Cancer patients and doctors report drug side effects differently

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In clinical trials for cancer, it is standard for clinicians rather than patients to report adverse symptom side effects from treatments, such as nausea and fatigue. At present, patient self-reporting, although important, is not a well studied source of this information. A new longitudinal study from researchers at Memorial Sloan-Kettering Cancer Center finds that while clinicians' and patients' reporting of treatment side effects are very different from each other, together they provide a more complete, clinically meaningful picture of the treatment experience.

The research was published online November 17 in the *Journal of the National* Cancer *Institute*. Ethan Basch, MD, a medical oncologist and member of the Health Outcomes Group at Memorial Sloan-Kettering, and colleagues, led an analysis of data gathered from more than 160 advanced lung cancer patients and their clinicians. All of the patients were treated at Memorial Sloan-Kettering.

The patients, both men and women with a median age of 63, were followed from 2005 to 2006 through an average of 12 office visits. All received chemotherapy during this time. Researchers tracked six common symptoms--fatigue, pain, nausea, vomiting, diarrhea, and constipation--and compared the side effects reported by the clinicians to those reported by the patients. The clinicians reported symptoms using the standard adverse event reporting tool for oncology trials, the National Cancer Institute's Common Terminology Criteria for Adverse Events (CTCAE.) Patients reported symptoms using a simplified version of the same reporting tool via a computer-based system.

Patients generally reported adverse symptoms earlier, more frequently, and with greater severity than their clinicians, and their responses appeared to better reflect real-time suffering. Patient-reported symptoms were more closely related to day-to-day health status, while clinicians' reports were more predictive of significant medical events. "The perspectives of both clinicians and patients provide a more complete picture of the negative impact of treatments compared with either perspective alone," said Dr. Basch. "Clinicians bring professional training and experience to their evaluations, whereas patients are in a better position to communicate their own subjective experiences," he adds.

The findings demonstrate the value of an approach that incorporates patient self-reporting of symptoms in cancer treatment trials. Such information has the potential to help both prospective prescribers and patients in understanding the anticipated side effects of treatment.

On the basis of this research Dr. Basch said, "We need to design models in which we can capitalize on what the patient is reporting in order to understand how toxic these drugs are. Our patients add tremendous value in their reporting; and by collecting this information we can actually enhance our understanding of toxicities in a way that will aid the FDA, aid clinicians, aid researchers, and aid patients themselves when they are trying to decide whether they want to start a treatment." He added that, "patient-reported adverse symptoms should be collected in clinical trials and reported in drug labels."

Source: Memorial Sloan-Kettering Cancer Center