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Context

Point-of-care testing (POCT) refers to diagnostic tests performed at or near the patient's location by a health care professional or other qualified personnel.[1] This can include tests conducted by patients themselves in the home or community setting (i.e., patient self-testing).[2] POCT may be performed in a variety of settings, such as hospitals, clinics, physician's offices, pharmacies, ambulances, nursing and long-term care facilities, or the patient's residence.[1] It may be advantageous compared with conventional testing, because it allows increased staff and patient mobility, portability across community and rural settings, and rapid turnaround time for test results. These factors may expedite decision-making and patient management and increase efficiency of care.[3]

The use of POCT in health care has been growing in recent years and this trend is expected to persist in the future.[3] Amid this expansion, Canadian jurisdictions may be seeking ways to achieve appropriate and effective implementation of POCT in health care delivery. Questions remain on various issues, such as the reliability, safety, quality, and cost-effectiveness of POCT, and the implications for the health care system of wider POCT adoption.[2,4-8] In addition, a range of regulatory, organizational, and technological considerations need to be addressed to ensure that POCT is performed under predictable, efficient, and integrated conditions and according to the highest standards of quality.[2-8]

A number of Canadian and international standards specific to POCT exist, such as International Organization for Standardization (ISO) 22870[1] and Canadian Standards Association (CSA) CAN/CSA-Z22870-07;[9] however, it has been suggested that there is a need for a general framework to guide the comprehensive and optimal integration of POCT into the Canadian health care system. Furthermore, little is known about the current POCT practices and policies implemented across Canadian institutions. Accordingly, a CADTH assessment of POCT has been proposed. This Environmental Scan of the current context of POCT in Canada will inform a future comprehensive assessment and other work on POCT by CADTH.

Objectives

The primary goal of this Environmental Scan is to identify and analyze evidence and information regarding how POCT is implemented and managed in jurisdictions across Canada. The scope includes POCT performed in urgent and emergency care settings (such as in hospitals and ambulances), in primary care settings, and by patients (self-testing).

The key objectives of this Environmental Scan are as follows:

1. Describe the current state of POCT and how it is being implemented or planned in Canadian jurisdictions.
2. Identify Canadian and international standards, guidelines, and policies on POCT that are in effect or being developed in jurisdictions across Canada.
3. Describe the issues and challenges affecting POCT implementation in Canadian and international jurisdictions.

Methods

The findings of this Environmental Scan are based on a limited literature search, responses to the *CADTH Point of Care Testing Survey* gathered as of March 7, 2017 (Appendix 13), and targeted consultations.

The limited literature search draws upon grey literature sources (i.e., information that is not published commercially and not found in bibliographic databases), including websites of professional organizations and accreditation organizations in Canada and internationally. Grey literature was identified by searching relevant sections of the CADTH *Grey Matters* checklist (https://www.cadth.ca/grey-matters).

As a complement to the literature search, survey responses were collected from key respondents involved in POCT or laboratory services in Canada. The survey was initially sent to key informants in the Yukon, Nunavut, Northwest Territories, British Columbia, and Alberta on November 30, 2016, and to respondents in Saskatchewan, Manitoba, New Brunswick, Nova Scotia, and Newfoundland on December 1, 2016. Further responses were obtained through word of mouth or direct respondent referrals. The original cut-off date for survey responses was December 14, 2016; however, the survey was recirculated to the list of key informants on January 19, 2017 (January 20, 2017, for New Brunswick) and responses were received by March 7, 2017. Key informants were individuals from a variety of roles, organizations, and agencies across these jurisdictions, including, but not limited to, those working in laboratory services, blood and diagnostic services, home care, emergency medical services, and pathology.

To validate findings and fill gaps in knowledge, targeted consultations were conducted during May and June of 2017 with key stakeholders in the POCT community who provided both clinical and decision-maker perspectives on behalf of Canadian groups with insight into the POCT environment. The consultations were conducted by phone using an unstructured interview format.

Findings

The information presented on POCT practices and policies in Canada is based on a limited literature search, survey results from key informants (gathered as of March 2017), and targeted consultations with key stakeholders (during May and June of 2017). Of the 59 informants surveyed, 16 provided responses: 13 responses were complete and three were incomplete. Only feedback from respondents who gave consent to use their survey information for the purpose of this report was included. Respondents represented the following provinces and territories: Newfoundland and Labrador (one response), Alberta (two complete responses, one incomplete), British Columbia (three complete responses, one incomplete), Northwest Territories (one response), Manitoba (one response), Ontario (one incomplete response), and New Brunswick (five responses). No other provinces or territories were represented by survey responses. Information regarding the organizations represented by the respondents is noted in Appendix 14. Further information regarding the viewpoints and occupations of the respondents was unavailable.

For the purposes of this scan, point-of-care tests or testing (referred to as POCT throughout the document) is defined as "any testing conducted outside a lab, in a hospital, in a clinic or by a health care organization providing ambulatory care."[11]

The Current State of Point-of-Care Testing and How It Is Being Implemented or Planned in the Jurisdictions

Information pertaining to POCT implementation across Canadian jurisdictions is limited. One Canadian study was identified that examined POCT practices in a large tertiary care academic health care centre in Eastern Ontario (The Ottawa Hospital).[2] Other information presented was gathered from the survey responses received and from consultations with stakeholders.

Settings

Survey respondents were asked several questions regarding the current state of POCT in their jurisdictions. The first question asked whether point-of-care (POC) tests were used in a variety of health settings and how often; the results are presented in Appendix 1, with respondent jurisdictions indicated. The survey findings indicate variation across Canada, but suggest that POCT is being used in diverse settings. POCT was reported to be used most often in emergent and urgent care, hospital in-patient care, primary care, rural care settings, and for patient self-testing. There was an indication during consultations with decision-makers that some settings — home care settings and pharmacies, for example — want to utilize POCT technology, but do not have the infrastructure to support it.

Based on feedback gathered during consultation with the clinical laboratory community, many settings where POCT is performed may not be licensed or accredited as laboratories, as they are not required to do so. Consequently, they are not subject to the same quality standards and regulatory requirements as central laboratories. Some health care settings are also removing their lab licences as they move away from conducting centralized laboratory testing on-site. Instead, these sites may ship samples externally to central labs and continue to conduct POC tests on-site that do not currently require laboratory licensing.

Conversely, where POCT is conducted in a setting that falls under the responsibility of a central lab, the quality standards and regulatory requirements are maintained. An example of this is the central laboratory oversight of POCT programs within the Eastern Ontario Regional Laboratory Association (EORLA) group of hospitals in Ontario. Central laboratories within each EORLA site oversee POCT programs within their hospitals. Thus, the central lab maintains a presence by advising on quality assurance, quality control, and results documentation, among other factors (Dr. Julie Shaw, Canadian Society of Clinical Chemists, Ottawa, ON: personal communication, 2017 Aug).

Personnel

According to a study by Shaw (2016),[2] POCT is typically performed by non–laboratory-trained individuals, such as nurses, physicians, respiratory therapists, perfusionists, anesthesia assistants, midwives, and paramedics, as well as patients. CADTH survey respondents were asked about what types of personnel (e.g., doctor, nurse, laboratory specialist, pharmacist, other health care provider) perform POCT in various settings; the responses are compiled by jurisdiction in Appendix 2. Based on the survey responses, nurses are the most common profession performing POCT. Other health professionals — including physicians, medical laboratory assistants and technologists, physicians' assistants, registered respiratory therapists, and those staffed in emergency medical services — were also noted to be involved in performing POCT; however, due to the high volume of non-responses, it was difficult to draw further conclusions.

Consultation with the clinical laboratory community substantiated that a broad range of occupations, including respiratory technologists and paramedics, have been involved in administering POCT (Dr. Julie Shaw: personal communication, 2017 Aug). Manitoba noted during consultation that the expectations within health practitioners' roles will evolve with the proliferation and availability of POCT (Michele Mathae-Hunter, Manitoba Health, Seniors and Active Living, Government of Manitoba, Winnipeg, MB, personal communication, 2017 Aug).

Process

Oversight

In Ontario, POCT performed in a hospital "falls under the responsibility of the laboratory and is subject to laboratory accreditation requirements."[2] Thus, although the testing is typically performed by non-laboratory personnel, in some settings the laboratory nevertheless remains accountable for ensuring that the testing complies with laboratory accreditation standards.[2] Feedback from consultation with the clinical laboratory community indicated that there is concern about the potential for erosion in the quality of testing with the movement of POCT from central laboratories due to limited understanding of quality assurance, quality control, and pre-analytic factors by the clinical staff who perform testing as well as owing to limitations with regards to the instrumentation available (Dr. Julie Shaw: personal communication, 2017 Aug).

Ordering

In practice, POCT in the hospital setting is "rarely performed as the result of a direct physician order."[2] The testing is often performed in emergency situations to facilitate rapid clinical decision-making; often, the choice to perform POCT is made by a nurse or other clinical team member in the moment.[2] The majority of POCT at The Ottawa Hospital is performed under medical directives (defined by The Hospital for Sick Children (SickKids) in Toronto as an "indirect physician order, used to expedite patient care by competent health professionals").[2,12] The Ottawa Hospital has a corporate policy regarding medical directives. It dictates that the "health care professional who initiates the medical directive must document this on a physician order sheet indicating which directive has been initiated, along with their signature and professional designation."[2]

Recording

In a survey conducted by the Canadian Society of Clinical Chemists reported within the study by Shaw et al., more than half of respondents (POCT coordinators and medical or scientific directors for POCT from 17 Canadian hospitals ranging in size from 100 to 1,300 beds) described using paper charting, rather than alternative (e.g., electronic) charting methods, to report POCT results in their institutions.[2] The lack of adequate documentation mechanisms and processes was reiterated during consultations with the clinical laboratory community, whose feedback included the issue that there is generally poor documentation of POCT results, poor infrastructure to allow results to be incorporated into patient charts, and poor mechanisms to support the transfer of information between sites. There were concerns that these challenges may contribute to repetition, unnecessary costs, and patient safety issues. It is possible that POCT operations with central laboratory oversight could achieve connectivity to the lab's documentation systems, leading to more consistent and appropriate charting of results, including the information necessary for proper interpretation of the results (i.e., reference intervals and units of measurement) (Dr. Julie Shaw: personal communication, 2017 Aug). Issues with documentation have been noted in the literature. An example is POC ultrasound, for which there is evidence of poor documentation. This can lead to health care practitioners being unable to confirm diagnoses.[13]

Training and Certification

Training and certification for personnel performing and overseeing POCT across jurisdictions is not standardized and appears to vary by setting in terms of factors such as the requirement for retraining or recertification and the oversight of training.

