Stewart WF, Lipton RB. The economic and social impact of migraine. Eur Neurol 1994;34 Suppl 2:12-7.

Stewart WF, Lipton RB, Liberman J. Variation in migraine prevalence by race. Neurology 1996;47(1):52-9.

Stewart WF, Lipton RB, Simon D. Work-related disability: results from the American migraine study. Cephalalgia 1996;16(4):231-8.

Stewart WF, Shechter A, Liberman J. Physician consultation for headache pain and history of panic: results from a population-based study. Am J Med 1992;92(1A):35S-40S.

Tansey MJ, Pilgrim AJ, Lloyd K. Sumatriptan in the acute treatment of migraine. J Neurol Sci 1993;114(1):109-16.

Tfelt-Hansen P, Henry P, Mulder LJ, Scheldewaert RG, Schoenen J, Chazot G. The effectiveness of combined oral lysine acetylsalicylate and metoclopramide compared with oral sumatriptan for migraine. Lancet 1995;346(8980):923-6.

To T, Wu K. Health care utilization and disability of migraine: the Ontario Health Survey. Can J Public Health 1995;86(3):195-9.

Turkewitz LJ, Casaly JS, Dawson GA, Wirth O, Hurst RJ, Gillette PL. Self-administration of parenteral ketorolac tromethamine for head pain. Headache 1992;32(9):452-4.

U.S. Department of Health and Human Services. The International Classification of Diseases, 9th Revision, Clinical Modification, Fifth Edition. Reston (VA): U.S. Department of Health and Human Services, Public Health Service, Health Care Financing Administration. DHHS Publication No. (PHS) 94-1260, 1994.

van Roijen L, Essink-Bot ML, Koopmanschap MA, Michel BC, Rutten FF. Societal perspective on the burden of migraine in The Netherlands. Pharmacoeconomics 1995;7(2):170-9.

Vernon HT. The effectiveness of chiropractic manipulation in the treatment of headache: an exploration in the literature. J Manipulative Physiol Ther 1995;18(9):611-17.

Von Korff M, Galer BS, Stang P. Chronic use of symptomatic headache medications. Pain 1995;62(2):179-186.

Von Korff M, Ormel J, Keefe FJ, Dworkin SF. Grading the severity of chronic pain. Pain 1992;50(2):133-49.

Von Korff M, Stang P. Prediction of the psychosocial and behavorial outcomes of headache. In: Olesen J, editor. Headache classification and epidemiology. New York: Raven Press, 1994: 367-71.

Von Korff M, Stewart WF, Lipton RB. Assessing headache severity. New directions. Neurology 1994;44(6 Suppl 4):S40-6.

Von Korff M, Wagner EH, Dworkin SF, Saunders KW. Chronic pain and use of ambulatory health care. Psychosom Med 1991;53(1):61-79.

Von Seggern RL, Adelman JU. Cost considerations in headache treatment. Part 2: Acute migraine treatment. Headache 1996;36(8):493-502.

Weingarten S, Kleinman M, Elperin L, Larson EB. The effectiveness of cerebral imaging in the diagnosis of chronic headache. Arch Intern Med 1992;152(12):2457-62.

Wilkinson M. Treatment of acute migraine: the British experience. Headache 1990;30(Suppl 2):545-9.

Winnem J. Prevalence of adult migraine in general practice. Cephalalgia 1992;12(5):300-3.

Yabroff KR, Schulman KA, Kong J, Rubenstein LE, Epstein AJ, Glick H. A health services approach for the evaluation of innovative pharmaceuticals and biotechnology products [abstract]. AHSR FHSR Annu Meet Abstr Book [no date];12:125.

Yen S, McIntire RW. Operant therapy for constant headache complaints: a simple response-cost approach. Psychol Rep 1971;28(1):267-70.

Ziegler DK, Paolo AM. Self-reported disability due to headache: a comparison of clinic patients and controls. Headache 1996;36(8):476-80.

Evidence Tables

Evidence Table 1: Health care provider consultation for chronic headache

Study	Dates and Methods	Headache Definition	Patient Population	N	Results
Clouse and Osterhaus, 1994	1/1/89-6/30/90 Retrospective claims review with matched control	ICD9 code 346 migraine headache	Patients enrolled in a United Health Care (UHC) Corporation-affiliated health plan. Age 18-64 with a UHC pharmacy benefit provision, at least one medical claim with ICD9 code = 346, and a pharmacy claim for a drug potentially used to treat migraine.[1] The comparison had no migraine diagnosis, had at least one medical claim and were matched by age, sex, enrollment duration, and subscriber/dependent status. All subjects had a minimum 12-month enrollment.	N = 1,336 migraine N = 1,336 non-migraine controls	Medical and pharmacy costs for the migraine group were 64% greater than for the control group 1,201/1,336 (90%) of the migraine group had been seen by a physician for their migraine headaches These patients had 2,616 migraine related visits, averaging 2.2 visits per person

[1] Potential medications included: ergot alkaloids, Esgic®, Fiorinal®, isometheptene, methysergide, Phrenillin®, narcotic analgesics, NSAIDs, antidepressants, calcium antagonists, and beta-blockers.

Evidence Table 1: Health care provider consultation for chronic headache (continued)

Study	Dates and Methods	Headache Definition	Patient Population	N	Results
Edmeads, Findlay, Tugwell, et al., 1993	4/89-4/90 Survey and diary	IHS migraine tension-type	Prevalence Study- Canadians age >15 were surveyed with random digit dialing. One respondent was selected per household; if there was more than one headache sufferer, then the one with the most recent birth date was chosen. Interview Study- 138 migraine and 83 tension-type respondents answered additional questions about their headaches.	Prevalence N = 1,573 Interview N = 221 Diary N = 150	Prevalence Study 64% of migraineurs had consulted a physician at some time for their headaches 45% of tension-type headache sufferers had consulted a physician at some time for their headaches 41% of migraineurs who sought care were referred to a specialist 32% of tension-type headache sufferers who sought care were referred to a specialist Interview Study 81% of the migraineurs sought the care of a physician; of these 36% continued in follow-up 71% of the tension-type headache sufferers sought the care of a physician; of these 28% continued in follow-up Reasons for discontinuing care included the availability of effective OTC medications, headaches of insufficient frequency or severity to continue receiving care, negative side effects of medications, or unhappiness with the physician
Green, 1977	1975-1976 Survey	Self-reported migraine	England: surveys distributed to people in managerial positions, members of Parliament, office and factory workers, school children, and bank and insurance agency employees.	N = 14,893 respondents	19.44% of males and 25.72% of females responding reported that they suffered from migraine. If migraine was defined as unilateral headache then the prevalence dropped to 10.3% of males and 15.94% of females. 66.3% of males and 73.5% of females had consulted a physician about their headaches

Evidence Table 1: Health care provider consultation for chronic headache (continued)

