PATIENT FOCUSED OUTCOMES: QUALITY OF LIFE AND LOST PRODUCTIVITY

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ABSTRACT:

Purpose: To determine the factors associated with health-related quality of life and lost workplace and non-workplace productivity of patients with migraine headache.

Scope: Migraine headache is a highly prevalent, chronic, and episodic condition. The direct and indirect costs of migraine headache have a large economic impact in the US.

Methods: Various methodologies were employed: 1) prospective convenience sample study to test the reliability of the primary headache survey (PHS); 2) literature review of lost productivity instruments; 3) literature review of lost productivity databases; and 4) retrospective, pooled, cross-sectional study using data from the1996 to 1999 Medical Expenditure Panel Survey.

Results: 1) The PHS appears to be internally consistent and reliable. 2) Of the 11 identified lost productivity instruments, six capture metrics that are suitable for direct translation into a monetary figure, and five measure both absenteeism and presenteeism. 3) Of the nine lost productivity databases reviewed, six capture metrics suitable for translation into a monetary figure, which allowed appraisal of the lost productivity for a given population. Of these six, all capture absenteeism and three capture presenteeism. 4) For individuals with migraine headache, a higher level of access to care is significantly associated with an increased likelihood to miss work and to miss a greater number of workdays. Depression, migraine severity, and healthcare use are important explanatory variables. Having health insurance may be a confounder between access to care and workplace absenteeism.

Key Words: migraine headache, access to care, absenteeism, presenteeism, productivity

PURPOSE:
The overall study objectives were to examine and measure the patient-focused outcomes of health-related quality of life (HRQoL) and lost workplace and non-workplace productivity of patients with migraine headache.

The specific didactic aims were to:

1. Receive didactic instruction related to health services research and health policy at Johns Hopkins Bloomberg School of Public Health (JHBSPH)
2. Obtain a Masters of Public Health degree from JHBSPH
3. Obtain a PhD in Health Services Research from JHBSPH

The specific experiential and research aims were to:

1. Develop and validate a primary headache questionnaire
2. Review the measures and methodologies for valuing lost workplace and non-workplace productivity of patients with migraine headache
3. Review the available productivity databases that capture lost workplace and non-workplace productivity
4. Determine the variables associated with lost workplace and non-work productivity of patients with migraine headache

SCOPE OF EXPERIENTIAL and RESEARCH COMPONENT:
Migraine Headache

Epidemiology
Migraine headache is a highly prevalent,(1) chronic, episodic condition that is often misdiagnosed(2) and undertreated.(3) Approximately 24 million Americans suffer from migraine headache(2); however, across the globe, 10 times as many individuals, 240 million, suffer from an estimated total of 1.4 billion migraine attacks annually.(4) The 1-year prevalence of migraine headache is approximately three times as high for women as it is for men (17.2 versus 6 percent)(5;6); the highest prevalence occurs between the ages of 30 and 49.(5) The cyclical hormonal changes associated with menses may account for some features of the increased migraine prevalence among women.(7)

Economic Impact

The estimates of the economic burden of migraine headache are substantial. In 1994, the associated healthcare costs for migraine headache were significant, reaching a value equivalent to approximately $US 1.25 billion in 2003 dollars.(8) The annual losses associated with lost workplace productivity secondary to migraine headache have been estimated to range from the equivalent of $US 16.2 billion(8;9) to $28.7 billion in 2003 dollars.(8).

Despite its high prevalence and significant economic impact, migraine headache within the United States is undertreated,(2;3) suggesting that the quality of the healthcare for individuals with this condition is less than optimal. Donabedian proposed that there are three dimensions by which the quality of healthcare can be evaluated; structure, process, and outcomes of care. The structure of healthcare refers to "organization arrangements and resources available to a particular provider, including the scope of hospital services, size and type of staff, and ownership characteristics."

The processes of healthcare refer to the "activities engaged in by medical personnel in delivering care," and outcomes assessment is the measurement of the results delivered by healthcare providers. Therefore, based on Donabedian's model, the overall goal of providing medical care may be to improve the functional state and general well-being of an individual. If this assumption is true, then the ultimate metric by which to measure the quality of healthcare is an outcome measure, such as workplace absenteeism or health-related quality of life (HRQoL).

