

# NINDS Headache Common Data Element (CDE) Project

## Recommendations from the Headache Preventive Therapies Subgroup

### Overview of the Headache Preventive Therapies Recommendations

The Preventive Therapies Subgroup's recommendations are categorized into eight 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.

- **Anxiety**: Beck Anxiety Inventory (BAI)<sup>^</sup>, Generalized Anxiety Disorder (GAD-7)<sup>^</sup>, State-Trait Anxiety Inventory (STAI)<sup>^</sup>
- **Cognition**: Behavior Rating Inventory of Executive Function (BRIEF) – Self Report Version<sup>^</sup>
- **Depression**: Beck Depression Inventory II (BDI-II)<sup>^</sup>, Hospital Anxiety and Depression Scale (HADS)<sup>^</sup>, Patient Health Questionnaire (PHQ-9)<sup>^</sup>
- **Functional Status**: Migraine Disability Assessment (MIDAS) Questionnaire<sup>^</sup>, Functional Disability Inventory (FDI)<sup>^</sup>
- **Quality of Life**: EuroQoL-5 Dimension Questionnaire (EQ-5D)<sup>^</sup>, Headache Impact Test-6 (HIT-6)<sup>\*</sup>, Migraine Specific Quality of Life Questionnaire (MsQoL original and v2.1)<sup>\*</sup>, SF-36v2<sup>^</sup>
- **Self Report Patient Satisfaction (Global Outcomes)**: Clinical Global Impression Index (CGI)<sup>^^</sup>, Headache Preventive Therapies Outcomes Guidelines<sup>^^</sup>, Mood Disorder Questionnaire<sup>^</sup>
- **Structured Diagnostic Interviews**: Mini-International Neuropsychiatric Interview (MINI)<sup>^</sup>, Structured Clinical Interview for DSM IV Dissociative Disorders (SCID-D)<sup>^</sup>
- **Pediatric**: Children Depression Inventory-2 (CDI-2)<sup>^</sup>, Pediatric Migraine Disability Assessment (PedMIDAS) Questionnaire – Pediatric<sup>\*</sup>, Pediatric Quality of Life Inventory (PedsQL)<sup>^</sup>, Kiddie-Schedule for Affective Disorders and Schizophrenia (K-SADS)<sup>^</sup>

*\*Proposed "Core" instrument*

*<sup>^</sup>Proposed "Supplemental" instrument*

*<sup>^^</sup>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 Preventive Therapies Subgroup

	<u>Anxiety</u>	<u>Cognition</u>	<u>Depression</u>	<u>Functional Status</u>	<u>Quality of Life</u>	<u>Self Report Patient Satisfaction</u>	<u>Structured Diagnostic Interviews</u>	<u>Pediatric</u>
<b>Core:</b>				<ul style="list-style-type: none"> <li>Headache Impact Test-6 (HIT-6)</li> </ul>	<ul style="list-style-type: none"> <li>Migraine Specific Quality of Life Questionnaire (MSQoL) (original and 2.1 versions)</li> </ul>			<ul style="list-style-type: none"> <li>Pediatric Migraine Disability Assessment (PedMIDAS) Questionnaire – Pediatric</li> </ul>
<b>Supplemental:</b>	<ul style="list-style-type: none"> <li>Beck Anxiety Inventory (BAI)</li> <li>Generalized Anxiety Disorder (GAD-7)</li> <li>State-Trait Anxiety Inventory (STAI)</li> </ul>	<ul style="list-style-type: none"> <li>Behavior Rating Inventory of Executive Function – Self Report Version (BRIEF)</li> </ul>	<ul style="list-style-type: none"> <li>Beck Depression Inventory II (BDI-II)</li> <li>Hospital Anxiety and Depression Scale (HADS)</li> <li>Patient Health Questionnaire (PHQ-9)</li> </ul>	<ul style="list-style-type: none"> <li>Migraine Disability Assessment Questionnaire (MIDAS)</li> <li>Functional Disability Inventory (FDI)</li> </ul>	<ul style="list-style-type: none"> <li>SF-36</li> </ul>	<ul style="list-style-type: none"> <li>Mood Disorder Questionnaire</li> </ul>	<ul style="list-style-type: none"> <li>Mini-International Neuropsychiatric Interview (MINI)</li> <li>Structured Clinical Interview for DSM IV Dissociative Disorders (SCID-D)</li> </ul>	<ul style="list-style-type: none"> <li>Children Depression Inventory-2 (CDI-2)</li> <li>Pediatric Quality of Life Inventory (PedsQL)</li> <li>Kiddie-Schedule for Affective Disorders and Schizophrenia (K-SADS)</li> </ul>

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	<u>Anxiety</u>	<u>Cognition</u>	<u>Depression</u>	<u>Functional Status</u>	<u>Quality of Life</u>	<u>Self Report Patient Satisfaction</u>	<u>Structured Diagnostic Interviews</u>	<u>Pediatric</u>
<b>Exploratory:</b>						<ul style="list-style-type: none"> <li>• Clinical Global Impression Index (CGI)</li> <li>• Headache Preventive Therapies Outcomes Guidelines</li> </ul>		

NINDS Headache Common Data Elements (CDEs)  
Headache CDE Preventive Therapies: Outcomes Subgroup Recommendations  
Beck Anxiety Inventory (BAI)

**Instrument Name**

Beck Anxiety Inventory (BAI)

**Classification**

Supplemental

**Overview**

Measures the severity of an individual's anxiety. A 21-question multiple-choice self-report inventory that is used for measuring how the subject has been feeling in the last week, focusing primarily on somatic symptoms. This examination is intended to assess short-term anxiety symptoms. The BAI is self-administered or verbally administered by a trained administrator, and each item is descriptive of subjective, somatic, or pain-related symptoms of anxiety. Each question has the same set of four possible answer choices.

