The College of Naturopaths of Ontario

# Inspection Committee Report

Stop the Clock Naturopathic Clinic
1553 Hurontario Street,
Mississauga, ON
L5G 3H7

Following a review of the Inspector's Report and all other documentation pertaining to the 5-year inspection of the above premises conducted on October 24, 2023 the Inspection Committee has issued an outcome of a pass with conditions.

Conditions

The conditions are:

1) As per Inspection Program Requirement 1.3.5: The AED is fully stocked, the AED pads are not expired, the battery is fully charged, and the unit is fully operational.

> The Committee requires that the AED pads are not expired and that a process, including creating and using a maintenance log, is in place to regularly check that the AED is fully operational.

2. As per Inspection Program Requirements 1.3.8: A crash cart is immediately available and fully stocked, and 2.3: Items Required on Crash Cart: IV tubing and administration sets and safety engineered needles.

> The Committee requires that administration sets and safety engineered needles are stocked on the crash cart.

3. As per Inspection Program Requirements 2.3.15: Items Required on Crash Cart: oxygen tank with regulator 0-10 L/min with mask or nasal canula.

> The Committee requires that the oxygen tank is fully functional, is inspected regularly for functionality and that is log is created and maintained to record this.

4. As per Inspection Program Requirement 3.5 Once a single-use vial has been punctured it must be used within 12 hours.

The Committee requires that all single-use vials are not used after 12 hours has elapsed since being punctured.

5. As per Inspection Program Requirements regarding the labelling of the IV bag, specifically:
5.2.3: The name of the person who compounded the IV bag, and the address and telephone number of the place where the bag was compounded, if different from above,
5.2.4: The names and strength of the drugs, substances, and any other ingredients used in the compounding, and the manufacturer if available,
5.2.5: The amount or percentage of each of the drugs, substances, and any other ingredients used to make the compounded product and the total quantity of the compounded product in the container,
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.

This inspection program requirement was deficient at the time of the previous inspection and a recommendation to remedy the issue was made by the Inspection Committee in the inspection outcome. Due to the deficiency not being remedied at the time of the 5-year inspection, the Committee requires that the following is always included on the iv bag label:

- premises address and telephone number,
- the strength of the drugs, substances, and any other ingredients used in the compounding,
- the amount or percentage of each drug, substances and any other ingredients used to make the compounded product,
- the date that the iv bag was prepared, and the date the iv bag was administered to the patient,
- the expiry date of the iv bag, even if the bag is to be used on the same day it is compounded,
- 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.

6. As per Inspection Program Requirements regarding the Quality Management Program:
8.1: The Quality Management Committee meets in accordance with the Policies and Procedures Manual.
8.3: Naturopathic doctor(s) performance is reviewed as it relates to IVIT processes and procedures.
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.
8.18: 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.

8.22: Reviews that drug and substance inventory is monitored, and the inventory log is properly maintained.
8.24: Reviews that expired drugs, substances, and equipment are labelled and properly disposed of.

> This inspection program requirement was deficient at the time of the previous inspection and a recommendation to remedy the issue was made by the Inspection Committee in the inspection outcome. Due to the deficiency not being remedied at the time of the 5-year inspection, the Committee requires that the Quality Management Program is reviewed to ensure it is complete and being implemented with respect to all requirements including those listed above.

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 1.3.3: Fire exits are clearly marked, and evacuation maps are prominently displayed in all patient areas.

> The Committee recommends that evacuation maps are easy to understand and clearly indicate where to exit in case of an emergency.

ii) 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.

> The Committee recommends that all drugs/substances are reviewed regularly for their expiration date and that once they are expired, they are labelled and then discarded appropriately such as through the Ontario Medications Return Program. Expired drugs/ substances are not to be stored in the refrigerator.

iii) As per Inspection Program Requirements regarding the Policies and Procedures Manual 4.2.5: Documentation for all equipment used for administering and compounding for IVIT:

- equipment operating manuals, where applicable,
- equipment maintenance contracts, where applicable,
- maintenance log, and
- inventory list.

> The Committee recommends that documentation in the Policies and Procedures Manual includes an equipment maintenance log, and an inventory list for all supplies used for administering and compounding for IVIT.

iv) As per Inspection Program Requirement regarding the Policies and Procedures Manual:

4.7.2: Frequency and reasons for Quality Management Committee meetings.
4.7.4: Performance review of naturopath(s) who perform IVIT procedures.
4.7.13: Developing and implementing methods to improve patient care.
4.7.14: Identifying and correcting deficiencies in the premises' policies and procedures.
4.7.17: 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.

4.7.22: Monitoring labelling and disposal of expired drugs, substances, and equipment,

> The Committee recommends that all Quality Management Program processes be established and documented in the Policies and Procedures Manual and implemented, including those listed above.

v) As per Inspection Program Requirements 5.1.2: LAFH is cleaned with sterile 70% isopropyl alcohol using a non-shedding/lint-free cloth or wipes before and after use and 5.1.9: All bottles, vials, containers, and equipment necessary for compounding are disinfected with 70% isopropyl alcohol using a non-shedding/lint-free cloth or wipes as they are placed under the LAFH prior to compounding.

