

Postmarketing Surveillance for Oncology Drugs

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Adverse effects of cancer therapies may occur more than three decades after drug administration. Continued vigilance in postmarketing use of oncology agents is necessary to accurately track adverse effects, update prescribing information, and alert healthcare providers in a timely manner. This article will define the processes involved in regulatory approval of oncology agents and discuss selected oncology drugs, labeling changes, and the role of oncology nurses in postmarketing surveillance by reviewing journal articles, governmental agency Web sites, federal regulatory documents, and pharmaceutical prescribing information. Oncology nurses administer and monitor cancer therapies in outpatient and inpatient settings and routinely assess patients for side effects of therapy; therefore, maintaining awareness of short- and long-term adverse effects after drug approval is important to patient safety. Nursing leadership should initiate, maintain, and manage an incident reporting system to effectively respond to changing needs. In addition, publication of case reports and articles on the emergence and management of postmarketing, treatment-related side effects in peer-reviewed nursing and medical journals may improve patient care and outcomes.

Oncology has experienced a significant increase in new drug approvals since the late 1980s. Fewer than a dozen agents were commonly employed in the treatment of patients with cancer 25 years ago. Since 2000, more than 40 new anticancer agents and cancer-related supportive care drugs have been approved for use by the U.S. Food and Drug Administration (FDA), 2007) (see Table 1). New medications may offer therapeutic benefit and improved safety profiles, leading to improved outcomes, survival, and quality of life for many patients with cancer. Approval of medications by the FDA often is a lengthy process designed to assess new agents in clinical trials for their efficacy in specific diseases and ensure that associated toxicities can be managed safely.

Although oncology nurses are well versed in the management of common toxicities (e.g., neutropenia, gastrointestinal side effects), targeted therapy agents have introduced them to new side effects, emphasizing dermatologic and other unique toxicities. However, unexpected toxicities may occur during the postapproval and postmarketing time frame with any agent. Adverse events detected during the postmarketing period for oncology drugs have included a variety of toxicities (e.g., venous thromboembolism with lenolidomide and thalidomide, psychiatric disturbances associated with interferons) (Ladewski et al., 2003). The toxicities may not have been apparent during the original controlled clinical studies because trials usually contain small sample sizes and require good organ function for eligibility, so infrequent adverse events can be difficult to detect (Trontell, 2004). For example, studies

At a Glance

- ◆ Patients with cancer have more treatment options than ever before, but therapies may have toxicities not yet identified by clinical trials.
- ◆ Postmarketing surveillance by healthcare professionals for toxicities related to cancer therapies and supportive care agents is essential to patient well-being.
- ◆ Oncology nurses should be vigilant in monitoring for and reporting unexpected side effects and adverse events related to therapy.

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Digital Object Identifier:10.1188/08.CJON.877-886