Study	Dates and Methods	Headache Definition	Patient Population	N	Results
Linet, Stewart, Celentano, et al., 1989 Migraine Prevalence Study (Washington County Study)	3/86-6/87 Telephone survey and diary	Migraine[2]	Washington County, Maryland residents age 12-29. Sample of all households with telephone.	N = 10,169 Not all subjects answered all questions	6.5% of 4,033 males with migraine headache said they had consulted a physician in the last 12 months, 8.1% said they had consulted a physician but it was over 12 months ago, 85.4% said they had never consulted a physician for their headaches 15% of 4,857 females with migraine headache said they had consulted a physician in the last 12 months, 12.9% said they had consulted a physician but it was over 12 months ago, 72% said they had never consulted a physician for their headaches.
Lipton and Stewart, 1993 American Migraine Study[3]	11/88-12/88 Mail survey	IHS migraine	Representative sample of 15,000 US households. Obtained responses from 20,468 people age 12-80.	N = 2,422	38% of 2,479 severe migraine sufferers had received a physician diagnosis of migraine 41% of women and 29% of men reported having been diagnosed Diagnosis was 40% more likely in people with an annual household income >$45,000 than in people with a household income of <$10,000 Women 30% more likely than men to be diagnosed Likelihood of diagnosis increased with age

[2] Data collection on this study began prior to the release by the Ad Hoc Committee of its new definition of migraine. Study questions were not revised to reflect the new definition.

[3] This publication includes data from both the American Migraine Study and the Migraine Prevalence Study. Only medication results from the American Migraine Study are presented in this paper and in this table.

Evidence Table 1: Health care provider consultation for chronic headache (continued)

Study	Dates and Methods	Headache Definition	Patient Population	N	Results
Mounstephen and Harrison, 1995	Dates unknown Survey	IHS migraine	Questionnaire distributed to a random sample of 476 employees of a chemical production and research facility. The sample was stratified by age and sex. The overall rate of work absence was validated by the company's human resources database. There were 423 respondents to the questionnaire, 62 of the 423 were classified as having IHS migraine.	N = 62	42% of migraineurs said they had never consulted a physician for their headaches 19.4% of migraineurs said they had consulted a physician in the last year
Osterhaus, Gutterman, and Plachetka, 1992	1986-1991 Mail survey	IHS migraine	Patients previously enrolled in 1 of 2 clinical trials of a headache medication. Patients had been diagnosed by a physician as having migraine according to the IHS criteria. Patients were age 18 or over and had at least a 1-year history of migraine.	N = 648	585/648 (91%) had consulted a physician for their headaches Mean number of clinic visits was 6.32; 7.6% of the people who sought the care of a physician had greater than 12 physician visits 8% of the people seeing a physician accounted for 25% of the visits

Evidence Table 1: Health care provider consultation for chronic headache (continued)

Study	Dates and Methods	Headache Definition	Patient Population	N	Results
Rasmussen, Jensen, and Olesen, 1992	1/89-7/89 Questionnaire Interview Physical examination	IHS migraine tension-type	Randomly selected people age 25-64 living in the western part of Copenhagen County (Denmark).	N =740 N = 119 migraine N = 578 tension-type	56% of migraineurs had consulted a general practitioner at some time for their headaches 16% of tension-type headache sufferers had consulted a general practitioner at some time for their headaches Consultation rate was higher among women than men For both migraine and tension-type headache there was a correlation between physician consultation and the frequency of headache attacks 16/740 (2%) had ever been admitted to a hospital for headache 16% of migraineurs and 4% of tension-type headache sufferers had consulted a specialist
Stang and Osterhaus, 1993	1989 Survey	Self-reported migraine	National Health Interview Survey	N = 116,929 respondents	Among those with self-reported migraine, 85% of women and 77% of men had ever sought the care of a physician for their headaches
van Roijen, Essink-Bot, Koopman-schap, et al., 1995	10/92 (interview) 6/93 (survey) Interview/ survey	IHS migraine migraine + tension-type	Representative sample of the Dutch population age 12 years and older. Questioned 10,480 people in face-to-face interviews; of these, 992 met IHS criteria, had had a headache attack in the last 12 months, and agreed to participate.	N = 436 headache sufferers responded to the survey N = 585 non-headache controls	70% of migraine patients consulted a physician for their headaches (lifetime) Average 1.3 consultations per year per patient 6% saw a neurologist 17% sought alternative practitioners

Abbreviations: ICD9 = International Classification of Diseases, 9th Revision; IHS = International Headache Society; OTC = over-the-counter; US = United States

Evidence Table 2: Emergency department (ED) utilization for treatment of chronic headache

Study	Dates and Methods	Headache Definition	Patient Population	N	Results
Celentano, Stewart, Lipton, et al., 1992 American Migraine Study	11/88-12/88 Mail survey	IHS migraine	Representative sample of 15,000 US households. Obtained responses from 20,468 people age 12-18.	N = 2,422	13% of males and 19.5% of females reported using the ED for treatment of their headaches at some point Rate of ED use varied by the type of medication used by the patient 27% of males and 33% of females taking prescription drugs used the ED. This was three times the rate among non-prescription drug users.
Clouse and Osterhaus, 1994	1/1/89-6/30/90 Retro-spective claims review with matched control	ICD9 code 346 migraine headache	Patients enrolled in a United Health Care Corporation (UHC) affiliated health plan. Age 18-64 with a UHC pharmacy benefit provision, at least one medical claim with ICD9 code=346, and a pharmacy claim for a drug potentially used to treat migraine.[1] The comparison group had no migraine diagnosis, had at least one medical claim, and were matched by age, gender, enrollment duration, and subscriber/ dependent status. All subjects had a minimum 12-month enrollment.	N = 1,336 migraine N = 1,336 non-migraine controls	238/1336 migraine patients used the ED for treatment of their migraine headaches. These 238 patients had a total of 700 visits to the ED. An additional 293 visits were made by 118/1336 migraine patients to the ED for the treatment of non-migraine headache.[2]
Edmeads, Findlay, Tugwell, et al., 1993	4/89-4/90 Survey and diary	IHS migraine tension-type	Canadians age >15 were surveyed with random digit dialing. One respondent was selected per household; if there was more than one headache sufferer, then the one with the most recent birth date was chosen.	N = 1,573	14% of migraineurs and 8% of tension-type headache sufferers had sought care in the ED

[1]Potential medications included: ergot alkaloids, Esgic®, Fiorinal®, isometheptene, methysergide, Phrenilin®, narcotic analgesics, NSAIDs, antidepressants, calcium antagonists, and beta-blockers.
[2]Study does not indicate the overlap between groups seeking care in the Emergency Department for migraine and non-migraine headaches.