The Shaw 2016 study reported that medical laboratory personnel at The Ottawa Hospital in Ontario have developed online training modules for the majority of POCT devices in use.[2] The modules are assigned to personnel operating POCT by the POCT team, and are accessible through the hospital's e-learning system. Operators are required to pass a 10-question quiz at the end of each module and must complete all of the training modules to obtain certification. Operators also use the online training modules as part of the annual recertification process. The online training modules can be updated annually to include any changes to POCT policies and procedures. Operators who perform one patient test and a set of quality control tests within their one-year annual certification window are automatically recertified on an annual basis; for operators who perform patient testing at regular intervals, certification does not expire. Operators who do not meet the auto-certification criteria are required to regain their certification by successfully completing the online training modules and exam, and quality control testing.[2]

Capital Health, a regional health authority in Nova Scotia, provides POCT training in part through online course modules including orientation to POCT and specific training on POC glucose meters, which lasts approximately 1.5 hours in total.[14] The training is offered to "all healthcare providers who perform POCT within the organization." Its completion is required to meet accreditation standards.[14]

CADTH survey respondents were asked what type of training or certification was required for personnel to perform POCT in their jurisdiction or institution. Thirteen respondents representing seven jurisdictions answered this question (Appendix 3). Based on the survey responses, POCT training and certification appears to vary across institutions, with many designing and implementing their own training programs. In general, the responses showed a trend toward training being provided by specific POCT staff or laboratory staff in a variety of formats, including online and hands-on training modules. In addition, survey responses indicated that some type of certification is often required (e.g., quizzes or competency testing), with the most common period of recertification being annually, where indicated.

Consultation with the clinical laboratory community emphasized the importance of providing training to POCT users for each individual instrument, rather than simply offering general POCT training. Further, the importance of providing education on pre-analytical factors (e.g., sample collection and preparation) was noted as important for its impact on quality and integrity (Dr. Julie Shaw: personal communication, 2017 August). The lack of laboratory training for staff who perform POCT has previously been suggested in the literature to be problematic because it "implies a lack of understanding of the principles of laboratory assays and good laboratory practices for ensuring the reliability of test results."[2,15]

Purpose of Point-of-Care Testing

Survey respondents were also asked to describe the purpose of POCT in their jurisdictions or institutions; answers from 14 respondents across seven jurisdictions are listed in Appendix 4. Based on survey responses, POCT is frequently performed with the intent to reduce turnaround time and expedite clinical decision-making, to increase patient convenience, and to provide access to testing in remote or rural settings or for patients in outpatient settings. The value of POCT tests in improving accessibility — serving the patient at the preferred time and place — was also noted during consultation with the clinical laboratory community (Dr. Julie Shaw: personal communication, 2017 August).

Funding for Point-of-Care Testing

Fifteen respondents from seven jurisdictions explained how POCT was funded in their province or territory (Appendix 5). Given the variability and low frequency of the responses, it was difficult to draw any conclusions regarding POCT funding across jurisdictions. Respondents noted that funding came from provincial health care budgets, health care facilities' operational and global budgets, vendor funding, laboratory services budgets, fee-for-service models, and patients paying out-of-pocket.

Point-of-Care Tests in Use in Canada

The availability of public information about tests used for POCT varies among provinces and territories. Only two provinces, Alberta and British Columbia, distinguished between POCTs that require laboratory accreditation and those that do not in publicly available provincial laboratory standards issued by the Colleges of Physicians and Surgeons.[16,17] Appendix 6 presents a summary of publicly available information gathered on tests used in POCT across jurisdictions, as well as accreditation requirements for specific tests, as they were stated in the source documents. Tests in use include blood-based tests, breath-based tests, and urine- or feces-based tests, among others. Among POCTs identified through a grey literature search as currently available across jurisdictions, the most common were the blood glucose test, the urine dipstick test, and the HIV-I and HIV-2 antibody test.

Point-of-Care Tests in Use Internationally

Two articles identified in the literature search examined POCT in primary care and emergency departments in international settings.[18,19] Findings are presented in Appendix 7 for comparison with the tests administered across Canadian jurisdictions. It should be noted that these lists are based on limited information, and do not represent a comprehensive inventory of all POC tests offered across Canadian or international health care institutions.

Canadian and International Standards, Guidelines, and Policies on Point-of-Care Testing in Effect or Being Developed in Jurisdictions Across Canada

Canadian Standards and Guidelines Related to Point-of-Care Testing

Canada does not have national mandatory accreditation requirements for clinical pathology laboratories and POCT.[10] Laboratory quality is largely a provincial responsibility; therefore, laboratory regulation and accreditation varies across the country.[10] Provinces and territories rely on laboratory and POCT oversight and management from provincial regulatory bodies, such as the provincial Colleges of Physicians and Surgeons and Colleges of Medical Laboratory Technicians, as well as accreditation from various accreditation bodies that survey clinical services in Canada, including Accreditation Canada, the Standards Council of Canada, and the Institute for Quality Management in Healthcare (IQMH).[10] Consultation with the clinical laboratory community noted the availability and use of IQMH guidance, as well as guidance by Accreditation Canada, which recommends that those administering POC tests be registered health professionals and receive adequate training (Dr. Julie Shaw: personal communication, 2017 Aug).

The international standard for POCT was developed by the International Organization for Standardization (ISO) in the form of ISO 22870:2016 *Point-of-care testing (POCT) – Requirements for quality and competence* standard as a companion to ISO 15189:2012 *Medical Laboratories – Requirements for Quality and Competence* standard, which laboratories need to meet prior to being able to obtain POCT accreditation.[1,9,20] The ISO 22870 standard specifies requirements for quality and competence in POCT performed in a hospital, clinic, or health care organization providing ambulatory care, and excludes patient self-testing in a home or community setting.[1] The ISO 22870 standard has been adapted to the Canadian setting by the Canadian Standards Association (CSA) in the form of CAN/CSA-Z22870-07 (R2013), which covers transcutaneous measurements, the analysis of expired air, and in vivo monitoring of physiological parameters in addition to the requirements covered by ISO 22870.[9] Based on publicly available information, Canadian medical laboratory accreditation organizations appear to generally base their requirements for quality and competence on ISO15189 (as well as ISO 22870 or the CAN/CSA- Z22870-07 [R2013] for laboratories seeking POCT accreditation).[9,11,21-24] Similarly, publicly available information indicates that provincial laboratory standards typically either outline their own requirements, and/or make explicit reference to ISO standards or standards followed by a particular accreditation organization (e.g., Accreditation Canada, which follows the ISO standards outlined above).[1,9] Appendix 8 summarizes laboratory and POCT standards used by Canadian accreditation bodies as well as the jurisdictions they accredit.

Based on publicly available information, certain provinces, such as Alberta, Saskatchewan, and Manitoba, rely on their provincial Colleges of Physicians and Surgeons[25-28] to set standards for laboratory quality that encompass POCT, whereas British Columbia's College of Physicians and Surgeons outlines detailed POCT standards through its Diagnostic Accreditation Program's *Laboratory Medicine Accreditation Standards*[29] document. In Alberta, the College of Physicians and Surgeons of Alberta accredits and endorses the use of POCT when it is carried out under the supervision of an accredited laboratory; however, it does not pursue accreditation status for a small number of tests (e.g., urinalysis dipstick screening and glucose meters) performed traditionally by physicians in their offices for their own patients.[16] The College of Physicians and Surgeons of Alberta also provides guidelines for non-laboratory physicians who perform POCT, which cover topics such as documentation, staff training, and quality control.[16,25,26,29]

The guidelines for POCT in unaccredited settings were updated in June of 2017, but because of the search time frame, the update is not captured within this report.[30] A comprehensive list of provincial, national, and international organizations pertaining to laboratory quality management can be found on the Canadian Society of Clinical Chemists website.[31]

Adherence to Standards

Appendix 9 outlines Canadian and/or international standards (including guidelines and policies) for medical laboratory competence and POCT, as well as the designated laboratory accreditation bodies for each Canadian jurisdiction gathered from a grey literature search, CADTH survey respondents, and stakeholder feedback from the College of Physicians & Surgeons of Alberta. As part of the CADTH survey, respondents were asked whether their jurisdiction or institutions adhered to Canadian or international standards in implementing POCT. Of the 14 respondents who answered this question, all reported "yes;" however, only 12 provided a description of the standards to which they adhere. Publicly available information on laboratory and POCT standards and guidelines was not identified for the Northwest Territories, Yukon, or Nunavut. Full descriptions of all standards relevant to POCT are presented in Appendix 10.

Governance Structures

Survey respondents were also asked about POCT-specific governance structures, legislation, frameworks, guidelines, policies, or processes that are in place or being developed in their jurisdictions; responses are provided in Appendix 11. Governance is currently carried out by provincial POC oversight groups in several jurisdictions or by local health authorities or laboratory groups, or is in development. Legislation, where referenced, is generally captured under existing laboratory frameworks or related to accreditation standards. Frameworks related to POCT quality are in development in some jurisdictions. Formal guidelines in use include those issued by the College of Physicians and Surgeons of Alberta and College of American Pathologists. Policies are established or in draft in many jurisdictions, and POC processes exist at the provincial and local level. In general, based on survey responses, structure for oversight and management of POCT appears to be largely in development and there is interest in standardization.

Point-of-Care Testing Training Standards

Information on POCT training standards across the jurisdictions was publicly available for the provinces of British Columbia, Nova Scotia, Manitoba, and Quebec.[27,32,33,34]

- British Columbia's Diagnostic Accreditation Program requires that POCT be performed in an organization that can provide an appropriate theoretical and practical training program, a competency assessment, and procedures for dealing with non-compliant POCT operators, and that POCT be performed by personnel who have completed training and demonstrated competence.[34]
- Nova Scotia's College of Medical Laboratory Technologists statement on POCT outlines the responsibilities of the POCT program testing manager, which include the development, implementation, and maintenance of a training and competency assessment program for all POCT personnel.[32] Furthermore, the College requires collaboration between a licensed medical laboratory technologist and other relevant health professionals in developing the POCT training and competence program.[32]

- In Manitoba, the *Manitoba Laboratory Standards,* which are issued by the provincial College of Physicians and Surgeons, state that a laboratory facility must "provide competency based safety training for all new employees as part of the orientation process."[27] It is unclear whether this encompasses POCT training.
- In Quebec, *Quality in Biomedical Laboratories Rules of Practice* states that the head of the biomedical department is responsible for establishing a multidisciplinary committee on POCT which, in turn, would develop a program of theoretical and practical training "appropriate for all personnel involved in POCT."[33] The *Rules of Practice* require that only those personnel who have completed their training can perform POCT.[33]

Canadian Standards Advising Who Can Perform Point-of-Care Testing

Publicly available information on standards specifying who should be able to perform POCT was identified for the provinces of British Columbia and Nova Scotia.[32,34]

British Columbia's Diagnostic Accreditation Program posits that its standards "do not define any specific occupational groups that can or cannot perform POCT" [34] beyond the training requirements noted in the previous section.

In Nova Scotia, the Nova Scotia College of Medical Laboratory Technologists is responsible for regulating the practice of medical laboratory technology and governing its members in "accordance with the *Medical Laboratory Act* and the regulations."[32] The College requires laboratory guidance and oversight of all POCT programs and activities by a licensed medical laboratory technologist, given that POCT can be performed by health professionals other than medical laboratory technologists.[32] Furthermore, the College mandates that POCT be "prescribed by an authorized practitioner and all results must be included into the client record,"[32] and requires POCT operators to have "education and training in the quality control procedures and knowledge of the analytical concept."[32]

Consultation with the clinical laboratory community also supported the suggestion that testing be conducted by certified health care professionals who have been trained and have demonstrated competence, and having laboratory personnel (e.g., laboratory technologists) present as part of the POCT care team. This may be particularly beneficial in the hospital environment, as such personnel may bring with them knowledge in quality standards, conduct, and reporting of laboratory testing, as well as linkages to central laboratory infrastructure (Dr. Julie Shaw: personal communication, 2017 Aug).