**Scoring**

The BAI items are scored on a scale between 0 and 3 and have a maximum score of 63. Total score (0-63), where Minimal Level of Anxiety (0-7); Mild Anxiety (8-15); Moderate Anxiety (16-25); Severe Anxiety (26-63).

**Comments/Special Instructions**

The BAI does not conform to the DSM-IV anxiety criteria. Unlike the State-Trait Anxiety Inventory (STAI), it does a better job of identifying anxiety as opposed to depression. It has adequate psychometric properties. The BAI discriminates well between anxious and non-anxious diagnostic groups in a variety of clinical populations.

**References**

Antony MM, Orsillo SM, Roemer L, eds. Practitioner's Guide to Empirically Based Measures of Anxiety. New York: Kluwer/Plenum; 2001.

Beck AT. An inventory for measuring clinical anxiety: psychometric properties. *J Consult Clin Psychol*. 1988; 56(6): 893-7.

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**

Anxiety is a common comorbidity in individuals who suffer from headaches/migraines.

NINDS Headache Common Data Elements (CDEs)  
Headache CDE Preventive Therapies: Outcomes Subgroup Recommendations  
Beck Depression Inventory-II (BDI-II)

**Instrument Name**

Beck Depression Inventory-II (BDI-II)

**Classification**

Supplemental

**Overview**

The BDI-II was developed in 1996 and was derived from the BDI. The 21-item survey is self-administered and is scored on a scale of 0-3 in a list of four statements arranged in increasing severity about a particular symptom of depression, bringing the BDI-II into better alignment with DSM-IV criteria. The cutoffs used differ from the original scale. The scale higher total scores indicate more severe depressive symptoms.

**Scoring**

The BDI-II contains 21 questions, with each answer scored on a scale value of 0 to 3. The cutoffs used are: minimal depression (0-13); mild depression (14-19); moderate depression (20-28); and severe depression (29-63). Higher total scores indicate more severe depressive symptoms.

**Comments/Special Instructions**

The BDI-II is one of the most widely used assessments for depression. It is self-administered, or verbally administered by a trained administrator, assessing the intensity of the depression in clinical and normal patients. The new (BDI-II) edition shows improved clinical sensitivity and it assesses symptoms over the preceding two weeks. It is available in English and Spanish.

With regard to construct validity, the convergent validity of the BDI-II was assessed by administration of the BDI-1A and the BDI-II to two sub-samples of outpatients (N=191). The order of presentation was counterbalanced and at least one other measure was administered between these two versions of the BDI, yielding a correlation of .93 ( $p < .001$ ) and means of 18.92 (SD = 11.32) and 21.888 (SD = 12.69) the mean BDI-II score being 2.96 points higher than the BDI-1A. A calibration study of the two scales was also conducted, and these results are available in the BDI-II manual. Consistent with the comparison of mean differences, the BDI-II scores are 3 points higher than the BDI-1A scores in the middle of the scale. Factorial validity has been established by the inter-correlations of the 21 items calculated from the sample responses.

**References**

Beck AT, Steer RA, Brown GK. *Manual for The Beck Depression Inventory - Second Edition (BDI-II)*. San Antonio: Psychological Corporation; 1996.

Beck AT, Steer RA, Ball R, Ranieri W. Comparison of Beck Depression Inventories -IA and -II in psychiatric outpatients. *J Pers Assess*. 1996; 67(3): 588-97.

Maizels M, Smitherman TA, Penzien DB. A Review of Screening Tools for Psychiatric Comorbidity in Headache Patients. *Headache*. 2006; 46 [Suppl 3]:(S98-S109).

Steer RA, Cavalieri TA, Leonard DM, Beck AT. Use of the Beck Depression Inventory for Primary Care to screen for major depression disorders. *GenHosp Psychiatry*. 1999;21:106-111.

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Beck Depression Inventory-II (BDI-II)

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<http://www.pearsonassessments.com/HAIWEB/Cultures/en-us/Productdetail.htm?Pid=015-8018-370&Mode=summary>.

**Rationale/ Justification**

Individuals who experience headaches/migraines also frequently suffer from depression.

NINDS Headache Common Data Elements (CDEs)  
Headache CDE Preventive Therapies: Outcomes Subgroup Recommendations  
Behavior Rating Inventory of Executive Function (BRIEF-SR)

**Instrument Name**

Behavior Rating Inventory of Executive Function-Self Report Version (BRIEF-SR)

**Classification**

Supplemental

**Overview**

The BRIEF-SR is useful in evaluating and treating adolescents (11 to 18 years of age) who have executive control problems: difficulties with reasoning, self-awareness, flexibility, organization, self-monitoring, memory capacity, or behavioral regulation. Complementing the *Behavior Rating Inventory of Executive Function* (BRIEF) Parent and Teacher Forms, this standardized, 80-item self-report scale captures an adolescent's view of his or her own purposeful, goal-directed, problem-solving behavior. This information can help determine how much external support an adolescent needs and how to best build a collaborative working relationship with him or her.

