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New Brunswick College of Pharmacists
Ordre des pharmaciens du Nouveau-Brunswick

POLICY: ADMINISTERING AND INTERPRETING POINT OF CARE TESTS

REVIEW FREQUENCY: Every three years
RESPONSIBILITY: Pharmacy Practice

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DEFINITIONS

Critical value: A value/result that represents a pathophysiological state at such variance with normal (expected values) as to be life-threatening unless something is done promptly and for which some corrective action could be taken.[1]

Informed consent: Process by which a fully informed client can participate in choices about their health care. It originates from the legal and ethical right that the client has to direct what happens to their body and from the ethical duty of the pharmacist to involve the client in their health care.[2]

Medical device incident: A failure of the device or a deterioration in its effectiveness or any inadequacy in its labelling or in its directions for use, which has led to the death or a serious deterioration in the state of health of a patient, user or other person, or could do so were the incident to recur.[3]

Medication therapy management: A healthcare service provided by pharmacists and other healthcare professionals to ensure the best therapeutic outcomes for patients.[4]

Point-of-care test (POCT): A form of test where a specimen is collected from a patient by a healthcare professional and analyzed rapidly at the site of patient care. In the context of this policy, the test is performed to manage drug therapy. This policy excludes patient self-monitoring.

Quality Management Program (QMP): Documentation to support safe practice and facilitate adherence to professional standards and legislation requirements. Expectations are provided in the referenced document.[5]

Standard Operating Procedure (SOP): Documents containing directions to ensure safe and uniform usage of POCT.

PURPOSE

This policy outlines expectations of pharmacy professionals when administering and interpreting POCT to support the provision of patient care and specifically, medication management. Pharmacy professionals will apply expectations set out in this policy within the framework of legislation and policies applicable to pharmacy practice in New Brunswick.

INTRODUCTION

POCT involves health professionals sampling, testing, and interpreting results to obtain data relevant to managing drug therapy for patients with chronic conditions. Technology advancements have led to the expanded availability of point-of-care devices to facilitate monitoring at the site of patient care. Having such data may allow pharmacists to better understand patients' health needs.

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1. Lundberg G. (1972). When to panic over abnormal values. Medical Laboratory Observer, 4, 47 – 54.
2. New Brunswick College of Pharmacists. (2014). Pharmacists' Expanded Scope: Minor Ailments.

3. Medical Devices Regulations. (1998), SOR/98-282. Retrieved from the Justice Laws website: https://laws-lois.justice.gc.ca/eng/regulations/sor-98-282/page-1.html
4. Adapted from Centers for Disease Control and Prevention. “Community Pharmacists and Medication Therapy Management”. Available from: https://www.cdc.gov/dhdsp/pubs/guides/best-practices/pharmacist-mtm.htm.
5. New Brunswick College of Pharmacists. (2017). Quality Management Program.

The following policy sets out expectations for implementing POCT in pharmacy practice.

1. SCOPE OF PRACTICE

The *New Brunswick Pharmacy Act, 2014* denotes that pharmacy professionals may engage in administering and interpreting tests as designated by the regulations.
The *Regulations of the New Brunswick College of Pharmacists, 2022* authorize:

- Administration by pharmacists or pharmacy technicians on a direct client care register.
- Ordering, interpreting, and communicating results by pharmacists on a direct client care register.

The following points summarize the role of each professional when carrying out POCTs:

- Pharmacists may administer POCT for the purpose of managing medication for drug therapy in accordance with the *Regulations* and the *Model Standards of Practice for Pharmacists and Pharmacy Technicians in Canada.*
- Pharmacy technicians may only administer tests following a pharmacist assessment and confirmation that the test is appropriate. A pharmacy technician may administer a POCT under the supervision of a pharmacist on a direct client care register.
- Following administration, the pharmacist is responsible for interpreting and communicating the results to the patient.
- Professionals may only perform testing if they possess the knowledge, skill, and competencies to carry out the test and when satisfying the requirements of this policy.

2. REQUIREMENTS

- POCT must be performed for the exclusive purpose of managing a patient's medications.
- POCT can be conducted for specimens involving capillary blood (from finger prick), saliva, or urine.
- All devices and materials used when performing POCTs must be approved for use by Health Canada. Appendix A provides details on accessing such information.
- All equipment and devices used must be in working condition with quality control measures, including calibration completed regularly. As a component of the pharmacy's Quality Management Program (QMP), documentation of appropriate calibration and maintenance is to be retained in accordance with the *Regulations* (17.22).
- To prevent inaccuracy of results and risk to patient outcomes, POCT must follow the manufacturer's intended use for the device.
- Each device used for POCT must have a written standard operating procedure (SOP) that is consistent with expectations outlined in the QMP and requirements of the manufacturer. SOP's are to be updated regularly to optimize patient safety and promote alignment with best practices. An SOP template is provided in Appendix B.
- Clear referral criteria must be established considering critical values, patient safety, and available healthcare resources.
- Pharmacy professionals involved in testing must receive sufficient training and follow manufacturer directions along with their organization's SOP's. Training is an ongoing process where performance assessments are regularly completed to ensure continuing competency.

- The SOP is to contain documentation of the operator's training and competency prior to performing testing.

3. PATIENT ASSESSMENT

Prior to performing POCT, the pharmacist is to perform an assessment of the patient. The patient assessment must consider patient specific factors in conjunction with the purpose and limitations of the test, to deem whether the test is appropriate. With the goal of avoiding test duplication, this assessment must include a review of all readily available information resources. Information resources would consist of but are not limited to considerations for laboratory data on the patient's Electronic Medical Record. Informed consent is required prior to carrying out a test. It is the pharmacist's duty to convey any limitations, benefits, risks, and costs to the patient.

