



Network

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Taking inventory

Symptom research and psychometrics

by Sandi Stromberg

Have you ever wondered who develops standardized tests, like the Scholastic Aptitude Test (SAT) for getting into college or the Graduate Record Exam (GRE) for graduate school?

How do they know what questions measure knowledge or intelligence?

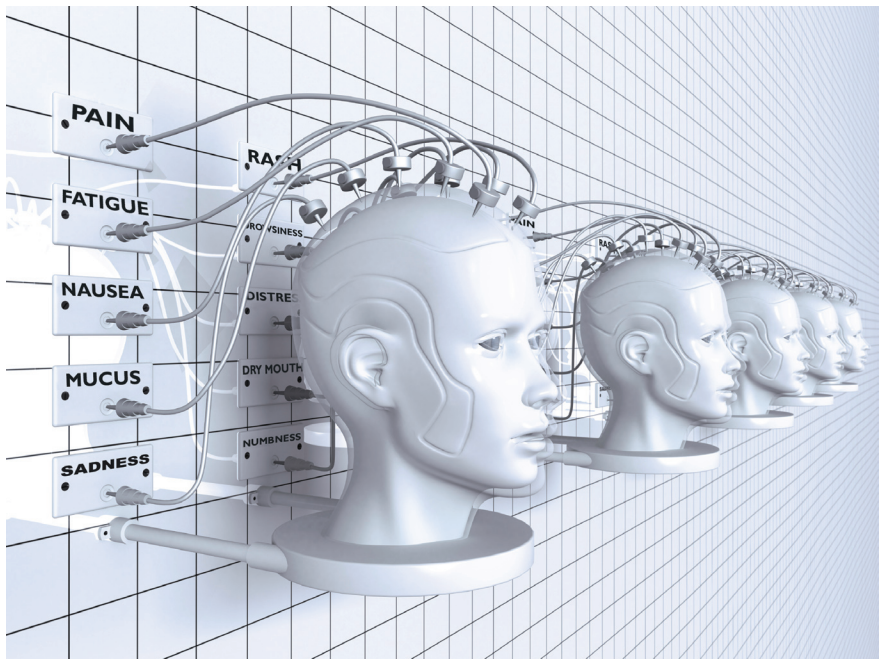
And how can they calculate what constitutes a passing score that says a person has the ability to follow a course of study?

Those who practice this specialized field are psychometricians, and their science is psychometrics, the study of the design and analysis of tests and questionnaires. Besides standardized tests, psychometricians also play a prominent role in the construction of patient-reported assessment tools for cancer-related clinical trials, such as symptom burden outcome.

Tito Mendoza, Ph.D., assistant professor in M. D. Anderson's Department of Symptom Research, is one such psychometrician. For the last 12 years, he and Charles Cleeland, Ph.D., chair of the department, have worked with researchers and health care professionals across the institution to help design and assess the reliability and validity of tools that measure the side effects of cancer and its treatments.

FDA demanding more rigor

Active in pain research for many years and instrumental in developing the Brief Pain Inventory now used in most clinical trials, Cleeland knew the importance of measuring and attending to patients' symptom distress long before it became a concern for federal agencies.



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“Now, the U.S. Food and Drug Administration is asking for more rigor in the assessment of symptoms and other patient-reported outcomes,” he says. “It wants more systematic and validated measures of symptoms that are both relevant and intelligible to patients.”

Thanks to Cleeland and his colleagues, M. D. Anderson is a leader in this field through the BPI, mentioned above, as well as the Brief Fatigue Inventory and the M. D. Anderson Symptom Inventory, known as the MDASI. The latter is a brief measure of the severity and impact of the 13 cancer-related symptoms and six daily functions they affect, regardless of disease site.

Based on what they learned developing the MDASI, they have been working with physicians and nurses across the institution to produce a subsequent series of site-specific inventories. Mendoza plays an active role from the beginning of the process.

The process of taking inventory

“Before a statistical analysis plan can be written and data collected, I need to know what the researcher wants to show — what the primary question is,” Mendoza says. “Then, I help figure out what information needs to be collected, how many patients to recruit and how many time points to include.”

Once he calculates how many patients need to be enrolled to find the answers, Mendoza designs how they will test the reliability and validity of the data they collect. Then, he steps back while the clinicians carry out their studies.

To develop the specific content for each of the symptom inventories, specialists in each specific disease site hold multidisciplinary focus groups, including patients and family members, to collect data on symptoms and functionality issues.

Ensuring reliability and validity

Once he has the data, the first thing Mendoza tests is reliability. One way of doing this is to measure across two time points, called the test retest. The caveat for choosing this method, however, is that the time between the first and second time points must be short enough so there can be no intervening factors.

“This means that if you ask patients about a symptom at one point, they give you similar answers at the second point, if nothing in the patient’s condition changes,” Mendoza says. “For example, if you take your temperature with a

thermometer, unless you develop a fever, you should get a similar result a few days later. If you don’t, your thermometer isn’t reliable. A variation, or noise, is coming from somewhere else. It’s like trying to hear a conversation above some ambient noise that we need to get rid of to understand the conversation.”

