Ontario College of Pharmacists
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Ontario College of Pharmacists
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10 February 2017 re: LM/7214399

Lisa Mueller
Investigator
Investigations and Resolutions
The College of Physicians and Surgeons of Ontario
80 College Street, Toronto, ON M5G 2E2

Dear Lisa,
Thank you for the material you provided for review. I wish to provide the following addendum after considering the materials.

ADDENDUM

It is encouraging to hear that several process improvements have been made, and that validation of the environment has been independently tested. These will improve patient safety and confidence.

When providing sterile manipulation/compounding services, it is important to 'keep the outside out, and the inside in'. (Meaning – to protect the sterile product from contamination and to protect the compounder/personnel/public from the drug) It is also important to maintain a culture of continuous quality improvement in the care setting, which Dr. Khan seems committed to.

The volatility of the carboplatin is not entirely the concern, but rather the toxic nature of the drug. Adequate and appropriate handling procedures are to be considered to ensure that inadvertent exposure to the drug is minimized. (From start (receiving) to the manipulation of the drug (compounding/preparation), to the finish (waste storage and handling)) This is for Dr. Khan's protection as well as for other people in the clinic.

Exposure can occur via absorption through skin: contact with contaminated vials, breaches in gloves, while cleaning up spills, handling contaminated waste, improper deactivation/decontamination procedures. Several strategies are employed to minimize accidental exposure: Air flow dynamic principles (eg. Negative pressure), cleaning protocols (deactivation of the drug then decontamination), preparedness (pick lists, staging- so that compounding activities are completed uninterrupted), and proper segregation/handling of waste materials.

Some of the references Dr. Khan referred to are outdated. In pharmacy practice, we refer to the following: http://napra.ca/Content_Files/Files/Mdl_Stnds_Pharmacy_Compounding_Hazardous_Sterile_Preparations_Nov2016_Revised.pdf which used USP<797>, USP<800> and other current Canadian resources. This Canadian document is new, however prior to its development, in Ontario we used the USP references as a resource. Hazardous product handling has evolved over the last few years, and it is not treated as casually as it once was. The Ontario College of Pharmacists is working with Cancer Care Ontario to develop strategies to minimize risk in all patient care settings,

Sterile HD compounding education resource: https://www.ip3network.com/ and https://www.criticalpoint.info/ (It seems that Medisca has removed their course selections from their website)

Bottom line: this practice is evolving and all practitioners need to keep up to date with current practices. It is about knowing and considering the risk of the drugs being used and taking precautions at every stage so they are handled safely to minimize the risk of exposure. Validation (routine environmental testing and routine staff blood work) should be encouraged to identify if there is a breach in protective measures, so that remedial action can be taken. It is about keeping you and your staff, patients and their caregivers/family safe.

Respectfully submitted,

Heather A. Arnott