The 80 items yield information for eight non-overlapping clinical scales that measure different aspects of executive functioning: Inhibit, Shift (with Behavioral Shift and Cognitive Shift subscales), Emotional Control, Monitor, Working Memory, Plan/Organize, Organization of Materials, and Task Completion. The clinical scales form two broader indexes, the Behavioral Regulation Index (BRI) and the Metacognition Index (MI) which yield an overall summary score called the Global Executive Composite (GEC). The BRIEF-SR also includes two validity scales: Inconsistency and Negativity.

**Scoring**

In just 10 to 15 minutes, the BRIEF-SR can be completed by any teen who can read at a 5th-grade-or-higher level, including those with attention disorders, language disorders, traumatic brain injury, lead exposure, learning disabilities, high-functioning autism, or other developmental, psychiatric, or medical conditions.

**Comments/Special Instructions**

The BRIEF-SR has demonstrated reliability, validity, and clinical utility as an ecologically valid assessment of executive functions across a range of conditions. The BRIEF-SR scales demonstrate appropriate reliability. Internal consistency is high for the GEC ( $\alpha = .96$ ) and moderate to high for the clinical scales ( $\alpha s = .72-.96$ ). Temporal stability is strong ( $r = .89$ ) for the GEC (over a period of approximately five weeks), and there is strong inter-rater agreement for the GEC with parent ratings on the BRIEF ( $r = .56$ ). Teacher ratings on the BRIEF correlated less strongly with adolescent ratings on the BRIEF-SR (GEC,  $r = .25$ ), but were well within expectations.

Correlational analyses with other self-report behavior rating scales (i.e., Child Behavior Checklist/Youth Self-Report [CBCL/YSR], The Behavior Assessment System for Children Self-Report of Personality [BASC-SRP], Child Health Questionnaire [CHQ], Profile of Mood States-Short Form [POMS-SF]) provide evidence of convergent and divergent validity for the BRIEF-SR.

Examination of BRIEF-SR profiles in a variety of clinical groups provides further evidence of validity based on clinical utility. BRIEF-SR ratings for groups of adolescents with ADHD-I, ADHD-C, insulin-dependent diabetes mellitus, autism spectrum disorders, and anxiety and depressive disorders showed different patterns of scale elevations for each group compared to matched control groups. Correlations

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Behavior Rating Inventory of Executive Function (BRIEF-SR)

between adolescent and parent ratings for the clinical groups were strong, suggesting good agreement much of the time.

**Reference**

Stoelting Company website:

<https://www.stoeltingco.com/stoelting/2271/1467/1494/Psychological/Behavior-Rating-Inventory-of-Executive-Function---Self-Report-Version-BRIEF-SR>

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<http://www4.parinc.com/Products/Product.aspx?ProductID=BRIEF-SR>.

NINDS Headache Common Data Elements (CDEs)  
Headache CDE Preventive Therapies: Outcomes Subgroup Recommendations  
Children's Depression Inventory 2 (CDI-2)

**Instrument Name**

Children's Depression Inventory 2 (CDI-2)

**Classification**

Supplemental

**Overview**

The CDI-2 contains 28 self-report items, each consisting of three statements. For each item, the individual is asked to select the statement that best describes his or her feelings for the past two weeks. The scale is brief and easy to administer and it can facilitate the multifaceted evaluation of children and adolescents, assessing cognitive, behavioral and affective signs of depression in 7-17 year old children and adolescents. The assessment is designed for a variety of situations, including schools, child guidance clinics, pediatric practices, and child psychiatric settings. The CDI is used by clinicians and counselors to assess self-reported key symptoms of depression, such as a child's feelings of worthlessness, loss of interest in activities, support diagnosis, and for treatment planning.

**Scoring**

The CDI-2 gives a total score and five subscores by age and gender and takes approximately 15-20 minutes to complete.

**Comment/Special Instructions**

The CDI-2 is brief and easy to administer, and its items target core aspects of childhood depression. Multi-rater system allows for comprehensive evaluation and Specially-designed QuikScore™ format allows you to score and evaluate results easily. There is also a short, 10-item version available.

**References**

Pearson- Assessment and Information. Children's Depression Inventory (CDI 2). <http://www.pearsonassessments.com/HAIWEB/Cultures/en-us/Productdetail.htm?Pid=015-8044-762>

Saylor CF, Finch AJ, Spirito A, Bennett B. The Children's Depression Inventory: A Systematic Evaluation of Psychometric Properties. *Journal of Consulting and Clinical Psychology*. 1984; 52(6): 955-967.