However, until recently, little healthcare data have been collected on the outcomes of care; data have been primarily collected on the structure and processes of care. Outcomes data, including workplace absenteeism and HRQoL, are now available from national surveys, such as the Medical Expenditure Panel Survey (MEPS). The MEPS was developed such that outcomes of care of the study respondents are collected, and data are now available to examine the quality of care that has been delivered. Therefore, the quality of care that individuals with migraine headache receive can be evaluated.

Access to Care

The quality of healthcare for individuals has many components related to access to care. Good access to healthcare may be desirable not only for an individual but for society, as well. The quality of an individual's access to care may be measured by its ability to improve an individual's functional state or well-being. Therefore, measuring an individual's workplace absenteeism or HRQoL may be a natural means to evaluate access to and the quality of healthcare.

Research has demonstrated that access to healthcare is associated with increased healthcare use and decreased mortality across various patient populations and healthcare conditions.(10) For example, the association between the early initiation of prenatal care and decreased prenatal deaths has been shown.(11) However, to date, there is a dearth of information available on the impact and association of access to healthcare with workplace absenteeism or HRQoL.

In a prospective investigation, Cunningham et al.(12) examined the association between access to healthcare and HRQoL of individuals with symptomatic HIV disease. In this study, patients were asked questions regarding their access to healthcare (e.g., accommodation, affordability, availability). The primary study outcome variables were physical and mental health composite scores measured with a HRQoL instrument. Patients were categorized into tertiles based by their baseline physical and mental HRQoL scores as well as by their high versus low access to care.(12) Access to care was assessed with a nine-item questionnaire that asked individuals about the affordability and availability of their USC, the accessibility to their USC, as well as the ability of their USC provider to be accommodating.(12)

For those patients in the middle tertile of baseline physical health scores, the physical health scores of individuals at 3 months with high access improved relative to the scores for those with low access to care. For individuals in the low and middle tertiles for baseline mental health scores, there were significant improvements in the 3-month mental health scores for individuals with high compared to low access of care.(12) In today's healthcare environment, with healthcare purchasers increasingly needing to implement cost containment strategies, such as limiting individuals' choices of health plans (13), there is the potential for decreased access to healthcare.

Therefore, within this context, it is important for purchasers and healthcare decision-makers to understand the value and impact of their decisions on the access to care and workplace absenteeism of their population.

Workplace Productivity

Lost productivity can be estimated based on measures of absenteeism and presenteeism.(14) Absenteeism is generally defined as the number of days missed from work or normal activities; presenteeism is the reduced productivity while at paid work or while performing normal activities.(15;16) There are two methods for placing a monetary value on lost productivity, the human capital approach (HCA) and the friction cost approach (FCA).

Depending on the methodology, the human capital approach (HCA) or the friction cost approach (FCA), used for valuing lost workplace productivity, the total lost workplace productivity of a population may be under- or overestimated as well. The HCA, introduced in the 1960s, estimates lost productivity by calculating the expected or potential earnings lost as a result of a disease or disorder. Within the HCA, 1-hour of lost productivity is valued as 1-hour of an individual's wage(17); however, wage may not be a true measure of one's total lost productivity. The HCA may overestimate the total lost workplace productivity because it assumes that no tasks are completed during the time missed from work, that no other employees complete the tasks while the sick employee is absent, and that work is not made up upon the return of the sick employee to the worksite.

Compared to the HCA, the FCA, a newer approach for valuing lost productivity, was first introduced by Koopmanschap in 1992.(16) The friction period is the time needed to replace a sick worker and is assumed to begin when a worker is first absent. The originators of the FCA feel it provides a better estimate of the actual lost productivity than the HCA because the FCA considers that, even when workers are absent, productivity levels may be maintained.

