Online Exclusive Article

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

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Purpose/Objectives: To assess the PCHIMX-1® (Doran International), a new sterile medical device intended by its manufacturer to improve the quality and safety of cytotoxic drug infusions, as well as its influence on manipulation times required for pharmacy technicians and nurses and its effect on infusion line outflow parameters.

Design: PCHIMX-1 assemblies were compared to standard infusion sets.

Setting: Pharmacy and oncology units of a French general hospital.

Methods: Reference assemblies (an infusion bag connected to an infusion set) were compared to PCHIMX-1 assemblies (PCHIMX-1 connected to two bags and to an infusion set). Two assessments were performed: (a) comparison of the times of manipulation during both preparation and administration of 5-fluorouracil infusion bags (n = 40) and (b) effect of PCHIMX-1 on infusion quality.

Main Research Variables: Manipulation times in the pharmacy (T_P) and in the ward (T_W) were measured, as well as flow rate and infusion efficiency.

Findings: The results showed that T_W was significantly increased, whereas T_P was significantly decreased; total time was unchanged. Results also showed that PCHIMX-1 significantly changed infusion efficiency; flow rate was not affected.

Conclusions: PCHIMX-1 obliges pharmacy technicians and nurses to change their handling procedures. The device does not have any influence on infusion flow rate but considerably improves infusion quality by ensuring that the full quantity of medication prescribed is administered.

Implications for Nursing: PCHIMX-1 guarantees that the complete prescribed dose of chemotherapy is administered without any change in infusion quality and adheres to the latest recommendations concerning occupational exposure protection.

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