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Cytotoxics in the academic research setting; a call for tailored guidelines

Dear Editor,

Hazardous drug handling and occupational exposure are two subjects that have been in ongoing discussion notably that continuous efforts are invested to improve safety (robotic preparation, transfer devices, etc.).

In your article entitled "Safe preparation and administration of cytotoxics", the authors placed emphasis on conforming to clinical practice guidelines whilst handling cytotoxics in the workplace. Essentially, the American Society of Health-System Pharmacists (ASHP) (1), the International Society of Oncology Pharmacy Practitioners (ISOPP), and other major national and international societies have evaluated the risk associated with hazardous material, including chemotherapy drugs, and consequently founded strict rigid guidance for their safe handling.

Historically, cytotoxic drug handling was restricted to the oncology wards and the hospital pharmacy compounding area. However, with the evolution of the industry and pharmacotherapy, this has moved to other areas of use such as companies providing pre-compounded intravenous chemotherapy, the clinics of oncologists, and the academic research laboratories.

Abiding by the guidelines on the safe handling of cytotoxics is by no means a luxury, and is subject to serious prosecution if breached (fines, imprisonment and disqualification). The Health and Safety Executive (HSE), Great Britain's independent regulator for work-related health safety and illness, has circulated an information sheet enclosing a legal consideration section to protect the employees from hazardous workplaces (1). Hence, theoretically, the same vigilant guidelines are expected to be implemented in academic research laboratories as well, and the ASHP guidelines states: "these guidelines should be implemented wherever hazardous drugs are received, stored, prepared, administered, or disposed." (2).

The use of cytotoxics in academic research laboratories is often limited compared to the clinical setting whereby doses, concentrations and frequency of preparation are significantly less.

With that said, one might question if guidelines that are more flexible might be tolerated for academic research laboratories. A perfect scenario would be finding a balance between safeguarding the safety of the researchers and taking into account the available resources and practicalities. More specifically, one would question the need for negative pressure rooms, the frequency of donning new gloves (every 30 minutes), the necessity of limiting the furniture (PC, printer, flasks, pipettes, etc.) (1) which are oftentimes necessary in an academic research laboratory, in addition to other similar considerations.

Regarding the work environment, the USP <797> requirements state that for compounding low volumes of hazardous drugs, a closed-system drug transfer device (CSTD) with a biological safety cabinet (BSC) is an acceptable alternative to negative pressure rooms(3). However, considering that the use of a CSTD can be cost prohibitive, some questions arise and remain unanswered; how many academic centers are

actually using CSTD's? In academic settings, would a BSC alone be enough considering the low volumes/doses handled, the diluted samples prepared, and the infrequent compounding?

Therefore, there might be a need to develop guidelines catering for academic research centers whereby the workplace requirements are less rigorous but swab contamination studies are recommended annually or every 6 months.

For instance, it is worth auditing not only the laboratory and office surfaces, but also the tray of the auto-sampler of the chromatography apparatus (HPLC, LCMS, etc...) for contamination caused by possible splash from the needle upon withdrawal of the cytotoxic drug from the sample vial. Since these instruments are shared resources between researchers, cytotoxic contamination could easily spread to humans and surfaces especially if other substances being tested do not require the use of PPE's.

On a final note, the suggested scheme is to establish an operational risk management tailored to fit the academic research laboratories, hence safeguarding the researchers while making the best use of the available resources.

Reference

(1) American Society of Health-System Pharmacists. ASHP guidelines on handling hazardous drugs. *AM J HealthSyst Pharm.* 2006; 63:117293

(2) HSE. Safe handling of cytotoxic drugs. HSE Information Sheet MISC615. Available from: <http://www.hse.gov.uk/pubns/misc615.pdf>

(3) Karl M.Kilgore, AIA. Cover Story: Designing a cleanroom to meet the updated USP<797> requirements. *Pharmacy purchasing and products magazine* 2008 5:4, 10-12