Within the FCA, Koopmanschap poses many assumptions and illustrations surrounding lost workplace productivity. Based on an empirical study, Koopmanschap(18;19) has suggested that absences shorter than those that lead to replacement should be valued as only 80% of the production value lost in that period. As a guide for analyses, Koopmanschap has also suggested that one half of the absences with duration shorter than 1 week do not incur indirect costs, as this lost productivity may be canceled or postponed.(18;20) For some occupations, work lost as a result of short-term absenteeism may be postponed and completed upon return to work, therefore producing no friction period.(21)

METHODS:

A. Didactic component

In order to meet the specific didactic aims, Dr. Lofland commuted via Amtrak's train service between 30th Street Train Station, Philadelphia, PA, and Penn Station, Baltimore, MD, once or twice a week. The coursework focused on health services research, health policy, and outcomes research with an educational format consisting of the traditional classroom as well as internet instruction through the JHBSPH Distance Education Program. Approximately one to two courses were taken during each 8-week term for 3 of the 4 years of the award period.

B. Research and Experiential Component

a. Specific Aim 1: Develop and validate a primary headache questionnaire

Study Site and Design

This was a prospective, convenience sample study conducted at a headache specialty physician office, which is associated with an academic medical center within the Philadelphia metropolitan area. The study protocol was approved by the academic medical center's institutional review board.

Patients

Patients with and without a diagnosis of primary headache were identified using the electronic medical record within the physician office. Patients were categorized according to their headache diagnosis into one of five cohorts: 1) migraine only, 2) cluster only, 3) tension-type only, 4) mixed headache type (e.g., migraine and cluster diagnoses), and 5) no specified headache type. Eligible patients were those between the ages of 18 and 65 years who had a visit to the physician practice between July 1, 2000, and June 30, 2001. Patients who met the inclusion criteria were invited to participate in the study. Individuals who agreed to participate in the study were mailed a survey and asked to return the completed survey along with a signed copy of the informed consent form. Eligible patients were given an incentive of a free video rental ($4 value).

Patients who failed to complete the survey or sign the consent form were excluded from the study. In order to evaluate the test-retest reliability of the PHS, enrolled participants were asked to complete a second PHS approximately 2 weeks after the completion of the first questionnaire until a total retest sample of 50 respondents was surveyed. Participants did not receive an additional incentive for completion of this second questionnaire.

The Primary Headache Survey **(**PHS) is a brief, 49-item questionnaire designed to examine the quality of care for patients with primary headache. The PHS was developed based on patient focus groups and expert opinion. Using the International Headache Society (IHS) diagnosis criteria(22) and a headache classification scheme,(23) the seven headache symptom questions of the PHS were developed in order to help operationalize the categorization of individuals by headache type. In order to capture an individual's HRQoL, the Short-Form 12
(SF-12) was included in the PHS. The SF-12 was selected because of its brevity as well as its demonstrated reliability and validity in multiple populations.(24)

In order to capture the disability associated with primary headaches, the Headache Impact Test-6 (HIT-6)(25) was included in the PHS. The HIT-6 was selected because it was 1) developed using questions from the most commonly used headache instruments (26-28), 2) brief (i.e., six questions), 3) reliable(29), and 4) valid.(29;30) The responses to each question of the HIT-6 are on a five-point Likert scale from none to severe difficulty, and these responses are added to calculate the final HIT-6 score. The final HIT-6 scores are classified into minimal, mild, moderate, and severe impact due to headache, with higher scores indicating increased severity.

The questions regarding access to, processes of, and outcomes of care were developed from input from a panel of headache experts as well as from instruments previously developed by the Foundation for Accountability.(31) These questions have a dichotomous (i.e., yes/no) response.

Data Analysis

All analyses were conducted using Statistical Analysis Software (SAS, Cary, NC, Release 6.12) with alpha set at 0.05. Patient demographic characteristics were described using descriptive statistics. To identify potential floor and ceiling effects associated with any of the PHS questions, the distribution of the responses for each question was reviewed. In addition, as a gross measure of reliability, the completion rate for each question of the PHS was assessed.

