Standing Committee on Social Policy Opening Remarks

Murray Glendining:

Good afternoon. My name is Murray Glendining and I am the Executive Vice President, Corporate Services & Clinical Support - and currently the Acting Chief Executive Officer - of the London Health Sciences Centre. I joined LHSC in June of last year and prior to that I was the Executive VP of Corporate Affairs at Hamilton Health Sciences Centre.

Joining me today as requested by the committee are:

- Neil Johnson, Vice President Cancer / Renal and Pharmacy Services at LHSC and Regional Vice President, Cancer Care Ontario
    - Neil is a pharmacist by training and has been with LHSC since 1988, progressing from staff pharmacist to Director of Pharmacy and through a range of executive responsibilities that include managing ED's, dialysis, medicine, and neurosciences.
    - Currently, Neil has a dual role, with operational responsibility at LHSC for Cancer and Renal Services and Pharmacy Services; and Cancer Care Ontario responsibilities that include implementing the Ontario Cancer plan in the South West region.
- Sandy Jansen, Director of Pharmacy Services at LHSC. Sandy is also a pharmacist and has been with LHSC since 2009 and became the Director of Pharmacy in 2011. Prior to joining LHSC, Sandy held a variety of roles in Pharmacy at St. Joseph's Health Care in London progressing from a clinical pharmacist in critical care to a variety of leadership roles in operations and medication safety.
- Toby O'Hara is the General Manager, Health Care Materials Management Services and
- Tony LaRocca, is our Vice President Community and Stakeholder Relations, responsible for communications at LHSC.

I would like to open with just a few remarks for the committee, after which I will turn to Neil and Sandy to provide you with more information on our response to this issue from a clinical, pharmacy and patient perspective. First, on behalf of this team and LHSC, let me extend our sincerest apologies to all of the patients and families who were affected by this unfortunate and unsettling issue. We know it has caused them a great deal of stress and anxiety, and in many cases it has shaken their trust in our organization and in the health system.

It is our goal, through close collaboration with all stakeholders, and active support of the review process led by Dr. Thiessen, to help rebuild that trust by ensuring all appropriate safeguards are in place for the patients we serve.

For context, LHSC is one of Canada's largest acute care academic health sciences centres, and provides the broadest range of acute care services in Ontario. Our nearly 10,000 staff and physicians care for the most medically complex and critically ill patients across southwestern Ontario, with more than 1 million patient visits each year, including over 150,000 emergency visits.

At LHSC, two key areas of focus are:

- Improving the Patient & Family Experience, and
- Excellence in patient care, service & safety

Underpinning these is our culture as a learning organization, which we hope is clearly reflected in our approach to the chemotherapy compounding issue. Through open and transparent communication, dialogue and collaboration with all system partners, and early and ongoing engagement of patients to help us shape our response, we are committed to being a meaningful partner in rebuilding system safeguards and trust.

At each step of the process, our focus has been to do right by the patient and to let our action planning evolve from that. Our patient advisors helped tremendously throughout this issue, and will continue to guide our interactions with impacted patients.

The initiatives that we implemented to connect impacted patients with the support and information they need have been quite successful in helping them begin to put this situation into context.

Our focus now turns to process issues and working with the reviews underway to identify any opportunities to improve safeguards, both in-hospital and system-wide, to prevent recurrences.

I will now ask Neil Johnson to provide the committee with a brief chronology of some of the events that have transpired since this issue was discovered.

Neil Johnson:

Thank you, Murray.

Before I walk through the sequence of events, I think a brief overview of our Cancer program might be helpful.

The London Regional Cancer Program at LHSC is one of the largest cancer centres in Ontario. As a research and education based centre, we have a long history of innovation and research. Today our centre sees over 7,000 new cancer patients each year with over 180,000 patient visits to our centre. Each day we see on average 28 new cancer patients and over 720 patient visits to our centre.

With these volumes, it becomes apparent why the chemotherapy dosage issue we are reviewing today impacted so many patients at LHSC.

We first learned of the possibility of this chemotherapy medication issue on Friday, March 22, at approximately 2:30pm, when the hospital was contacted by Lakeridge Health and advised of this potential issue. This information was relayed to our Director of Pharmacy, who immediately initiated steps to have the Cyclophosphamide and Gemcitabine compounded by Marchese pulled from use. Although the complete magnitude and facts were not clear at that time, the pharmacy team acted to ensure that no products were available for use. This action was completed at approximately 3:45 pm, thus immediately preventing any potential for further risk to patients. Our team also started to reach out to make contact with the medication supplier to obtain procedural information on product preparation. I became involved shortly afterward as I completed meetings that I was attending out of town. Our Director of Pharmacy notified our Group Purchasing Organization, Medbuy, and was able to speak to a staff member there who indicated she would review her records to see who was purchasing product from Marchese and notify these organizations.

