Patient-reported symptoms offer insight for clinical trials

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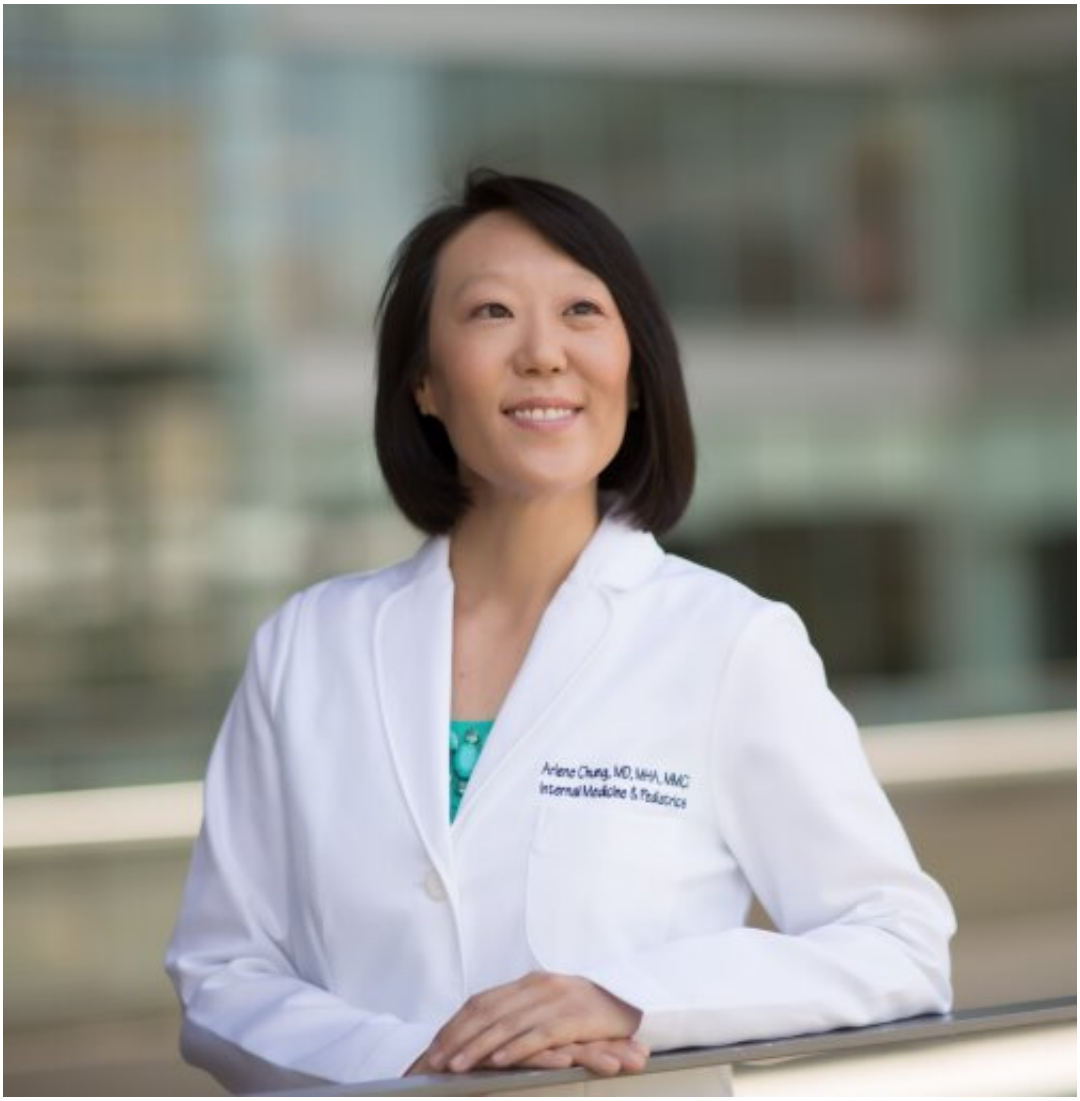

UNC Lineberger's Arlene Chung, MD, MHA, MMCi, assistant professor of medicine and pediatrics, and associate director of health and clinical informatics in the UNC School of Medicine.