Test-retest reliability of the individual PHS questions was assessed using Cohen's kappa and Pearson's correlation coefficient statistics, and the summary score for each section (e.g., access to care) was assessed as an intra-patient correlation using repeated measures ANOVA. A kappa statistic of greater than 0.75 represented excellent agreement, 0.40 to 0.75 represented intermediate to good agreement, and below 0.40 represented poor agreement.(32)

The internal consistency of the PHS was assessed by calculating a Cronbach's alpha on the summary score for each section of the questionnaire except the symptom questions. These questions are designed to characterize the individual's headache; these characteristics can be very divergent (e.g., unilateral pain vs. vomiting), and the only unifying factor is that they are result from the headache. It was assumed a priori that assessing the internal consistency of these questions would be inappropriate. Cronbach's alpha may range from 0 to 1, with 0.70 representing modest reliability.(32)

b. Specific Aim 2: Review the measures and methodologies for valuing lost workplace and non-workplace productivity of patients with migraine headache

A literature search, using MEDLINE, HealthSTAR, PsycINFO, and EconLit databases, covering the time period between 1966 and 2002, was first conducted to identify survey instruments to measure lost health-related productivity. The search strategy included individual terms and combinations from the following list: lost productivity, productivity, work loss, days missed from work, absenteeism, presenteeism, conceptual model, theoretical model, and indirect costs. A bibliography review of the retrieved manuscripts was performed to identify any additional health-related productivity instruments.

In addition to a literature review, a telephone-administered survey of business leaders and researchers who were actively involved or interested in productivity measurement was conducted. As part of the qualitative interviews, participants were asked to identify and appraise relevant instruments. Quality of life surveys, which have been used as an approximation for productivity impairment, were excluded from this analysis since these instruments do not directly measure productivity. Instruments were limited to those that were developed specifically to collect health-related lost workplace productivity.

Next, an appraisal of the instruments was conducted from the societal perspective. Ideally, the instrument would yield an individual's 1) absenteeism and presenteeism for workplace activities, 2) usual number of work hours per day, and 3) usual number of workdays per week. In addition, the ideal instrument should be reliable as well as have face, content, construct, and criterion validity.

Therefore, the specific evaluation criteria were: 1) reliability, 2) content validity, 3) construct validity, 4) criterion validity, 5) productivity metric(s), 6) instrument scoring technique, 7) suitability for direct translation into a monetary figure, 8) number of items, 9) mode(s) of administration, and 10) disease state(s) in which it has been tested. Because lost productivity is a relatively new field of study, it was anticipated that some of the above aspects would not be available for all of the identified instruments. For example, criterion validity refers to the ability of an instrument to produce the same results as an identified gold standard.(33) Within the field of productivity measurement, there is no agreed upon gold standard for either absenteeism or presenteeism. In addition, for many occupations, there is no gold standard for productivity.

Instruments were considered to be suitable for direct monetary translation if they captured a quantifiable unit of time lost from work activities, which could be multiplied by a monetary value (e.g., wage) for the time. The total cost of an individual's compensation (i.e., gross wages, fringe benefits, and the employer's portion of the payroll taxes) was used to monetize the value of health-related lost productivity. In addition, an instrument's characteristics, including length, mode of administration, and translation into language(s) other than English, were reviewed.

c. Specific Aim 3: Review the available productivity databases that capture lost workplace and non-workplace productivity

An internet search using the search engine www.google.com was conducted to identify publicly available national databases or surveys within the United States that collect lost productivity data. The search strategy included individual terms and combinations from the following list: lost productivity, productivity, work loss, days missed from work, absenteeism, presenteeism, survey, public, and database.

The websites of the Centers for Disease Control and Prevention (CDC), the Agency for Healthcare Research and Quality, the Centers for Medicare and Medicaid Services, the Robert Wood Johnson Foundation, and the Inter-University Consortium for Political and Social Research were reviewed. In addition, the expert opinion of a thought leader within the field of productivity measurement was obtained to determine if any national surveys were overlooked within this review.

Each identified survey was reviewed for the following aspects: 1) the productivity metrics captured (i.e., absenteeism and presenteeism) and 2) suitability for translation into a monetary figure. A survey was suitable for translation into a monetary figure if it contained a productivity metric that collects a quantifiable unit of time lost from work or non-work activities in which the quantity may be multiplied by a monetary value (e.g., wage) for the time. This study was conducted from the US societal perspective. Healthcare purchasers, such as employers, may be more concerned with particular aspects of the total cost of labor.

d. Specific Aim 4: Determine the variables associated with lost workplace and non-work productivity of patients with migraine headache

Study Design

This was a retrospective, cross-sectional study conducted using 1996 to 1999 data of the Medical Expenditure Panel Survey (MEPS).

