Assessing Workplace Compliance With Handling of Antineoplastic Agents

Jackie Gambrell, RN, BSN, OCN®, and Susan Moore, RN, MSN, ANP, AOCN®

Oncology nurses and ancillary support personnel who work in oncology settings are at risk for exposure to antineoplastic drugs in their workplaces. A review of the literature reveals issues of environmental contamination and personal exposure. Although the United States has no formal regulations regarding hazardous drugs, including cytotoxic agents, guidelines have been published and are readily available to improve workplace safety. Oncology healthcare workers must be aware of the serious nature of antineoplastic drug exposure and the avenues available to initiate a simple, highly effective, problem-solving process called SOLVE® to make medical workplaces safer.

At a Glance

✦ Handling antineoplastic agents incorrectly increases risk for personal and environmental exposure.
✦ Compliance with organizational guidelines in the proper handling of antineoplastic agents should be assessed routinely.
✦ SOLVE® is a very effective and positive process that can be used by organizations to measure outcomes regarding compliance in the handling of antineoplastic agents.

The likelihood that a worker will experience adverse effects from hazardous drugs increases with the frequency of exposure, and the risk of adverse effects rises significantly with a lack of proper work practices.

Currently, neither NIOSH, the Occupational Safety and Health Administration (OSHA), nor the American Conference of Governmental Industrial Hygienists has established recommended exposure limits (RELs) or threshold limit values for workplace safety in regard to hazardous drugs. RELs refer to concentrations of chemical substances and represent conditions under which it is believed that no adverse health effects occur.
which almost all workers may be repeatedly exposed over their working lifetimes without adverse health effects (NIOSH, 2004). In the absence of such data, employers must implement and enforce more stringent guidelines to govern workplace safety. Moreover, employees must take personal ownership of the issues and work with healthcare administrators to make healthcare workplaces safer and free of hazards.

A review of the literature shows that issues of environmental contamination and personal exposure have been well researched. Several studies have documented cytotoxic contamination of workers (Labuhn, Valanis, Schoeny, Loveday, & Vollmer, 1998; Pethran et al., 2003.) Studies have demonstrated surface contamination during drug preparation as well as contamination of administration areas (Connor, Anderson, Sessink, Broadfield, & Power, 1999; NIOSH, 2004; Polovich, 2003). Guidelines related to personal protection have been proposed and implemented for oncology healthcare workers. However, no formal regulations exist in the United States regarding hazardous drugs, including cytotoxic agents. The literature reveals global opportunities for improvement in handling of hazardous drugs; Norway is the only country that has regulations regarding the handling and processing of chemotherapy (Kajser, Underberg, & Beijnen 1990).

Evidence reveals opportunities to improve the process of handling hazardous drugs. Adverse reproductive outcomes such as spontaneous abortions (Stuckert et al., 1990) and infertility (Valanis, Vollmer, Labuhn, & Glass, 1997) have been reported in healthcare workers exposed to cytotoxic agents. Several studies have documented cytotoxic contamination of workers (Labuhn et al., 1998; Pethran et al., 2003). Multiple studies have demonstrated contamination of the environment in drug preparation and administration areas (Connor et al., 1999; NIOSH, 2004; Polovich, 2003). This article outlines practical steps to assess antineoplastic drug safety and implement measures to reduce the risk of exposure to all workers who prepare and administer hazardous drugs.

Many guidelines and recommendations have been published on the handling of antineoplastic agents and hazardous drugs. The OSHA guidelines are well known in the nursing profession (OSHA, 2004). Other organizations that have produced guidelines include the Oncology Nursing Society (Polovich, White, & Kelleher, 2005), the American Society of Hospital Pharmacists (ASHP, 2006), WorkSafe Victoria (2003), and the International Society of Oncology Pharmacy Practitioners (Eitel, Scherrer, & Kummerer, 2005). Conner, Anderson, Sessink, and Spivey (2002) published an extensive list of more than 50 references featuring guidelines and recommendations for the handling of antineoplastic agents.

On March 25, 2004, NIOSH released a comprehensive analysis and description of specific suggestions regarding prevention of occupational exposure to antineoplastic and other hazardous drugs in healthcare settings. With an abundance of information in the literature on the risks of personal exposure to cytotoxic drugs, oncology nurses must assess compliance with published guidelines both as individual healthcare providers and as members of healthcare organizations and outline measures to increase compliance when necessary.

