

Content Validity of Self-Report Measurement Instruments: An Illustration From the Development of the Brain Tumor Module of the M.D. Anderson Symptom Inventory

Terri S. Armstrong, MS, APRN, BC, Marlene Z. Cohen, RN, PhD, FAAN,
Lillian Eriksen, RN, DSN, and Charles Cleeland, PhD

Purpose/Objectives: To illustrate one technique for establishing content validity of measurements using the initial development and testing of the M.D. Anderson Symptom Inventory Brain Tumor Module.

Data Sources: Published articles, book chapters, and subjective judgments of experts.

Data Synthesis: Content validity is the essential first step in the development of items to be included in a measurement instrument. Content validity is a criterion-referenced process that is judged by how well each item in a newly developed instrument reflects its respective objective or content domain. The stages in addressing content validity include a developmental stage and a judgment-quantification stage. Steps involved in the developmental stage include domain identification, item generation, and instrument formation. The judgment-quantification stage is when experts review the items and either report validity of the items subjectively or with an empirically referenced method, such as calculation of the content validity index. The content validity of a set of questions designed to measure symptoms in a population of patients with primary brain tumors was ascertained by using the calculation of the content validity index.

Conclusions: The final version of the M.D. Anderson Symptom Inventory Brain Tumor Module consists of the 13 core items and 18 additional items designated as valid by a panel of experts. The instrument will be administered to a group of patients to determine construct validity and reliability of the items.

Implications for Nursing: Self-report instruments are used to measure various health outcomes in oncology. Oncology nurses are in a key position to develop such instruments to be used in clinical care and research of symptoms associated with cancer. Understanding the process of content validation is an essential first step in developing new instruments.

Self-report instruments commonly are used in research about and care of patients with cancer to collect health-related information. This information may relate to adverse events, disease- or treatment-related symptoms, psychological status, satisfaction with care, and health outcomes. Assessing content validity is considered one of the most critical first steps in instrument development (Beck & Gable, 2001). Content validity concerns how well the questions or items correspond to the concept being measured (Saw & Ng, 2001) or adequately represent the domain of content (Beck & Gable).

Key Points . . .

- ▶ Content validity refers to how well questions or items in a tool represent the concept of interest.
- ▶ Steps in developing a content-valid measurement include a developmental stage and a judgment-quantification stage.
- ▶ Several methods are available to identify the domains of interest and validate items once selected.
- ▶ Careful selection of experts to review items for content validity is imperative to ensure accuracy of the process.

The stages in addressing content validity include a developmental stage and a judgment-quantification stage. Steps involved in the developmental stage include domain identification, item generation, and instrument formation. The judgment-quantification stage is when experts review the items and report validity of the items subjectively or with an empirically referenced method, such as calculation of the content validity index. An instrument must have content validity, or the measurement of other forms of validity and reliability are meaningless.

This article will review approaches to selecting valid items for inclusion in an instrument and provide an example of the

Terri S. Armstrong, MS, APRN, BC, is a doctoral candidate in the School of Nursing and an advanced practice nurse at the University of Texas M.D. Anderson Cancer Center; Marlene Z. Cohen, RN, PhD, FAAN, is the John S. Dunn Sr. Distinguished Professor in Oncology Nursing in the School of Nursing at the University of Texas Health Science Center, a professor in the Department of Symptom Research at the University of Texas M.D. Anderson Cancer Center, and a nurse researcher at Lyndon B. Johnson General Hospital; Lillian Eriksen, RN, DSN, is an associate professor in the School of Nursing at the University of Texas–Houston; and Charles Cleeland, PhD, is the McCullough Professor of Cancer Research and chair in the Department of Symptom Research at the University of Texas M.D. Anderson Cancer Center, all in Houston, TX. (Submitted October 2003. Accepted for publication July 18, 2004.)

Digital Object Identifier: 10.1188/05.ONF.669-676

process in how the items were generated and their content validity assessed for the M.D. Anderson Symptom Inventory Brain Tumor Module (MDASI-BT) (see Figure 1). The instrument is being developed to measure the occurrence and severity of symptoms that occur in patients with primary brain tumors over the course of their illness (from diagnosis through recurrence to the end of life). The instrument is designed as a broad indicator of symptoms and is not designed for in-depth symptom assessment.