Evidence Table 2: Emergency department (ED) utilization for treatment of chronic headache (continued)

Study	Dates and Methods	Headache Definition	Patient Population	N	Results
Linet, Stewart, Celentano, et al., 1989 Migraine Prevalence Study (Washington County Study)	3/86-6/87 Telephone survey and diary	migraine[3]	Washington County, Maryland residents age 12-29. Sample of all households with a telephone.	N = 10,169 Not all subjects answered all questions	5.32% of males and 3.4% of females had seen a physician in the ED for their headaches in the last 12 months
Michel, Pariente, Duru, et al., 1996	Dates unknown Survey	IHS migraine	Used a "poll-base" to screen 6,000 French households for adults (≥18 yrs) who met cirtieria for IHS migraine in the previous 3 months. Mailed a questionnaire with a variety of health-related questions, not pertaining to migraine. A second survey was sent to a group who screened positively for migraine and to a matched controlled group without migraine.	N = 478 migraine N = 525 controls	In the previous 6 months, 5% of migraineurs and 6% of controls had been seen in the ED (difference not significant).
Osterhaus, Gutterman, and Plachetka, 1992	1986-1991 Mail survey	IHS migraine	Patients previously enrolled in 1 of 2 clinical trials of a headache medication. Patients had been diagnosed by a physician as having migraine according to the IHS criteria. Patients were age 18 or over and had at least a 1-year history of migraine.	N = 648	308/648 (48%) had used the ED for treatment of their headaches 22% of people using the ED had 1-2 visits, 15% had more than 5 visits; and 15% of the ED users accounted for 60% of all visits.

Abbreviations: ED = emergency department; ICD9 = International Classification of Diseases, 9th Revision; IHS = International Headache Society; US = United States

[3]Data collection on this study began prior to the release by the Ad Hoc Committee of its new definition of migraine. Study questions were not revised to reflect the new definition.

Evidence Table 3: Hospital admission for treatment of chronic headache

Study	Dates and Methods	Headache Definition	Patient Population	N	Results
Clouse and Osterhaus, 1994	1/1/89-6/30/90 Retrospective claims review with matched control group	ICD code 346 migraine headache	Patients enrolled in a United Health Care Corporation (UHC) affiliated health plan. Age 18-64 with a UHC pharmacy benefit provision, at least one medical claim with ICD9 code=346, and a pharmacy claim for a drug potentially used to treat migraine.[1] The comparison group had no migraine diagnosis, had at least one medical claim, and was matched by age, sex, enrollment duration, and subscriber/dependent status. All subjects had a minimum 12-month enrollment.	N = 1,336 migraine N = 1,336 non-migraine controls	142/1336 (11%) of migraineurs were hospitalized in the study period for their headaches. This group had 306 hospitalizations.

[1]Potential medications included: ergot alkaloids, Esgic®, Fiorinal®, isometheptene, methysergide, Phrenilin®, narcotic analgesics, NSAIDs, antidepressants, calcium antagonists, and beta-blockers.

Evidence Table 3: Hospital admission for treatment of chronic headache (continued)

Study	Dates and Methods	Headache Definition	Patient Population	N	Results
Michel, Pariente, Duru, et al., 1996	Dates unknown Survey	IHS migraine	Used a "poll-base" to screen 6,000 French households for adults (≥ 18 yrs) who met cirtieria for IHS migraine in the previous 3 months. Mailed a questionnaire with a variety of health-related questions, not pertaining to migraine. A second survey was sent to a group who screened positively for migraine and to a matched controlled group without migraine.	N = 478 migraine N = 525 controls	In the previous 6 months, 7% of migraineurs and 8% of controls had been hospitalized.
Micieli, Frediani, Cavallini, et al., 1995	1/90-1/91	IHS migraine tension-type cluster	Patients recruited from the Headache Research Centers of the Neurological Institute of the University of Pavia and the University of Milan (Italy). Patients were referred from general practice (70%) and self referred (30%).	N = 400	Lifetime Utilization of Hospital Resources: Episodic HA (including migraine) / Chronic tension-type HA / Mixed migraine + tension-type HA Mean # of hospital admissions: 0.1 / 0.3 / 0.1 Mean # of days in hospital: 0.8 / 4.8 / 0.7

Evidence Table 3: Hospital admission for treatment of chronic headache (continued)

Study	Dates and Methods	Headache Definition	Patient Population	N	Results
Osterhaus, Gutterman, and Plachetka, 1992	1986-1991 Mail survey	IHS migraine	Patients previously enrolled in 1 of 2 clinical trials of a headache medication. Patients had been diagnosed by a physician as having migraine according to the IHS criteria. Patients were age 18 or over and had at least a 1-year history of migraine.	N = 648	43/648 (7%) had been hospitalized for treatment of their headaches.
Rasmussen, Jensen, and Olesen, 1992	1/89-7/89 Questionnaire Interview Physical examination	IHS migraine tension-type cluster	Randomly selected people age 25-64 living in the western part of Copenhagen County (Denmark).	N = 740 (total) N = 119 migraine N = 578 tension-type	16/740 (2%) had ever been admitted to a hospital for a headache.
Stang and Osterhaus, 1993	1989 Survey	Self-reported migraine	National Health Interview Study	N = 116,929 respondents	6.2% of males and 8.4% of females had been hospitalized for the treatment of their headaches during their lifetime.

Abbreviations: HA = headache; ICD9 = International Classification of Diseases, 9th Revision; IHS = International Headache Society

Evidence Table 4: Use of pharmaceutical agents in the treatment of chronic headache

Study	Dates and Methods	Headache Definition	Population Inclusion Criteria	Sample Size	Results
Celentano, Stewart, Lipton, et al., 1992 American Migraine Study	11/88-12/88 Mail survey	IHS migraine	Representative sample of 15,000 US households. Obtained responses from 20,468 people age 12-80.	N = 2,422	Statistically significant difference by sex (P<0.001) in the use of prescription medications Migraineurs reported an 80% greater use of prescription medication than subjects with "severe headache" 4.2% of males and 2.9% of females reported no medication use for their headaches Black migraineurs reported considerably less prescription medication use than whites Black females were less likely than white women or women from other racial groups to treat their headaches or to use prescription medications. Use of prescription medication increased with age; increasing from 26.0% of men <30 to 38.6% from 50-59. Prescription medication use increased among women from 32.9% at <30 to 44.9% at 50-59. Migraineurs with incomes < $20,000 were less likely than those with higher incomes to use prescription meds (but not significantly so). Rates of prescription use were highest in the Mountain Region and New England states and lowest in Atlantic and North Central Regions 52.3% of women and 38.3% of men with vomiting used prescription medications. 48.1% of women and 30.2% of men with visual aura used prescription medications. Level of disability was also related to prescription use, as was duration of attack.

