

Big Data and Pharmacovigilance: The Role of Oncology Nurses

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When new anticancer medications are approved, their safety profiles are often not fully understood. Oncology nurses have a responsibility to file reports of adverse drug events with safety registries such as MedWatch. If these registries receive prompt, complete, and accurate data from clinicians, agencies such as the U.S. Food and Drug Administration will have a stronger ability to detect hazards and to issue safety recommendations.

At a Glance

- In collaboration with physicians and pharmacists, oncology nurses have an obligation to contribute to national databases about medication safety. This is particularly important in the case of recently approved anticancer medications.
- Emerging systems allow patients to directly report symptoms and adverse effects.
- New techniques permit researchers to detect drug hazards by mining large-scale data from electronic health records and social media.

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The U.S. Food and Drug Administration (FDA) has approved new antineoplastic medications at an increasing rate in recent years (Asabere & Bastian, 2015). The agency approved 19 novel cancer medications from May 2014 to December 2015, marking the fastest pace of approvals in roughly two decades (Amanam, Gardner, Young-Lin, & Chan, 2016). Many of these new agents seem promising—but history suggests that at least a few of them will turn out to carry safety hazards that were not adequately appreciated during clinical trials. As these novel medications are rolled out throughout the world, oncology nurses

and other clinicians have an obligation to report significant effects and reactions to the drugs' manufacturers and to national registries of adverse pharmaceutical events. (In the United States, the major registry is the FDA's MedWatch system.)

However, clinicians' reports to MedWatch are just one element of a high-quality pharmacovigilance program in oncology. Research during the past decade has demonstrated that incorporating patients' own direct reports of their symptoms, not just clinicians' reports, is important (Basch et al., 2014). Researchers also have begun to discover previously unrecognized adverse drug

effects by mining data from electronic health records and from patients' online behavior (White, Harpaz, Shah, DuMouchel, & Horvitz, 2014).

Complete, timely, and accurate drug event reports are extremely important, particularly during the first few years after a new medication has been approved. Consider the history of gemtuzumab ozogamicin (Mylotarg®), a monoclonal antibody that was approved in 2000 for the treatment of acute myeloid leukemia. During the preapproval clinical trials, veno-occlusive disease had been noted as a potential adverse effect. After the drug entered the open market, new evidence suggested that veno-occlusive disease was a more frequent event than the original trials had indicated (McKoy et al., 2007). The safety and effectiveness of gemtuzumab ozogamicin came under increasing scrutiny, and the drug's manufacturer voluntarily withdrew it in 2010 (Richwine, 2010).

The gemtuzumab ozogamicin story suggests why maintaining accurate worldwide data sets about adverse effects associated with the newest antineoplastic medications will be vital. Programmed cell death protein 1 (PD-1) checkpoint inhibitors, such as nivolumab (Opdivo®), are proving to be extremely effective for certain patients with metastatic melanoma and a variety of other cancers (Rubin, 2015). At the same time, clinical trials of nivolumab found that patients sometimes suffered severe autoimmune reactions, including at least three fatal cases of pneumonitis (Topalian et al., 2014). As PD-1 checkpoint inhibitors enter widespread use in the marketplace, will the risk of severe autoimmune reactions turn out to