International Standards and Guidelines Related to Point-of-Care Testing

Publicly available information on laboratory and POCT standards and guidelines was identified for several countries besides Canada (the US, Australia, New Zealand, the UK, and the Netherlands) to provide an indication of current international context and trends in POCT and to compare differences and similarities in laboratory standards in use. Like Canada, some countries use ISO 15189 as the basis for accreditation for pathology laboratories and ISO 22870 as the accreditation standard for POCT, as well as their own developed standards for laboratory practice and POCT.[35-59] Key standards, guidelines, and accreditation organizations in each country are subsequently presented.

United States

In the US, the Centers for Medicare and Medicaid Services regulates all laboratory testing performed on humans (except research) through Clinical Laboratory Improvement Amendments (CLIA). The CLIA program is implemented by the Division of Laboratory Services within the Survey and Certification Group under the Center for Clinical Standards and Quality with the objective of ensuring quality laboratory testing.[35] Based on publicly available information, organizations such as the Clinical and Laboratory Standards Institute (CLSI) publish laboratory standards and guidelines that extend beyond federal regulations; groups like the National Academy of Clinical Biochemistry and the official Academy of American Association for Clinical Chemistry provide recommendations and practice guidelines for best practices in laboratory medicine, such as evidence-based laboratory medicine practice POCT guidelines.[15,35] Lastly, gathered information suggests that the College of American Pathologists, American Association for Laboratory Accreditation, and similar organizations provide accreditation services to clinical laboratories that meet CLIA requirements and CLSI standards, among other regulations.[15,35,39,60]

CLSI provides consensus-based clinical laboratory standards for POCT in the form of guidelines for specific tests (e.g., glucose measurements) and general provider guidelines.[36] CLSI standards are subsequently adopted by private and jurisdictional accreditation organizations like the College of American Pathologists in the US and British Columbia's Diagnostic Accreditation Program in Canada.[29,38] Examples of CLSI standards relevant to POCT include:

- *CLSI POCT04-Ed3: Essential Tools for Implementation and Management of a Point-of-Care Testing Program, 3rd Edition*. Clinical and Laboratory Standards Institute; 2016[36]
- *CLSI POCT07-A: Quality Management. Approaches to Reducing Errors at the Point of Care*. Clinical and Laboratory Standards Institute; 2010[36]
- *CLSI POCT09-A: Selection Criteria for Point-of-Care Testing Devices*. Clinical and Laboratory Standards Institute; 2010[36]

The College of American Pathologists (CAP) offers laboratory accreditation through its Laboratory Accreditation Program that helps to meet CLIA regulatory requirements, as well as CAP 15189, which is a quality management program that offers accreditation to ISO 15189.[60] As well as enforcing CLIA accreditation requirements, CAP requires laboratories to document quality control and operator competency for waived as well as non-waived testing.[60] To help laboratories meet their CAP accreditation requirements, CAP publishes a *Point-of-Care-Testing Checklist* that outlines laboratory accreditation components, as well as CAP standards specific to provider-performed testing, including a section on which tests can be performed.[38] Based on the examined information, provider-performed testing appears to encompass similar principles related to POCT performed by physicians on their own patients, as discussed in the College of Physicians and Surgeons of Alberta's *Unaccredited Point-of-Care Laboratory Testing Guideline for Physicians*.[37,38]

The American Association for Laboratory Accreditation offers several accreditation programs for clinical laboratories performing moderate- or high-complexity testing (as defined in 42CFR493, the federal government publication on laboratory requirements) based on CLIA, ISO 15189:2012 or American Association of Blood Banks standards; POCT accreditation is offered for clinical laboratories performing moderate- or high-complexity POCT.[39] The American Association for Laboratory Accreditation bases its POCT requirements on the ISO 22870 and ISO 22870:2012 standards and assesses a sample of the applicant laboratory's POCT services as part of its POCT accreditation.[39,40]

Australia

In Australia, the National Pathology Accreditation Advisory Council (NPAAC) is the principal provider of standards for pathology. It provides guidelines for POCT in regards to governance; preparation, specimen integrity, and individual test records; testing considerations; staff training; quality systems; environment; and workplace health and safety.[42,42,46,47] NPAAC has several publications related to accreditation of pathology laboratories:

- Requirements for Medical Pathology Services (First Edition 2013)[61]
- Requirements for the Supervision of Pathology Laboratories 2007 Edition[62]
- *Requirements for Enrolment and Participation in External Quality Assessment (Fifth Edition 2013)*[63]

Standards Australia also plays a significant role in developing national laboratory pathology standards in Australia and disseminating the standards developed by ISO.[42] In particular, Standards Australia reproduced ISO 15189 as Australian Standard AS 4633-2004, *Medical laboratories – Particular requirements for quality and competence*, which is regarded by NPAAC as the principal standard to be used as the basis for accreditation of pathology laboratories in Australia.[48] "In addition to coordinating activities with ISO, Standards Australia may develop specialized standards in its own right for 'local' applications," [42] such as AS 4760-2006, *Procedures for specimen collection and the detection and quantitation of drugs in oral fluid* and AS/NZ 4308-2008, *Procedures for specimen collection and the detection and quantification of drugs of abuse in urine*.[42,48-51]

Lastly, the Australasian Association of Clinical Biochemists and the Royal College of Pathologists of Australasia provide professional guidelines for POCT in Australia.[52,53]

New Zealand

New Zealand Best Practice Guidelines, published by the New Zealand Point-of-Care Testing Advisory Group, state that accreditation against ISO 15189:2012 and ISO 22870:2006 standards is not mandatory in New Zealand, but that it does "provide objective endorsement of the organization's overall quality management system for POCT and of competency to perform the testing and is recommended (where practical), for health providers who use POCT."[56] Pathology laboratories in New Zealand can obtain accreditation through International Accreditation New Zealand, which provides medical laboratory accreditation against ISO 15189:2012 as well as accreditation for specific criteria, such as POCT, which is accredited against ISO 22870.[55]

United Kingdom

Every member state in the European Union has a single national accreditation body, based on legislation.[54] The United Kingdom Accreditation Service (UKAS) is the UK's national accreditation body; Clinical Pathology Accreditation (CPA) recently became a wholly owned subsidiary of UKAS, and UKAS is currently in the process of transitioning CPA-accredited laboratories to UKAS accreditation against ISO 15189.[54,57] UKAS's Medical Laboratory Accreditation Program is based on ISO 15189:2012, and organizations can obtain POCT accreditation against ISO 22870:2006 in conjunction with ISO 15189.[54,57]

In Scotland, the Scottish Medical and Scientific Advisory Committee produced specific guidance regarding POCT entitled *Review of the Use of Point of Care Testing in Primary and Secondary Care in Scotland: A Report by a Short Life Working Group of the Scottish Medical and Scientific*

Advisory Committee, which provides recommendations but does not reference ISO standards.[58] Country-wide recommendations for general POCT use could not be identified for England, Wales, and Northern Ireland; however, publicly available information was identified for several hospitals and hospital trusts that have developed their own policies and standards regarding POCT, generally requiring that POCT follow the accreditation standards outlined by the CPA (now UKAS), which are based on ISO 15189 and ISO 22870.[59,45,44] Some examples are as follows:

- Wales — *Aneurin Bevan University Health Board Governance Policy for Point of Care Testing* [59]
- England — *Doncaster and Bassetlaw NHS Foundation Trust Point of Care Testing Policy and Guidelines* [45]
- Northern Ireland — *South Eastern Health and Social Care Trust Point of Care Testing (POCT) Policy* [44]

Netherlands

In the Netherlands, the Dutch Accreditation Council is the national accreditation body that provides accreditation and proficiency testing to medical laboratories and POCT accreditation, based on ISO 15189 and ISO 22870, respectively.[64] The National Institute for Public Health and the Environment, Ministry of Health, Welfare, and Sport, conducts research on the use of POCT in settings like primary care and nursing homes, and offers recommendations regarding the use of POCT.[41,43,64]

Issues and Challenges Affecting the Implementation of Point-of-Care Testing

Canadian Challenges

Challenges related to POCT relevant to the Canadian context were summarized from survey responses, literature review, and consultations with a policy decision-maker and a member of the clinical laboratory community. Common themes are subsequently presented.

Eleven survey respondents shared their views on the issues or challenges faced by their jurisdictions or institutions in the implementation of POCT, as well as what opportunities exist to enable the implementation of POCT. Common challenges pertained to cost, connectivity, operator proficiency, and roles and responsibilities with regards to POCT. Summarized responses across jurisdictions are listed in Appendix 12.

In addition, the literature review identified two studies that were relevant to this section of the report.[2,8] Shaw (2016) reported the results from a survey by the Canadian Society of Clinical Chemists that collected information about hospital POCT practices across Canada.[2] Aslan (2014) describes challenges related to POC glucose testing based on data from Ontario laboratories through the IQMH POC glucose proficiency testing program.[8]

Staffing-Related Challenges

The study by Shaw et al. noted that a 2014 survey conducted by the Canadian Society of Clinical Chemists reported that more than half of respondents (POCT coordinators and medical and scientific directors for POCT from 17 Canadian hospitals ranging in size from 100 to 1,300 beds) reported a lack of staff to support their POCT program as the biggest challenge to implementing POCT in their institutions.[2,8] Seven out of the 17 respondents indicated that their institutions had no medical laboratory technologists who were solely dedicated to supporting the POCT program.[7]

Lack of Standards

A review of POCT practices at The Ottawa Hospital indicated that the largest areas of challenge encountered in the institution were in relation to POCT accreditation standards, specifically: POCT orders documentation, POCT results documentation, and training, certification, and recertification of POCT operators.[2]

Orders Documentation

The study by The Ottawa Hospital indicated that POCT is rarely performed because of a direct physician order; therefore, the authors suggest it is necessary to design and properly document the initiation of medical directives that outline defined procedures for ordering POCT (a requirement to meet accreditation standards).[2]

Results Documentation

The Ottawa Hospital review indicated that it can be challenging to chart POCT results appropriately, particularly in the absence of connectivity between POCT instruments and the laboratory information system.[2] Shaw reported that, in The Ottawa Hospital, POCT results were not charted consistently and paper charting did not meet accreditation standards.[2] Electronic charting of patients' POCT results in their electronic medical records was considered ideal, but this type of connectivity is expensive and can be resource-intensive.[2]

There are numerous challenges associated with POCT devices, such as devices being able to only store information on a certain number of operators, number of patients, patient test results, and patient locations in the institution.[2] It is imperative to clearly distinguish POCT results from those produced in the central laboratory, because not doing so can lead to confusion for the clinicians interpreting the results.[2]

Training-Related Challenges

Consultation with the clinical laboratory community indicated that, in general, there is a need for institutions and organizations involved in curriculum setting for health care professionals to acknowledge the role of these professions in providing POCT and to provide appropriate background training on POCT or access to training. As well, training needs to convey that POCT is laboratory testing, and that there is an obligation to adhere to quality assurance standards. This is particularly important in situations where the onus of test quality falls solely on the individual or organization conducting the test without lab oversight (Dr. Julie Shaw: personal communication, 2017 Aug). Consultation with decision-makers in Manitoba noted that it will be important to continue to acknowledge the increasing role of POCT in the clinical setting, and to have educational bodies work with the clinical community to ensure that training reflects employer needs.

