Cancer drug labels missing key information about patients' symptoms

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Dr. Ethan Basch of UNC calls for pharmaceutical manufacturers to collect rigorous information on how drugs impact symptoms and quality of life starting early in drug development, and for the U.S. Food and Drug Administration (FDA) to include this information in drug labels.

For patients facing treatment for cancer, it is essential to understand how their symptoms will be affected. Symptoms like pain, fatigue, or nausea can result from the cancer, or from treatment side effects. The best way to collect this information is from patients themselves in research studies. But almost no drug labels in the U.S. include this information. As a result, incomplete information is available to patients and clinicians to help with treatment decisions.

"As an oncologist, when I sit with patients to discuss starting a new chemotherapy, their first questions are often 'How will it make me feel?' and 'How did patients like me feel with this treatment?'" said Ethan Basch, MD, director of Cancer Outcomes Research at the University of North Carolina.

In the July 10th issue of *The New England Journal of Medicine*, Dr. Basch calls for pharmaceutical manufacturers to collect rigorous information on how drugs impact symptoms and quality of life starting early in drug development, and for the U.S. Food and Drug Administration (FDA) to include this information in drug labels.

"As patients live longer with cancer, they must increasingly choose among agents with varying efficacy–toxicity balances. And as approved drugs continue to yield only tiny median survival benefits, patients understandably want to know how their peers felt during and after a treatment," said Dr. Basch.

In 2011, the FDA approved 15 new anti-cancer drugs, but only one of them, ruxolitinib, included symptom information in the label – reporting that multiple symptoms improve substantially when patients take the drug. This was actually the first cancer therapy in more than a decade to include symptom information in its label. Cancer labels stand in contrast to non-cancer labels, which describe symptoms about 25 percent of the time.

Research has shown that patients who experience worse symptoms and quality of life face a worse prognosis and are more likely not to follow treatment guidelines or may stop treatment altogether. The FDA has taken several steps to include the patient perspective in drug development, issuing guidance, collaborating with industry to develop standardized tools, and requesting funds from Congress to support these efforts.

Dr. Basch argues that the culture of pharmaceutical development must shift to include direct patient input during the earliest stages of research. For patients, physicians and insurers to have a true picture of a treatment's impact, they must have access to reliable data on how a drug will impact symptoms and daily quality of life, in addition to information about tumor response and survival.

"Ideally, moving forward, whenever representatives of a pharmaceutical company and a regulatory agency sit down to discuss a product-development program, they will ask the same question my patients ask of me: "How does this product make people feel?" said Dr. Basch.

Provided by University of North Carolina at Chapel Hill School of Medicine