Patient safety reporting and drug label accuracy missing vital information

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A Perspective piece in the *New England Journal of Medicine* calls for change in the way researchers and pharmaceutical companies collect and report adverse symptom information in clinical trials submitted to the Food and Drug Administration (FDA), and how the FDA represents this information on drug labels.

Ethan Basch, MD, outcomes researcher and medical oncologist at Memorial Sloan-Kettering Cancer Center, recommends that fundamental change is necessary in order to improve the process of evaluating the true toxicity of drugs. Dr. Basch has found that clinicians - the current responsible party for collecting and reporting symptoms in clinical trials - systematically miss important symptoms and often underestimate the severity of the symptoms they do notice. According to Basch, this leads to under-reporting of adverse events and, consequently to clinical trial results, publications, and drug labels that don't adequately represent the true toxicity of drugs.

To provide researchers, clinicians, and patients with more usable and valuable symptom information, Dr. Basch, who works closely with the FDA and National Cancer Institute on research issues, suggests that patients be given the tools to self-report adverse symptoms in clinical trials and online reporting between clinic visits, which can assist nurses and doctors with symptom management and improve communication.

According to Dr. Basch, "Patient self-reporting enhances the quality and comprehensiveness of symptom and adverse event data," and he notes that "patients must be given a voice in healthcare delivery, research, and regulatory processes, as they are the most important stakeholders and deserve access to the impressions of their peers when trying to decide whether to start a new treatment."

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