Evidence Table 4: Use of pharmaceutical agents in the treatment of chronic headache (continued)

Study	Dates and Methods	Headache Definition	Population Inclusion Criteria	Sample Size	Results
Clarke, MacMillan, Sondhi, et al., 1996	5/94-6/94 Survey	IHS migraine	Questionnaire mailed to 4,200 employees of the Royal Hull Hospitals Trust (UK). Of the 1,903 surveys returned, 158 (8.3%) were classified as having migraine.	N = 158	28% used prescription medications, 78% used OTCs 4/158 said they used sumatriptan 8/158 said they were using prophylactic treatment (either propranolol or pizotifen) 13% used alternative therapies such as acupuncture, homeopathy, or yoga

Evidence Table 4: Use of pharmaceutical agents in the treatment of chronic headache (continued)

Study	Dates and Methods	Headache Definition	Population Inclusion Criteria	Sample Size	Results
Edmeads, Findlay, Tugwell, et al., 1993	4/89-4/90 Survey and diary	IHS migraine and tension-type	Prevalence Study-Canadians age 15+ were surveyed with random digit dialing. One respondent was selected per household. If there was more than one headache sufferer then the one with the most recent birth date was chosen.	Prevalence N = 1,573	Prevalence study: Migraineurs- 44% used prescription medication, 91% non-prescription medication, 48% non-medical treatments, 6% preventive medications Tension-type headache sufferers-24% used prescription medications, 90% non-prescription medications, 34% non-medical treatments, 3% preventive medications In the interview study prescription medications were prescribed for 62% of those who had seen a physician; at the time of the interview 34% continued to use them. Non-prescription medications recommended for 50%; 25% of these people discontinued treatment. 63% of those interviewed who had never seen a physician also used medication; and 10% of these people who had never seen a physician for their headaches were using prescription medications. Migraine: 19% of headaches completely relieved by medication 62% of headaches partially relieved by medication Tension-type headaches: 43% of headaches completely relieved by medication 47% of headaches partially relieved by medication Migraine and tension-type headache sufferers used medications an average of 3 times per week. 21% of migraineurs and 17% of tension-type headache sufferers used medications more than one time per week.

Evidence Table 4: Use of pharmaceutical agents in the treatment of chronic headache (continued)

Study	Dates and Methods	Headache Definition	Population Inclusion Criteria	Sample Size	Results
Kryst and Scherl, 1994	Spring 1990 Telephone survey	Modified IHS migraine	Study question included as part of the Kentucky Health Survey. Sample households contacted through random digit dialing. Data only primary respondents only included as part of this analysis.	N = 55 migraine N = 32 serious non-migraine HA	82/87 (94.3%) of serious headache sufferers reported taking medication in the last year 41/82 (50%) used OTC and 35/82 (42.7%) prescription, 6/82 (7.3%) both 29/64 (45.3%) of headache sufferers who reported disabilities took only OTCs Interference with family relations was strongly associated with use of prescription medication (P=0.05) Use of prescription drugs was not related to income level or insurance coverage for prescription medications
Linet, Stewart, Celentano, et al., 1989 Migraine Prevalence Study (Washington County Study)	3/86-6/87 Telephone interview and diary study	Migraine	Washington County, Maryland residents 12-29 years old. Sample of all households with telephone.	N = 10,169 Not all subjects answered all questions	Age 12-17 18-23 24-29 Males 8.8% 16.2% 18.0% Females 10.9% 16.8% NA Among males, approximately twice as many in the older age groups had taken at least one prescription medication in the last 12 months than in the youngest age groups. Among females prescription drug use also increased with age.
Lipton and Stewart, 1993	11/88-12/88 Mail survey	IHS migraine	Representative sample of 15,000 US households. Obtained responses from 20,468 people age 12-80.	N = 2,422	95% of severe migraineurs have used some type of medication Most migraineurs take non-prescription medications rather than prescription Among women, 56.8% used non-prescription medications, 40.1% used prescription drugs, and 3.1% take no medications for their headaches Among men, 66.9% used non-prescription medications, 28.3% used prescription drugs, and 4.8% take no medications for their headaches 43% of men and 34% of women with 3+ headaches per month do not use prescription medication 61% of men and 47% of women with moderate or severe headache related disability do not use prescription medications

Evidence Table 4: Use of pharmaceutical agents in the treatment of chronic headache (continued)

Study	Dates and Methods	Headache Definition	Population Inclusion Criteria	Sample Size	Results
Micieli, Frediani, Cavallini, et al., 1995	1/90-1/91 Interview	IHS migraine tension-type cluster	Patients recruited from the Headache Research Centers of the Neurological Institute of the University of Pavia and the University of Milan. 70% had been referred from general practice and 30% were self referred.	N = 400	Headache Characteristics and Response to Therapy:

HA	Total	Episodic HA (including migraine)	Mixed migraine + tension-type HA	Chronic tension-type
Analgesic consumption				
None	7.5%	6.9	8.7	7.7
Monthly	28.0	33.5	17.4	5.8
Weekly	46.6	49.0	47.8	36.5
Daily	12.7	8.6	17.4	30.8
More than 1/day	5.3	2.0	8.7	19.2
Analgesic efficacy				
None	6.4	6.6	4.8	6.3
Fair	44.3	39.5	57.1	60.4
Good	49.3	53.9	38.1	33.3
Preventive therapy				
None	46.8	47.9	50.0	45.5
Fair	31.2	25.0	25.0	40.9
Good	22.1	27.1	25.0	13.6

Evidence Table 4: Use of pharmaceutical agents in the treatment of chronic headache (continued)

Study	Dates and Methods	Headache Definition	Population Inclusion Criteria	Sample Size	Results
Mount-stephen and Harrison, 1995	Dates unknown Survey	IHS migraine	Questionnaire distributed to a random sample of 476 employees of a chemical production and research facility. The sample was stratified by age and sex. The overall rate of work absence was validated by the company's human resources database. There were 423 respondents to the questionnaire; 62 of the 423 were classified as having IHS migraine.	N = 62	10% of migraineurs obtained their medication by prescription 13% used prophylactic medication
Rasmussen, Jensen, and Olesen, 1992	1/89-7/89 Questionnaire Interview Physical examination	IHS migraine and tension-type	Randomly selected people, 25-64 years old, living in the western part of Copenhagen county (Denmark).	N = 740	38/77 (49%) with migraine in the previous year used medication in the current year 480/549 (87%) with tension-type headache in the previous year used medication in the current year 31% of migraine and 59% of tension-type headache sufferers used medications with acetylsalicylic acid an average of 1-3 times a month. Significant correlation between frequency of headache and medication use 17% of migraineurs used ergotamine or dihydroergotamine agents 1-3 times per month 7% used preventive treatment (4% beta-blockers and 3% clonidine)

Evidence Table 4: Use of pharmaceutical agents in the treatment of chronic headache (continued)