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NINDS Headache Common Data Elements (CDEs)  
Headache CDE Preventive Therapies: Outcomes Subgroup Recommendations  
Clinical Global Impression Scale (CGI)

**Instrument Name**

Clinical Global Impression Scale

**Classification**

Exploratory

**Overview**

The Clinical Global Impression (CGI) Scale is a standardized assessment tool. Its goal is to allow the clinician to rate the severity of illness, change over time, and efficacy of medication; taking into account the patient's clinical condition and the severity of side effects. The CGI Scale is widely used in clinical psychopharmacology trials as an outcome measure.

The CGI Scale consists of three global subscales formatted for use with the Global Scoring Sheet. The first subscale, Severity of Illness, assesses the clinician's impression of the patient's current illness state; it is often used both before and after treatment. The next subscale, Global Improvement, assesses the patient's improvement or worsening from baseline, which is usually the beginning of a clinical trial. Sometimes a global improvement rating from the patient and the clinician is recorded. The third subscale, the Efficacy Index, attempts to relate therapeutic effects and side effects by deriving a composite score that reflects both the therapeutic effect and the concomitant adverse reactions or side effects. This subscale is essentially a ratio of benefit to risk that attempts to assess the overall efficacy of the treatment in relation to its adverse reactions. If therapeutic effects are regarded as gross profit and side effects as cost, this index is analogous to net profit. Thus, the index requires the clinician to make separate judgments regarding the therapeutic effectiveness of the treatment (with anchor ratings listed in the rows) and the adverse reactions (with anchor ratings listed in the columns).

**Scoring**

Scores on the Severity of Illness subscale range from 1 = not ill at all to 7 = among the most extremely ill. The Global Improvement subscale also goes from 1 = very much improved to 7 = very much worse. As illustrated, the Efficacy Index involves locating a rating on a matrix of therapeutic versus side effects. Scores range from 0 = marked improvement and no side effects to 4 = unchanged or worse and side effects outweigh therapeutic effects. Spearing et al. (1997) have developed a modification of the CGI Scale for use in assessing global illness severity and change in patients with bipolar disorder. It takes a clinician only 1–2 minutes to score the CGI Scale after a clinical interview.

**Comments/Special Instructions**

In one German study that is quite critical of the CGI Scale, the distribution of scores and normality of CGI items were examined at the first and last visits (8 weeks apart) in three clinical trials with a total of 175 patients with schizophrenia, depression, or anxiety disorders. The mean, standard deviation, skewness, and kurtosis were analyzed for each item and for each of the two visits. Scores on the Global Improvement and Therapeutic Effects subscales were highly correlated ( $r \sim 0.90$ ). However, there was only a moderate correlation ( $r \sim -0.47$  to  $-0.66$ ) between changes in the Severity of Illness and Global Improvement subscales, where one would expect a high correlation. Both improvement ratings (i.e., Global Improvement and Therapeutic Effects) appear to be rather independent of the Side Effects rating. Severity of Illness was also moderately correlated with the Side Effects rating. Test-retest reliability values were calculated by correlating the ratings of each item at the first visit with all respective ratings at subsequent visits. These test-retest correlations were rather low: for Severity of

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Clinical Global Impression Scale (CGI)

Illness, reliability values ranged from 0.20 to 0.81; for Global Improvement, from 0.15 to 0.78; for Therapeutic Effects, from 0.21 to 0.78; and for Side Effects, from 0.32 to 0.80. Another study in Germany found relatively good reliability scores for the CGI Severity of Illness ratings (0.66 and 0.41 for physicians and nursing staff, respectively) but not for Global Improvement (i.e., change) ratings in a sample of 12 psychogeriatric patients with dementia (0.51 and 0.35 for physicians and nursing staff, respectively).

During an 8-week clinical trial involving 116 patients with panic disorder and depression (Leon et al. 1993), the Hamilton Rating Scale for Depression (Ham-D), anticipatory anxiety, and panic frequency each had positive significant relationships with clinician ratings of severity on the CGI Scale (concurrent validity). In addition, the scale had good sensitivity to change over time.

**References**

Guy W. ECDEU Assessment Manual for Psychopharmacology —Revised (DHEW Publ No ADM 76-338). Rockville, MD, U.S. Department of Health, Education, and Welfare, Public Health Service, Alcohol, Drug Abuse, and Mental Health Administration, NIMH

Guy W. Clinical Global Impressions (CGI) Scale. Psychiatric Measures, APA, Washington DC, 2000.

Spearing MK, Post RM, Leverich GS, et al: Modification of the Clinical Global Impressions (CGI) scale for use in bipolar illness (BP): the CGI-BP. *Psychiatry Res* 73:159–171, 1997

**Copyright Information**

The instrument is available in the public domain at: <http://miksa.ils.unc.edu/unc-hit/media/CGI.pdf>. Please see the CRF Module/Guidelines for the original instrument, along with its corresponding data dictionary.

NINDS Headache Common Data Elements (CDEs)  
Headache CDE Preventive Therapies: Outcomes Subgroup Recommendations  
EuroQoL-5 Dimension Questionnaire (EQ-5D)

**Instrument Name**

EuroQoL-5 Dimension Questionnaire (EQ-5D)

**Classification**

Supplemental

**Overview**

EQ-5D is a standardized measure of health status developed by the EuroQol Group in order to provide a simple, generic measure of health for clinical and economic appraisal. The EQ-5D descriptive system comprises the following 5 dimensions: mobility, self-care, usual activities, pain/discomfort and anxiety/depression. Applicable to a wide range of health conditions and treatments, it provides a simple descriptive profile and a single index value for health status that can be used in the clinical and economic evaluation of health care as well as in population health surveys.