An instrument allowing for the measurement of symptoms that occur commonly as a consequence of cancer therapy and the specific neurologic symptoms that occur in the population of patients with primary brain tumors does not exist. The MDASI has been validated for the measurement of symptoms that occur commonly in people with systemic cancer and as a result of cancer therapy. The format allows for the rating of symptom severity and interference with daily life (situational meaning), two important components of the conceptual model which guide research and practice (Armstrong, 2003). The MDASI uses a Likert-type format to allow patients to self-report the severity of nine symptoms in the past 24 hours. Six additional questions address interference of symptoms with daily activities. It has demonstrated reliability and construct and discriminant validity in a variety of patients with solid tumors other than brain tumors (Cleeland et al., 2000). The instrument currently is used in daily clinical practice, as well as a measurement of symptom severity in ongoing clinical trials of therapies for a variety of cancer types. The MDASI will serve as the core instrument to which a brain tumor module will be added.

Step 1: Content and Domain Specification

Several strategies are available to help determine an instrument's content domain. Having a well-thought-out plan of item construction helps to ensure content validity (Beck & Gable, 2001). The first step should include delineating an instrument's content domain, or the content area that relates to the variable of interest (Gable & Wolfe, 1993; Waltz & Bausell, 1981). According to Lynn (1986), a thorough review of the literature on the topic helps to ensure that all dimensions of the domain are identified. Qualitative data, such as clinical experience, results of focus groups, or individual qualitative interviews, also can add to understanding of all dimensions and subdimensions of the content area (Beck & Gable). Once an initial query had been completed, Beck and Gable described several strategies designed to delineate the content domain of the items, including the facet-design approach, the item-form/item-frame approach, and the linguistic-transformation approach (Beck & Gable; Guttman, 1969; Osburn, 1968). Table 1 outlines the steps involved in each of these processes.

Domain Identification in Development of the M.D. Anderson Symptom Inventory Brain Tumor Module

The concept of interest in forming the MDASI-BT is the symptom experience of patients with primary brain tumors. Lenz, Pugh, Milligan, Gift, and Suppe (1997) developed a middle-range theory of unpleasant symptoms and defined symptoms as "perceived indicators of change in normal functioning as experienced by patients" (p. 3). This middle-range theory considers each symptom to be a multidimensional

experience that can be measured separately or in combination with other symptoms. Another definition views symptoms experienced with primary brain tumors as the perception of the frequency, intensity, distress, and meaning occurring as symptoms are produced and expressed (Armstrong, 2003).

Symptoms in Primary Brain Tumors

The effects of a brain tumor on neurologic function are determined by its location in the brain and increased intracranial pressure, as well as the symptoms produced by treatment procedures (Rabbitt & Page, 1998). In general, primary brain tumors do not metastasize outside of the central nervous system (CNS); therefore, symptoms that occur are neurologic in origin, although treatment-related symptoms can be generalized.

Literature pertaining to symptoms in the population of patients with primary brain tumors was reviewed using the National Center for Biotechnology Information's PubMed. The review was limited to research articles that were available in English. Key words for the search included "brain tumor" and "symptoms." Most completed studies were epidemiologic, were more than 20 years old, or included symptoms reported in association with clinical trials evaluating new therapies that no longer are used in this patient population; these were excluded from review. The remaining articles revealed that tumors and associated edema invade or compress brain tissues, resulting in either generalized symptoms of increased intracranial pressure or specific symptoms based on tumor location in the brain (Armstrong & Gilbert, 1996; Maire, Coudin, Guerin, & Caudry, 1987; Scheibel, Meyers, & Levin, 1996). In addition, treatment of a tumor or associated signs also may result in symptoms (Armstrong & Gilbert; Rabbitt & Page, 1998).

Step 2: Conceptual and Operational Definitions

Formulating conceptual and operational definitions of the dimensions to be included is the next step in instrument development (Beck & Gable, 2001). Three dimensions were identified for inclusion in symptom measurement in the population of patients with primary brain tumors: (a) generalized neurologic symptoms, (b) focal neurologic symptoms, and (c) treatment-related symptoms that may be different than in the general population of patients with cancer. Generalized neurologic symptoms are defined as those associated with global neurologic dysfunction caused by increased intracranial pressure or altered signal transmission in the brain. Focal neurologic symptoms are defined as those associated with specific anatomic locations in the brain. Treatment-related symptoms are defined as specific symptoms associated with therapy designed to treat a tumor or associated signs and symptoms.