Study	Dates and Methods	Headache Definition	Population Inclusion Criteria	Sample Size	Results
Von Korff, Galer, and Stang, 1995	1989-1990 Questionnaire	IHS migraine	Patients making headache related visits to primary care provider at Group Health of Puget Sound. Patients were 18-75 years old and had to be continuously enrolled for one year. Patients were excluded if they planned to disenroll or if they did not have a telephone.	N = 662	Percent of headache patients reporting frequent medication use in the previous month: Prescription: Baseline 18.4%, One year 10.3, Two years 10.1, Chronic 7.7 Non-Prescription: Baseline 20.1, One year 19.0, Two years 17.7, Chronic 15.9 Poly Pharmacy: Baseline 5.6, One year 4.7, Two years 3.6, Chronic 2.6

Abbreviations: HA = headache; IHS = International Headache Society; NA = not available; OTC = over-the-counter; UK = United Kingdom; US = United States

Evidence Table 5: Cost-effectiveness of non-pharmacological treatments for chronic headache

Study	Study Design	Headache Definition	Patient Population	Number of patients; Interventions	Results
Attanasio, Andrasik, and Blanchard, 1987	Prospective Randomized	Ad Hoc tension-type	Patients recruited from a university based headache clinic.	N = 25 (total) Relaxation + cognitive-behavioral therapy (office-based) (N = 7) Relaxation + cognitive-behavioral therapy (home-based) (N = 8) Relaxation only (home-based) (N = 6)	No effect of treatment was seen. There was no significant difference in cost effectiveness between treatment groups.
Blanchard, Andrasik, Appelbaum, et al., 1985 Study 1	Prospective Randomized	Ad Hoc tension-type	Does not describe the setting in which patients were recruited. No inclusion or exclusion criteria.	N = 53 Relaxation + thermal biofeedback: Clinic-based (N = 26) Home-based (N = 27)	Both interventions had significant reduction in headache activity from baseline but were not significantly different from each other. The home-based intervention was much more cost-effective than clinic-based treatment (P=0.009).
Blanchard, Andrasik, Appelbaum, et al., 1985 Study 2	Prospective Randomized	Ad Hoc migraine mixed migraine and tension-type	Does not describe the setting in which the patients were recruited. No inclusion or exclusion criteria.	N = 39 (migraine) Relaxation + thermal biofeedback: Clinic-based (N = 21) Home-based (N = 18) N = 48 mixed migraine and tension-type Relaxation + thermal biofeedback: Clinic-based (N = 22) Home-based (N = 26)	Both interventions led to significant reductions in headache activity but they were not significantly different from each other. The home-based intervention was 4 times more cost effective for migraine (P<0.001) and 6 times more cost effective for mixed migraine + tension-type headache than clinic-based treatment.

Evidence Table 5: Cost-effectiveness of non-pharmacological treatments for chronic headache (continued)

Study	Study Design	Headache Definition	Patient Population	Number of patients; Interventions	Results
Blanchard, Jaccard, Andrasik, et al., 1985	Retrospective '81-'82 Prospective '83-'84	Chronic headache: migraine tension-type mixed migraine/ tension-type	Does not describe the setting in which the patients were recruited. No inclusion or exclusion criteria.	N = 73 Various combinations of relaxation and biofeedback training	Two-year medical costs associated with chronic headache before and after treatment. Category / Mean Pre-tx / Mean Post-tx Medication $225 $33 FP visits 80 15 Neuro visits 275 NA Hospital 211 3 Non-med 164 2 Total 995 52

Abbreviations: tx = treatment

Evidence Table 6: Work loss due to chronic headache

Study	Dates and Methods	Headache Definition	Patient Population	N	Results
Celentano, Stewart, Lipton, et al., 1992 American Migraine Study	11/88-12/88 Mail survey	IHS migraine	Representative sample of 15,000 US households. Obtained responses from 20,468 people age 12-80.	N = 2,422	Headache Related Disability: None: Males 15.3%, Females 11.2 Mild: Males 53.0, Females 50.8 Mod/Sev: Males 30.7, Females 36.9 Don't Know: Males 1.0, Females 1.1 As disability level increased, prescription medication used increased Moderate or severe disability was defined as the need for bed rest, absence from work or school, and inability to do usual activities
Clarke, MacMillan, Sondhi, et al., 1996	5/94-6/94	IHS migraine	Questionnaire mailed to 4,200 employees of the Royal Hull Hospitals Trust (UK). Of 1,903 surveys returned 158 (8.3%) were migraine.	N = 158	76% reported no time lost from work, 13% were absent one day, 6% two days, 6% three to five days, and 1% reported being absent more than six days The mean absence rate was 0.49 days per month or 2 days per year Employees with migraine spent 15.5 days per year at work with an attack, and were only 56% effective for an equivalent of 5.5 additional days of work lost An average of two days' absence per year due to headache would be equivalent to about 20% of all the sickness related absence in the NHS
Edmeads, Findlay, Tugwell, et al., 1993	4/89-4/90 Survey and diary	IHS migraine tension-type	Diary Study—done 3 months after Prevalence and Interview studies (1/90-3/90). 95 migraine and 55 tension-type headache sufferers completed diaries about their headaches.	Diary N = 150	11% of the migraine and 4% of tension-type headache occurrences caused the person to leave or not attend work

Evidence Table 6: Work loss due to chronic headache (continued)

Study	Dates and Methods	Headache Definition	Patient Population	N	Results
Green, 1977	1975-1976 Survey	Self-reported migraine	England: surveys distributed to people in managerial positions, members of Parliament, office and factory workers, school children, and bank and insurance agency employees.	N = 14,893 respondents	Just over 1/3 of males and just under 1/3 of females said they were never absent from work due to migraine Migraineurs were absent from work approximately 4 days/year due to headache
Jones and Harrop, 1980	8/79 Survey	Self-reported migraine	Employees of General Foods Ltd. (UK). Surveyed 2,100 employees, 895 responses returned. Of the 895, 20% reported migraine at some time.	N = 895 respondents	Over 8 months, 98 employees lost 281 work days due to migraine Mean number of days absent, 2.87; extrapolated to 1 year, the mean number of days lost would be 4.30 36/111 migraine attacks during the study period occurred at work
Kryst and Scherl, 1994	Spring 1990 Telephone survey	Modified IHS migraine	Study questions included as part of the Kentucky Health Survey. Sample households contacted through random digit dialing. Data on only primary respondents included as part of this analysis.	N = 55 migraine N = 32 serious non-migraine	56.3% reported that headache affected their ability to work efficiently (outside or inside the home) 37.9% reported that headache affected their attendance at work or school Many respondents continued to attend work or school even though they had a headache

Evidence Table 6: Work loss due to chronic headache (continued)