Over the next few days, our investigation deepened and included:

- A review of LHSC's Purchase history. It was determined that Marchese was awarded the contract to provide compounded IV services to MedBuy hospitals in the late Fall 2011. Through the MedBuy contract with Marchese, the London Regional Cancer Program began purchasing Cyclophosphamide and Gemcitabine March 1, 2012 and the LHSC Inpatient Pharmacy began purchasing these products October 15, 2012.

- Using these purchase dates, an initial data extraction of computerized patient records was commenced to identify patients potentially impacted.

- LHSC then undertook a number of steps to begin to better understand the nature and extent of the problem.

- To determine that the problem did not pre-date the start of the Marchese contract, the previous external supplier of these medications (Baxter) was contacted to obtain procedural information on product preparation. It was determined that product concentration was exactly as labeled. In parallel, Marchese's Request for Proposal submission was reviewed.

- LHSC completed an internal assessment of the Marchese Chemotherapy medications by withdrawing all of the fluid in some of the medication bags on hand and measuring the volume. Three bags of each medication were drained and the fluid was measured. They were found to contain an average overfill of 11%.

- By March 26, the potential magnitude of this issue was becoming increasingly clear, leading to the initiation of a full Incident Management Team which convened at the beginning of the following day. At that initial meeting, it was decided to add the co-chairs of the LHSC Cancer Community Advisory Group to the daily incident review calls to help inform our response plan and interaction with patients. That day, calls were also placed to leadership at Cancer Care Ontario to notify them of our findings and approach. As well, LHSC's Pharmacy Manager began to place calls to other regional hospitals, including Windsor, to advise them of the issue. Additional external notifications of the issue were provided to the Ontario College of Pharmacists, Health Pro, Research colleagues and a phone message was left at Health Canada – all in an effort to further escalate the matter and ensure that any additional partners in the system that could be impacted were made aware of the problem.

After the data pulled from our computer systems was reconciled, the lists of impacted patients were shared with the respective clinical leaders, beginning the evening of March 27 for paediatric patients and the following day for all adult cancer patients and non-oncology patients. Clinical data were then pulled to enable detailed patient record reviews – a manual and very time intensive process involving many hundreds of files. In the afternoon of March 28, LHSC participated on a teleconference with CCO, and the Lakeridge and Windsor Regional hospitals to discuss the situation and to consider an aligned communication plan that aimed to ensure that – to the extent possible - patients first heard about the issue from their hospital. LHSC developed such a plan to notify impacted patients and connect them to the supports and information they would need, and to then communicate the issue more broadly to key constituents. Given that the greatest patient impact was at LHSC, it was clear that best efforts to contact patients would take several days after the clinical patient record reviews were completed, and initial roll out plans centred around this timeline.

Also on March 28, LHSC sent a letter to Marchese clearly articulating LHSC's concerns and requesting a reply to questions posed. That evening, Marchese sent an email outlining their process for compounding to LHSC's Director of Pharmacy.

A review of patient records ensued, with clinical staff working day and night over the next three days to retrieve all relevant clinical information required by medical staff in the review of their patients.

On April 1, it was reported that Windsor Regional Hospital had begun to inform patients. It was evident that this would accelerate broader public awareness before LHSC could effectively communicate with its larger volume of impacted patients, and work then began at LHSC to change our communications and response plan for patients. While Windsor's position is understandable and put their patient's interests at the forefront, it created a very unfortunate situation in London where so many patients heard about the issue in the media first, causing major concern for a much larger group of cancer patients who had received chemotherapy treatment during the period in question, even though the majority of those were not affected.

On April 2, patient disclosure to active LHSC patients commenced. Supports such as toll free phone lines for pediatric and adult patients and an external web site were implemented. Throughout that day and the next, finalized letters were produced for known living patients. As well, attempts to reach all patients by phone were made to notify them of the supports available and the letters that they would receive over the coming days. In addition, several media interviews were provided that day to share what we could.

As calls from patients were received, patients in emotional crisis were escalated to receive immediate attention from their clinical teams. Several medical oncologists contacted patients directly. For deceased patients, best efforts were made to determine next of kin addresses and specific letters were prepared for them.

