

Infusion Clinics in Ontario

Issue: What is the prevalence of private infusion clinics in Ontario and how are they regulated?

Private infusion clinics are facilities that administer infusion services for treatments that are not currently covered under OHIP. Information on utilization of infusion clinics is not tracked by the MOHLTC.

Oversight of private infusion clinics is limited and falls outside the scope of independent health facilities (IHF) and out-of-hospital premises (OHPs). Risks include biologic, quality and safety risks to patients.

In September 2015, HQO submitted to the Minister a report entitled, "Building an Integrated System for Quality Oversight in Ontario's Non-Hospital Medical Clinics." The recommendations included that IHF and OHP quality programs should be consolidated into a single regulatory model that can easily encompass procedures not currently regulated in existing programs.

s.12(1)

Background:

In November 2016 Health Canada received a complaint regarding the safe storage and handling of Remicade infusions for

- or patients with inflammatory conditions (e.g. rheumatoid arthritis, inflammatory bowel disease).
- The Health Canada complaint alleged that 'cold chain' temperature control protocols were broken when they were shipped in bulk to infusion clinics and stored in 'bar-type' fridges.
- 15 years ago Health Canada approved the administration of Remicade infusions in hospital outpatient clinics or doctors' offices but in recent years hospitals have stopped offering the service and private infusion clinics have filled the gap.

Current Status¹:

- Private infusion clinics are facilities that administer infusion services for treatments that are not currently covered under OHIP (i.e. they are administered in the out-patient setting) but may be covered under the Ontario Drug Benefit (ODB) Program. Some private clinics are stand-alone facilities operated by companies that distribute and/or dispense IV/injectable drugs and others may be physician offices.
- Private infusion clinics are accessed to receive drugs not covered by systemic funding.

Infusion Clinics in Ontario

Issue: What is the prevalence of private infusion clinics in Ontario and how are they regulated?

- Patients are receiving chemotherapy in private infusion clinics concurrently with or instead of funded treatment provided by the regional cancer facilities.
- Services may include medications and natural health products (e.g. naturopathic products).
- Patients receive care in a private infusion clinic either through:
 - Referral from their physician (i.e. physician refers, prescribes, and continues to monitor patient during course of treatments); or
 - Referral from patient (i.e. patients refer themselves and are cared for by the private infusion clinic exclusively).
- The infusion clinic model is the prevalent business model for administration of many biologics (and emerging biosimilars) in Canada.
- The Ontario College of Pharmacy assesses and accredits several types of pharmacies in Ontario. These include:
 - Community pharmacies and remote dispensing locations
 - Drug preparation premises
 - Hospital pharmacies
 - Private infusion clinics may or may not have pharmacies on site.
 - Only the private infusion clinics with a pharmacy and a pharmacist and/or pharmacy technicians providing services would be subject to the College's assessment. The college is not currently inspecting private infusion clinics.
- The College does not inspect private infusion clinics.

Funding

- Infusion clinics are supported by funding from pharmaceutical manufacturers of injectable/IV drugs. Drug companies contract with Specialty Pharmacy service providers to deliver Patient Support Programs (PSPs). The programs may include reimbursement support, pharmacy dispensing, distribution of the drugs to clinics, physician payments and infusion clinics where the drugs are administered.
- Under PSPs a professional fee may be paid to physicians for administration of a drug intravenously (IV) and a medical supervision fee may be provided for on call services. The companies claim these professional fees are not for Ontario Health Insurance Plan (OHIP) eligible services, and are not for dispensing of the drug.
- Although these administration fees may be attributed to reconstitution and/or administration only, they may be viewed as incentives for physicians to prescribe and administer select drugs. The availability of a PSP may also influence drug choice by physicians and impact patient access to treatment. Products that have a well-established PSP and associated network of physicians have a competitive advantage over new drug products that would have to establish their own separate PSPs.
- Larger PSP providers generally administer a number of different drugs under contract with different drug manufacturers and own accredited pharmacies to dispense the drug

Infusion Clinics in Ontario

Issue: What is the prevalence of private infusion clinics in Ontario and how are they regulated?

products. These Specialty Pharmacies as they call themselves, specialize in the sterile preparation and dispensing of injectable/IV drugs to the infusion clinics.