Study	Dates and Methods	Headache Definition	Patient Population	N	Results
Linet, Stewart, Celentano, et al., 1989 Migraine Prevalence Study (Washington County Study)	3/86-6/87 Telephone survey and diary	Migraine[1]	Washington County, Maryland residents age 12-29. Sample of all households with telephone.	N = 10,169 Not all subjects answered all questions	Work or school missed: Men / Women None 91.7% / 85.9 1/2 day 6.1 / 10.2 all day 1.8 / 3.7 missing 0.4 / 0.2 Disability was most pronounced among women ages 24-29; this was the least affected age group in males
Micieli, Frediani, Cavallini, et al., 1995	1/90-1/91 Interview	IHS migraine tension-type cluster	Patients recruited from the Headache Research Centers of the Neurological Institute of the University of Pavia and the University of Milan (Italy). 70% had been referred from general practice and 30% were self referred.	N = 400	Headache during work hours was reported to be completely disabling by 58.5% episodic headache patients, 70.6% of chronic tension-type headache patients, and 30.4% of migraine + tension-type headache patients Missed work days per month 5.1 for episodic headache patients, 3.7 for chronic tension-type headache patients, 2.4 for mixed migraine + tension-type headache patients

[1]Data collection on this study began prior to the release by the Ad Hoc Committee of its new definition of migraine. Study questions were not revised to reflect the new definition.

Evidence Table 6: Work loss due to chronic headache (continued)

Study	Dates and Methods	Headache Definition	Patient Population	N	Results
Mounstephen and Harrison, 1995	Dates unknown Survey	IHS migraine	Questionnaire distributed to a random sample of 476 employees of a chemical production and research facility. The sample was stratified by age and sex. The overall rate of work absence was validated by the company's human resources database. There were 423 respondents to the questionnaire, 62 of the 423 were classified as having IHS migraine.	N = 62	Based on the duration and frequency of migraine attacks, the authors calculated that women would experience 144 hours of headache per year and men 44 hours. Some of these hours would be during work, but they did not collect this information specifically.
Newland, Illis, Robinson, et al., 1978	7/73-2/74 Mail survey	Self-reported headache	Population based sample in Southampton, England	N = 2,066 respondents	Among 655 men reporting any headache in the past year, 42 (6%) reported work loss averaging 3.7 days. All work loss occurred among men reporting headaches associated with at least one feature of migraine (unilateral distribution, warning, or nausea).
Osterhaus, Gutterman, and Plachetka, 1992	1986-1991 Mail survey	IHS migraine	Patients previously enrolled in 1 of 2 clinical trials of a headache medication. Patients had been diagnosed by a physician as having migraine according to the IHS criteria. Patients were age 18 or over and had at least a 1-year history of migraine.	N = 648	29/56 males reported missing work in 1 month, they were absent an average of 2.5 days per month 250/445 females reported missing work in 1 month, they were absent an average of 2.1 days per month 55/56 men reported reduced work effectiveness; 60% as effective 430/445 women reported reduced work effectiveness; 56.3% as effective Of the 56% of employed respondents who reported missing work due to headache, a mean of 2.2 work days were missed Employed respondents worked an average of 5.8 days with migraine in the previous month Annual cost of lost labor (including benefits) men: $6,864 and $3,600 for women

Evidence Table 6: Work loss due to chronic headache (continued)

Study	Dates and Methods	Headache Definition	Patient Population	N	Results
Rasmussen, Jensen, and Olesen, 1992	1/89-7/89 Questionnaire Interview Physical examination	IHS migraine tension-type	Randomly selected people age 25-64 living in the western part of Copenhagen County (Denmark).	N = 740 N = 119 migraine N = 578 tension-type	29/67 (43%) of gainfully employed migraineurs said they had been absent from work at least one time in the last year due to headache 91% were absent less than 7 days, but 9% said they were absent 7-14 days 56/472 (12%) of tension-type headache sufferers said they had been absent from work at least one time in the last year due to headache 16% said they were absent more than 14 days Women had a higher absence rate than men, but not significantly so Absence rate among migraineurs was significantly higher than among tension-type headache sufferers
Stang and Osterhaus, 1993	1989 Survey	self-reported migraine	National Health Interview Survey	N = 116,929 respondents	Estimated 825,916 restricted activity days per 2 weeks among employed persons or 3.465 restricted activity days per migraineur per year Estimate that housewives lose 38.5 million days of activity per year Based on wages lost, they calculated that the 6,196,378 employed migraineurs lost 1.4 billion dollars per year

Evidence Table 6: Work loss due to chronic headache (continued)

Study	Dates and Methods	Headache Definition	Patient Population	N	Results
Stewart, Lipton, and Liberman, 1996 Baltimore County Study	11/93-8/94 Telephone survey	IHS migraine	Households contacted through random digit dialing. Subjects were eligible if age 18-65. Respondents were included if they had at least one headache which was not attributable to injury, hangover, pregnancy, or cold or flu.	N = 1,775 migraine	<u>Women</u> missed work or school: never 32.7% White, 34.3 Black, 57.1 Asian-American rarely 30.9, 30.4, 14.3 1/2 the time 16.3, 13.1, 14.3 ≥1/2 the time 20.1, 22.3, 14.3 % reduced work efficiency none 7.3, 14.6, 16.7 <25% 22.8, 20.5, 16.7 25-49% 35.4, 35.4, 0.0 50-74% 17.6, 11.9, 50.0 ≥75% 16.9, 17.6, 16.7 <u>Men</u> missed work or school: never 43.4 White, 42.4 Black, 0.0 Asian-American rarely 31.6, 27.3, 66.7 1/2 the time 8.9, 19.7, 0.0 ≥1/2 the time 16.1, 10.6, 33.3 % reduced work efficiency none 9.2, 17.7, 0.0 <25% 23.7, 19.4, 0.0 25-49% 36.5, 37.1, 50.0 50-74% 14.8, 4.8, 50.0 ≥75% 15.8, 21.0, 0.0 No difference was seen by race in frequency of missed work or duration of attack Black women reported more frequent attacks but were significantly less likely to report reduced efficiency at work Black men were also less likely to report reduced efficiency

Evidence Table 6: Work loss due to chronic headache (continued)

