

NINDS Headache Common Data Element (CDE) Project Recommendations from the Headache Acute Therapies Subgroup

Overview of the Headache Acute Therapies Recommendations

The Acute Therapies Subgroup's recommendations are categorized into four domains. The following are the list of domains with the corresponding instrument recommendations. Please note that the Pediatric recommendations are grouped as a separate category.

- **Functional Status:** Functional Disability (Functional Disability Inventory)*, Headache Needs Assessment Survey (HANA)^, Migraine Disability Assessment (MIDAS) Questionnaire^^
- **Quality of Life:** Headache Impact Test-6 (HIT-6)^, SF-36 Functional Status (SF-36 v1 and SF-36 v2)^, Headache Impact Questionnaire (HImQ)^, Migraine Specific Quality of Life Questionnaire (MsQoL v2.1)^, Health-Related Quality of Life (HRQoL)^, Quality of Life (SF-12)^
- **Patient-Reported Outcomes:** Headache Acute Therapies Outcomes Guidelines*
- **Pediatric:** Peds Quality of Life^^

**Proposed "Core" instrument*

^ Proposed "Supplementary" instrument

^^Recommended "Exploratory" instrument – Instrument requires validation but may fill gaps in currently validated instruments and/or substitute for recommended instruments once validation is complete.

These recommendations are also presented in the table on the following page.

**NINDS Headache Common Data Element (CDE) Project
Recommendations from the Headache Acute Therapies Subgroup**

	<u>Functional Status</u>	<u>Quality of Life</u>	<u>Patient-Reported Outcomes</u>	<u>Pediatric</u>
Core:	<ul style="list-style-type: none"> Functional Disability (Functional Disability Inventory) 		<ul style="list-style-type: none"> Headache Acute Therapies Outcomes Guidelines 	
Supplemental:	<ul style="list-style-type: none"> Headache Needs Assessment Survey (HANA) 	<ul style="list-style-type: none"> Headache Impact Test-6 (HIT-6) SF-36 Functional Status (SF-36 v1 and SF-36 v2) 		
Exploratory:	<ul style="list-style-type: none"> Migraine Disability Assessment (MIDAS) Questionnaire 	<ul style="list-style-type: none"> Headache Impact Questionnaire (HImQ) Migraine Specific Quality of Life Questionnaire (MsQoL v2.1) Health-Related Quality of Life (HRQoL) Quality of Life (SF-12) 		<ul style="list-style-type: none"> Peds Quality of Life

NINDS Headache Common Data Elements (CDEs)
Headache CDE Acute Therapies Subgroup Recommendations
24-Hour Migraine Quality of Life Questionnaire (24-hr MQoLQ)

Instrument Name

24-Hour Migraine Quality of Life Questionnaire (24-hr MQoLQ)

Classification

Supplemental

Overview

The 24-Hr-MQoLQ is a 15-item, self-administered questionnaire aimed at assessing the quality of life of migraine sufferers within a 24-hour period after having taken migraine medication and within the first 24 hours of a migraine attack. The items cover five domains: work, social, energy and vitality, feeling and concerns, and symptoms. The 24-Hr-MQoLQ is designed to assess the health of specific populations at a point in time.

Scoring

The 24-Hr-MQoLQ was developed to be brief. On average, the majority of migraineurs can complete the questionnaire in 5 to 10 minutes.

Comments/Special Instructions

The 24-Hour Migraine Quality of Life Questionnaire was developed and validated with adult migraineurs aged 18 and older. This instrument has also been translated in several languages. The questionnaire was specifically developed and validated to cover the entire 24-Hour period after a migraineur first takes migraine therapy for an acute migraine attack, previously this period lacked a condition-specific quality of life questionnaire. If the time frame is modified in anyway, the questionnaire is no longer valid and its measurement characteristics are not known.

The 24-Hour Migraine Quality of Life Questionnaire has not been tested specifically in patients with lower literacy skills. However, the questionnaire, instructions and response options were tested and found to have the following reading levels: 61.7 for Flesch Reading Ease and 5.8 years for the Flesch-Kincaid Grade Level. Therefore, the questionnaire may be appropriate for use in lower literacy populations.

