



The College of Naturopaths of Ontario

Inspection Committee Report

EnviroMed Clinic
88 Prince Arthur Avenue,
Toronto, ON
M5R 1B6

Following a review of the Inspector's Report and all other documentation pertaining to the 5-year inspection of the above premises conducted on March 2, 2023 the Inspection Committee has issued an outcome of a pass with conditions.

Conditions

The condition is:

1. As per Inspection Program Requirements 3.1: Tables 2 and 5 of the *General Regulation* are stocked for compounding for and/or administering by IVIT only when a delegation is in place, and 3.2: Drugs/substances not listed on Tables 2 and 5 of the *General Regulation* are stocked for compounding for and/or administering by IVIT only when a delegation is in place.

The Committee requires that the premises does not stock drugs/substances that are not listed on Tables 2 and 5 and must remove Travasol from the premises as it contains amino acids not included on Tables 2 and 5 and is not currently being administered under a delegation.

Recommendations

When Inspection Program Requirements are partially met and do not warrant a condition being placed on the premises, the Inspection Committee makes recommendations to the premises.

The Committee makes the following recommendations:

i) As per Inspection Program Requirement 1.2.8: A telephone, in person or online infectious disease screening protocol is consistently implemented when communicating with patients and scheduling appointments, and regarding the Policies and Procedures Manual 4.5.5: A telephone, in person or online infectious disease screening protocol used when communicating with patients and scheduling appointments.

The Committee recommends that a telephone screening protocol be developed, documented in the Policies and Procedures Manual, and used to screen patients with acute infections prior to when they arrive at the premises.

ii) As per Inspection Program Requirement 2.1.6: Spill kit is readily available to clean gross spills of blood.

The Committee recommends that a spill kit be assembled and readily available when needed to decontaminate gross spills of blood.

iii) As per Inspection Program Requirements 2.2.6: Cleaning and disinfecting of patient surfaces, equipment, and instruments is recorded in a cleaning log, 7.6: The cleaning and disinfecting log is kept up to date.

The Committee recommends that the log for cleaning patient surfaces, equipment, and instruments is used and kept up to date.

iv) As per Inspection Program Requirement 2.4.12: Equipment and Supplies Readily Available – snacks (crackers, fruit juices).

The Committee recommends that snacks such as crackers and fruit juices are readily available as an emergency supply.

v) As per Inspection Program Requirement 3.6: Once a multi-dose vial has been punctured, it is not used beyond the manufacturer's beyond-use date or 28 days, whichever is shorter.

The Committee requires that all multi-use vials are not used beyond 28 days, including when the manufacturer's beyond-use date is longer than 28 days.

vi) As per Inspection Program Requirement 3.12: Expired or contaminated drugs, substances and equipment are labelled and stored separately from current products, to ensure they are not used before being properly discarded. (May use the Ontario Medications Return Program).

The Committee recommends that all the IVIT drugs and substances inventory is regularly checked for expired products and that they are stored separately and appropriately labelled until being discarded.

vii) As per Inspection Program Requirement regarding the Policies and Procedures Manual 4.1.3: Scope and limitations of the services provided at the premises.

The Committee recommends that the Policies and Procedures Manual also contains the limitations of services provided at the premises.

viii) As per Inspection Program Requirement regarding the Policies and Procedures Manual 4.1.4: Descriptions for all premises staff who are involved with patients receiving IVIT that define the scope and limitations of their duties and responsibilities.

The Committee recommends that the Policies and Procedures Manual includes the names of all premises staff that are involved with patients receiving IVIT care.

ix) As per Inspection Program Requirement regarding the Policies and Procedures Manual 4.2.8: Handling and disposal of biomedical and non-biomedical waste.

The Committee recommends that the Policies and Procedures Manual clearly outlines how both biomedical and non-biomedical waste is to be handled and disposed of.

x) As per Inspection Program Requirements regarding the Policies and Procedures Manual 4.3.1: All staff are aware of what Type 1 and Type 2 occurrences are and, 4.3.2: All staff are aware of when and whom they must report Type 1 and Type 2 occurrences to.