**Scoring**

Each of the 5 EQ-5D descriptive dimensions has 3 levels: no problems, some problems, severe problems. The respondent is asked to indicate his/her health state by ticking (or placing a cross) in the box against the most appropriate statement in each of the 5 dimensions. This decision results in a 1-digit number expressing the level selected for that dimension. The digits for 5 dimensions can be combined in a 5-digit number describing the respondent's health state. It should be noted that the numerals 1-3 have no arithmetic properties and should not be used as a cardinal score. Missing values should be coded as '999'. Ambiguous values (e.g. the line crosses the VAS twice) should be treated as missing values.

**Comments/Special Instructions**

EQ-5D is designed for self-completion by respondents and is ideally suited for use in postal surveys, in clinics, and in face-to-face interviews. It is cognitively undemanding, taking only a few minutes to complete. Instructions to respondents are included in the questionnaire. The EQ-5D self-report questionnaire (EQ-5D) essentially consists of two pages comprising the EQ-5D descriptive system (page 2) and the EQ VAS (page 3). There is also an optional page of demographic questions. There is also an extended version of EQ-5D that incorporates the valuation task but this is only used for valuation studies and is not relevant for clinical users.

**Reference**

Fisk JD, Brown MG, Sketris IS, Metz LM, Murray TJ, Stadnyk KJ. A comparison of health utility measures for the evaluation of multiple sclerosis treatments. *J Neurol Neurosurg Psychiatry* 2005 76:58-63.

Putzki N, Fischer J, Gottwald K, Reifschneider G, Ries S, Sieve A, Hoffmann F, Käfferlein W, Kausch U, Liedtke M, Kirchmeier J, Gmünd S, Richter A, Schicklmaier P, Niemczyk G, Wernsdörfer C, Hartung HP and for the "Mensch im Mittelpunkt" Study Group (2009), Quality of life in 1000 patients with early relapsing–remitting multiple sclerosis. *European Journal of Neurology*, 16: 713–720.

**Copyright Information**

This instrument is copyright protected and can be accessed at this website: <http://www.euroqol.org/eq-5d/how-to-obtain-eg-5d.html>.

NINDS Headache Common Data Elements (CDEs)  
Headache CDE Preventive Therapies: Outcomes Subgroup Recommendations  
Generalized Anxiety Disorder 7-item scale (GAD-7)

**Instrument Name**

Generalized Anxiety Disorder 7-item scale (GAD-7)

**Classification**

Supplemental

**Overview**

The GAD-7 is an anxiety scale that can be used for assessing anxiety severity in clinical practices and in research. This is a brief, 7-item self-report anxiety scale with good reliability. Increasing scores on the scale are associated with multiple domains of functional impairments. The GAD-7 has an excellent internal consistency and good test-retest reliability. The scale inquires about symptoms over the preceding two weeks.

**Scoring**

The scoring ranges from 0 to 3 on each question, leading to a total score of 0-21. Thus a score of 10 represents a reasonable cut-off point for identifying cases of GAD, whereas the scoring ranges of 5, 10, and 15 could represent mild, moderate and severe Generalized Anxiety Disorder. This test takes approximately 5 to 10 minutes to complete.

**Comments/Special Instructions**

The GAD-7 can be used in diverse clinical settings and can be generalized to primary care. But it focuses only on one anxiety disorder, though many more exist, and further evaluation of the patient should be considered for diagnosis. However, the same cut-off score has been shown to be good at detecting other anxiety disorders.

The GAD-7 has excellent internal consistency and good test-retest reliability. Most patients diagnosed with GAD were above the cut-off point of 10, and most patients without GAD were below 10.

**References**

Kroenke K, Spitzer RL, Williams JB, Löwe B. The Patient Health Questionnaire Somatic, Anxiety, and Depressive Symptom Scales: a systematic review. *General Hospital Psychiatry* 32 (2010) 345–359.

Spitzer RL, Kroenke K, Williams JB, Löwe B. A brief measure for assessing generalized anxiety disorder: the GAD-7. *Arch Intern Med.* 2006 May 22;166(10):1092-7.

**Copyright Information**

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**Rationale/ Justification**

Anxiety is a common comorbidity in individuals who suffer from headaches/migraines.

NINDS Headache Common Data Elements (CDEs)  
Headache CDE Preventive Therapies: Outcomes Subgroup Recommendations  
Hospital Anxiety and Depression Scale (HADS)

**Instrument Name**

Hospital Anxiety and Depression Scale (HADS)

**Classification**

Supplemental

**Overview**

The HADS is a 14-item self-report scale that consists of a depression and an anxiety scale, each with 7 items. The scale was designed to screen for mood disorders in general (non-psychiatric) medical outpatients. It focuses on subjective disturbances of mood rather than physical signs, and aims at distinguishing depression from anxiety. Compared to other instruments scales, it focuses on emotional aspects of anxiety disturbances, as opposed to somatic and cognitive symptoms.