References

Medical Outcomes Trust Website: <http://www.outcomes-trust.org/index.html>

Hartmaier SL, Santanello NC, Epstein RS, Silberstein SD. Development of a brief 24-hour migraine-specific quality of life questionnaire. *Headache*. 1995 Jun;35(6):320-9. PubMed PMID: 7635717.

Santanello NC, Hartmaier SL, Epstein RS, Silberstein SD. Validation of a new quality of life questionnaire for acute migraine headache. *Headache*. 1995 Jun;35(6):330-7. PubMed PMID: 7635718.

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Rationale/ Justification

It may not be relevant to collect quality of life for a single migraine attack.

NINDS Headache Common Data Elements (CDEs)
Headache CDE Acute and Preventive Therapies Subgroup Recommendations
Functional Disability Inventory (FDI)

Instrument Name

Functional Disability Inventory (FDI)

Classification

Supplemental

Overview

The Functional Disability Inventory (FDI) was developed by Walker and Greene to assess illness-related activity limitations in children and adolescents with a variety of pediatric conditions. It has been used frequently in the functional assessment of pediatric pain, including acute pain and chronic pain such as headaches. The instrument consists of 15 items concerning perceptions of activity limitations.

Scoring

The 15 items assess function across a range of daily activities over the past 2 weeks (e.g., going out with friends, participating in gym class or sports, being in school all day). Respondents rate the level of difficulty of each item from 0 (“no trouble”) to 4 (“impossible”). A total score is derived from the sum of the items. Higher scores indicate greater disability

Comments/Special Instructions

Available in over 20 languages. Examination of the psychometric properties of the FDI demonstrated that it is a reliable and valid measure of functional limitations for children and adolescents with chronic pain. The measure has demonstrated internal consistency and test-retest reliability and correlates with school absence rates (Walker & Greene, 1991). Currently, the FDI is the most common measure of functional disability for pediatric pain populations.

Reference

Claar RL, Walker LS. Functional Assessment of pediatric pain patients: Psychometric Properties of the Functional Disability Inventory. *Pain* 121 (2006). 77-84.

Logan DE, Scharff L. (2005). Relationships Between Family and Parent Characteristics and Functional Abilities in children with recurrent Pain Syndromes: An Investigation of Moderating Effects on the Pathway from Pain to Disability. *Journal of Pediatric Psychology*, 30(8),698-707.

Walker LS, Greene JW. (1991). The functional disability inventory: Measuring a neglected dimension of child health status. *Journal of Pediatric Psychology*, 16, 39–58.

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NINDS Headache Common Data Elements (CDEs)
Headache CDE Acute Therapies Subgroup Recommendations
Headache Needs Assessment Survey (HANA)

Instrument Name

Headache Needs Assessment Survey (HANA)

Classification

Exploratory

Overview

The Headache Needs Assessment Survey (HANA) is a brief, self-administered questionnaire that assesses two dimensions of the impact of migraine: frequency and bothersomeness. This instrument has seven questions with the corresponding subscales: Anxiety/Worry, Depression/Discouragement, Self-control, Energy, function/Work, Family/Social Activities, and Overall Impact. For each item, the respondent provides data on both frequency and bothersomeness.

Scoring

Scoring for the HANA is the product of the item scores that resulted from seven weighted problem scores. These scores are summed to yield a total score (range, 7 to 175).

Comments/Special Instructions

The HANA has good internal consistency, reliability, construct validity and responsiveness. The HANA has demonstrated good test-retest reliability (.77) and internal consistency (.92). There is statistically significant correlation between HANA and Headache Disability Inventory total scores and high correlations with disease and treatment characteristics.

References

Cramer, J, Silberstein, S, Winner, P. 2001. Development and Validation of the Headache Needs Assessment (HANA) Survey.

Turk, D, Melzack, R. Handbook of Pain Assessment. 3rd Edition. *Assessment of Headaches*. Chapter 18. Pg 362.

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NINDS Headache Common Data Elements (CDEs)
Headache CDE Acute Therapies Subgroup Recommendations
Headache Impact Questionnaire (HImQ)

Instrument Name

Headache Impact Questionnaire (HImQ)

Classification

Exploratory

Overview

The HImQ is a 16-item, self-administered questionnaire used to measure pain and activity limitations from headache, though not specifically migraine, over a 3-month recall period. It includes headache duration, last headache, pain intensity (two questions), need for bedrest (two questions), disability in specific domains of activity (seven questions about interference with ability to work, do household chores, and engage in non-work activity), and symptoms (two questions). This instrument was developed to capture information about pain and headache-related disability to help doctors and patients evaluate the impact of headache on the individual's daily life. Headache-related disability is expressed as hours or days of lost productivity and functioning.