Of reliability and validity, Mendoza says they use more tests of validity because it’s more important. “You can have a reliable tool, but if it isn’t relevant or valid, it’s not very helpful.”

In a recent study to analyze data collected by David I. Rosenthal, M.D., and his colleagues for the MDASI-HN (head and neck; described on page 4 of this issue), he chose three validity measures: construct validity, known groups and concurrent validity.


Construct validity: This method helps determine underlying factors — latent constructs not directly measurable but that can be observed with indicators. For example, a family’s socioeconomic status (SES) cannot be directly measured, but you can measure a host of variables such as the parents’ occupations, education levels and incomes that are indirect measurements that affect the SES rating.

Known group validity: Using the Eastern Cooperative Oncology Group performance status as the grouping variable, Mendoza wanted to determine if patients with poor ECOG performance status also reported severe symptoms on the patient self-assessment symptom inventory (MDASI), and if patients with good ECOG performance status reported fewer and less severe symptoms.

Concurrent validity: This measures how well a self-report tool correlates with the well-established measurement of overall health, the SF12v2 from the Rand Corporation. If there is an overlap in results between the two tools, that provides another example of the self-assessment tool’s validity.

A growing series of inventories

To date, Cleeland, Mendoza and other members of their team have produced symptom inventories that include MDASI-BT (brain tumor), MDASI-Thy (thyroid), MDASI-Lung and MDASI-HF (heart failure).

In turn, these collaborations are allowing health care professionals in each area to collect solid, scientific evidence that can be used ultimately to design interventions to relieve the symptom burden caused by cancer and its treatments. 

Physician with a mission

Symptoms of head and neck cancers

by Sandi Stromberg

When David I. Rosenthal, M.D., arrived at M. D. Anderson six years ago, he brought with him a deep concern about the symptom burden his patients experienced as a result of cancer treatment.

While successful advances have been made in the treatment of head and neck cancers over the last 10-15 years, the acute toxicity can be significant and also cause long-term functional impairment.

This is true for several types of cancer patients, including those with oropharynx (the base of the tongue and tonsils) cancers, many of whom underwent operations in the past. Today, standard treatment for them consists of adding chemotherapy as a sensitizer to intensify the effect of radiation on the tumor and to kill more cancer cells.

While cancer control and survival rates are excellent, and the organs are preserved numerically, many patients experience worse symptoms with chemoradiation than with radiation therapy alone, and certain functions, such as swallowing, may be impaired.

"I was looking for some instrument to assess the side effects they deal with," Rosenthal says. "But most instruments were concerned only with 'quality of life.' While this is important, the tools to measure it often miss many of the most relevant symptoms that our patients suffer. Of the 30 to 40 questions, I would find that only one or two were relevant."

Where to start?

Rosenthal wanted a general symptom screening instrument for all patients with head and neck cancers that would be valid before, during and after treatment, independent of whether they had surgery, radiation, chemotherapy or any combination.

To develop the specific content for the patient questionnaire, he worked with Cleeland and other head and neck specialists, including medical, dental and surgical oncologists, speech-swallowing-language pathologists and patient and family focus groups. Together they identified symptoms and functionality issues.

From his years of experience, Rosenthal knew one of the most common symptoms for patients with head and neck cancers is dry mouth, which can have both



functional and comfort implications.

"Another important toxicity is mucositis, sometimes called 'the sun-burn effect' of radiation given with or without chemotherapy, on the mouth, throat and esophagus," he says. "This can lead to the inability to eat or swallow."


He wanted to make sure the questionnaire was very sensitive to mucositis symptoms.

What they learned

"One thing we noticed in our trials is that some patients get a lot of mucus in their throat when they have bad mucositis," Rosenthal says. "It's a significant symptom that hadn't been reported before. Yet, mucus in the throat can be so copious that some patients focus on management of secretions all the time. They're constantly gargling, suctioning. They can't sleep. They gag and regurgitate."

In all, the study identified nine head and neck cancer-specific symptoms, separate from the 13 core MDASI.* They are mouth and throat sores, problems with tasting food, constipation, problems with teeth or gums, skin pain, burning or rash, difficulty with voice or speech, choking or coughing, difficulty chewing or swallowing, and excess mucus in the mouth and throat.

Not only were they able to validate the MDASI-HN, but also in a subsequent study where they compared it with the quality-of-life Functional Assessment of Cancer Therapy-Head and Neck, it proved to be more predictive of the severity of radiation-induced mucositis.

Since validation, the tool has been incorporated into some clinical trials, including a Phase III, Radiation Therapy Oncology Group trial. However, hopes are that when technology allows, the MDASI-HN will become an integral part of a patient's electronic medical record as M. D. Anderson researchers work toward understanding symptom burden and finding interventions to treat and ultimately prevent debilitating side effects for cancer survivors. 

* For a review of the 13 core MDASI symptoms that may be experienced by any cancer patient, see the spring 2007 issue of *Network*, also online in the archives at www.mdanderson.org/publications/network.