Step 3: Generating Items

Once dimensions of the concept of interest are decided, the next step is to generate items that represent each of the dimensions. Items were selected for the MDASI-BT by review of the literature on symptoms associated with primary brain tumors in the three dimensions of generalized neurologic symptoms, focal symptoms, and treatment-associated symptoms. Table 2 outlines the symptoms included in each of these domains.

Date: _____

Study Name

Subject Initials: _____

Protocol #

Study Subject #: _____

PI:

Rev:

M. D. Anderson Symptom Inventory (MDASI) Core Items

Part I. How severe are your symptoms?

People with cancer frequently have symptoms that are caused by their disease or by their treatment. We ask you to rate how severe the following symptoms have been in the last 24 hours. Please fill in the circle below from 0 (symptom has not been present) to 10 (the symptom was as bad as you can imagine it could be) for each item.

	Not Present										As Bad As You Can Imagine	
	0	1	2	3	4	5	6	7	8	9	10	
1. Your pain at its WORST?	<input type="radio"/>	<input type="radio"/>										
2. Your fatigue (tiredness) at its WORST?	<input type="radio"/>	<input type="radio"/>										
3. Your nausea at its WORST?	<input type="radio"/>	<input type="radio"/>										
4. Your disturbed sleep at its WORST?	<input type="radio"/>	<input type="radio"/>										
5. Your feelings of being distressed (upset) at its WORST?	<input type="radio"/>	<input type="radio"/>										
6. Your shortness of breath at its WORST?	<input type="radio"/>	<input type="radio"/>										
7. Your problem with remembering things at its WORST?	<input type="radio"/>	<input type="radio"/>										
8. Your problem with lack of appetite at its WORST?	<input type="radio"/>	<input type="radio"/>										
9. Your feeling drowsy (sleepy) at its WORST?	<input type="radio"/>	<input type="radio"/>										
10. Your having a dry mouth at its WORST?	<input type="radio"/>	<input type="radio"/>										

(Continued on next page)

Figure 1. M.D. Anderson Symptom Inventory

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Date: _____

Subject Initials: _____

Study Subject #: _____

	Not Present										As Bad As You Can Imagine	
	0	1	2	3	4	5	6	7	8	9	10	
11. Your feeling sad at its WORST?	<input type="radio"/>											
12. Your vomiting at its WORST?	<input type="radio"/>											
13. Your numbness or tingling at its WORST?	<input type="radio"/>											

Part II. How have your symptoms interfered with your life?

Symptoms frequently interfere with how we feel and function. How much have your symptoms interfered with the following items in the last 24 hours:

	Did Not Interfere										Interfered Completely
	0	1	2	3	4	5	6	7	8	9	10
14. General activity?	<input type="radio"/>										
15. Mood?	<input type="radio"/>										
16. Work (including work around the house)?	<input type="radio"/>										
17. Relations with other people?	<input type="radio"/>										
18. Walking?	<input type="radio"/>										
19. Enjoyment of life?	<input type="radio"/>										

Figure 1. M.D. Anderson Symptom Inventory (Continued)

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Generalized neurologic symptoms are those related to global neurologic dysfunction as a result of increased intracranial pressure. Generalized symptoms include headaches and seizure activity (Maire et al., 1987; Rabbitt & Page, 1998). Headaches

are the first symptom in 35% of those diagnosed with a brain tumor and occur at some point in the disease trajectory in 70% of patients (McKeran & Thomas, 1980; Rabbitt & Page). One-third of patients experience a seizure as a first symptom, and