A review of the study conducted by The Ottawa Hospital indicated that online POCT training can be an attractive option, particularly when there are many individuals to train and limited human resources options for POCT program support; but "online training may not be suitable for all learners and does not necessarily allow for a demonstration of competency by the learner."[2]

Quality-Related Challenges

Quality assurance as it relates to sample preparation, test utilization, and test performance is another challenge in the Canadian context.

For example, quality assurance of POC glucose testing in hospital settings was noted in the study by Aslan et al. as an additional challenge for many institutions.[8] The concern about the accuracy of POCT test results is not unfounded, as a recent Canadian study reported higher imprecision in point-of-care glucose measurement compared with laboratory glucose.[8]

One issue identified during consultation with the clinical laboratory community concerns the need for a philosophy shift related to how tests are conducted and with regards to general oversight of POCT. It was noted that there is a lack of clinical buy in regarding the importance of quality assurance as well as a lack of accountability regarding the responsibility for overseeing quality assurance practices, which can be an issue, particularly when there is no central laboratory oversight. This lack of regulation is also of concern as it relates to appropriate test utilization. With the lack of established quality assurance practices, there are risks to patient safety. Central laboratories must adhere to standards when it comes to the precision and reliability of testing; consistency in test results may not be maintained at the same level in the current POC environment (Dr. Julie Shaw: personal communication, 2017 Aug).

Concern was also expressed from the clinical laboratory community perspective about the lack of understanding of the importance of monitoring instrument performance and functionality, suggesting that in this sense, laboratory testing moving to the POC environment risks moving away from the high standards of quality that have been achieved by the laboratory community for central laboratory testing. If it is not possible to maintain appropriate quality of testing, then the benefit of providing testing services to patients in a timely and accessible manner is negated (Dr. Julie Shaw: personal communication, 2017 Aug).

Funding-Related Challenges

Funding structures were also identified as challenges during consultation with the clinical laboratory community. Without regulation, there is ambiguity regarding who is responsible for paying for POCT, particularly outside of the hospital setting. It was stated that POCT is generally more expensive than central laboratory testing (Dr. Julie Shaw: personal communication, 2017 Aug) Consultation with decision-makers in Manitoba raised the important consideration of the cost of quality assurance, which needs to be factored into acquisition decisions appropriately (Michele Mathae-Hunter: personal communication, 2017 Aug).

Patient-Related Challenges

Patient perception was another challenge identified during consultation with the clinical laboratory community. In circumstances where patients have limited access to conventional laboratory testing, POC tests may be attractive from the vantage point of accessibility and timelines *(*Dr. Julie Shaw: personal communication, 2017 Aug). This may not properly acknowledge some of the limitations of POCT (e.g., quality assurance).

The Ottawa Hospital review indicated that inaccurate patient identification by a POCT device can occur, particularly when information is added through manual entry. Scanning patient barcodes with the POCT device to obtain accurate demographic information can remedy this problem, but POCT devices vary in their ability to scan patient barcodes.[2]

International Challenges

Five major themes emerged in the international literature on barriers and challenges to the implementation of POCT, including: challenges posed by POCT regulations, costs associated with POCT implementation, quality of POCT, accuracy of the results, staff-related challenges, and connectivity issues. Although they were not specific to Canada, similar challenges are likely also experienced in Canadian institutions and affect POCT implementation across jurisdictions.[4,5,7] This is reflected in the challenges reported by Canadian jurisdictions and stakeholders summarized previously and shown in Appendix 12.

The three identified studies were published in 2016 and focused mainly on US settings. One study examined barriers to the use of POCTs in US family medicine clinics; another provided a narrative review of studies published in the Unites States and Europe; and the third paper was a review by American authors on issues in the practical implementation of POCT.[4,5,7]

Major Themes Identified

Issues related to accreditation and regulation:

- Meeting federal and accreditation agency requirements can be difficult because different accreditation organizations may set different requirements (e.g., CLIA sets minimal requirements, but other accreditation agencies [e.g., CAP] set additional ones).[5]

- Rigorous reporting and documentation requirements can make POCT difficult to maintain, and traditional laboratory instrumentation regulations may not be applicable to modern POCT devices.[4]

Issues related to cost:

- POCT connectivity leads to additional costs associated with connecting POCT devices to laboratory and hospital information systems.[4,5]
- POCT does not attract specific budget allocations.[4]
- The initial costs of implementing a POCT system can be high. There are costs associated with ensuring that a laboratory is accredited to and complies with the appropriate international standards; there is the upfront cost of purchasing analyzers, test strips, and reagents; and there is the labour involved in their set-up and daily operation (e.g., staff training, quality checks, data entry procedures).[4,7]
- The cost per test for POCT is higher than for traditional central laboratory testing.[4]
- Mismanagement of POCT materials can lead to increases in cost, such as when operators fail to document the correct reagent expiration dates — which, when discovered, leads to them being discarded.[5]
- Variability in results between POCTs and central laboratory instruments may lead to doubts about the validity of POCT, which forces staff to order additional confirmatory tests, thereby increasing costs. [5,7]
- Family physicians feel that greater availability of POCT would lead to an increase in unnecessary testing. [7]
- Reimbursement is a major hurdle to POCT implementation because reimbursement for specific tests varies from country to country. [4]
- The cost-effectiveness of a POCT system is difficult to gauge; cost-comparison studies against traditional central laboratory testing methods are complex. [4]

Issues related to the quality of POCT and the accuracy of POC devices:

- Operator education and monitoring of certification can be difficult in large institutions with thousands of operators. However, a small international systematic review (of six studies) demonstrated that nurses can be trained to improve POCT administration using a wide range of training methods and in different health care settings, particularly when the training program is designed with the support of laboratory professionals.[5,65]
- Lack of training may lead to device operation by untrained or non-competent staff. [4]
- Mismanagement of POCT materials, such as forgetting to document correct expiration dates and failing to use refrigerated controls correctly (e.g., urine controls), can reduce POCT accuracy. [5]
- Failure to perform quality control on manual POCTs and continuing to perform the tests even when quality control fails acceptable ranges is problematic. [5]
- Failure to clean and disinfect POCT devices can lead to disease transmission.[5]
- POCT devices can be more challenging than traditional central laboratory methods with regard to quality control monitoring.[4]
- There is variability in results between POCTs and central laboratory instruments; surveyed family physicians were concerned about the accuracy of POCT, stating that they end up following up all POCTs with a confirmatory laboratory test, especially if the result is positive.[5,7]

- There are issues with poor usability of devices resulting from lack of standardization, inadequate clarity of output of POCT results, and poor user instructions.[4]
- Issues associated with using POCT devices in resource-limited settings can affect test precision: POCT devices, due to their portability, can be affected by adverse storage conditions; uninterrupted power may not be available for consistent refrigerated storage of supplies.[5]
- Documenting manual POCT results is associated with nurse distraction.[5]
- Physicians were concerned about the risk of error in reporting results for tests without electronic medical record interface (due to the absence of seamless data entry).[7]

Issues related to staffing:

- Laboratories are reluctant to entrust clinics with the responsibility for quality control processes and calibration procedures; this hesitation is due to insufficiently trained staff using the devices.[4,7]
- Using POCT in resource-limited settings can be difficult because finding the right staff with laboratory management experience to supervise POCT may be challenging.[5]
- Family physicians felt that over-reliance on POCTs would undermine physicians' clinical skills.[7]
- POCT may lead to an increase in testing volume, which may increase workload, extend patient visits, and overwhelm providers.[4,7]
- Physicians reported insufficient health care personnel within clinics to manage additional testing.[7]
- POCT use may lead to reduced levels of staff satisfaction and increased friction between staff groups.[4]
- Several family physicians reported perceived resistance to POCT adopt by a clinic's overarching health care system and its central laboratories.[4,7]
- POCT technology may cause disruptive, complex workflow changes, which can create barriers to its adoption.[4]

Issues related to connectivity:

- POCT results are typically presented in a simplistic manner, and often need to be manually recorded by the operator due to the lack of adequate connectivity, leading to issues related to the transportation of values in the test results.[4]
- Only a limited amount of data can be stored in electronic POCT devices.[4]
- POCT connectivity standards exist, but there is no single POCT interface.[5]
- Ideally, organizations performing POCT should use software that allows them to capture the testing information and manage regulatory compliance to facilitate the integration of POCT results into patients' electronic health records and make them immediately available to care teams; however, such software represents additional costs to the system.[66]
- Ideally, an organization that performs POCT should have a system that tracks operator training and certification dates. It should also have quality control and calibration verification to allow for monitoring of each device in order to assure quality testing and meet regulatory requirements; however, such software requires financing.[66]

Suggested Strategies

Several author suggestions regarding strategies for the use of POCT were noted in the articles examined during the search.[2,5,7,8,15] Author suggestions generally pertained to POCT training and reassessment, as well as the accuracy of POCT, and are noted below. Aside from the National Academy of Clinical Biochemistry document,[15] which provides graded evidence-based guidelines for POCT, the recommendations summarized below stemmed from non-systematic literature reviews and qualitative studies. Therefore, they should be interpreted with caution.

Training and Reassessment

Several suggestions were identified in the literature and gathered from the study by Shaw et al.[2] Most importantly, the National Academy of Clinical Biochemistry strongly recommends "training programs to improve the quality of POCT,"[15] stating that "training and ongoing certification of operators should be one of the major priorities for effective POCT."[15] Proficiency reassessment is also important; it is suggested that POCT operators be "re-assessed for competency at regular intervals to ensure patient safety and to be compliant with accreditation standards."[2] Lastly, given that each organization is responsible for its POCT accreditation and training, one study suggests a POCT committee to "provide support to comply with regulatory requirements, offer necessary training sessions, manage new test requests, develop procedures, and help maintain and validate POCT devices."[5]

Accuracy of Point-of-Care Testing

Although not addressed as a challenge by the survey respondents, the accuracy of POCT devices was deemed a potential challenge in the literature and during consultations. The variability in the testing results may be due to the design and intended use of POCT differing from that of laboratory analysis; it may also be due to the "less stringent performance criteria allowed for POC testing."[8] Variability also exists between types of POCT devices, which can undermine a provider's trust in the device and cause them to order follow-up confirmatory laboratory tests.[7] Therefore, Hardy et al. (2016) suggest making POCT diagnostic accuracy data available to clinics along with guidance on how test results should be interpreted.[7]

Limitations

The findings of this Environmental Scan present an overview of current context and trends in POCT in Canada. A systematic search was not conducted. Limited information was publicly available on POCT policies and practices across Canada. The key informant survey was intended to provide a firsthand account of current practices across Canadian institutions; however, due to the low response rate (16 responses), information was obtained from a small sample of Canadian institutions and was not representative of all provinces and territories. The informant survey results were supplemented by the decision-maker and clinical laboratory perspectives provided during targeted consultations, which are not representative of the views of all stakeholders across Canada. Furthermore, information on the standards and guidelines for Northwest Territories, Yukon, and Nunavut was not publicly accessible. The key Canadian paper that was used to inform Canadian POCT practices was based on a large tertiary care academic health care centre setting,[2] and may not have been representative of other settings or institutions, such as primary care. In addition, due to limited information, an important aspect of POCT — patient self-testing at home or in the community environment (e.g., point-of care coagulation monitors for anticoagulation therapy) — was not adequately addressed within in this report. Thus, the Environmental Scan provides a limited understanding of current POCT practices and policies across the Canadian landscape.