The MEPS, conducted by the Agency for Healthcare Research and Quality (AHRQ), uses an overlapping panel design and provides information on access to care, health status, healthcare utilization and cost, prescription medication use, work, and sociodemographic characteristics of a nationally representative sample of the non-institutionalized civilian population within the US.(34) The institutional review boards of Thomas Jefferson University and Johns Hopkins University stated that the study qualified for exempt status.

Study Population

Individuals between 18 and 65 years of age who met the following criteria were included in this analysis: 1) member of the US civilian, noninstitutionalized population for their entire respective study calendar year; 2) eligible to receive the access to care questions of the MEPS; 3) had missing data for no more than four of the 10 access to care questions; and 4) had complete data for the number of missed workdays.

Data Collection

Within the MEPS, respondents are asked to report all of their health conditions, regardless of whether the condition was associated with a medical event or prescription use. The conditions were mapped to the International Classification of Diseases, 9th Revision, Clinical Modification (ICD-9-CM) diagnostic codes. Individuals were categorized as having migraine headache if they had an ICD-9-CM diagnostic code of 346.

Days Missed From Work

An individual's reported annual number of days missed from work was estimated as the sum of the number of workdays in which at least ½ of the day was missed due to illness/injury in round 1 and 2 of the respondent's respective study year plus the proportion of days missed from work in round 3 that occurred in the respective study year. The number of days missed from work during round 3 was adjusted by the proportion of round 3 that was included in the respective study year; the proportion could be calculated based on the exact date of the survey, which was available in the data. Because the survey asks the individual the number of days in which *at least one-half* day of work was missed, the total number of days missed was conservatively estimated by multiplying the reported number by 0.5.

Presence of Health Insurance

Within the MEPS, a dichotomous variable indicates if an individual reported not having health insurance for the entire study year. This variable was included in the analyses noted below.

Healthcare Use

During each round of the MEPS, respondents are asked the number of office-based and emergency department visits that they had. Variables indicating the presence of at least one reported office-based visit and the presence of at least one reported emergency department visit were constructed and included in the analyses.

Covariates

The variation in workplace absenteeism was evaluated in relation to a number of covariates. These included age, gender, race/ethnicity (White vs. other), level of education (not more than a high school diploma, more than a high school diploma), marital status (married vs. other), physical and mental health status, number of medical conditions (total number of ICD-9-CM diagnostic codes), migraine severity, and presence of depressive condition.

Within the MEPS, each person's perceived physical and mental health status is rated on a 5-point scale: excellent, very good, good, fair, and poor. The variables were dichotomized such that responses of excellent, very good, and good were recoded as "1" and other responses were recoded as "0."

The MEPS does not explicitly collect information on the severity of disease. Therefore, a dichotomous variable for migraine severity was constructed to indicate the presence or absence of severe migraine headaches. A response of 'yes' indicated that an individual reported at least one migraine-related hospitalization and/or use of at least one prescription for a prophylactic migraine medication based on the US Headache Consortium Evidence-Based Treatment guidelines(35;36) and MICROMEDEX® Healthcare Series.(37) To help ensure that the reported use of pain medications was for migraine headache, individuals who reported having cancer and/or an acute pain condition (e.g., fracture) were excluded from the analysis.

Breslau et al.(38) revealed that there is an association between migraine headache and depressive disorders. The lifetime prevalence of depression is approximately three times greater in those with migraine or severe headaches compared with individuals without a headache condition.(38) In addition, research has shown that the presence of a depressive condition is associated with considerable workplace absenteeism.(39)

However, the presence of this condition has not been considered in investigations estimating the lost workplace productivity of individuals with other healthcare conditions or disorders.(40;41) In our investigation, individuals were categorized as having a depressive condition if they had an ICD-9-CM diagnostic code of 311.(42)

DATA ANALYSIS

In all analyses, the unit of analysis was an individual. Statistical Applications Software (version 8.12) of the SAS Institute (Cary, NC) was used to create the analytic datasets. STATA Statistical Software (version 7.0) was used to perform descriptive, bivariate, and regression analyses (Stata Corporation, College Station, TX, 2001). The dependent variable in all analyses was the annual number of days missed from work. A p-value less than 0.05 was considered statistically significant. In addition, the results of each explanatory variable were assessed to determine if the direction of effect was consistent across the study models.