Scoring

The HImQ score is derived from eight items and is the sum of average pain intensity (on a scale of 0 to 10) and total lost days in all three domains of activity (work for pay, housework, and nonwork activity). Reduced effectiveness day equivalents are also considered. Score calculation involves both addition and multiplication.

Comments/Special Instructions

The HImQ has been reported to have excellent reliability.

References

Stewart, WF, Lipton RB, Simon, D, Korff MV, Liberman, J. 1998. Reliability of Illness Severity Measure for Headache in a Population sample of Migrain Sufferers.

Gagne, Joshua J.; Leas, Brian; Lofland, Jennifer H.; Goldfarb, Neil; Freitag, Frederick; and Silberstein, Stephen, "Quality of care measures for migraine: a comprehensive review" (2007). *School of Population Health Faculty Papers*. Paper 39. <http://jdc.jefferson.edu/healthpolicyfaculty/39>

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NINDS Headache Common Data Elements (CDEs)
Headache CDE Acute and Preventive Therapies Subgroup Recommendations
Headache Impact Test-6 (HIT-6)

Instrument Name

Headache Impact Test-6 (HIT-6)

Classification

Supplemental

Overview

The Headache Impact Test™ (HIT-6™) is a tool that measures the impact headaches, though not specifically migraine, have on a person's ability to function on the job, at home, at school, and in social situations. HIT was developed by an international team of headache experts from neurology and primary care medicine in collaboration with the psychometricians who developed the SF-36™ health assessment tool. The HIT builds on previous work by pooling items from 4 existing measurement instruments:

Migraine Specific Questionnaire (MSQ), Headache Disability Inventory (HDI), Headache Impact Questionnaire (HIMQ), and Migraine Disability Assessment Score (MIDAS). Items cover a broader spectrum of health outcomes than any of the original scales, ranging from pain to emotional distress. The HIT-6 is a static, short-form version of the HIT for paper-and-pencil administration.

Scoring

Scores from the six questions are added to create a total score that helps you better describe the impact of headache on your life

Comment/Special Instructions

Headache Impact Test called HIT-6 is available in over 25 languages. HIT-6™ takes less than five minutes to complete and has similar accuracy to the Internet HIT.

References

Gagne, Joshua J.; Leas, Brian; Lofland, Jennifer H.; Goldfarb, Neil; Freitag, Frederick; and Silberstein, Stephen, "Quality of care measures for migraine: a comprehensive review" (2007). *School of Population Health Faculty Papers*. Paper 39. <http://jdc.jefferson.edu/healthpolicyfaculty/39>

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NINDS Headache Common Data Elements (CDEs)
Headache CDE Acute Therapies Subgroup Recommendations
Health Related Quality of Life-14 (HRQOL-14)

Instrument Name

Health Related Quality of Life-14 (HRQOL-14)

Classification

Supplemental

Overview

The CDC's 14-item HRQoL survey allows subjects to rate their overall health status and the influence of various symptoms on their daily activities. This is a publically available, standardized instrument that allows comparisons of a subject's self-reported quality of life among various populations. The HRQOL-14 is comprised of three different modules including the Healthy Day core questions, which using 4 questions allows individuals to rate their own physical and mental health status, the Activity Limitations module , which using 5 questions allows subjects to describe how their healthproblems affect their functionality, and Healthy Days Symptoms module, which uses five questions to determine how common individuals experience a variety of symptoms.

Scoring

Unlike other health profiles, the CDC HRQOL-14 does not use a summary score and is not based on psychometrically derived or preference-based weights. The only scoring used is with a summary "unhealthy days" index, computed by adding a respondent's physically and mentally unhealthy days, with a maximum of 30 for one person.

