MEDICOR CANCER CENTRES

December 29, 2016

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

File #LM/7214399

Dear Ms Mueller:

Re: **Report of Kirsty Albright, RN**

Thank you very much for allowing me to respond to Ms. Albright's report regarding the preparation and administration of chemotherapy at Medicor Cancer Centres as observed on February 10, 2016. I am pleased that after a thorough inspection of my premises and chemotherapy practices, Ms. Albright determined that my patients are not exposed to harm or injury.

By way of important context, I would first like to point out to the Committee that the standards for chemotherapy administration do vary across North America, and are based upon opinions and recommendations from various experts, dealing with the administration of a multitude of chemotherapy agents (both volatile and non-volatile).

Most standards regarding policies and procedures, personal protective equipment, ventilated cabinets, syringes and intravenous sets, transport and labeling, and education and training are not requirements per se, but *guidelines*, and often are NOT evidence-based. In fact as stated in the *Recommendations for Ontario* publication:

> *"…no studies have been carried out examining the effectiveness of these precautions in reducing rates of cancer, adverse reproductive outcomes, or acute adverse effects associated with exposure to cytotoxic drugs among health care workers…"*

Safe Handling of Parenteral Cytotoxics: Recommendations for Ontario, http://ascopubs.org/doi/full/10.1200/jop.091014

With this in mind, I would invite the Committee to apply this context to the assessment of my practices vis a vis various other guidelines or standards. It is also important to bear in mind that the standards referenced in Ms. Albright's report may not strictly apply since at Medicor we only use non-volatile chemo drugs (e.g. carboplatin and occasionally gemcitabine) which require fewer handling precautions.

This should not be interpreted as an acknowledgment of a deficiency of any kind. Rather, I simply wish to provide context for the Committee's consideration of Ms. Albright's comments.

That said, I took great care to consider many of Ms. Albright's comments respecting certain practices reviewed, and wish the Committee to know that I am committed to ensuring that my practices and patient care are of the highest quality. To that end, we have made a number of changes to our policies and practices arising directly from feedback provided by Ms. Albright, at my request, at the conclusion of her inspection on February 10, 2016.

I believe it will be helpful for me to provide some additional comments to assist the Committee in its review of this matter. The following is my detailed response to Ms. Albright's observational report dated June 6, 2016.

Observed Preparation of Chemotherapy

Ms. Albright opined that the Medicor facility did not meet the standards of practice expected for the preparation of chemotherapy. She then went on to list specific observations in this regard. My response to these observations is as follows:

Chemotherapy Preparation Area

No ante-room leading to the BSC room.

This has been addressed in detail in the response to Ms. Arnott's report. References have been provided showing that a formal ante room is not required. Regardless, the space has since been modified, and the Director's office has been relocated to a different area of the facility. There is now a dedicated ante-room leading to the BSC room.

The absence of negative pressure in the BSC room.

This has been addressed in detail in the response to Ms. Arnott's report. A negative pressure room is not required by the existing standards (especially since we do not use volatile hazardous drugs), and it has been proven there is no risk to patients or staff by way of advanced environmental testing (environmental assessment report is enclosed from EH&S Consulting Inc).

Carpet present in the ante-room area and chemo administration areas.

We are not aware of any requirement that carpet cannot be present in an office where chemotherapy is administered. In the event of a chemotherapy spill on a carpeted area (which has never happened to date), we do have chemo spill kits in all chemo administration locations that will decontaminate

chemotherapy spilled on any type of surface. The BSC room has a tiled floor and smooth walls which can all be easily cleaned and decontaminated according to existing guidelines.

Personal Protective Equipment

Gloves were not worn when moving cytotoxic chemo bags

It was explained to Ms. Albright that our chemo handling standard is higher than that of a typical hospital pharmacy in a significant way: we wash and decontaminate chemo vials before they are used. That means chemo is not present on the outside of vials and as a result, will not be transferred to the cytotoxic chemo bags that hold the chemo syringes. Regardless, our policy has been revised to require handling cytotoxic chemo transport bags with gloves at all times according to Ms. Albright's recommendation.