Table 1. Strategies to Delineate Content Domain of Items

Strategy	Steps	Advantage(s)
Facet-design approach (Guttman, 1969)	<ol style="list-style-type: none"> 1. Content domain is specified and mapped out. 2. Fixed categories in the content domain are identified and linked by a mapping sentence. 3. Variable elements in each category are identified. 	<ul style="list-style-type: none"> • The use of the overall mapping sentence; items can be generated easily by changing the elements in one or more of the fixed categories.
Item form/item frame (Osburn, 1968)	<ol style="list-style-type: none"> 1. Item form shell is fixed, containing one or more variable elements. 2. Replacement sets for each of the variable elements are identified, which leads to the definition of a group of item sentences. 	<ul style="list-style-type: none"> • Item forms/item frames are very specific in the way in which the content domain is defined and how items are generated.
Linguistic-transformation approach	<ol style="list-style-type: none"> 1. A passage from written material is transformed by the use of a rule for generating items. 	<ul style="list-style-type: none"> • Simple • Consistent item generation (different test developers given the same page and same transformation rule generate similar items)

50%–70% of patients experience a seizure at some point in their disease (McKeran & Thomas). In about 50% of patients who experience one or more seizures, the seizure is generalized (Armstrong, Kanusky, & Gilbert, 2003). Focal symptoms are those caused by focal dysfunction related to location of the tumor in the brain. Common focal symptoms include difficulty with cognition, speech, strength, and sensory function (Armstrong & Gilbert, 1996; Rabbitt & Page; Scheibel et al., 1996).

Although the information in the previous paragraph about symptoms in people with brain tumors often is cited, it is based on patient samples from the early 1960s and 1970s (McKeran & Thomas, 1980). The data for these early studies were collected primarily in a retrospective fashion, from physician-completed histories and physical examinations at the time of initial diagnosis. In addition to these difficulties with the age of the data and their retrospective nature, much of the data were collected prior to the widespread use of magnetic resonance imaging (MRI). This may be important because a recent review indicated that the use of MRI might lead to earlier diagnosis, which may affect symptom presentation (Radhakrishnan et al., 1995). In addition, none of the early studies reported symptom occurrence at the time of recurrence, and data related to neurologic symptom variability during modern treatment regimens usually are not collected in a standardized fashion.

Symptoms associated with therapy for brain tumors have been well described and include worsening of existing neurologically based physical and psychological symptoms and development of new symptoms (Lee, Nauert, & Glass, 1986; Maire et al., 1987; Scheibel et al., 1996). The most common therapy for all types of primary CNS tumors is radiotherapy to the brain. Transient side effects associated with radiation include acute effects of nausea, hair loss, tinnitus and hearing loss, focal skin reactions, and worsening of existing neurologic symptoms (Dropcho, 1991). In addition, short- and long-term effects on cognition, focal neurologic symptoms, and level of arousal have been reported (Armstrong, Mollman, Corn, Alavi, & Grossman, 1993; Faithfull, 1991; Kiebert et al., 1998; Strohl, 1998).

The items for the MDASI-BT were generated from the literature and clinical experience and, thus, warrant review by experts as to the relevance of symptoms in patients currently diagnosed with primary brain tumors. The initial MDASI-BT consisted of 25 symptoms for expert review (see Table 2).

Step 4: Obtaining Judgmental Evidence

Evidence for content validity is a process for judging the adequacy with which appropriate content has been sampled and the adequacy with which the content is reflected in the instrument items (Beck & Gable, 2001). Two methods for testing judgmental content validity include the use of content experts to subjectively rate the quality of the items and the use of empirical techniques such as latent partition analysis, index of content validity (CVI), or an average congruency percentage to quantify the judgments of experts.

Experts to review items for content validity should be chosen with caution because the usefulness of the rating by

Table 2. Common Symptoms in Patients With Primary Brain Tumors by Domain

Domain	Symptom
Generalized	<ul style="list-style-type: none"> Headaches Pressure in head Seizures Fear of seizures Difficulty concentrating Sleepiness
Focal	<ul style="list-style-type: none"> Weakness on one side of the body Change in sensation on one side of the body Difficulty getting dressed Difficulty speaking Difficulty understanding spoken or written word Change in vision Double vision Loss of vision Difficulty remembering things that occurred recently Tremors in arms or legs Difficulty swallowing Weakness on one side of the face or mouth Change in hearing Difficulty sitting upright Difficulty walking
Treatment related	<ul style="list-style-type: none"> Change in bowel pattern (diarrhea or constipation) Change in appetite Change in appearance Change in weight

the expert will depend on his or her level of expertise in the domain (Beck & Gable, 2001). A person may be considered an expert by caring for people with the concept of interest or actually experiencing the concept firsthand. A history of publishing in refereed journals, conducting research, or presenting on a national level related to the concept of interest have been recommended as a criteria for selecting content experts (Grant & Davis, 1997; Grant & Kinney, 1992).