University of North Carolina Lineberger Comprehensive Cancer Center researchers and collaborators found that allowing patients to write, in their own words, about treatment-related symptoms they experienced while participating in clinical trials can provide valuable information.

In a first-of-its-kind study published in the *Journal of the American Medical Informatics Association*, researchers examined two different methods of collecting symptom information directly from patients during clinical trials: They could either write in their own symptoms or choose them from a library of medical terms.

This represents a departure from the traditional way of collecting information about treatment-related symptoms, or adverse events, from patients during clinical trials. Researchers said patients typically answer questions about pre-selected symptoms. But when they allowed patients to write or choose their own symptoms in the study, a wide range of additional issues were revealed, ranging from pain to insomnia, issues with concentration, to muscle spasms and mouth sores.

"Currently, the standard practice for trying to capture symptom information directly from patients involves using trial-specific questionnaires," said the study's lead author UNC Lineberger's Arlene Chung, MD, MHA, MMCi, assistant professor of medicine and pediatrics, and associate director of health and clinical informatics in the UNC School of Medicine. "Our research reveals that this approach may not be sufficient to capture what patients are experiencing during cancer treatments, and offering a free-text functionality provides important information about additional symptoms."

The researchers used software developed by the National Cancer Institute to study the impact and feasibility of having patients report

additional symptoms beyond those assessed in trial-specific questionnaires. The software allowed patients to enter additional symptoms either by typing into a text box and choosing from selections offered from a drop-down menu, or by typing their own words entirely.

They surveyed 1,760 patients participating in three separate, multi-institutional cancer clinical trials about their symptoms in trial-specific questionnaires, and offered the opportunity to add supplemental symptoms through these two additional methods. The questionnaires used items from a library of symptoms from the National Cancer Institute's Patient-Reported Outcomes version of the Common Terminology Criteria for Adverse Events (PRO-CTCAE). "Trial-specific adverse event questionnaires are usually based on what is anticipated in terms of the symptoms patients may experience during a given treatment regimen," Chung said. "Giving patients the opportunity to author their own symptomatic adverse event reports provides a more patient-centered way for them to let us know about any additional symptoms experienced beyond what is elicited from trial-specific questionnaires."

They found many patients were willing to report additional symptoms. Patients provided, on average, more than two entries each. About 58 percent of patients entered supplemental symptom information, of which 1,474 were dropdown entries and 913 were free-text narratives. Researchers were able to manually map the adverse events from the majority of the free-text narratives to a dictionary of standard medical terms or to the National Cancer Institute's PRO-CTCAE terminology.

The most commonly patient-reported symptoms were problems with tasting food and drink, muscle spasms, headache, nosebleeds, problems with concentration, dry mouth, fatigue, insomnia, and numbness and tingling in hands or feet.

The study team said that they believe allowing patients to submit their own symptom reports is important. Many patients experienced diverse types of symptoms, and there were symptoms revealed that were not assessed in trial-specific questionnaires.

Their findings also helped illuminate which types of symptoms researchers might expect for a given treatment under study. This kind of information would be especially useful during early-stage clinical trials, researchers said, when less is known about possible symptomatic adverse events.

"Allowing patients to create their own symptomatic adverse event reports about their experience as they receive cancer treatments is critical," Chung said. "It ensures that the care team is aware of what symptoms are burdening our patients, and we can also develop a better understanding about the toxicities experienced with various cancer treatment regimens so that we can better counsel our patients on what may be expected during treatment."

In the future, researchers suggested that informatics tools could be useful in helping to capture all of the different symptoms that patients wrote themselves. For the study, researchers manually reviewed all of these symptoms. They plan to design and develop additional software to mine patients' free-text narratives using natural language processing and machine learning to allow for structured event reporting.

"This will allow for these symptomatic adverse events to be structured in a way that can allow this important information to be reported as adverse events to the U.S. Food and Drug Administration, and also be reported back to clinicians via the electronic health record so that these symptoms can be addressed in a timely fashion," Chung said.

More information: Arlene E Chung et al. Patient free text reporting

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of symptomatic adverse events in cancer clinical research using the National Cancer Institute's Patient-Reported Outcomes version of the Common Terminology Criteria for Adverse Events (PRO-CTCAE), *Journal of the American Medical Informatics Association* (2018). DOI: 10.1093/jamia/ocy169

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