Study	Dates and Methods	Headache Definition	Patient Population	N	Results
Stewart, Lipton, and Simon, 1996 Follow-up to American Migraine Study	11/88-12/88 Mail survey	IHS migraine	The first American Migraine Study survey was mailed to a representative sample of 15,000 households. A total of 20,468 individuals age 12-80 responded. Using IHS criteria and data from that survey, 2,355 people age 18 or over with one or more migraine attacks in the previous year were identified. A second survey, the "Headache Disability and Healthcare Questionnaire," was sent to these individuals during the 12 months covered by the original survey.	N = 1,663	Median number of missed workdays was 1 for men and 2 for women. Average number of missed workdays was 3.8 for men and 8.3 for women. At least one day of work was missed in the last year by 56.4% of men and 73.6% of women. Men reported 42% effectiveness at work; women 34%. Lost work day equivalents (LWDE): LWDE / Men / Women 0 / 6.1% / 12.0% 1-2 / 20.9% / 31.8% 3-5 / 21.9% / 18.1% 6-10 / 16.1% / 14.0% 11-20 / 15.5% / 9.4% 21+ / 19.5% / 14.7%
van Roijen, Essink-Bot, Koopmanschap, et al., 1995	10/92 (interview) 6/93 (survey) Interview/ survey	IHS migraine migraine + tension-type	Representative sample of the Dutch population age 12 years and older. Questioned 10,480 people in face-to-face interviews; of these, 992 met IHS criteria, had had a headache attack in the last 12 months, and agreed to participate.	N = 436 headache sufferers responded to the survey N = 585 non-headache controls	10% of women and 2% of men reported some absence from work due to headache Based on a 2-week recall period, women reported 3.9 days/year and men 1.0 day/year absent from work due to headache Women had 22.8 hours/year and men 18.7 hours/year of reduced productivity due to headache Women reported having 73% efficiency at work with a headache and men 69% efficiency

Abbreviations: IHS = International Headache Society; Ltd. = Limited; mod = moderate; NHS = National Health Service; sev = severe; UK = United Kingdom; US = United States

Appendixes

Appendix A:
Original Electronic Search Strategy

1	exp headache/
2	headache$.tw.
3	(head adj ache$).tw.
4	1 or 2 or 3
5	cost$.tw.
6	economi$.tw.
7	practice pattern$.tw.
8	exp "costs and cost analysis"/
9	physician's practice patterns/
10	5 or 6 or 7 or 8 or 9
11	4 and 10

The search strategy was run in Ovid version of the MEDLINE, HealthStar, and CINAHL databases.

$ indicates unlimited truncation, used to retrieve all possible suffix variations of a root word (e.g., the search "disease$" would retrieve the word "disease," as well as the words "diseases," "diseased," etc.

The *adj* operator requires that the query terms before and after will be found when adjacent and in the specified order.

The extension *.tw* indicates that the antecedent terms is used in a text-word search in titles and abstracts.

The term *exp* indicates the *explode* function in which the indicated term and terms one or more levels beneath in the MeSH tree structure are included.

Appendix B:
Revised Electronic Search Strategy

1	exp headache/
2	headache$.tw.
3	(head adj ache$).tw.
4	1 or 2 or 3
5	cost$.tw.
6	economi$.tw.
7	practice pattern$.tw.
8	exp "costs and cost analysis"/
9	physician's practice patterns/
10	exp drug utilization/
11	ut.fs.
12	5 or 6 or 7 or 8 or 9 or 10 or 11
13	4 and 12

The search strategy was run in the Ovid version of the MEDLINE, HealthStar, and CINAHL databases.

Terms from the Medical Subject Heading (MeSH) lexicon/taxonomy are indicated in bold face; the term *explode* indicates that the immediately following MeSH heading and also those one or more levels beneath in the MeSH tree structure are included; for example exp drug utilization includes drug utilization review. The extension *.fs* indicates that all citations coded with the antecedent MeSH subheading will be identified.

$ indicates unlimited truncation, used to retrieve all possible suffix variations of a root word (e.g., the search "disease$" would retrieve the word "disease," as well as the words "diseases," "diseased," etc.

The *adj* operator requires that the query terms before and after will be found when adjacent and in the specified order.

The extension *.tw* indicates that the antecedent terms are used in a text-word search in titles and abstracts.

Appendix C:
List of Excluded Articles

Articles passing the title-and-abstract screen but excluded from consideration in the report

	Reference	Disposition
1	Adelman and Vonseggern, 1995	Does not report original research (review article)
2	Akpek, Arac, Atilla, et al., 1995	Subject: Diagnostic imaging
3	Appleby, 1996	Does not report original research (review article)
4	Baker, 1983	Subject: Diagnostic imaging
5	Beaty and Haynes, 1979	No utilization or cost data reported
6	Becker, Green, Beaufait, et al., 1993a	Subject: Diagnostic imaging
7	Becker, Green, Beaufait, et al., 1993b	Subject: Diagnostic imaging
8	Becker, Iverson, Reed, et al., 1988	Subject: Diagnostic imaging
9	Becker, Riess, and Hoag, 1996	Methodological: Emergency room utilization data were reported on only the small fraction of treated patients who continued dihydroergotmaine (DHE) treatment for more than three months.
10	Broadhead, Larson, Yarnall, et al., 1991	No utilization or cost data reported
11	Burke and Andrasik, 1989	No utilization or cost data reported
12	Business & Health, 1992	Does not report original research (review article)
13	Cady and Shealy, 1993	No utilization or cost data reported
14	Carrera, Gerson, Schnur, et al., 1977	Subject: Diagnostic imaging
15	Cull, Wells, and Miocevich, 1992	COULD NOT OBTAIN COPY
16	Cypress, 1981	Does not report original research (review article)
17	Dahlöf, 1995	No utilization or cost data reported
18	Davey and Leeder, 1992	Does not report original research (review article)
19	de Lissovoy and Lazarus, 1994	Does not report original research (review article)
20	Demaerel, Boelaert, Wilms, et al., 1996	Subject: Diagnostic imaging
21	Diamond and Medina, 1989	Does not report original research (review article)
22	Dumas, Pexman, and Kreeft, 1994	Subject: Diagnostic imaging
23	Feczko, 1992	Does not report original research (letter)
24	Friedman and Taub, 1984	No utilization or cost data reported
25	Frolund and Frolund, 1986	Population not primary headache