Conclusions

This Environmental Scan was conducted with the intent to examine information on the implementation and management of POCT across Canadian jurisdictions. The Environmental Scan consisted of a literature search that examined several peer-reviewed publications, but drew primarily upon grey literature sources, including websites of professional organizations and accreditation organizations in Canada and internationally. As a complement to the literature search, survey responses were collected from key respondents involved in POCT or laboratory services in Canada; however, due to the low response rate, it was difficult to draw generalizations or conclusions from the survey data. Detailed consultations were conducted from the decision-maker and clinical laboratory community perspective to fill gaps in the information, but not all perspectives are represented.

Based on feedback from the 16 survey respondents (13 complete responses and three incomplete responses), POCT in Canada is often performed by nurses, which was consistent with the information reported by a Canadian study on POCT implementation in hospital settings.[2] POCT is most often performed in emergent and urgent care settings, as well as in the hospital in-patient care setting, and is frequently performed with the intent to reduce turnaround time, increase patient convenience, and provide access to testing in remote or rural areas. In addition, POCT training and certification appear to vary across institutions, with many designing and implementing their own training programs. The variability in training and certification methods is also supported by the fact that many of the provincial accreditation standards identified designate training as the responsibility of each individual laboratory.[2,14]

Canada does not have national standards and guidelines pertaining to laboratory accreditation and POCT;[10] however, most jurisdictions (except for Nunavut, Northwest Territories, and Yukon, which do not have publicly available provincial accreditation standards) have their own clinical laboratory accreditation standards that often encompass POCT.[16,17,25,27-29,32,33,67-71] Provincial standards, as evidenced by several of the regulatory documents identified during the search, are often based on ISO 15189 and ISO 22870 (or CAN/SCA Z15189 and CAN/SCA Z22870-07, their Canadian-adapted counterparts) and/or standards mandated by referenced accreditation organizations (typically, Accreditation Canada, which follows the previously outlined ISO and CAN/SCA standards).[16,17,25,27-29,32,33,67-71] Based on feedback from one stakeholder, the provinces of Alberta, Saskatchewan, and Manitoba have formed a Western Canada Diagnostic Accreditation Alliance (WCDAA) that enforces numerous POCT and POCT-related standards, including ISO 15189 and ISO 22870, with the intent to share processes related to diagnostic laboratory accreditation.

In regard to barriers to POCT implementation, survey respondents noted challenges stemming from their institutions' organizational structures, particularly related to authority and accountability for POCT, as well as the lack of departmental buy in and financial support for POCT connectivity. Respondents also identified challenges pertaining to the quality of POCT, such as operators not adhering to proper POCT procedures, and their institutions' lack of resources to carry out quality control and monitor operator proficiency. Survey responses were consistent with the literature, noting barriers associated with the lack of POCT connectivity and staff authority. The respondent feedback emphasized that, without POCT connectivity, manual entry must be performed for all test results, which poses the risk for incorrect or absent recording of results, and may hinder the ability to monitor quality control processes and operator competency; furthermore, connectivity may be costly and difficult to finance without organizational support. Staff-related issues noted in the survey responses appear to concentrate around authority, with laboratory staff being uncomfortable with

non-laboratory personnel performing POCT, and with non-compliance with the recommended POCT protocols by non-laboratory-trained operators. In general, the literature and survey data suggest that financial and organizational barriers need to be addressed to implement POCT aligned with accreditation standards.

Based on limited survey results and consultations from the Manitoba decision-maker and clinical laboratory perspective, there appears to be jurisdictional interest in expanding and improving support for POCT in Canada, but uncertainty remains about the status of these technologies. There are challenges involved in adopting and implementing POCT, and there is variability in its use and management across jurisdictions. Future inquiries on this topic should focus on the quality control processes employed by institutions across Canadian jurisdictions; on POCT in remote settings (particularly in the jurisdictions of Yukon and Nunavut, for which POCT information was not obtained); on POCT connectivity; and on the implementation of POCT in Canadian institutions, such as POCT devices currently in use and provider sentiments toward POCT use.

Future Directions

POCT is a moving target. Added challenges include rapid technology development, widespread marketing, and pressure to adopt new technologies. Philosophical constructs related to the management of laboratory testing may need to shift around POCT to recognize the unique challenges associated with this technology. The findings of this report have identified a need for the development of regulatory structure, guidance frameworks, and consistent evaluation processes for POCT to support the quality, reliability, and safety of these tests across the varied contexts and applications of their use. This will be an ongoing challenge, as these products continue to develop rapidly and emerge into the Canadian market. Ensuring that there is adequate return on investment and real benefit to patients — not just through indirect characteristics of the tests (e.g., ease of use) — is also important. With the current pace of diffusion, the ability to manage this technology will depend on understanding what is needed to support safe and effective implementation.

Beyond the scope of this report, there are also broad considerations regarding POCT that need to be addressed. Consultation with decision-makers raised the importance of ethical considerations in POCT. As well, implementation issues may differ substantially depending on setting and population of interest; inquiry in this area would be valuable.

The need for greater awareness of the importance of laboratory quality, training and retraining requirements, and reporting mechanisms for test documentation to support the proliferation of these tests across Canadian health care settings has been reported. This will require the engagement of policy-makers, clinical practitioners, laboratory communities, manufacturers, patients, and caregivers in a coordinated approach. Pressure related to managing disruptive technologies is expected to increase. Forward planning will help position decision-makers and practitioners to implement POCT appropriately in the future.

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Appendix 1: Settings in Which Point-of-Care Testing is Used Across Surveyed Jurisdictions

Setting	Number of Responses			
	Not at All	Rarely	Sometimes	Often
Emergent and urgent care (e.g., emergency department, ICU)	0	0	4[BC, MB, NL]	11[AB, BC, NT, NB, ON]
Pre-hospital setting (e.g., EMS, ambulance)	1[BC]	1[NB]	4[NB, NL, NT, ON]	4[AB, BC, NB]
Primary care	0	1[NB]	4[AB, BC, NL, NT]	8[AB, BC, NB, ON]
Hospital in-patient care	0	0	4[AB, BC, MB, NT]	10[AB, BC, NB, NL, ON]
Operating room	0	2[AB, NB]	3[BC, NL, NT]	6[AB, BC, NB, ON]
Community care (e.g., pharmacies, home care)	1[BC]	2[BC, NB]	7[AB, BC, NB, NT, ON]	3[AB, NL]
Long-term care facilities	0	1[NB]	5[AB, NT]	5[AB, BC, NB, NL]
Specialty clinics (e.g., pre-natal, diabetic, diagnostic imaging, STI screening)	0	0	5[AB, BC, NL, NT]	6[AB, BC, NB, ON]
Private laboratories	5[BC, NB, NL, NT, ON]	0	1[AB]	1[BC]
Patient self-testing	0	2[BC, NT]	0	9[AB, BC, NB, NL, ON]
Rural care settings	0	0	3[NB]	9[AB, BC, MB, NL, NT, ON]
Remote care settings	2[AB, NB]	0	1[NB]	6[AB, BC, NL, NT, ON]

AB = Alberta; BC = British Columbia; EMS = emergency medical service; ICU = intensive care unit; MB = Manitoba; NB = New Brunswick; NL = Newfoundland and Labrador; NT = Northwest Territories; ON = Ontario; STI = sexually transmitted infection.

Appendix 2: Personnel Performing Point-of-Care Testing in the Surveyed Jurisdictions

Setting	AB[a]	BC[a]	MB	NB[a]	NL	NWT	ON
Emergent and Urgent Care	R.1. Nurse[b] R.2. Nurse, MD R.3. Nurse, RRT	R.1. No response R.2. RN, MD R.3. MD, NP, RN, MLT R.4. Nurse, MD	R.1. MD, RN, PA	R.1. Nurse, MD R.2. Nurse R.3. Nurse, MD R.4. No response R.5. No response	R.1. Nurse	R.1. Nurse	R.1. Nurse, MD
Pre-Hospital	R.1. Nurse R.2. Nurse, EMS R.3. EMS	R.1. No response R.2. No response R.3. Unknown R.4. No response	R.1. No response	R.1. No response R.2. No response R.3. Nurse, MD EMT R.4. No response R.5. No response	R.1. Nurse	R.1. Nurse	R.1. Nurse, MD
Primary Care	R.1. Nurse R.2. Unsure R.3. Nurse	R.1. No response R.2. RN, LPN R.3. MD, NP, RN R.4. Nurse	R.1. No response	R.1. No response R.2. Nurse R.3. MD, nurse, NP R.4. Nurse R.5. No response	R.1. Nurse	R.1. Nurse, NP	R.1. Nurse, MD
Hospital In-Patient Care	R.1. Nurse R.2. Nurse R.3. No response	R.1. No response R.2. RNs, LPN R.3. NP, RN, MLT R.4. Nurse	R.1. No response	R.1. Nurse R.2. No response R.3. Lab, nurse, MD R.4. RN, LPN R.5. No response	R.1. Nurse	R.1. Nurse, RRT, MLT, MLA	R.1. Nurse
Operating Room	R.1. Nurse R.2. Nurse R.3. Nurse, anesthesia technologist, MD	R.1. No response R.2. RN, perfusionist R.3. RN, MLT R.4. Perfusionist	R.1. No response	R.1. No response R.2. No response R.3. RRT, anesthetist, perfusionist R.4. No response R.5. No response	R.1. RRT	R.1. Nurse	R.1. MD, anesthesia assistant

Setting	AB[a]	BC[a]	MB	NB[a]	NL	NWT	ON
Community Care	R.1. Nurse R.2. Nurse R.3. Nurse	R.1. No response R.2. RRT R.3. No response R.4. Nurse	R.1. No response	R.1. No response R.2. No response R.3. MD, nurse, NP R.4. RN, dieticians R.5. RN, LPN	R.1. Nurse, home care workers, clients	R.1. Nurse, NP	R.1. Nurse
Long-Term Care Facilities	R.1. Nurse R.2. Nurse R.3. Nurse	R.1. No response R.2. RN, LPN R.3. No response R.4. Nurse	R.1. No response	R.1. Nurse, LPN R.2. No response R.3. RN, LPN R.4. No response R.5. No response	R.1. Nurse and others	R.1. Nurse	R.1. Nurse
Specialty Clinics	R.1. Nurse R.2. Nurse R.3. Nurse	R.1. No response R.2. No response R.3. NP, RN R.4. Nurse	R.1. No response	R.1. No response R.2. No response R.3. RN, LPN, pharmacist R.4. No response R.5. No response	R.1. Nurse	R.1. Nurse, NP	R.1. Nurse
Private Laboratories	R.1. N/A R.2. MLA R.3. No response	R.1. No response R.2. No response R.3. No response R.4. No response	R.1. No response	R.1. No response R.2. No response R.3. N/A R.4. No response R.5. No response	R.1. N/A	R.1. N/A	R.1. N/A
Rural Care	R.1. Nurse R.2. Nurse, EMS R.3. Nurse	R.1. No response R.2. RN R.3. Physicians, NP, MLT R.4. No response	R.1. MD, RN, PA, NP, extended practice nurse	R.1. No response R.2. No response R.3. Nurse, lab staff, MD, NP R.4. RNs, dieticians R.5. RN, LPN, laboratory	R.1. Nurse	R.1. Nurse, NP	R.1. Nurse, MLT

Setting	AB[a]	BC[a]	MB	NB[a]	NL	NWT	ON
Remote Care	R.1. N/A R.2. Nurse, EMS, MLT R.3. No response	R.1. No response R.2. RN R.3. MD, NP, MLT R.4. No response	R.1. No response	R.1. No response R.2. No response R.3. N/A R.4. No response R.5. No response	R.1. Nurse	R.1. Nurse, NP	R.1. Nurse, MLT
Other Setting, Type of Personnel Performing POCT	R.1. Laboratory, MLT R.2. No response R.3. Diagnostic imaging nurse, technicians	R.1. No response R.2. No response R.3. No response R.4. R.4. No response	R.1. No response	R.1. No response R.2. No response R.3. No response R.4. No response R.5. No response	R.1. No response	R.1. No response	R.1. No response

AB = Alberta; BC = British Columbia; EMS = emergency medical service; LPN = licensed practical nurse; MB = Manitoba; MD = medical doctor; MLA = medical laboratory assistant; MLT = medical laboratory technologists; N/A = not applicable; NB = New Brunswick; NL = Newfoundland and Labrador; NP = nurse practitioner; NWT = Northwest Territories; PA = physician assistant; POCT = point-of-care testing; R.1. = respondent 1; R.2. = respondent 2; R.3. = respondent 3; R.4. = respondent 4; RN = registered nurse; RRT = registered respiratory therapist.