4. ENVIRONMENT

Pharmacy settings where POCT services take place must:

- Have a designated space for specimen collection that allows for adequate cleaning and infection control procedures. Professionals are directed to review and implement routine infection control practices set out in Appendix C.
- Provide enough space for patient privacy and safe workflow.
- Have appropriate disposal systems for sharps and biohazardous materials.
- Have personal protective equipment available as required per infection control protocol.
- Safely store devices and materials according to the manufacturer's operating conditions to maintain equipment functionality.

5. DOCUMENTATION

Documentation is to occur during or promptly after the POCT is carried out, and record, at a minimum, the following in the patient record:

- Patient consent.
- The test provided and the result.
- The action taken based on the interpretation of the test along with the rationale for the decision.

6. ACTION & FOLLOW-UP

A pharmacist is responsible for taking action on POCT results as well as subsequent patient monitoring and follow-up. A collaborative practice agreement is not required for performing POCT, however, action taken after the test must follow the professional's scope of practice. Professional judgement must be used to determine appropriate next steps based on test results.

After administration of a POCT, the following must be part of the POCT procedure:

- Interpretation of the test must be completed in the context of patient-specific factors based on information gathered during the assessment.
- Patients are to be informed of results in a timely manner, and decisions on a follow-up plan are to be discussed.
- Action must be taken on the test result. This may include altering the dose of a medication that is within the pharmacist's scope of practice, collaborating with another provider to prescribe or deprescribe, or developing a plan for ongoing monitoring. The decision to do nothing or not take action is a decision that is to be documented
- In the case an action falls outside of the scope of practice of the pharmacist or the patient requires assessment by another provider referral should be made to another professional who is deemed appropriate.
- Appropriate collaboration and communication is to be undertaken with other healthcare professionals responsible for treatment of chronic conditions relevant to the test performed.
- In the case of a critical value, professionals must use their professional judgement to determine if the patient requires referral to another provider for assessment.
- Maintaining a list of available community providers, facilities, or resources may assist in facilitating referral when such a case arises.

7. CONFLICT OF INTEREST

Pharmacy professionals may only carry out POCT services when it is determined to be in the best interest of the patient. Pharmacy professionals must perform POCT within the Code of Ethics framework where values-based decision making (VBDM) is to be applied.

APPENDIX A – Licenced devices

All materials used must have an active licence as listed on the Medical Devices Active Licence Listing found at the following webpage: https://health-products.canada.ca/mdall-limh/

Searches can be made by using the company name, licence name, device name, company ID, licence number, or device identifier.

Following confirmation of Health Canada approval all devices and equipment are to be documented in the standard operating procedure.

As per the Medical Devices Regulations, medical devices are classified based on risk category where the lowest risk is Class I and the greatest risk falling into Class IV.

Professionals may consider these risks to determine any inherent risk of using the device and mitigate risk where possible.

APPENDIX B- Standard Operating Procedure Template

The following Standard Operating Procedure Template is an example of the required items that must be documented and reviewed by staff involved in POCT services. A separate procedure must be available for each service or device offered and readily available for review. This template should be modified to effectively serve each practice site.

Standard Operating Procedure	
Title	**Date created:** **Date updated:** **Created by:**
Purpose	
Limitations	For example: Are there any populations that should be excluded from testing? Are there limitations to interpretations that can be made?
Performance Specifications	**Sensitivity:** **Specificity:** **Other Relevant Information (accuracy, precision, reliability):**
Name of Device	Are the device and equipment Health Canada approved? **YES** ☐ Device License Number:
Required equipment & materials	
Infection control measures	
Type of sample & appropriate collection/handling techniques	

Procedural steps on how to accurately complete the test	
Device calibration & quality control	**Calibration steps:** **Internal Quality Control:** **External Quality Control:** **Control Test Procedure:** **Frequency of Control Testing:**
Documentation of quality assurance	Date: _____ Performed by: _____ Steps taken:
Interpretation of results & considerations for critical values	
Process for notification of patient	
Storage & Stability	
Training requirements	
	Professionals trained to perform test: Name: _____ Date: _____ Limitations: _____ Documentation of ongoing training/ assessment: _____

APPENDIX C – Resources

The following list are educational materials that professionals may utilize to supplement one's knowledge. Reviewing these items are not mandated, however, it is the professional's responsibility to ensure necessary competencies are possessed to support safe patient care practices. Information contained within such resources may not be applicable to New Brunswick practice, professionals should use them within the context of New Brunswick legislation.

Educational Programs

Pharmachieve: Point-of-Care Testing by Pharmacy Professionals

- Overview of glucose, Haemoglobin A1C, lipids, and INR testing.
- https://pharmachieve.com/courses/all-courses

Canada's Drug and Health Technology Agency

Canada's Drug and Health Technology Agency: Evidence on Point-of-Care Testing

- This resource provides evidence-based synthesis of research on POCT.
- https://www.cadth.ca/point-care-testing-summary-evidence

Infection Control Measures

Health Canada Routine Practices and Additional Precautions for preventing the Transmission of Infection in Healthcare Settings.

- Provides evidence-based recommendations to support infection prevention in a healthcare setting.
- https://www.canada.ca/en/public-health/services/publications/diseases-conditions/routine-practices-precautions-healthcare-associated-infections.html