- Current pharmacy reimbursement policies in Ontario and other provinces provide a mark-up on the drug cost to cover pharmacy distribution costs. The injectable/IV products provided at the infusion clinics are generally high cost drugs that garner significant revenue for the Specialty Pharmacy through the mark-up. In Ontario, the mark-up on claims with drug cost greater than \$10000 was reduced from 8% to 6% in October 2015.

Prevalence

- MOHLTC does not track the use of private infusion clinics in Ontario.
- In 2017 the Regional Systemic Treatment Program (RDTP) facilities conducted a brief assessment for Cancer Care Ontario of private infusion clinic utilization for:
 - Physician-Referred Private Infusion Clinics
 - Of the 22 facilities who responded, 15 use infusion clinics.
 - According to RSTP, the volumes of patients accessing these private infusion clinics vary by site and may be as high as 20 patients per month. This number is only an estimate as there is no formal process to track referrals to private infusion clinics at cancer facilities.
 - Patient-Referred Private Infusion Clinics
 - Patients refer themselves to these clinics and utilization may not be known to the cancer team or to the RSTP facilities.

Risks:

1. Influence of Pharmaceutical Companies.

- Many private insurance companies will only fund therapies given in a private infusion clinic and not in a hospital setting.
- Many private insurance companies or pharmaceutical companies have agreements with specific private infusion clinics limiting where patients can get their privately funded treatments.

2. Biologics

- Biologics are one of the fastest growing classes of drugs reimbursed under the ODB Program. Once these drugs lose their patent, lower cost biosimilar products can be introduced. They are not like generic products and are not interchangeable with the originator biologic.
- Physicians may be influenced to prescribe a certain biologic.
- Physicians may be reluctant to switch to or start their patients on biosimilars due to fees paid to the physician by the brand manufacturer.
- The ministry's savings potential due to market entry of biosimilars may be less than expected if physicians continue to get administration fees for branded biologics.

3. Cancer

Risks to quality of care and patient safety may include::

Infusion Clinics in Ontario

Issue: What is the prevalence of private infusion clinics in Ontario and how are they regulated?

- Presence of a physician during administration of treatment varies among private infusion clinics.
- Patients may not be receiving drugs that have been prepared and stored in accordance with safe handling guidelines.
- Treatment may not be evidence-informed.
- Patients may be receiving medications dispensed by entities or pharmacies that are not regulated or accredited by the Ontario College of Pharmacists (OCP).

4. Regulation: Limited Oversight and Variable Standards

- Despite potential risks to patient safety, a growing number of privately funded procedures are being delivered outside hospitals with variable quality and safety standards, and with the regulation limited to those authorities health regulatory colleges have over their members.
- There is generally, no oversight of private infusion clinics. Private infusion clinics fall outside the scope of two important regulatory frameworks (independent health facilities (IHF) and out-of-hospital premises (OHP)) because they may offer services that are not publicly funded and/or do not require anesthesia or sedation.
- However, any regulated health professionals providing a service in an IV infusion clinic are subject to the oversight of their respective regulatory Colleges. Also, these sites would be subject to infection prevention and control standards and could be inspected against these standards by the clinic's local Public Health Unit.
- In September 2015, HQO submitted to the Minister a report entitled, "Building an Integrated System for Quality Oversight in Ontario's Non-Hospital Medical Clinics." The report contains 12 recommendations to improve alignment of current quality oversight programs for IHFs and OHPs.

s.12(1)

- To bring private infusion clinics under the CHF regime, a regulation would have to be passed identifying infusion clinics or their services as CHF services for the purposes of making them subject to the legislation.
- In addition, an inspection body would have to be identified to develop standards, hire inspectors, conduct inspections, prepare inspection reports and ensure compliance with quality and safety standards.

5. Funding Options:

- Further analysis is required to consider funding options to support appropriate oversight and consistent standards.

Infusion Clinics in Ontario

Issue: What is the prevalence of private infusion clinics in Ontario and how are they regulated?

Prepared by: Kim Lamers- Bellio, Senior Program Consultant
Branch/Division: Health Services Branch
Phone: 613-536-3009
Originated: August 8, 2017
Approved by: Kathryn Boone, A/Director, Health Services Branch

' Some material from a May 2017 Cancer Care Ontario (CCO) Briefing Note: '