The Committee recommends that the Policies and Procedures Manual includes a process to ensure that all staff are made aware of what Type 1 and Type 2 occurrences are, and how staff are to report Type 1 and Type 2 occurrences when they occur.

xi) As per Inspection Program Requirement regarding the Policies and Procedures Manual 4.4.10: How to ensure a regulated health professional accompanies the patient during the transfer.

The Committee recommends that the Policies and Procedures Manual section regarding the urgent transfer of patients contains procedures to ensure that a regulated health professional accompanies the patient during the transfer.

xii) As per Inspection Program Requirement regarding the Policies and Procedures Manual 4.5.4: Protocol for hand hygiene when performing IVIT procedures.

The Committee recommends that a protocol for hand hygiene to be followed when performing IVIT procedures be included in the Policies and Procedures Manual.

xiii) As per Inspection Program Requirement regarding the Policies and Procedures Manual 4.6.1: Processes to ensure completion of staff training for:

- infection prevention and control,
- proper use of personal protective equipment (PPE)
- proper hand hygiene,
- emergency procedures,
- waste disposal,
- inventory handling and storage,
- handling gross blood spills,
- cleaning equipment and patient surfaces, and
- other areas as determined by the premises.

The Committee recommends that the process for staff training outlined in the Policies and Procedures Manual includes recording when the training is completed and the staff members who have done the training.

xiv) As per Inspection Program Requirements regarding Quality Management processes included in the Policies and Procedures Manual, specifically:

4.7.2: Frequency and reasons for Quality Management Committee meetings.

4.7.3: Staff review of the Policies and Procedures Manual, at least annually.

4.7.4: Performance review of naturopath(s) who perform IVIT procedures.

- 4.7.5: Reviews that staff who are involved in delegated procedures are aware of and have met all requirements outlined in the *Standard of Practice for Delegation* and Part III of the *General Regulation*.
- 4.7.6: Performance review of non-medical staff involved in any of the premise's IVIT related processes and procedures.
- 4.7.7: Reviewing that staff are aware of and trained in the premise's emergency procedures, including use of the AED.
- 4.7.8: Reviewing that staff are aware of and consistently using the telephone, in person, and online infectious disease screening protocol when communicating with patients and scheduling appointments.
- 4.7.9: Reviewing that staff are aware of how and when to use personal protective equipment (PPE).
- 4.7.10: Reviewing that staff are aware of procedures to follow in the event of exposure to blood and body fluids.
- 4.7.11: Monitoring and evaluating the quality of patient care provided.
- 4.7.12: Tracking and reviewing patient outcomes.
- 4.7.13: Developing and implementing methods to improve patient care.
- 4.7.14: Identifying and correcting deficiencies in the premises' policies and procedures.
- 4.7.15: Reviewing all Type 1 and Type 2 reporting and record keeping requirements.
- 4.7.17: Selecting, at least annually, and reviewing 5-10 patient records to assess:
- quality of care to patients,
 - completeness and accuracy of entries,
 - documentation of informed consent,
 - appropriateness of treatment,
 - follow-up to abnormal laboratory test results, and
 - adherence to the Standard of Practice for Record Keeping.
- 4.7.18: Monitoring adherence to infection control practices pertinent to IVIT.
- 4.7.19: Monitoring proper cleaning procedures for patient surfaces and IVIT equipment.
- 4.7.22: Monitoring labelling and disposal of expired drugs, substances, and equipment.
- 4.7.23: Monitoring use of logs for inventory, cleaning, and maintenance.
- 4.7.24: Reviewing proper handling and disposal of all biomedical and non-biomedical waste.
- 8.1: The Quality Management Committee meets in accordance with the Policies and Procedures Manual.
- 8.2: Staff reviews the Policy and Procedures Manual at least annually.
- 8.3: Naturopathic doctor(s) performance is reviewed as it relates to IVIT processes and procedures.
- 8.4: Non-medical staff performance is reviewed as it relates to IVIT processes and procedures.
- 8.6: Reviews that all staff are aware of and trained in the clinic's emergency procedures, including use of the AED.
- 8.7: Reviews that staff are aware of and consistently use the telephone, in person, and online infectious disease screening protocol when communicating with patients and scheduling appointments.
- 8.8: Reviews that staff are aware of how to use personal protective equipment (PPE) in order to protect themselves and others.
- 8.9: Reviews that staff are aware of procedures to follow in the event of exposure to blood and body fluids.
- 8.10: The quality of patient care provided is monitored and evaluated.
- 8.11: Patient outcomes are tracked and reviewed.
- 8.12: Methods to improve patient care are developed and implemented.