[a] Several respondents from this province provided responses.

[b] Survey respondents sometimes indicated "nurses" as personnel who performed POCT in their institution, without specifying whether they were RNs or LPNs. Where "nurse" is stated rather than "LPN," "RN," or "NP," the type of nurse was unclear.

Appendix 3: Respondent-Reported POCT Training/Certification Across Jurisdictions

Jurisdiction (Number of Survey Respondents)	POCT Training/Certification			
	Training Provider	Type of Training	Certification	Recertification
AB (3)	POCT POCT staff + end-user groups Not specified	Learning module, continuing education Program, not specified Not specified	Quiz Not specified	Annual Interval not specified Not specified
BC (3)	Not specified	Training courses (sometimes with video), "train the trainer," read procedures Hands-on and/or online Varied	Competency checklist + quiz; quiz + observe someone performing the test Not specified	Not specified
MB (1)	Lab staff	Not specified	"Ongoing competency assessment"	Not specified
NB (3)	Laboratory services Laboratory specialist Not specified	Test-specific Hands-on Online	Not specified	Annual Interval not specified Not specified
NL (1)	POCT committee	Not specified	For hospital sites only, type not specified	Not specified
NT (1)	Not specified	Online or in writing	Practical competency assessment	Annual
ON (1)	Not specified	"Specialized training"	Must be a regulated health care professional	Annual

AB = Alberta; BC = British Columbia; MB = Manitoba; NB = New Brunswick; NL = Newfoundland and Labrador; NT = Northwest Territories; ON = Ontario; POCT = point-of-care testing.

Appendix 4: Respondent-Reported Purpose of Point-of-Care Testing Across Jurisdictions

Jurisdiction (Number of Survey Respondents)	Purpose of POCTs (Frequency of Response)
AB (3)	Reduce TAT[a] (3) In-home patient support (1) Provide testing not provided by laboratory (1) Cost savings (1)
BC (3)	Reduce TAT (3) Remote settings (staffing not feasible and/or not enough volume to support use of larger equipment) (2) Convenience (e.g., INR in anticoagulation clinics, A1C in pediatric diabetic clinics) (1) Support screening programs (e.g., STI/HIV clinics) (1) Support methadone and opioid treatment programs (1) Preliminary results reporting (1) Specific use in: ED, ICU, OR, diabetic clinics (1)
MB (1)	Reduce TAT (1) Remote settings (1)
NB (4)	Reduce TAT (4) Reduce need for call-in (1) Small-volume testing (e.g., neonatal patients) (1) Cost efficiency (1) Rural settings (1)
NL (1)	Reduce TAT (1) Convenience (e.g., home glucose monitoring, pregnancy screens) (1)
NT (1)	Screening and monitoring in urgent, acute, and remote settings (1)
ON (1)	Reduce TAT (1) Monitor glycemia (1) Provide immediate patient advice (outpatients) (1) Make immediate clinical decisions in the OR (1)

A1C = glycated hemoglobin; AB = Alberta; BC = British Columbia; ED = emergency department; ICU, intensive care unit; INR = international normalized ratio; MB = Manitoba; NB = New Brunswick; NL = Newfoundland and Labrador; NT = Northwest Territories; ON = Ontario; OR = operating room; POCT = point-of-care testing; STI = sexually transmitted infection; TAT = turnaround time.

[a] "Reduce TAT" refers to reducing patient wait times or ED wait times, facilitating timely patient care, moving patients through the system more quickly.

Appendix 5: Respondent-Reported Funding for Point-of-Care Testing Across Jurisdictions

Jurisdiction (Number of Survey Respondents)	Funding of POCT (Frequency of Response)
AB (3)	Operational budget and vendor (1) Laboratory services (1) Provincial health system (Alberta Health Services) (1)
BC (3)	Specific user (department, area, ward, clinic) (2) Fee-for-service (community) or global funding (health authorities) (1)
MB (1)	Provincial health system (Manitoba Health) (1)
NB (5)	Operational budget[a] (4) Health global budget (primary care setting) (1)
NL (1)	Health authority (health care centre) or patient (pharmacy) (1)
NT (1)	Laboratory (1)
ON (1)	Individual clinic units (in hospital) or patient (outside hospital) (1)

AB = Alberta; BC = British Columbia; MB = Manitoba; NB = New Brunswick; NL = Newfoundland and Labrador; NT = Northwest Territories; ON = Ontario; POCT = point-of-care testing.

[a] One respondent specified that the POCT devices may be purchased with funding from the ministry or a hospital foundation as a capital expenditure, or may be acquired from the vendor in conjunction with an agreement to purchase consumables.

Appendix 6: Available Point-of-Care Tests and Point-of-Care Test–Specific Accreditation Requirements Across Jurisdictions

Test Type	AB[16]	BC[17]	MB	NB[a]	NL[72]	NS[73]	NT	NU	ON	PE[70]	QC	SK	YK
Blood													
Blood gases	–	–	–	■	–	■	–	–	–	–	–	–	–
Blood glucose	–	□	–	■	■	■	–	–	–	■	–	–	–
Cardiac marker identification/ quantification	●	–	–	–	–	■	–	–	–	–	–	–	–
Chemistry	–	–	–	–	–	■	–	–	–	–	–	–	–
Coagulation testing (e.g., D-Dimer and INR)	●	–	–	–	–	■	–	–	–	■	–	–	–
Hematology	–	–	–	–	–	■	–	–	–	–	–	–	–
Hemoglobin	●	□	–	–	–	–	–	–	–	–	–	–	–
HIV-I-HIV-2 antibody test (INSTI)[74]	■	■	■	–	–	–	–	–	■	–	■	■	■
Mono test	–	–	–	–	–	–	–	–	–	■	–	–	–
Sedimentation rate	–	□	–	–	–	–	–	–	–	–	–	–	–
Streptococcus A	–	–	–	–	–	–	–	–	–	■	–	–	–
WBC and/or differential	–	□	–	–	–	–	–	–	–	–	–	–	–
Breath													
Alcohol	–	–	–	–	–	–	–	–	–	■	–	–	–
Urine or Feces													
Drug screening/testing	●	□[b]	–	–	–	–	–	–	–	■	–	–	–
Occult blood – feces	–	□	–	–	–	–	–	–	–	■	–	–	–
Pregnancy test (standard kit)	□	□	–	–	–	■	–	–	–	■	–	–	–
Urinalysis, chemical and/or microscopic	□	□	–	■	–	■	–	–	–	■	–	–	–
Other													
Examination for pinworm ova	–	□	–	–	–	–	–	–	–	–	–	–	–
Examination for trichomonas and/ or candida	□	□	–	–	–	–	–	–	–	–	–	–	–
Fern test	–	□	–	–	–	–	–	–	–	–	–	–	–
Ketone (not specified in breath, blood, or urine)	–	–	–	–	–	–	–	–	–	■	–	–	–
KOH test	–	□	–	–	–	–	–	–	–	–	–	–	–
Microscopic examination of smears, hair, nails (for bacteria, ectoparasites, fungi, worms, eosinophils)	□	□	–	–	–	–	–	–	–	–	–	–	–
Semen examination for presence of sperm	–	□	–	–	–	–	–	–	–	–	–	–	–
Wound swabs	–	–	–	■	–	–	–	–	–	–	–	–	–
Other, Identified by Stakeholder(s)													
Tests performed in non–Alberta Health Services settingsa	□	–	–	–	–	–	–	–	–	–	–	–	–
All POCT conducted under the care of the laboratorya	□	–	–	–	–	–	–	–	–	–	–	–	–

— = not specified or information unavailable; • = available POCT, accreditation not required; □ = available POCT, accreditation required;
■ = available POCT, not specified whether accreditation required; AB = Alberta; BC = British Columbia; INR = international normalized ratio;
KOH = potassium hydroxide preparation; MB = Manitoba; NB = New Brunswick; NL = Newfoundland and Labrador; NS = Nova Scotia; NT = Northwest Territories;
NU = Nunavut; ON = Ontario; PE = Prince Edward Island; POCT = point-of-care testing; QC = Quebec; SK = Saskatchewan; WBC = white blood cell count;
YT = Yukon.

[a] Information provided during stakeholder feedback.

[b] Restricted to physicians authorized to prescribe methadone for the management of opioid addiction.[17]

Appendix 7: Point-of-Care Tests Identified as Being Used Internationally in Primary Care and Emergency Departments

Country	Most Commonly Reported POCTs Used in Primary Care	POCTs and Instruments Used in Emergency Departments
Australia, Belgium, Netherlands, UK, US	• Urine pregnancy test • Urine leucocytes or nitrite • Blood glucose • INR • Hemoglobin • Fecal occult blood • Throat swab for group A • Streptococci; C-reactive protein • Quantitative beta-human chorionic gonadotropin • A1C • Nose/throat swab for influenza • Platelet count[19]	None identified
Finland	None identified	• Sodium, potassium and glucose (by Cobas b 123 POC system) • C-reactive protein (by Afinion) • CREA • APHOS • ALT • Total Bil and AMYL (by Reflotron Plus) • D-dimer (by Cobas h232 POC system) • Complete blood count (by PocH-100i)[18]

A1C = glycated hemoglobin; ALT = alanine aminotransferase; AMYL = amylase; APHOS = alkaline phosphatase; Bil = bilirubin; CREA = creatinine; INR = international normalized ratio; POCT = point-of-care testing or test.

Appendix 8: Publicly Available Laboratory and Point-of-Care Testing Standards Across Canadian Accreditation Bodies and Jurisdictions

Accreditation Body	Laboratory Standards Enforced	Jurisdictions Accredited by the Accreditation Body
Accreditation Canada[11]	Plus 15189 (ISO 15189:2003); CAN/SAD Z22870	PE
Canadian Standards Association[75]	CAN/CSA-Z22870-07 (R2013)	QC
IQMH[21,24]	ISO 15189 *PLUS* ™ (except for ISO 15189 *PLUS*™ – Specimen Procurement) includes the ISO 15189:2012 requirements, international standards for safety (ISO 15190), standards for POCT (ISO 22870), and government regulation and generally accepted principles of good practice	BC, NB, NL, NS, ON
Standards Council of Canada[22,23]	ISO 15189:2012; CAN-P-1562:2006 (adoption of ISO 22870:2006), CAN-P-1571:2003 (adoption of 15190:2003), and CSA Z920-10 (where applicable)	Not identified

BC = British Columbia; CAN-P = Canadian Procedural; CSA = Canadian Standards Association; IQMH = Institute for Quality Management in Healthcare; ISO = International Organization for Standardization; NB = New Brunswick; NL = Newfoundland and Labrador; NS = Nova Scotia; ON = Ontario; PE = Prince Edward Island; QC = Quebec.