Since this study used pooled, cross-sectional data collected with a complex study design, special weighting techniques were needed so the appropriate standard errors were calculated (i.e., one cannot assume simple random selection). Therefore, the STATA Statistical Software (version 7.0), which employs the Taylor-series linearization method, was used(34) for analyses, including the stratification variables and weights provided with the MEPS.

The Rasch Model

The Rasch model was used to create a score for each respondent's level of access to care based on his or her responses to the characteristics of USC. The Rasch model assumes that the probability of an individual's response depends on the item and the individual.(43)

In this manuscript, the item characteristic refers to how hard the USC characteristic is to obtain, and the person characteristic refers to the perceived level of access to care with USC provider. The Partial Credit model, a specific Rasch model that considers items that have more than two types of responses, was used in this study.

We evaluated the Rasch model infit and outfit statistics to determine if each characteristic of USC deviated by an unacceptable amount from the expected response.(43) Six of the 10 characteristics of USC have ordinal responses. For items such as this, infit and outfit mean square errors (MSEs) of ≤0.6 or ≥1.4 are considered problematic.(43)

The model produced estimates of each characteristic of USC item difficulty and respondents' level of access scores. This access to care score was included in the multivariate analyses as an independent variable. The Winsteps software (Chicago, IL) was used to produce these results.(44)

Skewed days missed from work data

A two-part model was used to estimate the annual number of days missed from work for the study population.(45) To implement the two-part model, first, a multivariate logistic regression model was performed in which the probability of incurring any days missed from work was estimated.

Since the days missed from work data had a skewed distribution, the number of days missed from work was transformed using a logarithmic scale.(46) For the second part of the two-part model, a multivariate linear regression model was performed and the number of log transformed days missed from work, conditional on missing at least one workday, was estimated. One of the advantages of the two-part model is that it allows one to examine the associations with missing any workdays and associations with the number of workdays missed separately.(40)

Endogeneity

An important statistical issue throughout this study is endogeneity. Emergency department and office-based visits and workplace absenteeism may be endogenous in the days missed from work equation; having more days missed from work may make an individual more likely to seek future emergent care. The instrumental variables (IV) technique has the potential to alleviate endogeneity.

The IV technique requires one or more variables, instruments, which affect healthcare use but have no direct affect on the missed workdays. The IV technique uses the variation in the instrument, which is associated with variation in healthcare use, to estimate the effect of healthcare utilization on missed workdays.(47) Instruments are not always available and can be difficult to find. (47) The presence of a retirement plan was tested to determine if it was a suitable IV in this study.

RESULTS:

A. Didactic Component

Over the course of this award, Dr. Lofland obtained a Masters in Public Health degree in May 2001 and a PhD in Health Policy and Management, Health Services Research in May 2004 from the JHBSPH. As part of this award, the courses completed and the thesis topic are presented below (**Table 1**):

Table 1: Completed JHBSPH Courses and Thesis Topic

JHBSPH Course Number	Completed Courses
300.701	Doctoral Seminar in Health Policy and Management I
300.702	Doctoral Seminar in Health Policy and Management II
300.703	Doctoral Seminar in Health Policy and Management III
309.62	HMOs & Managed Care
311.615	Quality of Medical Care
300.704	First Year Doctoral Capstone
140.624	Statistical Methods in Public Health IV
309.861	Graduate Seminar in HSR
309.714	Patient Outcomes and Quality of Care
300.87	Research and Proposal Writing Seminar
550.865	Public Health perspectives on Doctoral Research
188.680.81	Fundamentals of Occupational Health
309.712	Assessing Health Status & Patient Outcomes
309.715	Advanced Methods in HSR & Evaluation II
306.665	Research Ethics and Integrity
340.608.81	Observational Epidemiology
182.625.81	Principles of Industrial Hygiene
Thesis Title	Access to Health Care and Workplace Absenteeism for Individuals with Migraine Headache

