

Study validates tool for patient reporting side effects in cancer clinical trials

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A multicenter study involving Mayo Clinic researchers has found that the National Cancer Institute's Patient Reported Outcomes version of the Common Terminology Criteria for Adverse Events (PRO-CTCAE), was accurate, reliable and responsive, compared to other, established patient-reported and clinical measures. The study is published today in the journal *JAMA Oncology*.

"In most [cancer clinical trials](#), information on side effects is collected by providers who have limited time with their [patients](#) and current patient

questionnaires are limited in scope and depth," says the study's lead author Amylou Dueck, Ph.D., a biostatistician on Mayo Clinic's Arizona campus. PRO-CTCAE is a library of items for patients to directly report on the level of each of their symptoms, to enhance the reporting of side effects in cancer [clinical trials](#) which is normally based on information from providers. The study itself is unprecedented as more than 100 distinct questions about symptomatic adverse events were validated simultaneously."

Researchers recruited more than 1,000 patients from nine clinical practices across the U.S., including seven cancer centers. These patients reflected the geographic, ethnic, racial and economic diversity in cancer clinical trials. Patients in the study also had a wide range of cancer types.

Patients were asked to fill out the PRO-CTCAE questionnaire before appointments. Researchers then compared the patient reports against other established measures of symptoms, including case and quality of life reports, and prescription information.

Researchers were able to validate 119 of 124 PRO-CTCAE questions against established measurement tools. The five questions that were not validated could not be evaluated due to underrepresentation in the study population.

"This is a landmark study demonstrating that meaningful information about [adverse events](#) can be elicited from patients themselves, which is a major step for advancing the patient-centeredness of clinical trials," says the study's senior author, Ethan Basch, M.D., of Memorial Sloan Kettering Cancer Center and the Lineberger Cancer Center of the University of North Carolina.

PRO-CTCAE is now embedded in a number of clinical trials underway.

Provided by Mayo Clinic

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