Appendix 9: Standards Related to the Implementation of Point-of-Care Testing Across Canada Identified Through Publicly Available Information and Survey Responses

Province/ Territory	Provincial Guidelines/ Policies Identified	Laboratory Accreditation Body	Laboratory and POCT Standards Identified	Canadian or International Standards Reported by Survey Respondents
AB	*Unaccredited Point-of-Care Laboratory Testing Guideline for Physicians*[16]	College of Physicians and Surgeons of Alberta[25]	ISO 15189[10]	R.1. ISO; Accreditation Canada; IQMH; CAP R.2. CPSA; ISO; Accreditation Canada R.3. CPSA; ISO S.1. WCDAA (Alberta) – Standards for Diagnostic Laboratory Accreditation: General (section 11 – POCT) is used for accreditation in AB[a]
BC	College of Physicians and Surgeons' Diagnostic Accreditation Program *Accreditation Standards 2015;*[29] College of Physicians and Surgeons *Accreditation Standards: Patient Safety: Point-of-Care Testing*[17]	College of Physicians and Surgeons' Diagnostic Accreditation Program[17,29]	ISO 22870; CLSI POCT07-A; CLSI POCT09-A; ISO 15189; CLSI POCT04; ISO 22789; CAP COM.30300; DAP ACR; CSA Z316.7 7.3; CAP POC.09190);[29]	R.1. DAP of BC R.2. CPSBC; DAP, which is moving toward accrediting laboratories to ISO15189 R.3. College of Physicians and Surgeons
		IQMH	ISO 15189 PLUS™[76]	
MB	Not identified	College of Physicians and Surgeons of Manitoba[27,28]	ISO 15189[10]	R.1. Accreditation Canada; CAP; ISO
NB	New Brunswick Society of Medical Laboratory Technologists *Point of Care Testing Position Statement*[67]	IQMH	ISO 15189 PLUS™[76]	R.1. ISO 15189 R.2. ISO 15189; Accreditation Canada; Laboratory Medicine R.3. IQMH
NL	Not identified	IQMH	ISO 15189 PLUS™[76]	R.1. ISO15189; ISO22870; Accreditation Canada; IQMH

Province/ Territory	Provincial Guidelines/ Policies Identified	Laboratory Accreditation Body	Laboratory and POCT Standards Identified	Canadian or International Standards Reported by Survey Respondents
NS	*Nova Scotia Diagnostic Imaging and Pathology & Laboratory Medicine Initiative: Framework & Guidelines for Safe and Effective Management of Point of Care Testing in Nova Scotia;* *Capital Health Point of Care Testing (Laboratory Diagnostic Bedside Testing) Administrative Manual;*[68] Nova Scotia College of Medical Laboratory Technologists *Point of Care Testing (POCT) Position Statement*[32]	IQMH; Accreditation Canada[68,73]	ISO 15189 PLUS™[76]	No survey responses received
NT	Not identified	Not identified	Not identified	R.1. Accreditation Canada
NU	Not identified	Not identified	Not identified	No survey responses received
ON	Ministry of Health and Long-Term Care *Point-of-Care Testing Policy and Guideline for Hospitals with a Licensed Laboratory*[71]	Ontario Medical Association through IQMH	ISO 15189 PLUS[76] ISO 15189, ISO 22870[71]	No survey responses received
PE	*Provincial Laboratory Services Point of Care Manual*[70]	Accreditation Canada[69]	Not identified; presumably CAN/ SAD Z22870-07 in conjunction with Plus 15189 (ISO 15189:2003)	No survey responses received
QC	Ordre Professionnel des Technologistes Médicaux du Québec *Quality in Biomedical Laboratories, Second Edition: Rules of Practice*[33]	Canadian Standards Association	CAN/SCA Z22870-07 and CAN/SCA Z15189[33]	No survey responses received
SK	College of Physicians and Surgeons of Saskatchewan *Laboratory Quality Assurance Program Policy Manual;*[26] *Guidelines for the Use of HIV Point of Care (POC) Test Kits in Saskatchewan*[77]	College of Physicians and Surgeons of Saskatchewan	ISO 15189[10]	No survey responses received

Province/ Territory	Provincial Guidelines/ Policies Identified	Laboratory Accreditation Body	Laboratory and POCT Standards Identified	Canadian or International Standards Reported by Survey Respondents
YT	Not identified	Not identified	Not identified	No survey responses received

AB = Alberta; BC = British Columbia; CAP = College of American Pathologists; CLSI = Clinical and Laboratory Standards Institute; CPSA = College of Physicians & Surgeons of Alberta; CPSBC = College of Physicians and Surgeons of British Columbia; DAP = Diagnostic Accreditation Program; IQMH = Institute for Quality Management in Healthcare; ISO = International Organization for Standardization; ISQua = International Society for Quality in Healthcare; MB = Manitoba; NB = New Brunswick; NL = Newfoundland and Labrador; NS = Nova Scotia; NT = Northwest Territories; NU = Nunavut; ON = Ontario; PE = Prince Edward Island; POC = point-of-care; POCT = point-of-care testing; QC = Quebec; R.1. = respondent 1; R.2. = respondent 2; R.3. = respondent 3; S.1. = stakeholder 1; SK = Saskatchewan; WCDAA = Western Canadian Diagnostic Accreditation Alliance; YT = Yukon.

Note: ISO 15189 PLUS™ typically includes ISO 22870 (except for ISO 15189PLUS™ – Specimen Procurement).

[a] The WCDAA POCT standards reference the following: Accreditation Canada Standards – POCT; CLSI Guidelines (POCT12, POCT04, GP47, POCT07, QMS03, QMS16, QMS01, POCT09, C24, GP17; CAP–POC, COM, CHM, GEN Checklists; CSA Z8000-11; Government of Canada – Guidance for the Risk Based Classification System of IVDs; Government of Alberta – Occupational Health & Safety Code; Government of Canada – Hazardous Products Regulations; Government of Canada – WHMIS 2015: ISO 15189; ISO 22870; ISQua Principles; CPSA Infection Prevention & Control Standards: CPSA Guideline for the Performance of Point-of-Care Laboratory Testing in Unaccredited Settings (to be published in 2017); replaces 2007 CPSA document, "Unaccredited Point-of-Care Laboratory Testing Guideline for Physicians."

Appendix 10: National and International Standards Relevant to Point-of-Care Testing in Canada

Standard	Notes
ISO 11073-90101:2008 *Health informatics Point-of-care medical device communication – Part 90101: Analytical instruments – Point-of-care test*[78]	Scope: specifies framework for communication (protocol, not policy) between POCT devices, access points, data concentrators, and laboratory information systems
ISO 15189:2012 *Medical laboratories –Requirements for quality and competence*[20]	Applies to: medical laboratories Users: medical laboratories (quality management, self-assessment), laboratory customers, regulating authorities, accreditation bodies
ISO 15189 *PLUS*™[21]	Laboratory accreditation standard program; issued by the Institute for Quality Management in Healthcare Based on: ISO 15189:2012, ISO 15190, ISO 22970:2006, provincial statutes and regulations, Health Canada guidelines, and national and international consensus-based standards and guidelines
ISO 15190:2003 Medical Laboratories – Requirements for safety[79]	—
ISO 15197:2013 – *In vitro diagnostic test systems – Requirements for blood-glucose monitoring systems for self-testing in managing diabetes mellitus*[80]	Applicable setting: patient self-testing Users: manufacturers and performance-assessment organizations (e.g., regulatory authorities)
ISO/TS 22789:2010 Health informatics – Conceptual framework for patient findings and problems in terminologies[81]	Scope: specifies framework for categorizing findings and problems (structure and function) directly related to patients
ISO 22870:2016 *Point-of-care testing (POCT) – Requirements for quality and competence*[1]	Applicable settings: hospitals, clinics, and health care organizations providing ambulatory care Excludes: patient self-testing in a home or community setting (but some document elements may apply) Intended to be used in conjunction with ISO 15189
CAN/CSA Z902-15 *Blood and blood components*[82]	Applicable settings: any organization that collects, processes, stores, or uses human blood components for transfusion May be useful in settings where blood products, but not blood components, are managed (e.g., a hospital pharmacy)
CSA Z316.7-12 *Primary sample collection facilities and medical laboratories – Patient safety and quality of care –Requirements for collecting, transporting, and storing samples*[83]	Intended to be used in conjunction with CAN/CSA-Z22870
CAN/CSA-Z22870-07 (R2013) – *Point-of-Care Testing (POCT) – Requirements for Quality and Competence (Adopted ISO 22870:2006, first edition, 2006-02-01, with Canadian deviations)*[9]	Applicable settings: hospitals, clinics, and health care organizations providing ambulatory care Excludes: patient self-testing in a home or community setting (but some document elements may apply) Intended to be used in conjunction with ISO 15189

Standard	Notes
CAN-P-1562:2006 – *Point-of-care testing (POCT) – Requirements for quality and competence (Adoption of ISO 22870:2006)*[84]	Canadian adaptation of: ISO 22870:2006 Intended to be used in conjunction with ISO 15189 Applicable settings: hospitals, clinics, and health care organizations providing ambulatory care Excludes: patient self-testing in a home or community setting (but some document elements may apply)
CAP Accreditation Checklists (*All Common, Point-of-care testing*)[85]	Checklists containing accreditation program requirements Scope: general; or specific to the setting, provider or type of test
CLSI POCT04-Ed3 – *Essential Tools for Implementation and Management of a Point-of-Care Testing Program, 3rd Edition*[86]	Provides guidance on how to ensure POCT results are comparable to those obtained in a laboratory setting
CLSI POCT07-A – *Quality Management: Approaches to Reducing Errors at the Point of Care, 1st edition*[87]	Provides framework for a standardized error tracking system Purpose: reduce risk, increase POCT quality, collect standardized data for point of reference
CLSI POCT09-A – *Selection Criteria for Point-of-Care Testing Devices, 1st Edition*[88]	Provides guidance on selecting POCTs based on patient population and setting

CAN-P = Canadian Procedural; CAP = College of American Pathologists; CSA = Canadian Standards Association; CLSI = Clinical and Laboratory Standards Institute; ISO = International Organization for Standardization; POCT = point-of-care testing.

