June 12: Dr. Sandra Mitchell, Capturing Symptom Burden and Treatment Tolerability in Cancer Clinical Trials, Patient-Reported Outcomes-Common Terminology Criteria for Adverse Events (PRO-CTCAE)

SYNOPSIS:

The standard lexicon for reporting adverse events in National Cancer Institute sponsored clinical trials is the Common Terminology Criteria for Adverse Events (CTCAE). Currently, adverse events are reported by clinicians, yet evidence suggests that compared to patient-report, clinicians may underestimate symptom severity and onset.

The NCI Patient Reported Outcomes-Common Terminology Criteria for Adverse Events (PRO-CTCAE) is a new patient-reported outcome measurement system that elicits the frequency, severity and interference of 78 treatment toxicities that can be reported from the patient perspective. This presentation offers an overview of the PRO-CTCAE measurement system and the interdisciplinary consortium in which it is being developed and tested, and suggests the trial contexts in which patient reporting of toxicity is likely to provide the greatest value and informational yield, as well as the challenges faced in developing this approach to adverse event reporting. Session details...

After outlining the factors that drive an expanding imperative to incorporate the patient perspective into the assessment of treatment tolerability and safety, the traditional approach to adverse event reporting is contrasted with a paradigm that seeks to incorporate the patient perspective. The key elements of the PRO-CTCAE measurement system are exhibited, and the research challenges, gaps in knowledge, and the issues that will need to be resolved to fully implement this new approach are examined. The presentation concludes by highlighting (i) NCI efforts to make PRO-CTCAE more widely available to investigators in the extramural community, including academic and industry investigators both in the U.S. and internationally; (ii) ongoing PRO-CTCAE consortium studies to evaluate and refine both the PRO-CTCAE items and the electronic system for patient-reported AE ascertainment and to scale up for integration into the clinical trial workflow and into existing platforms for electronic data capture and electronic health records; and (iii) envision some of the future directions for PRO-CTCAE, as both a drug development tool and as a potential platform upon which to build improvements in symptom management and care quality for patients participating in cancer clinical trials.

BIOs:

Dr. Sandra A. Mitchell is a research scientist in the Outcomes Research Branch of the Applied Research Program, Division of Cancer Control and Population Sciences, at NCI. Her work focuses on the development and testing of measures of symptom burden, physical function, and sleep and fatigue in patients with cancer, and the application of these outcomes to evaluate therapeutic response and treatment toxicity in clinical trials. Her methodologic interests include latent variable mixture modeling to characterize underlying heterogeneity, as well as analysis and interpretation issues surrounding patient-reported outcomes, including health-related quality of life.

A board certified acute-care nurse practitioner, Dr. Mitchell maintains a clinical practice as an Oncology Nurse Practitioner with the Experimental Transplantation and Immunology Branch, NCI Intramural Program, focusing on long-term survivors of allogeneic hematopoietic stem cell transplantation with chronic graft-versus-host disease. She also serves as the program director for the development and testing of PRO-CTCAE, a new measurement system to integrate patient reporting of symptomatic adverse events into cancer clinical trials.

Dr. Mitchell received her undergraduate and master's degrees from the University of Toronto and the University of Rochester, and received a Ph.D. from the University of Utah with a focus in quantitative methods. The author of more than 50 peer-reviewed publications in the areas of symptom management, functional status, cancer survivorship, and the application of quality-of-life outcomes in evaluating therapeutic response to treatment, Dr. Mitchell's work has been recognized with numerous awards, including two NIH Clinical Center Director's Awards and the Oncology Nursing Society's Award for Excellence in Nursing-Sensitive Patient Outcomes.

SUMMARY:

Topic: Capturing Symptom Burden and Treatment Tolerability in Cancer Clinical Trials, Patient-Reported Outcomes-Common Terminology Criteria for Adverse Events (PRO-CTCAE)

Speaker: Dr. Sandra A. Mitchell

Date: Wednesday, June 12, 2013

Time: 11 AM – 12 PM

Presentation: A screen cast of the presentation will be available for viewing after the event here on our Speaker Series Videos page and on the NCI's CBIIT Speaker Series YouTube Playlist .

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