B. Research and Experiential Component

a. Specific Aim 1: Develop and validate a primary headache questionnaire

In total, 902 patients were identified for the study; 502 individuals agreed to participate and were mailed a PHS and an informed consent form. Of these, 334 patients completed the PHS, completed an informed consent form, and were enrolled in the study. The average age of the study participants was 47 years and 74% were women. The SF-12® mental component scores (MCS) and physical component scores (PCS) followed a pattern seen in previous studies of migraineurs, with lower scores than population norms**.** The HIT-6 scores were similar for the subset of 48 patients completing the two PHS surveys and the entire study population.

Reliability

For the test retest reliability analysis, 50 patients completed two PHS questionnaires. For these individuals, all of the PHS questions, except for those in the access to care dimension, had a percent agreement of at least 79%, and all the access to care questions had a percent agreement below 56%. All questions of the symptoms and outcomes to care dimensions and 10 of the 12 questions of the process of care dimension had a kappa statistic of 0.4 or higher. However, the access to care questions all had a kappa statistic of less than 0.4.

For all study patients, all questions of the PHS were found to have a completion rate of at least 94%. All the access questions had $\leq$ 45% of their responses at the ceiling, 10 of the 12 questions of the process questions had $\geq$70% of their responses at the ceiling, and all of the outcomes questions had $\geq$67% of their responses at the ceiling.

For internal consistency, Cronbach's alpha for the summary score for each dimension was calculated. For each dimension of the PHS, Cronbach's alpha was greater than 0.7.

DISCUSSION

This study demonstrated that the PHS is internally consistent and that there is good agreement among the PHS questions. This survey is brief and self-administered, which decreases patient burden and allows an individual to complete the questionnaire while sitting in the physician's office, at home, or possibly over the internet. The process questions appear to demonstrate good to intermediate agreement; however, two questions addressing follow-up appointments and prescribed medications showed poor agreement. For the outcomes, all of the questions demonstrated at least good agreement, with the question addressing a better understanding of headaches showing excellent agreement.

Conversely, the tests of the reliability of the access questions appear to have mixed results. A gross measure of a question's reliability is to examine the percentage of missing values associated with it. The assumption is that, if a question is not meaningful to a respondent, then the respondent will not answer the question. Therefore, a high percentage of missing data associated with a question may suggest that the question is not meaningful and potentially not reliable. Given the 94% completion rate, the access questions appear to be meaningful to patients and may be reliable.

However, the low agreement associated with each access question may refute this conclusion. Possible reasons for low agreement between two administrations of the questionnaire are that 1) the specific questions are unreliable, 2) there was a change in healthcare use between questionnaire administrations, or 3) there was a change in access to care between survey administrations.

Given that the population was drawn from a tertiary headache specialty physician practice and over 79% of the patients reported experiencing > 2 headaches per month, the study population may be suffering from severe headaches and may have sought additional healthcare services between survey administrations. Therefore, it is possible that the low kappa statistics may have been a result of changes in healthcare use.

Given the results of our study, modification to the PHS is recommended. Those questions within the access and process dimensions that demonstrated poor agreement need to be reviewed and considered for possible revision or exclusion from the final questionnaire.

It is important to recognize the limitations of this study. The first is the lack of generalizability of the study population to a primary care population. The population for this study was recruited from a headache specialty physician office. Therefore, these patients may have been suffering from more severe headaches, as discussed earlier, and may have been referred to a specialty practice for the management of their headaches. As with any newly developed questionnaire, additional analyses are needed to confirm the PHS's psychometric properties in larger and more diverse patient populations in order to improve the questionnaire's generalizability.

To address this concern, the PHS is currently being tested in a managed care population in which individuals are being recruited from primary care as well as from specialty physician practices. A second limitation was patients' subjective reporting of access and process data. Patients may have underestimated the care that they received and may not have accurately remembered the information that was discussed during the physician office visit.