**Scoring**

The HADS is comprised of two sub scales, Depression and Anxiety. Each subscale has a score ranging from 0-21. Items are rated on a 4-point Likert-type scale ranging from 0 to 3, generating a scale range of 0 to 42 points, with higher scores representing greater symptom severity. The anxiety subscale has 3 items that refer to panic and 4 to generalized anxiety. Add the A questions to get a score for anxiety and the D questions for depression. Scores of 0-7 indicate normal levels of anxiety and depression; 8-10 indicate borderline abnormal anxiety and depression levels and 11-21 suggest abnormal levels of anxiety and depression.

**Comments/Special Instructions**

The HAD Scale is presented as a reliable instrument for screening for clinically significant anxiety and depression in patients attending a general medical clinic. This scale has also been shown to be a valid measure of the severity of these disorders of mood and therefore the repeated administration of the scale at subsequent visits to the clinic will give the physician useful information concerning progress.

**Reference**

Ferentinos P, Paparrigopoulos T, Rentzos M, Zouvelou V, Alexakis T, Evdokimdis I. Prevalence of major depression in ALS; Comparison of a semi-structured interview and four self- report measures. Amyotrophic Lateral Sclerosis 2011; Early online 1-6

Snaith RP. "The Hospital Anxiety And Depression Scale". Health Quality Life Outcomes. 2003; 1:29.

Wicks P, Abrahams S, Masi D, Hejda-Forde S, Leigh PN, Goldstein LH Prevalence of depression in a 12-month consecutive sample of patients with ALS. Eur J Neurol. 2007 Sep;14(9):993-1001.

Zigmond AS, Snaith RP. The Hospitalized Anxiety and Depression Scale. Acta Psychiatric Scand. 1983 Jun; 67(6): 361 – 70.

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NINDS Headache Common Data Elements (CDEs)  
Headache CDE Preventive Therapies: Outcomes Subgroup Recommendations  
Kiddie-Scheduled for Affective Disorders and Schizophrenia – Present and Lifetime Version 1.0 (K-SADS-PL v1.0)

**Instrument Name**

Kiddie-Scheduled for Affective Disorders and Schizophrenia – Present and Lifetime Version 1.0 (K-SADS-PL v1.0)

**Classification**

Supplemental

**Overview**

The K-SADS-Present and Lifetime(PL) version is a semi-structured diagnostic interview designed to assess current and past episodes of psychopathology in children and adolescents according to DSM-III-R and DSM-IV criteria. Probes and objective criteria are provided to rate individual symptoms. The primary diagnoses assessed with the K-SADS-PL include: Major Depression, Dysthymia, Mania, Hypomania, Cyclothymia, Bipolar Disorders, Schizoaffective Disorders, Schizophrenia, Schizophreniform Disorder, Brief Reactive Psychosis, Panic Disorder, Agoraphobia, Separation Anxiety Disorder, Avoidant Disorder of Childhood and Adolescence, Simple Phobia, Social Phobia, Overanxious Disorder, Generalized Anxiety, Obsessive Compulsive Disorder, Attention Deficit Hyperactivity Disorder, Conduct Disorder, Oppositional Defiant Disorder, Enuresis, Encopresis, Anorexia Nervosa, Bulimia, Transient Tic Disorder, Tourette's Disorder, Chronic Motor or Vocal Tic Disorder, Alcohol Abuse, Substance Abuse, Post-Traumatic Stress Disorder, and Adjustment Disorders. The probes that are included in the instrument do not have to be recited verbatim, and they are provided to illustrate ways to elicit the information necessary to score each item. The interviewer should feel free to adjust the probes to the developmental level of the child, and use language supplied by the parent and child when querying about specific symptoms.

**Scoring**

It takes approximately 45-75 minutes to complete.

**Comments/Special Instructions**

The K-SADS-PL is administered by interviewing the parent(s), the child, and then achieving summary ratings which include *all* sources of information (parent, child, school, chart, and other). When administering the instrument to pre-adolescents, conduct the parent interview first. In working with adolescents, begin with them. When there are discrepancies between different sources of information, the rater will have to use his/her best clinical judgment. In the case of discrepancies between parents' and child's reports, the most frequent disagreements occur in the items dealing with subjective phenomena where the parent does not know, but the child is very definite about the presence or absence of certain symptoms. This is particularly true for items like guilt, hopelessness, interrupted sleep, hallucinations, and suicidal ideation. If the disagreements relate to observable behavior (e.g. truancy, fire setting, or a compulsive ritual), the examiner should query the parent(s) and child about the discrepant information. If the disagreement is not resolved, it is helpful to see the parent(s) and child together to discuss the reasons for the disagreement. Ultimately the interviewer will have to use his/her best clinical judgment in assigning the summary ratings.

**References**

Kaufman, J., Birmaher, B., Brent, D., Rao, U., Flynn, C., Moreci, P., Williamson, D., and Ryan, N. 1997. Schedule for Affective Disorders and Schizophrenia for School-Age Children—Present and Lifetime

NINDS Headache Common Data Elements (CDEs)  
Headache CDE Preventive Therapies: Outcomes Subgroup Recommendations  
Kiddie-Scheduled for Affective Disorders and Schizophrenia – Present and Lifetime Version 1.0 (K-  
SADS-PL v1.0)

version (K-SADS-PL): Initial reliability and validity data. J Am Acad Child Adolesc Psychiatry. 1997 Jul; 36(7):980-8.