26	Furlong, Pryse-Phillips, Crowley, et al., 1996	Methodology: Utilization data were not a primary outcome of the study and were obtained haphazardly on small proportion of patients (less than 50%). Low follow-up rate severely biases the utilization results.
27	Futterman and Hill, no date	Abstract only, no full report
28	Ganiats, Carson, Hamm, et al., 1994	Abstract only, no full report
29	Ginsberg, Israeli, Cohen, et al., 1996	Population not primary headache
30	Greiner and Addy, 1996	Methodology: Work loss data not quantifiable (only reported as increased, decreased or unchanged)
31	Hackett, 1994	Does not report original research (review article)
32	Hoffert, 1994	Does not report original research (review article)
33	Holroyd and Penzien, 1990	No utilization or cost data reported
34	Hopkins, 1989	Population/utilization data not specific for headache
35	Hopkins, 1996	No utilization or cost data reported
36	Hudzinski and Zebrick, 1996	Population not primary headache
37	Ilacqua, 1994	No utilization or cost data reported
38	Jhingran, Cady, Rubino, et al., 1996	No utilization or cost data reported
39	Kahn, Sanders, Lyons, et al., 1993	Subject: Diagnostic imaging
40	Kent, 1996	Does not report original research (review article)
41	Klapper, 1995	No utilization or cost data reported
42	Knaus and Davis, 1978	Subject: Diagnostic imaging
43	Knaus, Wagner, and Davis, 1981	Subject: Diagnostic imaging
44	Kozma, Mauch, Reeder, et al., 1994	Does not report original research (review article)
45	Kozma and Reeder, 1995	Does not report original research (review article)
46	Kroenke and Mangelsdorff, 1989	No utilization or cost data reported
47	The Lancet, 1992	Does not report original research (editorial)
48	Larson, Omenn, and Lewis, 1980	Subject: Diagnostic imaging
49	Lipton, Amatniek, Ferrari, et al., 1994	Does not report original research (review article)
50	Lipton, Stewart, and Von Korff, 1994	Does not report original research (review article)
51	Lipton, Stewart, and Von Korff, 1995	Does not report original research (review article)
52	Luciani, Osterhaus, and Gutterman, 1995	No utilization or cost data reported
53	Mayou, Seagroatt, and Goldacre, 1991	Population/utilization data not specific for headache
54	McGrath, Humphreys, Keene, et al., 1992	No utilization or cost data reported
55	Mitchell, Osborn, and Grosskreutz, 1993	Subject: Diagnostic imaging
56	Murray, 1963	No utilization or cost data reported
57	Nuechterlein and Holroyd, 1980	No utilization or cost data reported
58	Pascual, Polo, and Berciano, 1990	No utilization or cost data reported
59	Peters, Fraim, and Masel, 1983	No utilization or cost data reported
60	Rapoport, 1994	Does not report original research (review article)
61	Richardson and McGrath, 1989	Does not report original research (review article)

62	Robinson, 1993	Format: Data reported elsewhere
63	Saadah, 1992	No utilization or cost data reported
64	Sage, Wilson, and Benness, 1980	Subject: Diagnostic imaging
65	Sands, Mulloy, Goldstein, et al., 1990	Not primary headache population (population includes Diagnostic-Related Groups 24, 25, 26 [seizure with headache])
66	Scarani, Beghi, and Tognoni, 1987	Subject: Not related
67	Silberstein and Lipton, 1996	Does not report original research (review article)
68	Silvestrini and Bernardi, 1994	Subject: Diagnostic imaging
69	Sinclair, Kovacs, Hillis, 1993	Subject: Diagnostic imaging
70	Solomon, 1994	Does not report original research (review article)
71	Spencer and Daugird, 1990	No utilization or cost data reported
72	Stang and Von Korff, 1994a	No utilization or cost data reported
73	Stang and Von Korff, 1994b	No utilization or cost data reported
74	Stang, Osterhaus, and Celentano, 1994	Does not report original research (review article)
75	Steiner, 1995	Does not report original research (review article)
76	Stewart and Lipton, 1994	Does not report original research (review article)
77	Stewart, Shechter, and Liberman, 1992	Secondary analysis of previously published data
78	Tansey, Pilgrim, and Lloyd, 1993	No utilization or cost data reported
79	Tfelt-Hansen, Henry, Mulder, et al., 1995	No utilization or cost data reported
80	To and Wu, 1995	Methodological: Utilization data reported were for all causes; the proportion of physician consultation, emergency room use and hospitalization attributable to migraine were not described. Diagnosis of migraine was not collected systematically in the survey, but required that subjects volunteer this diagnosis.
81	Turkewitz, Casaly, Dawson, et al., 1992	No utilization or cost data reported
82	Vernon, 1995	Does not report original research (review article)
83	Von Korff, Ormel, Keefe, et al., 1992	No cost or utilization data reported
84	Von Korff and Stang, 1994	No utilization or cost data reported
85	Von Korff, Stewart, and Lipton, 1994	No utilization or cost data reported
86	Von Korff, Wagner, Dworkin, et al., 1991	Methodological: Utilization data not specific to migraine
87	Von Seggern and Adelman, 1996	Does not report original research (review article)
88	Weingarten, Kleinman, Elperin, et al., 1992	Subject: Diagnostic imaging
89	Wilkinson, 1990	Does not report original research (review article)
90	Yabroff, Schulman, Kong, et al.,	Abstract only, no full report
91	Yen and McIntire, 1971	Format: Case study
92	Ziegler and Paolo, 1996	No utilization or cost data reported

Appendix D:
Data Collection Form for Headache Cost Studies: Original Research

Source:

Dates of Data Collection:

Study Type:

Headache Definition Used:

Description of Study Population and Patient Sample Inclusion/Exclusion Criteria:

Intervention:

Method by Which Cost Results Were Obtained:

Results (include base year on which cost calculation is based):

Comments:

Reviewed by: _____
Date: _____

Explanation of Terms Used in Data Collection Form for Cost Studies

Source. Give the first three authors of the study, full title, journal, date, volume, and page citation for each article.

Dates of data collection. List the inclusive dates during which patients were enrolled and follow-up data were collected.

Publication dates of reviewed studies. List the inclusive dates of studies included in review articles/meta-analyses, with special attention to the date of the most recent study.

Study type. Give study type, Meta analysis, review of literature, randomized controlled clinical trial, other controlled clinical trial, etc. At minimum indicate prospective or retrospective data collection and active intervention or observation of study patients.

Headache definition. State method by which headache was defined in study patients (e.g., International Classification, Ad Hoc Committee Classification) or if non-standard definition include the definition used by the authors.

Total study population. For original studies or meta-analyses, give the total number of patients observed and the total included in each subgroup in the analyses.

Patient inclusion/exclusion criteria. List the criteria by which patients were either included or excluded from the study.

Intervention. For original studies discuss the interventions applied to each group of patients in the study (i.e., use of a new drug vs standard therapy or diagnostic test vs diagnostic test). What differences in the patterns of care of the patient groups are being tested?

Method of comparison. For review articles or meta analyses, describe the method by which comparisons are made between studies.

Method by which cost results were obtained. Describe the way in which costs (all direct and indirect) were calculated. Did the study actually calculate costs or did they really use charges? Indicate whether cost projections are based on a "gold-standard" of care or standard care currently provided. If actual costs were used, are the results discussed in terms of units of resources used or are costs used to project an estimated cost to some larger entity (e.g., a hospital, government program, or to the nation as a whole)? If cost projections are formulated, are numbers based on the incidence of headache or prevalence over a certain time period?

Results/conclusions. Describe as completely as possible the results of the study. State base year dollars in which results are given. Give descriptive information on patient population (sex, age, race, SES). Present results indicating all direct and indirect costs with direct costs classified as in-patient, out-patient, drug costs, or other expenses.

Comments. In this section please provide additional details which may facilitate future review of this data. Indicate if additional detailed results are available in the paper. Also include impression of overall study quality, especially if methodologic quality will call the results of the study into question.