Appendix 11: POCT-Specific Governance Structures, Legislations, Frameworks, Guidelines, Policies, or Processes in Place or Being Developed Across Surveyed Jurisdictions

Province/ Territory	Respondent Number	Yes	No	Notes[a]
Governance				
AB	1	•		NR
	2	•		In development
	3	•		Follow CPSA guidelines and develop governance structure from there
BC	1	•		Multidisciplinary Clinical Care Collaborative
	2		•	No separate policy
	3	•		Developing a POC interdisciplinary group
MB	1	•		In draft
NB	1	•		Through laboratory medicine and their respective primary care
	2	•		As per ROP of IQMH
	3	•		Within the regional health authority, all POCT is overseen by the regional POC committee
	4	•		NR
NL	1	•		NR
NWT	1		•	NR
Legislation				
AB	1	•		NR
	2		•	NR
BC	1	•		Accreditation Standards – Diagnostic Accreditation Program
	2		•	POCT is covered under the general legislation framework if provided by the laboratory and hospital settings
MB	1		•	NR
NB	1		•	NR
	2	•		As per ROP of IQMH
	3	•		There is provincial legislation in the Act Respecting Medical Laboratory Technologists that speaks to POCT
	4	•		NR
NL	1		•	NR
NWT	1		•	NR
Framework				
AB	1	•		NR
	2	•		Provincial quality framework currently in development
	3	•		Quality assurance programs are developed based on the CPSA guidelines
BC	1		•	NR
MB	1	•		In draft

Province/ Territory	Respondent Number	Yes	No	Notes[a]
NB	1	•		Through laboratory medicine and their respective primary care
	2	•		As per ROP of IQMH
	3	•		NR
NL	1	•		NR
NWT	1		•	NR
Guidelines				
AB	1	•		NR
	2	•		CPSA standard guidelines
	2	•		CPSA (also refer to CAP)
BC	1		•	NR
MB	1	•		In draft
NB	1	•		Through laboratory medicine and their respective primary care
	2	•		As per ROP of IQMH
	3	•		NR
	4		•	NR
NL	1	•		NR
NWT	1		•	NR
Policies				
AB	1	•		NR
	2	•		Developed and currently in final approval stage
	3	•		Developed based on CPSA guidelines
BC	1	•		We have a current POCT policy
	2		•	NR
	3	•		General POCT policy
MB	1	•		In draft
NB	1	•		NR
NB	1	•		Through laboratory medicine and their respective primary care
	2	•		As per ROP of IQMH
	3	•		NR
	4	•		Policies governing authority for implementation, use, training and monitoring exist within the regional health authority and are controlled by the POC committee
NL	1	•		NR
NWT	1	•		NR
Processes				
AB	1	•		NR
	2	•		Provincially standardized processes for some programs; some zone-dependent; moving toward standardization as much as possible
	3	•		Developed based on CPSA guidelines

Province/ Territory	Respondent Number	Yes	No	Notes[a]
BC	1	•		We have POCT-specific procedures available on our intranet
	2		•	NR
	3	•		There are various processes for the POCT that are already in place
MB	1	•		In draft
NB	1	•		Through laboratory medicine and their respective primary care
	2	•		As per ROP of IQMH
	3	•		NR
	4	•		Policies governing authority for implementation, use, training and monitoring exist within the regional health authority and are controlled by the POC committee
NL	1	•		NR
NWT	1	•		NR

AB = Alberta; BC = British Columbia; CAP = College of American Pathologists; CPSA = College of Physicians & Surgeons of Alberta; IQMH = Institute for Quality Management in Healthcare; MB = Manitoba; NB = New Brunswick; NL = Newfoundland and Labrador; NR = no response; NWT = Northwest Territories; POC = point-of-care; POCT = point-of-care testing; ROP = required organizational practices.

[a] Note: Responses provided are direct quotes from respondents.

Appendix 12: Challenges to Point-of-Care Testing Implementation Across Surveyed Jurisdictions

Jurisdiction (Number of Survey Respondents, Stakeholders)	Challenges Identified by Respondents
AB (2,1)	Organizational structure with governance support Increasing demand for POCT programs with little or no increased staffing or tools Lack of connectivity of devices currently in use Lack of funding to support implementation of new programs Lack of legislation or regulatory oversight for POCT performed in unaccredited or non-AHS settings (e.g., pharmacies, physician offices, private long-term care sites, etc.) Challenges associated with the delay in implementing the newly released AHS POCT policy
BC (3)	Challenging to implement for laboratory staff when others who are performing POCT are not accountable, given the organizational structure No clear responsibility or accountability "Buy-in" from operators required to ensure quality control, accuracy of results, and training of personnel administering and interpreting the results Connectivity is expensive and requires support from other departments within the organization Uncontrolled use of POCT test kits and provision of POCT services in pharmacies, which are not accredited in BC Lack of adherence to protocol POCT results may require confirmation through traditional laboratory methods No formal POCT interdisciplinary group Manual transcription of patient results due to organization not having positive patient ID scanning
MB (1,1)	Need for clear definition of roles and responsibilities due to many stakeholders involved in implementation Lack of connectivity of devices currently in use Lack of clear direction on how to enter results into patient records No current staffing model to support POCT Differences in result reference ranges between POCT devices Appropriate communication between health care providers Cost and rationalization of need Reluctance and uncertainty in some laboratory staff to use POCT
NB (3)	Challenges associated with vetting requests for POCT through the regional POCT Committee Budget constraints and accuracy of POCT equipment Cultural changes associated with POCT within the organization; educating members of the organization about POCT and the required laboratory oversight
NL (1)	Cost and rationalization of need Quality control and maintaining user proficiency Documentation of POCT results into health record Insufficient staff to support POCT in health care centres

NT (1)	Challenging to overcome issues with authority in regard to standard implementation The Accreditation Canada standard is challenging to implement for laboratory staff when others who are performing the POCT are not accountable, given the organizational structure

AB = Alberta; AHS = Alberta Health Services; BC = British Columbia; ID = identification; MB = Manitoba; NB = New Brunswick; NL = Newfoundland and Labrador; NT = Northwest Territories; POCT = point-of-care testing.

Appendix 13: POCT Environmental Scan – English Survey

Objectives

1. Describe the current state of POCT and how it is being implemented or planned in the jurisdictions.
2. Identify Canadian and international standards, guidelines, and policies on POCT which are in effect or being developed in jurisdictions across Canada.
3. Describe the issues and challenges affecting POCT implementation in the jurisdictions.

First name, Last name

_____

☐ Yes, I agree to give my consent

☐ No, I do not agree to give my consent

To assist with our analysis, please provide background information on the following:

Your name (First name, Last name)

_____

Job title:

_____

Organization:

_____

Email:

_____

Which province/territory are you representing?

- ☐ Alberta
- ☐ British Columbia
- ☐ Manitoba
- ☐ New Brunswick
- ☐ Newfoundland and Labrador
- ☐ Northwest Territories
- ☐ Nova Scotia
- ☐ Nunavut
- ☐ Ontario
- ☐ Prince Edward Island
- ☐ Quebec
- ☐ Saskatchewan
- ☐ Yukon

Phone number including area code (e.g., 123-123-4567):

_____

Date:

_____/____/____ (YYYY/MM/DD) ____:____:____ (HH/MM/SS)

A. Objective: Describe the current state of POCT and how it is being used in the jurisdictions.

2. In your jurisdiction, are POC tests used in:

	Not at all	Rarely	Sometimes	Often
Emergent and urgent care (e.g., emergency dept., ICU)	☐	☐	☐	☐
Pre-hospital settings (e.g., EMS, ambulance)	☐	☐	☐	☐
Primary care	☐	☐	☐	☐
Hospital in-patient care	☐	☐	☐	☐
Operating room	☐	☐	☐	☐
Community care (e.g., pharmacies, home care)	☐	☐	☐	☐
Long-term care facilities	☐	☐	☐	☐
Specialty clinics (e.g., prenatal, diabetic, diagnostic imaging, STI screening)	☐	☐	☐	☐
Private laboratories	☐	☐	☐	☐
Patient self-testing	☐	☐	☐	☐
Rural care settings	☐	☐	☐	☐
Remote care settings	☐	☐	☐	☐

Other settings? Please specify

3. What type of personnel (e.g., doctor, nurse, laboratory specialist, pharmacist, other health care provider) perform the POCT in the following settings:

Emergent and urgent care

Pre-hospital settings

Primary care

Hospital in-patient care

Operating room

Community care

Long-term care facilities

Specialty clinics

Private laboratories

Rural care settings

Remote care settings

	Setting	Type of personnel performing POCT
Other setting		
Other setting		
Other setting		

4. What type of training or certification is required for personnel performing POCT in your jurisdiction or institution?

5. What is the purpose of POCT in your jurisdiction or institution? Please be specific (e.g., reduce turnaround time, provide diagnostic testing for a specific population, provide diagnostic testing in a remote care setting, etc.)

6. How is POCT funded in your jurisdiction?

B. Objective: Identify Canadian and international standards, guidelines, policies, etc. on POCT which are in effect or being developed in jurisdictions across Canada.

7. Does your jurisdiction or institution adhere to Canadian or international standards (i.e., ISO, Accreditation Canada, Institute for Quality Management in Healthcare, College of Physicians and Surgeons, etc.) in implementing POCT?

☐ Yes

☐ No

If yes, please identify the standards below.

8. Are there POCT-specific governance structures, legislation, framework, guidelines, policies, or processes in place or being developed in your jurisdiction or institution? Please complete the table below:

	Yes	No	Description
Governance structure	☐	☐	
Legislation	☐	☐	
Framework	☐	☐	
Guidelines	☐	☐	
Policies	☐	☐	
Processes	☐	☐	

Other (please specify)	**Yes**	**No**	**Description**
	☐	☐	

C. Objective: Describe the issues and challenges, as well as the opportunities affecting POCT implementation in the jurisdictions.

9. What issues or challenges (e.g., organizational, technological, infrastructure, etc.) is your jurisdiction or institution facing or expecting in the implementation of POCT? What opportunities exist to enable implementation of POCT?

D. General information

10. What is your profession or role? Please select all that apply.

Physician	☐
Nurse	☐
Laboratory specialist	☐
EMS personnel	☐
Pharmacist	☐
Health care administrator	☐
Policy-maker/government	☐
Other	☐

If other, please specify:

11. Do you work in one or more of these settings? Please select all that apply

Emergent and urgent care (e.g., emergency dept., ICU)	☐
Pre-hospital setting	☐
Primary care	☐
Hospital in-patient care	☐
Operating room	☐
Community care (e.g., pharmacies)	☐
Long-term care	☐
Specialty clinic (e.g., prenatal, diabetic, diagnostic imaging, STI screening)	☐
Private laboratory	☐
Rural care setting	☐
Remote care setting	☐
Laboratory	☐
Government	☐
Other	☐

If other, please specify:

12. Are you currently involved in or dealing with POCT? If yes, please describe the nature of your involvement.

E. Permission to contact and CADTH Environmental Scan use

13. Would you be willing to be consulted further on this topic, either through an informal phone call or by email?

- ☐ Yes
- ☐ No

Appendix 14: Information on Survey Respondents

Province or Territory	Organization Represented by Survey Respondents
Alberta	Alberta Health Services[a] Calgary Laboratory Services
British Columbia	Vancouver Island Health Authority St. Paul's Hospital, Providence Health Care British Columbia Ministry of Health, Laboratory, Diagnostics and Blood Services Branch, Diagnostic and Clinical Services Division
Manitoba	Diagnostic Services Manitoba
New Brunswick	Horizon Health Network[a] Department of Health New Brunswick
Newfoundland and Labrador	Department of Health and Community Services
Northwest Territories	Northwest Territories Health and Social Services Authority, Stanton Territorial Hospital
Ontario	The Ottawa Hospital and the Eastern Ontario Regional Laboratory Association

[a] Multiple respondents.