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NINDS Headache Common Data Elements (CDEs)  
Headache CDE Preventive Therapies: Outcomes Subgroup Recommendations  
Mood Disorder Questionnaire (MDQ)

**Instrument Name**

Mood Disorder Questionnaire (MDQ)

**Classification**

Supplemental

**Overview**

The Mood Disorder Questionnaire (MDQ) is a screening instrument for bipolar disorder that can easily be utilized in primary care settings. The MDQ can correctly identify 7 of 10 patients with bipolar disorder, while 9 of 10 patients without bipolar disorder would be correctly screened out. The MDQ includes 13 questions plus items assessing clustering of symptoms and functional impairment. The MDQ can provide primary care physicians with a quick and easy way to identify patients most likely to have bipolar disorder.

**Scoring**

If the patient answers “Yes” to seven or more of the 13 items in question number 1 and “Yes” to question number 2 as well as “Moderate” or “Serious” to question number 3 this would indicate a positive screen.

**Comments/Special Instructions**

The MDQ has both good sensitivity and very good specificity. The MDQ screens for manic symptoms related to bipolar disorder and is self administered by the patient or read orally by a trained examiner. Sensitivity of 73% and specificity of 90% for a cutoff point of 7 items answered “Yes.”

**References**

Hirschfeld RMA, Williams JBW, Spitzer RL, et al. Development and validation of a screening instrument for bipolar spectrum disorder: The Mood Disorder Questionnaire. *Am J Psychiatry*. 2000;157:1873-1875.

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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NINDS Headache Common Data Elements (CDEs)  
Headache CDE Preventive Therapies: Outcomes Subgroup Recommendations  
Mini-International Neuropsychiatric Interview (M.I.N.I.)

**Instrument Name**

Mini-International Neuropsychiatric Interview (M.I.N.I.)

**Classification**

Supplemental

**Overview**

The M.I.N.I. is a short structured diagnostic interview used by psychiatrists and clinicians that was developed in 1990. It assesses the disorders of the DSM-IV and ICD-10. It covers 17 Axis I disorders (i.e., mood, anxiety, substance use, psychotic, and eating disorders), a suicidality module and one Axis-II disorder (i.e., Antisocial Personality Disorder), with most disorders having a timeframe of 2-4 weeks except for two disorders. A follow-up module is included for each individual disorder for which the respondent has a positive initial screen. It was designed for multi-center clinical trials and epidemiology studies and to be used as a screening instrument in non-research clinical settings.

**Scoring**

The M.I.N.I. has an administration time of approximately 15 minutes

**Comments/Special Instructions**

A structured psychometric interview for DSM-IV and ICD-10 psychiatric disorders administered by a trained clinician. This can be completed in approximately 15 minutes.

The M.I.N.I. has been validated against the Structure Clinical Interview (SCID-P) for DSM diagnoses. Validation and reliability studies have been done comparing the M.I.N.I. to the SCID-P for DSM-III-R and the CIDI (a structured interview developed by the World Health Organization for lay interviewers for ICD-10). The results of these studies show that the M.I.N.I. has acceptably high validation and reliability scores, but can be administered in a much shorter period of time (mean  $18.7 \pm 11.6$  minutes, median 15 minutes) than the above referenced instruments.

A pediatric version is also available. Translations available in 43 languages.

**References**

Sheehan DV, Lecrubier Y, Sheehan KH, et al. The Mini-International Neuropsychiatric Interview (M.I.N.I.): the development and validation of a structured diagnostic psychiatric interview for DSM-IV and ICD-10. *J Clin Psychiatry*. 1998; 59(Suppl 20): 22-33.

**Copyright Information**

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**Rationale/ Justification**

Axis I disorders are common among headache patients, and structured interviews provide the most precise assessment of these diagnoses.

NINDS Headache Common Data Elements (CDEs)  
Headache CDE Preventive Therapies: Outcomes Subgroup Recommendations  
Patient Health Questionnaire Depression Module (PHQ-9)

**Instrument Name**

Patient Health Questionnaire Depression Module (PHQ-9)

**Classification**

Supplemental

**Overview**

The PHQ-9, a tool specific to depression, simply scores each of the 9 Diagnostic and Statistical Manual of Mental Disorders (DSM-IV) depressive episode criteria and is based on the mood module from the original PRIME-MD.

**Scoring**

Has a total score of 0-33. A score of 5, 10, 15, 20, are cutpoints for mild, moderate, moderately severe, and severe depression, respectively. It takes approximately 2 minutes to complete.

**Comments/Special Instructions**

The PHQ-9 is useful as a screening instrument, with high criterion and construct validity among medical patients. The PHQ-9 has high validity, and sensitivity and specificity for major depression of 88%, using a cutoff score of 10.

