

LHSC is committed to providing information and ongoing updates to our patients and families in follow up to the chemotherapy dilution issue. In this update, we wanted to share the latest information we have on the status of the province's review into the chemotherapy dosage issue and further inform you on our approach.

As well, because your safety and the quality of care are our highest priorities, we are providing you with more detailed information about our chemotherapy medication preparation practices, so that you can have complete confidence that all of the right procedures are in place to ensure your safety.

What is happening provincially with the chemotherapy issue?

The Government of Ontario, Health Canada, and the Ontario College of Pharmacists have each proposed regulation changes that will ensure greater oversight of drug compounding as more is learned about the issue.

The Minister of Health has appointed an external expert reviewer - Dr. Jake Thiessen - to look at all issues concerning the chemotherapy dilution issue. He has met with LHSC for an entire day, reviewing all of our information, asking questions of staff and physicians and touring our chemotherapy preparation areas, as part of his broader review of this issue which is ongoing.

The Ontario Legislative Standing Committee on Social Policy has also convened review meetings on the issue. LHSC appeared before this committee on April 29, 2013.

More information can be found at:

www.lhsc.on.ca/drugdosage or
www.health.gov.on.ca/en/public/programs/cancer/drugs/apply/.

What is the LHSC Pharmacy doing to ensure this never happens again?

LHSC Pharmacies have the highest safety standards for preparing medications. On March 22, 2013 preparation of these two medications was moved into LHSC. We have canceled all contractual arrangements with the previous supplier.

The following extra safeguards have been implemented to ensure safe and accurate doses are provided to patients.

1. All chemotherapy medications are now prepared within LHSC by our specially trained pharmacy staff.
2. When bulk solutions (i.e. solutions that are used for more than one patient) are prepared, the pharmacy uses a process called an "Independent Double Check" to be certain the concentration is 100% accurate. An Independent Double Check means that a second staff member completely checks and validates the work of the first staff member.
3. A tally of doses used of stock solutions is recorded so that, should there ever be another discrepancy, it will be detected and corrected immediately.

What training do LHSC staff members receive to ensure safety and quality?

All chemotherapy drugs are prepared at LHSC by specially trained pharmacists and pharmacy technicians. Pharmacy staff must pass both a written and practical test before they are allowed to prepare chemotherapy for patients.

What standards do you follow to make my chemotherapy medications?

LHSC follows the very strict standards that have been established by Cancer Care Ontario, the Canadian Association of Pharmacy in Oncology, the National Institute for Occupational Safety and Health, the Canadian Society of Hospital Pharmacists and the American Society of Health System Pharmacists.

How do you prepare my chemotherapy?



Many steps are involved in making your chemotherapy which is why we use the Independent Double Check process at each critical point.

At LHSC, nine different specially trained staff members (including your physician, chemo nurse, pharmacists and technicians) work together to make sure your chemotherapy is correct, as follows:

1. **The doctor orders your chemotherapy.** After assessing your status, blood work and your body's ability to handle the chemotherapy, your doctor prescribes the name of the drug, specific dose, dates of treatment, method of administration, and the duration of the treatment.
2. **An oncology pharmacist then reviews the doctor's order for accuracy and completeness.** This thorough check even includes recalculating the indicated dosage to validate its accuracy. This ensures the correct drug is ordered at the correct dose at the correct time. Each pharmacist processes one order at a time, so each order gets their full attention.
3. **An oncology pharmacy technician then enters the order into the computer system.** The computer system prints a label, to be attached to the bag or syringe of chemotherapy once prepared.
4. **A second oncology pharmacist then double checks the order entry and the label.** This independent comparison of the original doctor's order to the printed label ensures all the information is accurate.
5. **A pharmacy technician then gathers the supplies.** With the order confirmed for accuracy, a technician gathers all the supplies needed to make your doses (drug, needles, syringes, alcohol wipes). A different technician will then use these supplies to prepare the dose. This allows the technician preparing the dose to work without any interruption while making chemotherapy.
6. **With all supplies at hand, a highly trained pharmacy technician then prepares the dose.** This specialized



chemotherapy preparation work is performed inside a biological safety cabinet to keep the chemotherapy preparation sterile (germ-free) and to limit contact

between the chemotherapy particles and pharmacy staff. All chemotherapy doses are specifically calculated for each individual patient. The technician uses a syringe to remove the exact chemotherapy dose needed and adds it to either a fluid bag or a syringe.

7. **A third technician checks the final product.** A specially certified technician performs a final check which includes a visual and verbal check with the technician who prepared the drug. During this process there are absolutely no distractions. The focus of both staff members is exclusively on your chemotherapy dose. Once confirmed to be correct, your dose is labeled and delivered to the nursing unit.

What happens after the chemotherapy is prepared and checked?

After the drugs are prepared and checked in the pharmacy, they are delivered to the chemotherapy suite or inpatient ward. Two nurses then perform independent final checks to make sure that it is your chemotherapy and that the label matches your doctor's order.

Why did LHSC not identify the issue with chemotherapy for 1 year?

The bags of chemotherapy solution previously provided to LHSC by the outside supply company were not specific to a single patient – they were stock solutions that contained enough medication to provide several doses that would be drawn from the bags for different patients.



It was not known to us that these bags from the supplier were improperly labeled. It has since been learned that these bags were overfilled, containing small amounts of extra saline liquid. This meant that the medication concentration was lower than indicated on the label. The small amount of extra liquid was very difficult to see with the naked eye and, because several people would withdraw small amounts from the bags to prepare individual doses for patients, this overfill went undetected.

At LHSC, our practice is never to mix drug products for patients from two different suppliers, so within our process, bags from two different suppliers would never have been in the work area at the same time. As we understand it, at Peterborough Hospital, a technician had a bag of medication from both the old and new suppliers, side by side in the work area, and noted differences in the labeling. He then diligently asked questions of the supplier, which led to the identification of this issue.