Storing/Transporting of Hazardous Drugs

Ms. Albright commented about the storing/transporting of "hazardous drugs". Specifically, she was concerned that "hazardous drugs" were not stored separately from other drug products and not locked in such a manner that only properly trained staff may access the storage location.

Ms. Albright's report appears to contain an error. Hazardous/cytotoxic drugs are never stored in the receptionist's workspace or in the staff kitchenette, only ordinary drugs and natural medications were stored next to the kitchenette. Incidentally this has since been changed as part of a larger office modification, such that drugs and kitchenette are now totally separate. Narcotic drugs were always kept in a secure, locked cabinet, and remain there. Hazardous drugs are now only accessible through a door locked with a deadbolt.

In any event, we did appreciate Ms. Albright's comment related to the cross-storage of drugs/kitchen supplies, so that now the two are completely separate. Fridges and freezers are clearly labelled according to their permitted contents.

On a related note, I would appreciate clarification as to what "hazardous drugs" Ms. Albright believed were present in the reception area, so that if we have missed something, we can correct it immediately.

Temperature logs were not kept for medications.

While there was no temperature log on the drug refrigeration, we do utilize temperature monitoring in two forms: Min-max thermometers which serve the function of confirming that temperature-critical drugs are stored in the correct temperature range, and two different types of temperature indicator strips adjacent to the drugs, as a double-check.

Regardless of our previous practices, we have added 24 hour temperature monitoring with an alarm to strengthen our system according to Ms. Albright's recommendation. Separate temperature loggers are now present in the drug fridge and in the chemo storage area (BSC room).

Checking Medication Preparation and Labelling

Ms. Albright commented that chemotherapy admixtures and solutions prepared by me were not checked with a second person to ensure correct medication and quantity has been prepared and labelled correctly.

To be clear, we do not use carboplatin admixtures at all. Carboplatin is supplied in "ready to infuse" vials, and we do not dilute it, but place it directly into syringes within the BSC. Dilution occurs automatically during infusion only (which has no effect on the chemo dose delivered). Observing the volume of fluid in the syringe is a simple double-check of the correct chemo dose, which does not require a second staff member.

Also, unlike in hospital pharmacies or chemotherapy wards to which Ms. Albright may have had reference, we do not use many different types of chemotherapy. Rather, the primary chemo agent in use at Medicor is carboplatin, with the occasional use of gemcitabine (also prepared without admixture). In any event, there is inherent safety of our unique system, which is different than the system used in hospitals i.e. one can readily double-check the dose present in the chemo syringe at any time by simple observation. We also have a pre-chemo administration checklist, which includes such a mandatory double-check of the correct chemo dose.

We are not aware of a standard that requires a double check by a second staff member when a chemo drug is prepared for infusion, without dilution (no admixture).

Transporting of Cytotoxic Drugs

Ms. Albright observed that chemo drugs are transported in a sealed bag, but was concerned with the fact that Medicor does not use closed containers in addition, and there were no absorbent pads present in the containers.

The BCCA standard that we adhere to states:

"Hazardous drugs must be packaged and transported in a manner which minimizes the risk of HD exposure due to a spill or breakage during transit.

Hazardous drugs should be packaged in a sealed, leak-proof container with HD warning labels on the outside.

Some considerations when determining hazardous drug packaging for transport include:

- package hazardous drugs separately from non-hazardous drugs
- protect from light where required
- protect from breakage during transit
- contain any leakage if contents break or rupture
- use child-proof packaging for tablet containers (if appropriate)
- label appropriately with auxiliary instructions
- use methods for cooling drugs which require refrigeration (cold packs, dry ice)

Reusable packaging should be designated for HD transport only and must be decontaminated and re-used as per site-specific policies. Disposable HD packaging materials should be discarded as hazardous waste.

Site specific procedures for transporting hazardous drugs should be developed and maintained. Staff involved in transporting HDs must be properly trained to adhere to site specific HD transport procedures. The method of transporting hazardous drugs must not produce stress on the contents or packaging. Pneumatic tubes or other mechanical transport systems must not be used for hazardous drug transport.

