Supporting Quality and Patient Safety in Cancer Clinical Trials

Stephanie Badalucco, RN, BSN, and Kathleen Keane Reed, RN, MS

Adverse event (AE) reporting is a critical component of all cancer clinical trials, and the National Cancer Institute's Common Terminology Criteria for Adverse Events™ (CTCAE) is the primary system used by clinicians to describe the severity of AEs. The National Cancer Institute's Patient-Reported Outcomes version of the CTCAE (PRO-CTCAE) assesses patient self-reports of symptoms using a Web-based system that can be incorporated into all cancer clinical trials. Oncology clinical trial nurses are responsible for the protection and safety of patients enrolled in cancer trials and, therefore, should develop an understanding of PRO-CTCAE.

The National Cancer Institute's Community Cancer Centers Pilot (NCCCP) was launched in 2007 and targeted an estimated 85% of patients with cancer receiving care in the communities where they reside (National Cancer Institute [NCI], 2010b). The NCCCP is a partnership between the NCI and a network of community hospital cancer centers in rural, suburban, and urban areas in the United States. The mission of the NCCCP is to "enhance cancer care at community hospitals, and to create a platform to support basic, clinical, and population-based research" (NCI, 2010b, p. 1).

The original network consisted of 16 sites; however, funds from the American Recovery and Reinvestment Act permitted network expansion to 30 sites in 22 states (NCI, 2010b) (see Figure 1). NCCCP sites are engaged with academic centers in studying ways to improve the quality and safety of cancer care, including adverse event (AE) reporting in cancer clinical trials.

One such initiative is the validation study of the Patient-Reported Outcomes version of the Common Terminology Criteria for Adverse Events™ (PRO-CTCAE). NCCCP sites are participating in research assessing the psychometric properties of the PRO-CTCAE (NCI, 2009). The PRO-CTCAE includes a Web-based questionnaire composed of 81 symptoms from the CTCAE identified by NCI as significant and adaptable to patient self-reporting (NCI, 2010c). Participants can answer as many as 126 questions that assess for the presence, frequency, severity of symptoms, and symptom interference with the individual's activities of daily living (NCI, 2010c). Patient-reported symptoms are transmitted via the secure Web-based platform to the oncology research team. A patient's comprehension of the questions, in addition to the accuracy and efficiency of patient-reported outcomes, will then be assessed (A.C. Dueck, personal communication, January 4, 2011).

The goal of the PRO-CTCAE project is to use the system in all cancer clinical trials (NCI, 2010c). This validation study is being conducted at NCI-designated comprehensive cancer centers and NCCCP sites throughout the United States (see Figure 2). Patients are eligible if they have a diagnosis of cancer and are receiving chemotherapy, biologic therapy, molecularly targeted agents, or radiation therapy. About 900 patients will be enrolled nationally at participating institutions (A.C. Dueck, personal communication, January 4, 2011).

Adverse Events

Oncology clinical trial nurses are responsible for the protection and safety of patients enrolled in cancer trials and for AE reporting, and should develop an understanding of PRO-CTCAE prior to testing in the cooperative group clinical trial setting (Daugherty, Leos, Schmieder, Weiss, & Good, 2010). AEs are defined by NCI as "any unfavorable sign (including an abnormal laboratory finding), symptom, or disease temporally associated with the use of a medical treatment or intervention that may or may not be considered related to the medical treatment or intervention under investigation; the AE may be unexpected or expected" (NCI, 2010c, p. 1).

AEs are graded on a scale from 1 (mild) to 5 (death related to AE) and are captured during specific intervals and during routine care (NCI, 2010c). The CTCAE is supported by NCI's Cancer Therapy Evaluation Program and has been the primary system used by oncology research clinicians to describe the severity of AEs in cancer clinical trials (Trotti, Colevas,

Stephanie Badalucco, RN, BSN, is a staff research nurse and Kathleen Keane Reed, RN, MS, is a community physician liaison and research nurse, both in the Cancer Clinical Research Office at Hartford Hospital in Connecticut. The authors take full responsibility for the content of the article. The authors did not receive honoraria for this work. No financial relationships relevant to the content of this article have been disclosed by the authors or editorial staff.

Digital Object Identifier: 10.1188/11.CJON.263-265