

FEATURE ARTICLE

Failure Mode and Effect Analysis™: A Technique to Prevent Chemotherapy Errors

Norma Sheridan-Leos, RN, MSN, AOCN®, CPHQ®,
Lisa Schulmeister, RN, MN, CS, OCN®, and Steve Hartranft, MPH, CPHQ®

Promoting a culture of safety involves a philosophical shift from error measurement to proactive assessment of potential harm. Failure Mode and Effect Analysis™ (FMEA) is a prospective risk analysis technique that can be used to examine the chemotherapy administration process. FMEA is a systematic, multidisciplinary team-based approach to error prevention. This article reviews the process of conducting FMEA and provides suggestions on how FMEA can be applied to the chemotherapy administration process. Nurses who are knowledgeable about risk analysis techniques and the process for applying them in clinical practice have the potential to promote a culture of safety for patients receiving chemotherapy.

Chemotherapy used in the treatment of cancer tops the list of high-alert medications, outranking IV potassium chloride and insulin as potential threats to patient safety (Institute for Safe Medication Practices, 2003). Medications are designated as *high alert* (sometimes referred to as *high hazard*) when they have a high risk of causing significant patient harm when medication errors or adverse events occur. Chemotherapy agents fall into the category because chemotherapy-related errors not only can cause patient harm but also may be lethal.

Administration of chemotherapy is error prone for many reasons, and even small errors can cause major harm. Chemotherapy, as a classification of medications, is unique in that dosing is individualized and nonstandardized. Doses are computed on the basis of body size or other factors, such as renal function, and require patient-specific calculations. Sometimes dose adjustments are required, which adds second calculations to determine appropriate doses. In addition, most chemotherapy agents require reconstitution and preparation, and several are available in multidose vials in varying concentrations. Therefore, every time a chemotherapy dose is calculated, prescribed, transcribed, prepared, and administered, a multitude of possibilities for error exist.

Complex, multidrug chemotherapy protocols often are used to treat cancer, and the greater the number of medications administered, the greater the potential for error. Some chemotherapy agents are given in various ways (e.g., subcutaneously, via IV) in various doses (e.g., standard versus high) over various periods of time (e.g., bolus, continuous infusions). Each of the variations in how chemotherapy is prescribed and administered has potential for error. The continual introduction of new chemotherapy agents requires nurses to update their knowledge base. Without accessible information, medication errors can result. In addition to the oncology-specific risk fac-

At a Glance

- ◆ Chemotherapy used in the treatment of cancer tops the list of "high-alert" medications, outranking IV potassium chloride and insulin as potential threats to patient safety.
- ◆ The Joint Commission on Accreditation of Healthcare Organizations expects healthcare organizations to conduct annual, proactive risk management activities for high-risk processes.
- ◆ Failure Mode and Effect Analysis™ is a systematic, prospective, multidisciplinary team-based risk analysis process that identifies and assesses the effects of potential errors or system failures.

tors for error, chemotherapy errors can occur because of other factors, such as understaffing, poor communication, human error, fatigue, and environmental factors (e.g., clutter, noise) (Ogletree, 2001).

Finally, the process of ordering, preparing, dispensing, and administering chemotherapy is highly complex, involving many parts of an organization and requiring handoffs between people of varying clinical backgrounds and experience (including

Norma Sheridan-Leos, RN, MSN, AOCN®, CPHQ®, is a senior clinical quality improvement analyst at the University of Texas M.D. Anderson Cancer Center in Houston; Lisa Schulmeister, RN, MN, CS, OCN®, is an oncology nurse consultant in New Orleans, LA; and Steve Hartranft, MPH, CPHQ®, is vice president of quality and patient safety at the City of Hope National Medical Center in Duarte, CA. No significant financial relationship to disclose. (Submitted September 2005. Accepted for publication November 6, 2005.)

Digital Object Identifier: 10.1188/06.CJON.393-398