Unhealthy days are an estimate of the overall number of days during the previous 30 days when the respondent felt that either his or her physical or mental health was not good. To obtain this estimate, responses to questions 2 and 3 from the HRQOL-4 are combined to calculate a summary index of overall unhealthy days, with a logical maximum of 30 unhealthy days. Healthy days are the positive complementary form of unhealthy days. Healthy days estimate the number of recent days when a person's physical and mental health was good (or better) and is calculated by subtracting the number of unhealthy days from 30 days. Statistical computer software packages that analyze data are available.

Comments/Special Instructions

Several organizations have found these Healthy Days measures useful at the national level for (1) identifying health disparities, (2) tracking population trends, and (3) building broad coalitions around a measure of population health compatible with the World Health Organization's definition of health. The HRQOL measures and data also have been used for research or program planning by CDC's Cardiovascular Health and HIV/AIDS Programs as well as by the Public Health Foundation, the Foundation for Accountability, and several other government and academic programs.

References

CDC HRQOL-14 Measure Web site: <http://www.cdc.gov/hrqol/methods.htm#4>

Moriarty DG, Zack MM, Kobau R. The Centers for Disease Control and Prevention's Healthy Days Measures - population tracking of perceived physical and mental health over time. Health Qual Life Outcomes. 2003 Sep 2;1:37

NINDS Headache Common Data Elements (CDEs)
Headache CDE Acute Therapies Subgroup Recommendations
Health Related Quality of Life-14 (HRQOL-14)

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Rationale/ Justification

The HRQoL14 is one of many questionnaires that provide a summary score of an individual's overall perceived health status and health-related functional disability. Many headache disorders influence an individual's overall health and functional abilities. Therefore, it may be useful in some acute headache clinical trials to measure global health status. The HRQoL is a commonly used instrument with defined test characteristics. It is easy to administer and publically available. Because it is not specific to headache, the HRQoL can allow comparison with other symptoms and diseases. This instrument will be useful in acute headache therapeutic trials that seek to determine the influence of a particular therapy on longer-term outcomes. Investigators searching for a measure of global health status can choose between this instrument and other similar instruments such as the SF-12 and the SF-36.

NINDS Headache Common Data Elements (CDEs)
Headache CDE Acute and Preventive Therapies Subgroup Recommendations
Migraine Specific Quality of Life Questionnaire version 2.1 (MSQOL v2.1)

Instrument Name

Migraine Specific Quality of Life Questionnaire Version 2.1 (MSQoL v2.1)

Classification

Core

Overview

The MSQoL v.2.1 is a 14-item, self-administered instrument covering areas of specific concern to persons with migraine. Specifically, it addresses factors of role function-restrictive (7 questions), examines the degree to which performance of daily activities is limited by migraine, role function-preventive (4 questions), examines the degree to which performance of daily activities is prevented by migraine; and emotional function (3 questions), examines feelings of frustration and helplessness due to migraine. It was developed from the MSQoL v.1.0 and subsequently shortened for easier administration. Its content was improved by rewording certain items for greater clarification. The MSQoL v.2.1 is intended to respond to a perceived need to develop a health status measure that would adequately focus on the physical and emotional limitations that are typically associated with migraine headaches.

Scoring

MSQoL v.2.1 is available in both self-administered paper or computerized formats. The questionnaire takes about 10 minutes to complete. Previous experience has found the MSQoL v.2.1 to have minimal respondent burden. Patients are asked to provide their response to each question using a standard six-point Likert-type scale (None of the time; a little bit of the time; some of the time; a good bit of the time; most of the time; all of the time). Each MSQoL v.2.1 dimension is scored independently from 0 to 100 such that a higher score indicates a better quality of life. A scoring instruction manual is available through the Medical Outcomes Trust.

Comments/Special Instructions

MSQoL was developed by a team of Glaxo pharmacoeconomic research scientists in the early 1990s. MSQoL (Version 1.0) was first used in clinical trials in 1991. MSQoL v.2.1 is a revised version of the original MSQoL. The revisions were based upon psychometric analyses of data collected in clinical trials, and feedback from patient focus groups and interviews to refine questions, standardize response formats, and improve psychometric properties.

The psychometric properties of the US English MSQoL v.2.1 were assessed using data collected from two quasi-experimental designs. The three-factor structure of the MSQoL v.2.1 was assessed using confirmatory factor analysis. Multi-trait analyses were performed to evaluate the reliability, validity and responsiveness of the three MSQoL v.2.1 dimensions.