- 8.13: Deficiencies regarding policies and procedures are identified and corrected.
- 8.14: Reviews that staff are familiar with Type 1 and Type 2 occurrences.
- 8.15: Reviews that staff have met the reporting requirements for Type 1 and Type 2 occurrences.
- 8.16: Reviews that staff have met the record keeping procedures for Type 1 and Type 2 occurrences that have happened.
- 8.18: At least annually, a random selection of 5-10 patient records is reviewed to assess for:
- adherence to the *Standard of Practice for Record Keeping*,
 - documentation of informed consent,
 - completeness and accuracy of entries,
 - appropriateness of treatment, and
 - follow-up to abnormal laboratory test results.
- 8.19: Reviews that accepted standards of infection control practices pertinent to IVIT are being followed.
- 8.20: Reviews that cleaning procedures are being followed and the cleaning log is properly maintained.
- 8.21: Reviews that IVIT and emergency equipment is being maintained and the maintenance log is properly maintained.
- 8.22: Reviews that drug and substance inventory is monitored, and the inventory log is properly maintained.
- 8.23: Reviews that drugs and substances are properly stored, and the refrigerator temperature log is properly maintained.
- 8.24: Reviews that expired drugs, substances, and equipment are labelled and properly disposed of.
- 8.25: Reviews that biomedical and non-biomedical waste is being handled and disposed of properly.

The Committee recommends that Quality Management Program processes be established and documented in the Policies and Procedures, including documentation of implementation of the Quality Management Program (e.g., who and when reviews are completed).

xv) As per Inspection Program Requirement 4.8.1: Processes to ensure the criteria for making a delegation as outlined in the *Standard of Practice for Delegation* and Part III of the *General Regulation* are met.

The Committee recommends that the Policies and Procedures Manual includes processes to ensure that all criteria are met when a Registrant makes a delegation. This includes:

- The Registrant put in place a communication plan between themselves and the delegatee that dealt with the appropriate management of any adverse events that could have occurred as a result of the delegation, and
- Appropriate documentation of the delegation is readily available. Documentation should include, but is not limited to, information such as the risk of harm and potential benefits of the procedure, the safeguards in place, education and qualifications of the delegatee, insurance coverage, the communication plan, date of the delegation and conditions under which the delegation occurred.

xvi) As per Inspection Program Requirements regarding the Policies and Procedures Manual 4.9.1: All forms used at the premises (e.g. intake forms, IV treatment form, consent, Type 1

occurrence report, Type 2 occurrence tracking), and 4.9.2: Template of all logs including inventory, maintenance, cleaning, refrigerator temperature, etc.

The Committee recommends that all forms used at the premises, such as intake, consent and IV treatment forms, as well as a copy of the templates used for all logs, are included in the Policies and Procedures Manual.

xvii) As per Inspection Program Requirement 5.1.7: The person performing the compounding follows proper hand hygiene at the beginning, and before donning gloves to compound under the laminar air flow hood in accordance with *PIDAC – Infection Prevention and Control for Clinical Office Practice*.

The Committee recommends that hands are always washed prior to putting on gloves when starting to compound under the laminar air flow hood.

xviii) As per Inspection Program Requirement 5.1.16: Gloved hands are disinfected with 70% isopropyl alcohol before re-introduction into the LAFH or after gloves have been in contact with a non-sterile surface during the compounding procedure.

The Committee recommends that gloved hands are always washed with 70% isopropyl alcohol before returning to compounding under the hood.

xix) As per Inspection Program Requirements regarding the labelling of the IV bag, specifically: 5.2.2: The Registrant's name and title, address, and telephone number,

5.2.6: The date that the IV bag was:

- prepared,
- administered to the patient, and
- the expiry date,

5.2.7: The directions for storage of the IV bag,

5.2.8: The directions for use of IV bag, including dose, frequency, route of administration and any special instructions, and

5.2.9: Any cautionary information about the drug or substance.