Non- personnel transporting hazardous drugs should be aware of HD spill procedures. Spill kits should either accompany hazardous drug packages during transport or be easily accessible."

BCCA Pharmacy Practice Standards for Hazardous Drugs Jan 2012, Section I, page 52

Our transport system is sealed (zip-loc leak-proof cytotoxic chemo bags) and we have multiple spill kits readily available, therefore I believe Medicor is in compliance with the applicable standard.

Observed Administration of Chemotherapy

Personal Protective Equipment

Ms. Albright noted that "gowns were not changed when leaving the patient care area". This may be a misunderstanding, since I dispose of my chemo prep gown upon exiting the BSC room, and put on a new gown to administer chemo to patients. Once that process is completed, the second gown is also disposed of as hazardous waste.

MEDICOR CANCER CENTRES

An eye wash station has now been added, and a suction machine has been obtained according to Ms. Albright's recommendations on the date of the visit.

Emergency Supplies

Routine inspection of the emergency kit was conducted previously, but a monthly log of the emergency medication and supplies has now been added according to Ms. Albright's recommendation.

Quality assurance and education

BSC is already inspected and re-certified every 6 months. Routine inspections have been added for the IV pumps per manufacturers' guidelines, according to Ms. Albright's recommendation.

As discussed during Ms. Albright's visit, we are not able to locate any formal courses for handling of hazardous drugs that will accept physicians. For medical doctors, the principle of lifelong self-education is well-established and one I adhere to zealously. In the absence of an available formal hazardous drug handling course that will accept a physician student, I believe this principle of self-education should continue to be respected by the College in the case of my chemo-immunotherapy practice.

Conclusions

In conclusion, while I am encouraged that Ms. Albright believes my care and treatment do not expose my patients to harm or injury, I am also mindful of her comments and suggestions for improvement in certain areas. As set out above, Medicor has made concrete improvements to our policies and practices to reflect the continued level of high quality care that I provide to my patients.

As I have previously stated, I hope to be judged against established standards and feel that any such assessment will conclude that Medicor meets or exceeds relevant standards, while taking into account the significant differences between our "safe" chemo practice and a typical hospital oncology practice. We remain most willing to make appropriate improvements to our policies and practices, at any time, to bring ourselves into compliance with any new applicable standards.

Sincerely,

Akbar Khan, M.D.

Encl.

Medicor Cancer Centres Inc., 4576 Yonge St, Suite 301, Toronto, ON, M2N 6N4
Phone (416) 227-0037, Fax (416) 227-1915

File Number: 7214399
Investigator: Kirsty Albright RN, BScN, MScN

Qualifications/Practice
I completed a BScN degree at Ryerson University, and an MScN degree at York University. I have successfully completed Oncology education courses (DeSouza Chemotherapy and Biotherapy certification) and have given presentations both locally and internationally.
I have over 10 years of Acute Care Clinical experience in Oncology at the Odette Cancer Centre in Toronto. I have fulfilled a staff nurse role and currently practice as the Supervisor of the Ambulatory Chemotherapy unit, responsible for the daily operation of the Chemotherapy Unit, liaising with interprofessional members to ensure safe delivery of chemotherapy and biotherapy to 100+ patients per day and provide education to staff to advance/apply best practices and promote quality and safe patient care.
I have a broad spectrum of clinical expertise in the area of medical oncology and systemic therapy and possess strong theoretical knowledge, clinical competence and experience in antineoplastic/biotherapy administration/safe handling and vascular access.

Authority to Act as Medical Inspector
I have been informed and understand that although the College has retained me to provide an independent opinion, my duty in doing so in not to the College, nor is it to the member under investigation, but rather my duty is to assist the Inquiries, Complaints and Reports Committee and the Discipline Committee on matters within your expertise.

List of Material received from the College
Please see attached documents.

Date of Observation
February 10th, 2016

New documents obtained/List of additional people interviewed during investigation
Nil

Copy of Curriculum Vitae
Please see attached document.