Drugs that meet one or more of the following characteristics should be handled as hazardous: carcinogenicity, teratogenicity or developmental toxicity, reproductive toxicity, organ toxicity at low doses, and genotoxicity (ASHP, 2006). A list of drugs that are defined as hazardous by NIOSH can be found in Appendix A of an electronic document available from the Centers for Disease Prevention and Control (NIOSH, 2004). The complete NIOSH alert is available on the NIOSH Web site at www.cdc.gov/niosh/docs/2004-165/#b.

Page (2004) wrote that work practice environments do have an impact on patient outcomes. Friese (2005) stated that concerns expressed by the Institute of Medicine (IOM) about patient safety and work environment built on 20 years of research, which found that poor work environments resulted in unfavorable nurse and patient outcomes. IOM identified areas that needed improvement in healthcare organizations: evidence-based staffing standards, work-hour regulations, the creation of interdisciplinary teams, and the establishment of visible and responsive nursing leadership (Page). This prompts healthcare professionals to consider the following questions for their safety as well as the safety of their families, patients, and fellow workers.

- As a healthcare provider, are you personally aware of any or all of the guidelines?
- How does your work environment influence your compliance or noncompliance regarding guidelines for handling hazardous drugs?
- What could you do personally, professionally, and corporately to improve compliance with established guidelines for handling hazardous drugs?
- Does every level of the organization have incentives for policy compliance?
- Are supervisors and managers trained and qualified to understand and follow policies and procedures?
- Do you have a workplace reporting system for spills, accidents, and noncompliance issues?
- How is the reporting system managed, and how does it interface with the entire organization?

In light of the consequences of potential legal action arising from noncompliance, nurses should assess their personal practice and work environments. If assessment reveals compliance with guidelines, then schedule periodic assessments to verify continuing compliance, including updating policies according to organizational procedures. If practice is not compliant, an action plan to improve compliance is needed. A common theme in the literature is that policies and procedures for handling hazardous drugs are in place but that noncompliance persists at the implementation level with employees who are directly involved in the preparation and administration of hazardous drugs. Two studies documented antineoplastic drugs in the urine of pharmacy and nursing personnel (Pethran et al., 2003; Wick, Slawson, Jorgenson, & Tyler, 2003). Pethran et al. collected urine samples in 14 German hospitals over a three-year period. Cyclophosphamide, ifosfamide, doxorubicin, epirubicin, and platinum were identified in urine samples from many of the study participants. An investigation conducted in the United States demonstrated a reduction in the percentage of urine samples with measurable levels of cyclophosphamide or ifosfamide and the concentration of the drugs in the urine following use of a closed-system drug-preparation device for six months (Wick et al.).
Healthcare professionals can look to the manufacturing world to gain insight into methods to assess and implement change. Gilchrist and Mosher (2004) suggested that any organization can benefit from using a root cause analysis method, which is similar to the nursing process of assessment, nursing diagnosis, planning, implementation, and evaluation. Gilchrist and Mosher developed a five-step problem-solving process called SOLVE® (Action Services LLC, Rock Hill, SC) (see Figure 1).

(S) Situation assessment: Promote continuous improvement by proactively seeking out chronic business issues that result in financial loss.

(O) Organize the investigation: Encourage and empower self-directed, formal or informal problem-solving teams.

(L) Live evidence collection: Uncover the problem (FACTS).
   1. Find and interview people.
   2. Act quickly to begin the investigation.
   3. Collect physical evidence.
   4. Track time and position.
   5. Search for cause-and-effect relationships.

(V) Verify the analysis: Precisely define the incident to be investigated. Develop a hypothesis by asking how the incident could have occurred. Use the scientific method to uncover the physical, human, and organizational roots.

(E) Effective corrective action: Implement safeguards to prevent problem recurrence by eliminating root cause deficiencies.

SOLVE is a root-cause-analysis–based problem-solving method used to find and eliminate problems by applying the scientific method to uncover the cause-and-effect steps that permit nonconformance and to take immediate corrective action. The SOLVE methodology relies on personnel to openly and honestly expose organizational procedures, tools, and training that empower personnel to act. The intent of exposing human decisions is to understand and correct organizational systems that allow problems to occur, not to punish or blame the people who expose the shortcomings. The SOLVE method of problem resolution thrives in an organizational culture where people are recognized as the company’s most valuable resource and encourages an environment conducive to employee ownership and empowerment (Mosher & Gilchrist, 2004).

