Technical Evaluation of a New Sterile Medical Device to Improve Anticancer Chemotherapy Administration

Nicolas Simon, MSc, PharmD, Bertrand Décaudin, PharmD, PhD, Damien Lannoy, MSc, PharmD, Frédérique Danicourt, PharmD, Christine Barthélémy, PharmD, PhD, and Pascal Odou, PharmD, PhD

Occupational exposure of healthcare workers to antineoplastic agents has been acknowledged for years (Jochimsen, 1992). It can lead to biologic or clinical disorders such as chromosomal aberrations (Cavallo et al., 2005), miscarriages (Valanis, Vollmer, & Steele, 1999), premature deliveries, and low birth weights (Fransman et al., 2007). Since the 1980s, occupational exposure has been described in nurses who handle antineoplastic drugs (Selevan, Lindbohm, Hornung, & Hemminki, 1985). Considerable contamination has been noted in the air in the vicinity of laminar air-flow hoods (Sessink, Friemèl, Anzion, & Bos, 1994; Sessink, Timmermans, Anzion, & Bos, 1994; Sessink, van de Kerkhof, Anzion, Noordhoek, & Bos, 1994). Those authors also revealed the presence of anticancer drugs or metabolites in the urine of pharmacy and nursing staff who prepared cytotoxic drug infusion bags.

The Occupational Safety and Health Administration (OSHA, 1996) recommended protective measures, including ventilated biologic safety cabinets or isolators to reduce the risk of environmental contamination. OSHA also required that healthcare workers be educated and trained to reduce their risk of exposure and that they wear personal protective equipment when handling hazardous drugs.

In the 2000s, other sources of contamination were found. Drug vial surfaces appeared to be contaminated by cytotoxic drugs (Mason, Morton, Garfitt, Iqbal, & Jones, 2003). Moreover, preparation techniques exposed operators during manipulation, especially when needles were used (Spivey & Connor, 2003). Chemical contamination was found inside positive- and negative-pressure isolators (Crauste-Manciet, Sessink, Ferrari, Jomier, & Brossard, 2005; Hedmer, Tinnerberg, Axmon, & Jönsson, 2008; Mason et al., 2005). Several decontamination protocols have been assessed to clean workplace surfaces, but none completely removed chemical contamination by anticancer drugs (Roberts, Khammo, McDonnell, & Sewell, 2006). More so than in pharmacies, chemical contamination with anticancer drugs was found in oncology wards where...