The recommended number of experts to review an instrument has varied from a minimum of three (Lynn, 1986) to 2–20 (Gable & Wolf, 1993; Grant & Davis, 1997; Tilden, Nelson, & May, 1990; Waltz, Strickland, & Lenz, 1991). The final number should be based on the desired expertise and the range of expertise represented on the panel (Grant & Davis). Setting standards for choosing experts also will help to ensure a certain level of familiarity with the content and allow a more objective selection of reviewers (Grant & Davis).

Once experts have been chosen, guidelines for reviewing items should be stated clearly. One suggested method is to place incongruent items on the instrument and assess the experts' ability to detect these items; if the experts do not detect these items, their opinions should be thrown out (Beck & Gable, 2001). Disagreement among experts on relevant items should raise suspicion, but a review of the pattern of scoring may reveal evidence of why an incongruence occurred (such as misinterpretation of an item by one judge, not disagreement) and allow for clarification (Beck & Gable; Grant & Davis, 1997).

Techniques for quantifying the judgments of experts include average congruency percentage, CVI, and latent partition analysis. Average congruency percentage is a technique used infrequently (Popham, 1978). With this technique, experts read the specifications for the dimension and then rate the congruence of the items with the specifications (Beck & Gable, 2001). The proportion of items rated as congruent for each expert is converted to a percentage. The average congruency percentage is the mean percentage for all of the experts participating in the assessment. A percentage of 90% or higher is suggested as an acceptable average congruency percentage (Waltz & Bausell, 1981).

With the latent partition analysis procedure, content experts sort the items into any number of mutually inclusive content categories. These judgmental data then are reviewed to determine whether the content categories that reflect the experts' ordering of items match the proposed domains of the investigator (Waltz & Bausell, 1981).

CVI is recommended by several experts and is the most commonly used method of testing the validity of a measurement's content (Lynn, 1986; Waltz & Bausell, 1981). With this method, a four-point Likert-type scale is used (1 = not relevant or not representative to 4 = meaning very relevant and succinct). The four-point scale is preferred because it precludes the use of an ambivalent position (Lynn). The CVI then is calculated from the ratings of the content experts' assessment of the relevance of the items of an instrument. The CVI represents the proportion of items of the instrument that achieved a rating of three or four by the experts. A CVI of at least 0.80 is considered to be a good criterion for accepting an item as valid (Davis, 1992). The final instrument will consist of items that received a rating of three or four by the experts. In addition to judging the validity of each item, experts also are asked to identify any areas that were omitted from the

instrument. The same experts are asked to re-review the instrument if no item meets the 3–4 rating standard for content validity or if items are added. A 10- to 14-day period between assessments is considered sufficient to allow for independent review of the instrument if significant changes have been made (Lynn, 1986).

Use of the Content Validity Index in the M.D. Anderson Symptom Inventory Brain Tumor Module

For the purpose of empirical analysis of the content validity of the MDASI-BT, CVI was used. The rating tool for the experts to use was developed first (see Figure 2). This included items deemed relevant and two items (inability to sit upright and altered bowel pattern) that were added to assess the ability of the experts to see these items as incongruent with other neurologically based items.

Three groups of experts were chosen (those at a large comprehensive cancer center [University of Texas M.D. Anderson Cancer Center in Houston], clinicians outside of that center, and a patient and caregiver panel). Twenty experts (eight from outside the institution, eight from inside the institution, and four from the patient and caregiver group) served as the expert panel. Clinical experts met the following guidelines.