MSQoL v.2.1 is a reliable and valid instrument in migraine quality of life measurement. However, if your study is designed to compare the impact of migraine with another condition, a generic instrument such as the SF-36 should also be considered. Although several other disease-specific instruments measuring Health Related Quality of Life (HRQoL) in migraine have been developed, the MSQoL v.2.1 has been used most often in published clinical trials of migraine therapy. The MSQoL v.2.1 has demonstrated evidence of reliability, validity, and responsiveness.

NINDS Headache Common Data Elements (CDEs)
Headache CDE Acute and Preventive Therapies Subgroup Recommendations
Migraine Specific Quality of Life Questionnaire version 2.1 (MSQOL v2.1)

References

Medical Outcomes Trust Web site document: www.outcomes-trust.org/catalog2.doc

Gagne, Joshua J.; Leas, Brian; Lofland, Jennifer H.; Goldfarb, Neil; Freitag, Frederick; and Silberstein, Stephen, "Quality of care measures for migraine: a comprehensive review" (2007). *School of Population Health Faculty Papers*. Paper 39. <http://jdc.jefferson.edu/healthpolicyfaculty/39>

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Rationale/ Justification

This is a very useful and robust instrument and has been used in many headache trials.

NINDS Headache Common Data Elements (CDEs)
Headache CDE Acute and Preventive Therapies Subgroup Recommendations
Pediatric Quality of Life Inventory (PedsQL) Version 4.0

Instrument Name

Pediatric Quality of Life Inventory (PedsQL) Version 4.0

Classification

Exploratory

Overview

The PedsQL 4.0 is a valid, developmentally appropriate measure of QOL for children between the ages of 2 and 18 years . It is a brief 23-item measure that evaluates QOL in four areas of functioning: physical functioning (eight items), emotional functioning (five items), social functioning (five items), and school functioning (five items). The PedsQL 4.0 has four age ranges: toddlers (2–4 years), young child (5–7 years), child (8–12 years), and adolescents (13–18 years). Parent only report is obtained for toddlers (2–4 years).

Scoring

The PedsQL 4.0 asks respondents to indicate how much of a problem each item has been during the past month. For the child self report (8–18 years) and the parent report forms, respondents use a 5-point Likert scale to rate the item severity (0 = never a problem; 1 = almost never a problem; 2 = sometimes a problem; 3 = often a problem; 4 = almost always a problem). For the younger children (5–7 years), a simplified 3-point Likert scale, anchored with a happy and a sad face, is used (0 = not at all a problem; 2 = sometimes a problem; 4 = a lot of a problem) to increase further the developmental sensitivity of the measure.

The PedsQL 4.0 yields a total QOL score of 0-100 and two summary scores: Physical Health Summary Score and Psychosocial Health Summary Score. To obtain scores, items are reversed scored, transformed to a 0–100 scale (0 = 100, 1 = 75, 2 = 50, 3 = 25, 4 = 0), and averaged. Total scores near 0 indicate lower QOL while scores approaching 100 indicate higher QOL. To obtain the Physical Health Summary Score, the Physical Health Subscale is used (eight items) and a mean score is computed. To calculate the Psychosocial Health Summary Score, items in the Emotional, Social, and School Functioning subscales (15 items) are used and a mean score is computed. Individual subscale scores are calculated for each of the four areas of functioning by calculating mean scores for each subscale. The instrument can be completed in under 4 minutes.

Comments/Special Instructions

The PedsQL offers researchers interested in evaluating the QOL of pediatric patients the only valid, general measure of QOL which can be easily administered to children/adolescents and parents within a clinic setting and across a broad age range.¹ Some particular features include: PedsQL Disease-Specific Modules are available for asthma, arthritis, cancer, cardiac disease, and diabetes. Parents and children 8 years or older may self-administer the PedsQL or the administrator can read the instructions to the child. The instrument is translated in over 48 languages including Spanish.