The Committee recommends that the premises ensures that it complies with all labeling requirements as stated in the Inspection Program Requirements and the *Standard of Practice for Compounding* by ensuring that the following is always included:

- Registrant name and title, premises address, premises telephone number,
- the date that the IV bag was administered to the patient,
- the directions for storage of the IV bag,
- the directions for use of IV bag, including dose, frequency, route of administration and any special instructions, and
- any cautionary information.

xx) As per Inspection Program Requirement 6.1.1: The patient is questioned regarding any change in their symptoms, medications, and supplements; consideration has been given to possible new contraindications and if additional diagnostic tests are needed.

The Committee recommends that the patient is always questioned prior to treatment regarding changes to their health, medications, and supplements.

xxi) As per Inspection Program Requirement 6.1.2: Informed consent is obtained, and all the patient's questions are answered.

The Committee recommends that prior to beginning every IVIT, informed consent is always obtained, and patients are given the opportunity to ask questions.

xxii) As per Inspection Program Requirement 6.1.3: The patient is verified for the IVIT treatment being administered.

The Committee recommends that it is verified that the IV bag being administered is for the correct patient.

xxiii) As per Inspection Program Requirement 6.1.7: The person administering the IVIT washes their hands and dons gloves.

The Committee recommends that before administering the IVIT, hands are always washed rather than using an alcohol-based hand sanitizer before donning gloves.

xxiv) As per Inspection Program Requirement 6.2.12: The patient's vital signs are monitored during treatment when indicated, or for infusions that take longer than 30 minutes to administer:

- blood pressure,
- heart rate,
- respiratory rate or pulse oximeter reading, and
- temperature (when indicated).

The Committee recommends that patient vital signs are always monitored during IVIT treatment that exceeds 30 minutes to administer.

xxv) As per Inspection Program Requirement 6.2.21: Appropriate post-treatment instructions are given to the patient including reporting to the ND any serious health events such as shock or convulsions, infections, allergic reactions, and adverse reactions. Also any unscheduled treatments as a result of the IV treatment, that may include a visit to a hospital emergency department, or another health care practitioner are to be reported.

The Committee recommends that post-treatment instructions are given to the patient and that it is noted in the patient chart.

xxvi) As per Inspection Program Requirement 9.4.2: Documentation in the form of a notation in the patient record or a consent form that is dated, signed, and witnessed.

The Committee recommends that the informed consent forms provided to patients are always witnessed.

xxvii) As per Inspection Program Requirement regarding Patient Chart Requirements 9.6.4: Patient's history regarding exposure to and infection from methicillin resistance organisms (MROs).

The Committee recommends that the patient's history regarding methicillin resistant organisms (MROs) is documented in their patient file.

xxviii) As per Inspection Program Requirements 9.7.1: Whether or not the patient has fears/anxiety around IVIT treatment, and 9.7.2: Whether or not the patient has a history of fainting due to needles.

The Committee recommends that the patient's chart includes documentation of being asked about their fears/anxiety around IVIT treatment and history of fainting.

xxix) As per Inspection Program Requirements regarding Patient Chart Requirements 9.7.3.11: Required information related to the delivery of intravenous treatment - Vital signs - blood pressure, heart rate, respiratory rate or pulse oximeter reading and temperature (when applicable); before, during and after treatment, and 9.7.3.12: Monitoring of patient during IVIT in addition to vitals.

The Committee recommends that the patient's blood pressure, heart rate, respiratory rate or pulse oximeter reading and temperature (when applicable) are taken before, during and after treatment and are fully documented in the patient's file. The patient is also to be monitored during IVIT which should be documented in addition to the vitals being taken.

xxx) As per Inspection Program Requirement regarding Patient Chart Requirement 9.9.1:
9.9.1.1 The date of the delegation.
9.9.1.2 The particulars of the delegation.
9.9.1.3 Any applicable conditions.
9.9.1.4: The communication plan to deal with the management of any adverse events that may occur as a result of the delegation.
9.9.1.7 Informed consent specific to the delegation.

The Committee recommends that the patient file includes all required information regarding accepting a delegation, including:

- The date of the delegation.
- The particulars of the delegation.
- Any applicable conditions.
- The communication plan to deal with the management of any adverse events that may occur as a result of the delegation.
- Informed consent specific to the delegation.