- Worked in neuro-oncology for five years
- Published at least one article related to the care of patients with primary brain tumors
- Considered experts by the brain tumor community

Experts were chosen from outside the cancer center in case differences existed in symptom presentation or understanding that were institutional or regional in nature. Experts chosen represented many of the disciplines that care for patients with primary brain tumors, including neuro-oncology, radiation oncology, neurosurgery, psychiatry, neuro-oncology nursing, and neuro-oncology social workers. In addition, a patient and caregiver group also was identified to review items for relevance. This group was comprised of a family member who is a known advocate for patients with primary brain

The following is a list of potential symptoms that will be used in a self-assessment tool to measure the occurrence of multiple symptoms in people with brain tumors. You are being asked to serve as an expert in the evaluation of the content validity of the items, which are listed. Please rate each item on a four-point scale according to your opinion on the relevance of the symptom in patients with primary brain tumors. The ratings are as follows.

- 1 = not relevant
- 2 = unable to assess relevance without item revision, or item is in need of such revision that it would no longer be relevant
- 3 = relevant but needs minor alteration
- 4 = very relevant and succinct

In addition to the rating of relevance, please indicate either in the comment section or the end of the form any symptoms that you feel are relevant but have not been included. If you feel that rewording of an item is necessary, please indicate that as well.

Example	Relevance Rating				Comments or Rewording
	1	2	3	4	
Weakness on one side of the body					_____

Figure 2. Example of Rating System for Calculating Content Validity Index

tumors and operates an independent, recognized Web site with symptom and treatment information; a patient who is a national advocate, traveling most of the year for fund-raising and awareness events; and a caregiver-patient dyad.

All experts received the instrument for review in electronic and paper format and were given one month to complete it. All participants returned the questionnaire. The 20 experts then were broken into groups of patients and caregivers, physicians and neuropsychologists, and nurses and social workers for analysis of responses.

Results

For the purpose of analysis, the experts were divided into three subgroups of seven nurses and social workers, nine physicians and psychologists, and four patients and caregivers. According to Lynn (1986), at least 80% of reviewers should rate an item as a 3 or 4 for the item to be considered valid. For the testing of the MDASI-BT, six of seven nurse and social worker experts, seven of nine experts in the physician and neuropsychologist group, and three of four patients and caregivers needed to consider the item relevant for content validity to be recognized for the MDASI-BT. The results of the CVI analysis are provided in Table 3.

The CVI was generated for each item in the three subgroups. Then the researcher team reviewed comments regarding rewording and individual scoring of each item. Eight items were found relevant (i.e., it was a common symptom in this patient population and the item is worded succinctly) by all three groups of experts and will be included in the final instrument. Several reviewers suggested that one item of this group, "seizures," be expanded to a second item, "change in seizure activity," to reflect not only how bad seizures are perceived to be but also subjective changes in the quality of the seizures. Nine items were endorsed by two groups and also were included in the final instrument. Rewording was suggested for "difficulty completing tasks" to "difficulty starting or completing tasks" because patients may experience either problem. Three items, "change in vision," "double vision," and "loss of vision" were combined to be worded as "change in vision" to capture any visual change, which commonly occurs in this patient population. Although all of the symptoms were deemed valid by at least one group of reviewers, several suggested that using "change in vision" should be adequate to collect data on all of the separate vision changes that occur. The instrument is designed as a broad indicator of symptoms and not for in-depth symptom assessment.

The item "afraid of having seizures" was expanded based on reviewer comments about "fear" (again to capture any fear, not a specific fear). Although "change in appetite" and "change in weight" were endorsed by two groups, reviewers commented that the item "lack of appetite" in the core MDASI should suffice, and the item "change in appearance" could encompass "change in weight" as well as other symptoms that affect appearance.

Interestingly, headaches, one of the most common symptoms noted in the literature to be associated with primary brain tumors, was not endorsed by the physician panel. Several physicians commented that patients do not complain of headaches frequently. The item was endorsed by the other two groups. The meaning of this variability is unclear and highlights the importance of establishing this tool to allow