The PedsQL 4.0 demonstrated good internal consistency (a child = 0.88, a parent = 0.90) in healthy children and children with acute or chronic illnesses and headache in prior research. Construct validity for the measure was established through known-group comparisons, which revealed expected differences in the quality of life (QOL) of healthy children vs. children with acute or chronic illnesses. An additional measure of validity was provided through correlations between QOL scores and criterion

NINDS Headache Common Data Elements (CDEs)
Headache CDE Acute and Preventive Therapies Subgroup Recommendations
Pediatric Quality of Life Inventory (PedsQL) Version 4.0

variables such as the number of days that the child needed medical care and the number of days missed from school or work. While the PedsQL 4.0 is a valid and practical tool for examining QOL in children/adolescents and families within a busy clinic setting, it does not provide a complete assessment of the many specific psychosocial variables that comprise the QOL construct, or include a reliable, disease-specific module for pediatric headache.¹ PedsQL 4.0 has been described as one of the three available general measures of QOL in childhood and adolescence with adequate psychometric properties for application in clinical research.

References

¹SW Powers, SR Patton, KA Hommel, and AD Hershey. Quality of Life in Paediatric Migraine: Characterization of Age-Related Effects Using PedsQL 4.0. *Cephalalgia*. February 2004 24; 120-127, doi:10.1111/j.1468-2982.2004.00652.x

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NINDS Headache Common Data Elements (CDEs)
Headache CDE Acute Therapies Subgroup Recommendations
12-Item Short Form Health Survey (SF-12)

Instrument Name

12-Item Short Form Health Survey (SF-12)

Classification

Supplemental

Overview

The SF-12 is a shorter version of the SF-36, designed to reproduce the Physical Component Summary (PCS) and the Mental Component Summary (MCS) scores. The SF-12 Health Survey is a self-administered questionnaire that includes 12 questions from the SF-36 Health Survey (Version 1). These include: 2 questions concerning physical functioning; 2 questions on role limitations because of physical health problems; 1 question on bodily pain; 1 question on general health perceptions; 1 question on vitality (energy/fatigue); 1 question on social functioning; 2 questions on role limitations because of emotional problems; and 2 questions on general mental health (psychological distress and psychological well-being). The SF-12 is a self report measure.

Scoring

The survey takes two minutes to complete. Scoring of individual items is identical to the SF-36 Health Survey. Scoring algorithms are then applied to produce the PCS and MCS scores.

Comments/Special Instructions

The SF-12 Health Survey was developed using normative data for the SF-36 Health Survey in the United States. An acute (1 week) version of the SF-12[®] Health Survey is also available. Like the SF-36 Health Survey, the SF-12 Health Survey has been recently updated by QualityMetric Incorporated. The new version is known as the SF-12v2 Health Survey (Version 2).

The SF-12 is a suitable measure for large group epidemiological studies (greater than n = 500) where information on the SF-36 Health Survey Summary Scores (PCS + MCS) is required. Test-retest reliability for PCS = 0.89, MCS = 0.76. The SF-12 showed good correlation with other measures and criterion of how well the SF-12 reproduces the PCS and MCS scores was good. Normative data is available for males and females. This instrument is appropriate for ages 14 years and up.

Jenkinson, Chandola, Coulter & Bruster (2001)² in the United Kingdom have made a useful contribution in this area. However, in Australia, little research has been reported on the use of SF-12 with people from a non-English speaking background and Aboriginal and Torres Strait Islanders.

References

Ware Jr. John, E. (2055). Sf-12fi health survey (version 1.0). Retrieved from <http://ahsri.uow.edu.au/ahoc/documents/sf12review.pdf>

Jenkinson C, Chandola T, Coulter A, Bruster S. An assessment of the construct validity of the SF-12 summary scores across ethnic groups. *Journal of Public Health Medicine* 2001; 23:187-194.

NINDS Headache Common Data Elements (CDEs)
Headache CDE Acute Therapies Subgroup Recommendations
12-Item Short Form Health Survey (SF-12)

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Rationale/ Justification

The SF 12 is one of many questionnaires that provide a summary score of an individual's overall health status, perceived health status, and health-related functional disability. Many headache disorders influence an individual's overall health and functional abilities. Therefore, it may be useful in some acute headache clinical trials to measure global health status. The SF12 is a commonly used instrument with defined test characteristics. It is easy to administer. Because it is not specific to headache, the SF12 can allow comparison with other symptoms and diseases. This instrument will be useful in acute headache therapeutic trials that seek to determine the influence of a particular therapy on longer-term outcomes. Investigators searching for a measure of global health status can chose between this instrument and other similar instruments such as the HRQoL-14 and the SF36.