Any employee desiring to seek answers to a problem can use SOLVE. Based on a problem’s potential impact in terms of dollars or risk, a formal or informal team is assembled for problem analysis. The team defines the problem and begins the investigation by examining known facts, which stimulate investigators to generate plausible hypotheses to explain cause-and-effect relationships. The hypotheses are verified, become fact, and, when further investigated through hypothesizing and verifying, lead to the problem roots. The problem roots are underlying causes; when eliminated, they prevent problem recurrence. Corrective action items resulting from the investigation must be followed to completion to ensure problem elimination.

Investigation teams may or may not be responsible for all phases of the corrective action process. Team members who have control and influence over the areas where the problems occurred can take immediate action and implement team decisions as soon as possible. If a team has influence only in the area where the problem occurred, it should appoint a team member to champion the corrective action phase with management, who can take the plan for change to completion. Speak with the manager who owns the problem and is responsible for resolution and help the person complete problem corrective action. The problem will be eliminated only after the root cause of the problem is identified and corrective actions are fully implemented.

With the SOLVE method, the root cause of exposure issues associated with antineoplastic drugs can be identified and corrected. Healthcare administrators are aware that active or passive regulatory noncompliance can be uncomfortable from a public relations perspective as well as costly from a litigation standpoint. Regulatory agencies provide government guidelines, which must be followed to ensure compliance. When using the SOLVE process in addressing compliance issues with antineoplastic drugs, define the incident or undesirable event as antineoplastic drug regulatory noncompliance. To complete the problem definition, list the FACTS, or outstanding issues that further define the incident. Being broad and all-inclusive, the FACTS can be grouped into either government regulations or organizational noncompliance. Healthcare administrators can further examine governmental regulations to include all governing agencies and listing all applicable regulations. Likewise, a review of an individual healthcare organization should uncover potential areas of noncompliance. Consider using a logic tree diagram to display problem definition, as well as all phases of the investigation. Figure 2 contains a logic diagram, which may be used as an investigation model.

Begin an investigation by researching government regulations and organizational noncompliance items that apply to a specific healthcare organization. Administration can start the process by informing employees of the reasons for conducting the investigation. Explain that the investigation is to ensure governmental compliance and improve safety, not to punish or blame employees. Addressing such issues proactively will help to secure employee acceptance of the initiative more quickly. Ask for volunteers to lead the new initiative. Initially, start with one area, such as preparation, listed under organizational noncompliance. Team

---

**Figure 1. SOLVE®: A Five-Step Problem-Solving Process**

*Note: Based on information from Gilchrist & Mosher, 2004.*
members should plan to spend time observing work practices in the area and noting situations that may require follow-up. Ask questions such as “How can a situation exist in the preparation area that might create an organizational noncompliance situation resulting in antineoplastic drug regulatory noncompliance?” Examples of potential problems include:

- Counting out individual, uncoated oral doses and tablets from multidose bottles
- Crushing tablets to make oral, liquid doses
- Reconstituting powdered or lyophilized drugs
- Diluting reconstituted powder or concentrated liquid forms of hazardous drugs
- Compounding potent powders into custom dose capsules

Involve team members in developing hypotheses directed at the underlying problems that could be causing noncompliance. When all possible hypotheses have been uncovered, each hypothesis must be examined and verified to uncover the path to noncompliance. The verification process relies on factual evidence, which can be found through employee interviews and investigative data gathering. The investigator continues to ask “How can …?” questions until problem roots—basic items that, when corrected, will prevent problem recurrence—appear. The essence of all investigations is to uncover and improve the organizational root, or company policies, procedures, manuals, or training that empower employees to conduct business. With practice, the SOLVE method of problem analysis becomes a way of life and a basic continuous improvement tool.

Evidence supports practice change in the area of handling hazardous drugs. A single person armed with relevant evidence and determination can make a positive difference in employee and organizational outcomes as they relate to the process of handling hazardous drugs. Hold all members accountable to provide and maintain a safe and pleasant workplace. Do not become discouraged during the evaluation process. Remember that old habits are hard to break. Consistently reinforce the expectations for the handling of hazardous drugs. All healthcare employees have the right to work in safe environments and, when valued and empowered, embrace the opportunity to improve their personal and professional safety in their workplaces.

Author Contact: Jackie Gambrell, RN, BSN, OCN®, can be reached at gambrellj@charter.net, with copy to editor at CJONEditor@ons.org.

References