On April 8, 9 and 10, open forums were conducted, with over 300 patients and family members attending. The goal was to be open and transparent about everything we knew and to answer any questions they may have. Each session included a detailed presentation to explain the specific preparation processes for chemotherapy and how the overfill situation for the supplies received had impacted medication dosage. As well, a review of the chronology of the issue was provided and a presentation was made by medical oncologists to discuss clinical implications. Questions followed and each of the sessions lasted until all patient questions were addressed to the best of our ability.

On April 9, as part of its due diligence practice, LHSC initiated a second review to ensure that all possible patient impacts were captured in the initial assessment. During this review, it was discovered that the chemotherapy medications may have been used in the inpatient setting earlier than initially believed. This resulted from an internal transfer of the subject medications from the Cancer program pharmacy to the inpatient pharmacy, which occurred before the inpatient area began purchasing these medications directly from the supplier. An immediate review of records commenced and a further 26 potentially impacted patients were identified. These patients were notified by staff and physicians prior to the media announcement of this development on April 12.

At this point, a final patient tally was completed. All told, 691 patients were affected by this issue, 40 of whom were pediatric patients.

On April 15, LHSC received a verbal report from the Quebec laboratory to which it had sent a sample of the affected Marchese cyclophosphamide product. The lab report confirmed LHSC's internal finding in relation to the fluid overfill. The concentration of the medication was less than that of a properly reconstituted vial. Specifically, the concentration of Cyclophosphamide was 17.5mg/ml versus the target - if prepared accurately – of 20mg/ml.

Our focus now is on working diligently with all stakeholders to review this situation and help safeguard the system to prevent any recurrence.

I will now ask Sandy Jansen, Director of Pharmacy Services, to comment in more detail on our pharmacy processes.

Sandy Jansen:

Thank you, Neil. Pharmacy Services provided at LHSC are among the most comprehensive of any hospital in Canada. We employ nearly 250 people including 65 pharmacists and 150 pharmacy technicians.

Annually, pharmacy processes over 2 million medication orders; dispenses over 4.9 million unit doses; 18,000 bags of IV nutrition, 15,000 inpatient chemotherapy admixtures, and 600,000 IV admixtures.

Chemotherapy doses are prepared in two distinct pharmacy areas within the department. Dispensing for ambulatory patients occurs in a specialized pharmacy in our London Regional Cancer Program and for inpatients in a specialized pharmacy on our adult oncology ward. LRCP Pharmacy sees approximately 80 ambulatory patients per day and compounds on average 185 doses per day and nearly 44,000 doses per year. The Pharmacy department dispenses 20 doses per day for adults and 20 for children who are admitted to our hospital. All Pharmacists and pharmacy technicians receive special training and are certified before being allowed to work in the preparation and dispensing of chemotherapy.

The Pharmacy at LHSC utilizes the services of Medbuy, a Group Purchasing Organization. In the fall of 2011 a Request For Proposal for a variety of services was tendered by Medbuy. IV compounding services was one of the elements of this RFP. This resulted in a competition between three suppliers with the eventual selection of Marchese as the winner, with supply commencing to LHSC from Marchese in March 2012.

Since first receiving notification of the potential issue with these products on March 22, 2013, LHSC has taken the following steps to ensure the safety of its drug products:

- LHSC immediately stopped purchasing all externally sourced compounded IV products and made arrangements for all of these products to be prepared by LHSC Pharmacy staff

- Additional staffing and shifts have been added to accommodate increased workload

- No patient treatments were delayed or cancelled as a result of these changes

- LHSC initiated reconstitution volume checks on stock solution products and now keeps a running tally of expected volume of product used compared to actual volume of product used to account for usage and potential overfill

- As an added precaution, an internal review of all products compounded in-house is underway, with a focus on stock solutions and high risk items, including parenteral and other compounded products. Each process will be validated to ensure that appropriate controls are in place

As an academic health sciences centre, we want to use this experience as a shared learning opportunity and will engage other peer hospitals in the discussion of events and a sharing of best practices

Murray Glendining:

Thank you, Sandy.

I hope we have provided the committee with a better understanding of the circumstances surrounding this entire matter. I would like to reinforce that LHSC is supportive of, and actively collaborating with, Dr. Thiessen's review and will continue to review our processes and procedures to ensure complete safety of operations based on our learnings and this review process.

Our team will be pleased to answer any questions you may have to the best of our ability.