1. Please provide your opinion as to whether the Medicor facility, and specifically the mixing and administration of chemotherapy in the facility, meets the standards of practice expected for the preparation and administration of chemotherapy? Please explain your answer and provide specific examples to support your opinion.

Observed Preparation of Chemotherapy

Overall, the mixing of chemotherapy in this facility does not meet the standards of practice expected for the preparation of chemotherapy.

Concern: ***Chemotherapy Preparation Area***
Why? There was no dedicated ante room or area (clean area that precedes the buffer zone; where biological safety cabinet is located) for donning of personal protective equipment and storing supplies and equipment. This space was located in the Director's office.
The 'mixing' room was not a negative pressure room that could prevent any spilled medication from leaving the room.
The handling and labelling of chemotherapy took place on the desk and carpeted floor in the Director's office space. Work practices related to general hygiene practices – such as not permitting eating or drinking in areas where drugs are handled were not followed.
Tasks were not coordinated (i.e. gathering equipment/supplies) resulting in the MD opening the 'mixing' room door 3 times. This increased movement caused a disturbance in the airflow resulting in directing drug aerosols outside of the hood and into the adjoining room. This was evidenced by a strong alcohol odour both when the 'mixing' room door opened and was closed. The work area was not sufficiently ventilated. This directly affects the decontamination and cleaning of surfaces within the biological safety cabinet (mixing) room.

Concern: ***Personal Protective Equipment***
Why? Nitrile gloves were not worn during all hazardous drug-handling activities. Specifically, when handling and transporting the non-sealed plastic yellow cytotoxic bag from the 'mixing' room to the carpeted floor in the Director's office. The risk of exposure to the hazardous drug is considerably high.

Concern: ***Storing/Transporting of Hazardous Drugs***
Why? Hazardous drugs were not stored separately from other drug products and not locked in such a manner that only staff properly trained have access to the storage location (stored in receptionist workspace and staff kitchenette/medical and equipment storage area).
Temperature logs were not kept. Maintaining high standards and closely monitoring temperatures of medication is critical for ensuring product integrity and patient safety regarding the storage of medications.

Concern: ***Checking Medication Preparation and Labeling***
Why? Chemotherapy admixtures and solutions prepared by MD were not checked with second person (i.e. another MD, nurse) to ensure correct medication and quantity has been prepared and labelled correctly.

Fridges and freezers were not clearly labelled (i.e. Food only or Specimens only). Safety systems must be in place to indicate storage contents.

Concern: ***Transporting of Cytotoxic Drugs***
Why? Although the drugs were placed in a sealable plastic bag, the bagged contents were not inside a **closed** container with disposable absorbent pads to contain any spillage if discovered.

Observed Administration of Chemotherapy

Concern: ***Personal Protective Equipment***
Why? Gowns were not changed when leaving the patient care area. Eye protection, namely a sink with an eye wash station was absent. In the event of a worker's exposure to antineoplastic agents by skin/eye contact, required equipment was not available, thus procedures and best practice cannot be followed.

Concern: ***Emergency Supplies***
Why? A crash cart (with defibrillator, suction machine etc.) is required on-site due to the potential of drug induced chemotherapy hypersensitivity reactions. Documented monthly checks of the emergency medications and equipment in the red rectangular tool box was missing but is required to assure emergency supplies and equipment are functional and fully stocked at all times.

Concern: ***Quality Assurance and Education***
Why? Infusion pumps have no scheduled quality checks and MD has obtained no Certification course in Safe Handling of Hazardous Drugs (including Medication Ordering, Preparation, Packaging, Labeling and Administration).
Quality checks are important to ensure all equipment is performing adequately which promotes patient safety. Formal training on safe handling and obtaining and maintaining Certification courses (recertification annually) is necessary for understanding and acquiring skills, knowledge, understanding, ideas, concepts and tools associated with preparing and administering hazardous drugs.

2. Please advise whether, in your inspection of the facility, Dr. Khan's patients were exposed or likely to be exposed to harm or injury? Please notify me immediately if you form this opinion at any time.

Based on my observations, findings and concerns noted above, and in my inspection of the facility, Dr. Khan's patients at this time are not exposed to harm or injury.