The scale is available in multiple languages, including: Arabic, Assamese, Chinese (Cantonese, Mandarin), Czech, Dutch, Danish, English, Finnish, French, French Canadian, German, Greek, Gujarati, Hindi, Hebrew, Hungarian, Italian, Malay, Malayalam, Norwegian, Oriya, Polish, Portuguese, Russian, Spanish (US), Swedish and Telugu.

**References**

Kroenke K, Spitzer RL, Williams JB. The Patient Health Questionnaire-2: validity of a two-item depression screener. *Med Care*. 2003; 41(11): 1284-92.

Maizels M, Smitherman TA, Penzien DB. A Review of Screening Tools for Psychiatric Comorbidity in Headache Patients. *Headache*. 2006; 46 [Suppl 3]:S98-S109.

**Copyright Information**

This instrument is available in the public domain at: [http://www.phqscreeners.com/pdfs/02\\_PHQ-9/English.pdf](http://www.phqscreeners.com/pdfs/02_PHQ-9/English.pdf).

**Rationale/ Justification**

Depression is a common comorbidity among headache patients.

NINDS Headache Common Data Elements (CDEs)  
Headache CDE Preventive Therapies: Outcomes Subgroup Recommendations  
Structured Clinical Interview for DSM-IV-TR Axis I Disorders Research Version (SCID-I)

**Instrument Name**

Structured Clinical Interview for DSM-IV-TR Axis I Disorders Research Version (SCID-I-RV)

**Classification**

Supplemental

**Overview**

The SCID-I-RV is a semi-structured interview for diagnosing psychiatric disorders along major DSM-IV Axis I. This instrument is composed of separate modules which correlate to categories of diagnoses. Most sections commence with a leading question that allows the interviewer to "skip" the subsequent questions if not met. All diagnoses symptoms are coded as present, subthreshold, or absent. The interview is intended to be administered by a clinician or trained mental health professional. However with training, non-clinician research assistants can administer the measure.

**Scoring**

An administration booklet and score sheet are required to correctly score the SCID-I-RV. Computer-assisted versions of the SCID-I-RV are also available.

**Comments/Special Instructions**

Reliability and validity of the SCID for DSM-III-R and DSM-IV have been reported in several studies. With regard to reliability, the range in reliability is enormous, depending on the nature of the sample and research methodology (i.e., joint vs. test-retest, multi-site vs. single site with raters who have worked together, etc.). Determining the validity is a more difficult question because of the lack of established gold standards for psychiatric diagnoses. In lieu of such a gold standard, "best estimate" diagnoses are often used as the clinical standard.

The SCID-I-RV, the standard research version is used in both research and clinical settings and is organized into diagnostic modules that include interview questions, diagnostic criteria and ratings all within a single interview booklet. The Clinician Version, SCID-CV, is an abridged version of the SCID-I-RV, adapted specifically to cover diagnoses most commonly seen in clinical settings; however, the SCID-CV may also be used in research settings. One significant difference is that the SCID-CV is published in two parts: a reusable Administration Booklet (with color-coded tabs) and one-time-use-only score sheets.

**References**

First MB, Spitzer RL, Gibbon M, Williams JBW. *Structured Clinical Interview for DSM-IV-TR Axis I Disorders Research Version, (SCID-I)*. New York: Biometrics Research Department, New York State Psychiatric Institute; 2002.

**Copyright Information**

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NINDS Headache Common Data Elements (CDEs)  
Headache CDE Preventive Therapies: Outcomes Subgroup Recommendations  
State-Trait Anxiety Inventory (STAI)

**Instrument Name**

State-Trait Anxiety Inventory (STAI)

**Classification**

Supplemental

**Overview**

The STAI measures the presence of anxiety symptoms relating to both current (state) anxiety and long-standing (trait) anxiety in research and clinical settings. The STAI is a validated 40-item self report assessment device which are divided into separate measures of state and trait anxiety each comprising of 20-items. The two measures comprise the inventory, one consisting of 20 items measuring state anxiety, and the other of 20 items measuring trait anxiety. The STAI is frequently used to measure anxiety in populations with headache.

**Scoring**

On each of the two measures the twenty questions are scored on a four point Likert scale, some of which are reverse scored. The STAI is self-administered and it takes 2-5 minutes to complete.

**Comments/Special Instructions**

The STAI's psychometric properties are adequate. While the scale is meant to measure anxiety, it is problematic in that it overlaps substantially with depression.

The STAI has been adapted in more than 30 languages for cross-cultural research and clinical practice.

**Reference**

Antony MM, Orsillo SM, Roemer L, eds. Practitioner's Guide to Empirically Based Measures of Anxiety. NewYork: Kluwer/Plenum; 2001.

Bieling J, Antony MM, Swinson RP. The State-Trait Anxiety Inventory: Structure and content re-examined. Behav Res Ther. 1998;36:777-788.

Maizels M, Smitherman TA, Penzien DB. A Review of Screening Tools for Psychiatric Comorbidity in Headache Patients. Headache. 2006; 46 [Suppl 3]:S98-S109.

Spielberger CD, Gorsuch RL, Lushene R, Vagg PR, Jacobs GA. Manual for the State-Trait Anxiety Inventory (Form Y). Palo Alto, CA: Mind Garden; 1983.

**Copyright Information**

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**Rationale/ Justification**

Anxiety is a common comorbidity among headache patients.