Despite these limitations, the study demonstrates that the PHS is a reliable questionnaire that, in the future, may be used to assist clinicians, healthcare organizations, and patients as a means to assess quality of care for individuals with primary headache. The PHS may help stimulate conversation between physicians and patients, leading to increased communication regarding headache treatment and management.

b. Specific Aim 2: Review the measures and methodologies for valuing lost workplace and non-workplace productivity of patients with migraine headache

Eleven health-related productivity survey instruments were identified from the literature, and one additional instrument was identified via the qualitative interviews. The literature was reviewed for the additional instrument, the MacArthur Health and Productivity Questionnaire. However, as of the writing of this report, there is no published information on this instrument; therefore, no descriptive information is provided. The questionnaires were presented in chronological order so that the evolution of the measurement tools may be examined.

In summary, reliability and validity testing have been performed for eight of the 11 identified surveys. Of the 11 survey instruments identified, six capture metrics that are suitable for direct translation into a monetary figure. Of those six, the unnamed hepatitis instrument measures absenteeism only, and the other five, which are the Osterhaus technique, WPAI, HLQ, MWPLQ, and the WPI, measure both absenteeism and presenteeism. All of the identified instruments, except for the WPI, are available as paper and are self-administered questionnaires; however, readers should note that instruments might be available in other modes of administration (e.g, internet).

CONCLUSION

This review provides a comprehensive list of the published, peer-reviewed survey instruments available to measure health-related lost workplace productivity. Of the 11 instruments identified, six capture lost productivity suitable for direct translation into a monetary unit. As the field of productivity measurement matures, new tools may be developed with the intent of allowing researchers to incorporate productivity findings into cost-effectiveness and cost-benefit analyses. Subsequently, with these instruments, society and healthcare decision-makers will be able to make better-informed decisions concerning the value of the medications, disease management, and health promotion programs that they purchase and individuals receive.

c. Specific Aim 3: Review the available productivity databases that capture lost workplace and non-workplace productivity

Of the nine databases reviewed, six capture metrics suitable for translation into a monetary figure, allowing the lost productivity of a given population to be appraised.

Of these six, all capture absenteeism and three, the MEPS, the MIDI, and the NHIS, capture presenteeism. The MIDI and the NHIS collects a respondent's absenteeism and presenteeism for *both* the workplace and non-workplace settings.

This review provides a taxonomy of productivity measurement within the currently available national databases and surveys within the United States. As the field of productivity measurement matures, productivity metrics, such as presenteeism, will need to be captured as part of national population-based surveys. Subsequently, with more precise data and methods to estimate patients' lost productivity, health policy decision-makers and employers will be able to make better-informed decisions concerning the impact of disease and the value of medications at a population level.

d. Specific Aim 4: Determine the variables associated with lost workplace and non-work productivity of patients with migraine headache

Of the 703 migraineurs, 538 (77%) reported missing work time. Of those who missed work, the mean (SE) annual number of missed workdays was 4.4 (0.39). A higher level of access to care (p=0.025) and presence of depression (p=0.033) were significantly associated with missing a greater number of workdays. Severe migraines were significantly (OR=2.01, SE=0.51, p=0.006) associated with an increased likelihood to miss workdays. When health insurance was included in the model, a higher level of access to care was *now* significantly associated with the increased likelihood to miss workdays (OR=1.04, SE=0.021, p=0.05). From the original model, the odds ratio (1.035 to 1.040) and the SE (0.020 to 0.021) increased slightly. When healthcare use was included in the model and health insurance was removed, 1) emergency department visits were significantly (p=0.006) associated with missing a greater number of workdays, and 2) access to care was significantly associated with missing a greater number of workdays (p=0.028). When having health insurance and healthcare use were simultaneously included in the model, a higher level of access to care was significantly associated with greater likelihood to miss work (OR=1.040, SE=0.0212, p=0.05) and missing a greater number of workdays (p=0.005). However, a change of one standard deviation in the score would be associated with a 12% change in the odds to miss work and only an 8 percentage point change in the number of missed workdays.

Contrary to what was expected, a higher level of access to care is significantly associated with an increased likelihood to miss work and with missing a greater number of workdays. Depression, migraine severity, and healthcare use are important explanatory variables. Having health insurance may be a confounder between access to care and workplace absenteeism.

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