> The Committee recommends that a new surface of the cloth is used for each wipe when cleaning the laminar air flow hood and for each item place under the laminar air flow hood.

vi) As per Inspection Program Requirement 5.1.4: Calculate osmolarity before compounding.

> The Committee requires that the osmolarity is always calculated and documented in the patient chart prior to compounding.

vii) As per Inspection Program Requirements 5.1.5: All needed bags, vials, and containers are collected and checked for beyond use date, concentration, leaks, defects that could compromise sterility, and abnormal appearance – cloudiness, colour, and precipitate, 5.1.15: Once compounded, the IV bag is checked for leaks, and abnormal appearance – cloudiness, colour, and precipitate and 6.1.5: Collect iv bags and inspect for leaks, cloudiness, colour, and precipitate.

> The Committee recommends that all vials and containers used before compounding, and the IV bag after it is compounded and prior to being administered to the patient are always checked for leaks, defects, abnormal appearance, and precipitate.

viii) As per Inspection Program Requirements 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*, 6.1.7: The person administering the IVIT washes their hands and dons gloves.

> The Committee recommends that hands are always washed prior to putting on gloves when

compounding and administering the IVIT.

ix) As per Inspection Program Requirement 5.1.8: The person performing the compounding dons a make, gown, and gloves at the minimum; (hair, shoe, and beard (when applicable) covers are optional).

The Committee recommends that in addition to wearing gloves and a gown while compounding, a mask is also worn.

x) As per Inspection Program Requirement 5.1.14: All drugs and substances are added to the iv bag and mixed well.

The Committee recommends that once the drugs and substances are added to the iv bag that it is mixed well.

xi) As per Inspection Program Requirement 5.1.19: The IV bag label is disposed of in a secure manner, such that any identifying information is destroyed or unreadable.

The Committee recommends that the iv bag label is always properly disposed of, and that any identifying information is either destroyed or made unreadable.

xii) As per Inspection Program Requirements 6.1.10: Pre-treatment vitals are taken, and 6.2.20: Post-treatment vital signs are taken:

- blood pressure,
- heart rate,
- respiratory rate or pulse oximeter reading, and
- temperature.

The Committee recommends that the patient's pulse oximeter reading is always taken prior to and after administering the IVIT and that their temperature is always taken prior to the IVIT, and taken after the IVIT when indicated.

xiii) As per Inspection Program Requirement 6.2.14: The angiocatheter/needle is checked to ensure it is intact and there is no breakage.

The Committee recommends that after removing the angiocatheter/needle it is always checked to make sure that it is still intact and there has not been any breakage.

xiv) As per Inspection Program Requirements 6.2.15: Pressure is applied with gauze or a cotton ball once the angiocatheter/needle is removed, and 6.2.16: A bandaid is applied or cotton ball taped down over the insertion site.

The Committee recommends that pressure is applied with gauze or a cotton ball once the angiocatheter/needle is removed, and that a bandaid is applied or cotton ball taped down over the insertion site.

xv) As per Inspection Program Requirement regarding Patient Chart Requirements 9.1.1: Registrant's name, clinic name, address, and telephone number.

The Committee recommends that the appointment record always contains the clinic's name, address and telephone number.

xvi) As per Inspection Program Requirement regarding Patient Chart Requirements – Patient Financial Record 9.2.2: Patient's name, address, and telephone number.

The Committee recommends that the patient's name, address, and telephone number are fully documented in the patient financial record.

xvii) As per Inspection Program Requirements regarding Patient Chart Requirements – Patient Financial Record 9.2.4: Fees for naturopathic consultation (billed separately from all other fees), and 9.2.5: Fees for supplements, injectables, etc. are itemized and separate from the naturopathic consultation fee.

The Committee requires that the naturopathic consultation fee is always billed separately from the fees for supplements, injectables, etc.

xviii) As per Inspection Program Requirement regarding Patient Chart Requirements 9.3.7: All written records are legible.

The Committee recommends that all written records are recorded legibly.

xix) 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.

xx) As per Inspection Program Requirement regarding Patient Chart Requirements 9.6.10: An assessment of the information collected and a diagnosis.

The Committee recommends that all patient charts always contain documentation of the assessment based on the information collected.

xxi) As per Inspection Program Requirement regarding Patient Chart Requirements 9.6.11: Proposed treatment plan.

The Committee recommends that all patient charts always contain documentation of the proposed treatment plan.

xxii) As per Inspection Program Requirement regarding Patient Chart Requirement 9.7.3: An IVIT specific form containing the following information:

9.7.3.8. Start time
9.7.3.9. End time
9.7.3.10: Drip rate
9.7.3.11. vital signs – blood pressure, heart rate, respiratory rate or pulse oximeter reading and temperature (when applicable); before, during, and after treatment.

The Committee recommends that patient charts consistently contain complete and accurate documentation of the following IVIT specific information:

- Dosage and frequency
- Start time
- End time
- Drip rate
- All vital signs – blood pressure, heart rate, respiratory rate or pulse oximeter reading and temperature (when applicable); before, during, and after treatment.