NINDS Headache Common Data Elements (CDEs)
Headache CDE Acute and Preventive Therapies Subgroup Recommendations
36-Item Short Form Health Survey (SF-36) Version 2.0

Instrument Name

36-Item Short Form Health Survey (SF-36) Version 2.0

Classification

Supplemental

Overview

The SF-36 is a multi-purpose, short-form health survey with only 36 questions. It yields an 8-scale profile of functional health and well-being scores as well as psychometrically-based physical and mental health summary measures, and a preference-based health utility index. It is a generic measure, as opposed to one that targets a specific age, disease, or treatment group. Accordingly, the SF-36 has proven useful in surveys of general and specific populations, comparing the relative burden of diseases, and in differentiating the health benefits produced by a wide range of different treatments.

Scoring

The interpretation of SF-36v2™ Health Survey results has been greatly simplified with the norm-based scoring of its health domain scales and component summary measures. It is recommended that users base their interpretations on norm-based scores (Mean = 50, *SD* = 10) rather than 0–100 scores. The advantage of norm-based scoring can be illustrated by comparing the SF-36v2™ Health Survey profile scored using the original 0–100 algorithms with the profile based on the norm-based scoring algorithms for the same sample. Because the standard deviations for each scale are equalized at 10, it is easier to see exactly how far below or above the general population mean a score is in standard deviation units, and comparisons of health domain scale and component summary measure scores across the SF-36v2™ Health Survey can be made directly.

It is important to *not* “mix” or combine NBS and 0–100 scores for the purpose of analyzing or reporting data. Mixed scores have been reported in the published literature and have resulted in erroneous conclusions about the hypotheses being tested. If a data set includes both NBS and 0–100-based scores, one can use the algorithms presented in Chapter 5 or the QualityMetric Health Outcomes™ Scoring Software 2.0 to convert all scores to a single metric (in most cases, NBS is the recommended metric). It is also important to clearly document the norms and scoring algorithms used in reports of “Study Methods” accompanying results based on the SF-36v2™ Health Survey 1998 U.S. general population norms. Further, because tables and figures are sometimes distributed separately, it is also important to include explicit references to *SF-36v2™ Health Survey 1998 U.S. general population norms* and to *norm-based scoring (NBS)* in tables and figures presenting results based on the more current 1998 U.S. general population norms.

Comments/Special Instructions

Widely used generic measure of health status. Wide range of norms and translations available. Allows comparison to healthy individuals and other disease states. Relatively weighted toward objective function. Multiple modes of administration are offered, including online, PDA, and more. The SF-36v2 is available in more than 140 translations in both standard four-week and acute one-week recall periods.

References

Ware JE, Sherbourne CD. The MOS 36-Item Short-Form Health Survey (SF-36®): I. conceptual framework and item selection. *Med Care* 1992; 30(6):473-83.

NINDS Headache Common Data Elements (CDEs)
Headache CDE Acute and Preventive Therapies Subgroup Recommendations
36-Item Short Form Health Survey (SF-36) Version 2.0

McHorney CA, Ware JE, Raczek AE. The MOS 36-Item Short-Form Health Survey (SF-36®): II. psychometric and clinical tests of validity in measuring physical and mental health constructs. *Med Care* 1993; 31(3):247-63.

Ware JE, Kosinski M, Keller SK. SF-36® Physical and Mental Health Summary Scales: A User's Manual. Boston, MA: The Health Institute, 1994.

Ware J.E., Kosinski M., Dewey J.E. How to Score Version Two of the SF-36 Health Survey. Lincoln, RI: QualityMetric, Incorporated, 2000.

Ware, J.E., Kosinski M. SF-36 Physical and Mental Health Summary Scales: A Manual for Users of Version 1, Second Edition. Lincoln, RI: QualityMetric Incorporated, 2001. Maizels M, Smitherman TA, Penzien DB. A Review of Screening Tools for Psychiatric Comorbidity in Headache Patients. *Headache*. 2006; 46 [Suppl 3]:(S98-S109).

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Rationale/ Justification

Quality of life and functional impairment/disability are common problems among headache patients and are increasingly being used as outcome endpoints in clinical trials.