Table 3. Content Validity Index Results by Rating Group

Items Rated	Nurse/ Social Worker Group	Physician/ Psychologist Group	Patient/ Caregiver Group
Weakness on one side of the body	0.86	1.00	1.00
Change in sensation on one side of the body	1.00	1.00	1.00
<i>Difficulty getting dressed^a</i>	0.86	0.56	0.75
<i>Difficulty completing tasks</i>	1.00	0.66	1.00
<i>Difficulty concentrating</i>	0.86	0.88	0.75
Difficulty speaking	1.00	1.00	1.00
Difficulty understanding spoken or written word	0.86	1.00	1.00
<i>Change in vision</i>	1.00	0.77	1.00
Double vision	1.00	0.88	1.00
<i>Loss of vision^a</i>	0.86	0.66	0.75
Difficulty remembering things that occurred recently	1.00	1.00	1.00
<i>Tremors in arms or legs</i>	1.00	0.33	1.00
<i>Difficulty swallowing^a</i>	1.00	0.66	0.75
<i>Weakness on one side of face or mouth^a</i>	1.00	0.66	0.75
<i>Pressure in head^b</i>	0.71	0.66	1.00
<i>Headache</i>	1.00	0.66	1.00
Seizures	0.86	0.88	1.00
<i>Afraid of having seizures</i>	1.00	0.33	1.00
<i>Sleepiness</i>	0.86	0.55	1.00
<i>Change in hearing^a</i>	1.00	0.66	0.75
<i>Change in appetite</i>	0.86	0.66	1.00
<i>Change in appearance^b</i>	0.71	0.33	1.00
<i>Change in weight</i>	0.86	0.56	1.00
<i>Change in bowel pattern (diarrhea or constipation)^a</i>	0.86	0.22	0.75
Difficulty walking	0.86	0.86	1.00
<i>Difficulty sitting upright^a</i>	0.86	0.22	0.75

^a Endorsed by nurse/social worker group only

^b Endorsed by patient/caregiver group only

Note. Bolded text indicates items endorsed by all three groups. Italicized text indicates items endorsed by two groups.

for patient self-report to improve knowledge related to symptoms thought of as common in this patient population. Several patients commented that "pain" was better described as "pressure" because incongruence exists between the high reported incidence of "headache pain," the low relevance reported by the physician panel, and the rewording suggested by the authors' clinical experience and patient report. Headache pain was left in for validation and combined with the wording of "pressure."

An additional item, "change in appearance," also was validated only by the patient and caregiver group. The item initially had been developed based on the authors' clinical experience. Patients had reported that change in appearance, associated with craniotomy, hair loss, or steroid-induced changes in facial and body appearance, often resulted in change in mood and activity. Several panel members commented on the importance of this as a symptom in the illness. Therefore, the researchers decided to keep the item in the initial tool for further validation by patients.

The reviewers suggested 14 additional items for consideration. The items tended to fall into two categories: actual

1. Weakness on one side of the body
2. Change in body sensation
3. Difficulty understanding
4. Difficulty speaking
5. Difficulty remembering
6. Change in seizure activity
7. Seizures
8. Difficulty walking
9. Difficulty starting or completing tasks
10. Difficulty concentrating
11. Change in vision
12. Headache or pressure in the head
13. Sleepiness
14. Fear
15. Change in appearance
16. Change in appetite
17. Change in bowel pattern
18. Irritability

Figure 3. Final List of Symptoms Based on Content Validity Index Analysis

signs of disease or treatment (e.g., fluid leak, incision breakdown) and psychological impact (e.g., fear, anger, irritability). Because many of the suggestions would occur only in the perioperative period, they did not seem relevant for a tool

designed to measure symptoms across the illness continuum, and many actually represented signs. However, emotional symptoms have been reported to occur at any point during the illness and were listed by more than half of the reviewers as important to include in the list of relevant symptoms. As a result, irritability was added to the list of symptoms for inclusion in the initial tool, and “fear of seizures” was expanded to “fear” as note above.

Conclusion

The process of assessing content validity is an important first step in instrument development. As a result of this process, 18 symptoms (see Figure 3) were deemed relevant to the population of patients with primary brain tumors and will be added to the core MDASI for the next phase of instrument development, reliability testing, and other assessments of construct and predictive validity.

The authors wish to thank Mark R. Gilbert, MD, and Joann Aaron, MA, for their thoughtful review of this article and continued support.

Author Contact: Terri S. Armstrong, MS, APRN, BC, can be reached at tsarmstr@mdanderson.org, with copy to editor at rose_mary@earthlink.net.

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