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Review

Point-of-care testing: A position statement from the Canadian Society of Clinical Chemists

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1. Introduction

This is a position statement on point of care testing (POCT) presented on behalf of the Canadian Society of Clinical Chemists (CSCC) by members of the POCT interest group of the CSCC. The CSCC represents clinical laboratory scientists and medical professionals with expertise in laboratory quality management, method evaluation, and oversight of diagnostic testing.

The positions stated are based on consensus by the authors, who met monthly over a sixteen month period, as well as member consultation with final approval from the CSCC governing council. Consensus was achieved through review of relevant literature and standards related to POCT along with dialogue and discussion by the authors.

This position statement provides overarching guidelines to ensure that POCT in clinical environments is performed on the right patient, at the right time, and in a safe, effective and high quality manner. POCT has its origins in clinical biochemistry, but the field has expanded and now includes other laboratory disciplines (e.g. hematology, microbiology, and genetics). Due to the ongoing expansion of new tests, technologies and their applications, this document does not detail specific tests; it focuses on the quality management principles for all POCT.

The intended setting for POCT in this document includes any patient care environment where a healthcare professional performs testing on a patient specimen outside of a clinical laboratory. This document does not apply to patient self-testing. The CSCC recognizes that differences exist between organizations with on-site clinical laboratories (e.g. hospitals) and independent community entities without such facilities (e.g. private clinics, mobile services, and pharmacies). While this could impact availability of laboratory resources to support POCT, the involvement of both a qualified laboratory professional and an accredited clinical laboratory is essential to ensure the delivery of a safe, effective and quality POCT program.

The remainder of this document details the position of the CSCC on essential aspects of an effective, valuable POCT program that supports improving patient care. The reader is referred to the discussion for more details on each aspect.

1.1. Governance of POCT within organizations

1.1.1. Position

CSCC recommends that a multidisciplinary committee provide oversight and support to those performing POCT, including all aspects presented below.

1.2. Appropriateness of POCT

1.2.1. Position

CSCC supports the use of POCT when patient care can be augmented significantly above traditional laboratory testing, or when patient care may be significantly compromised by reliance on laboratory testing. The intended use for POCT should be clearly defined and the improvement to patient care be demonstrated over time.

1.3. Laboratory oversight

1.3.1. Position

The CSCC recommends oversight of the POCT program by the

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accredited laboratory when within the same organization. In settings without a laboratory service, the CSCC recommends that quality assurance (QA) for POCT be provided by an external, accredited laboratory with a suitable Laboratory Director, or equivalent, with appropriate qualifications. Personnel from the laboratory or an assigned role as a POCT Coordinator is required to ensure day-to-day operation meets the QA requirements of the POCT program.

1.4. Importance of evidence base

1.4.1. Position

CSCC recommends an evidence-based approach to the implementation of a POCT program. This evidence includes previously published studies or local trials that demonstrate the effectiveness of POCT. Clinical need, financial impact, test utilization and quality requirements are aspects that must be included.

1.5. Compliance with accreditation standards

1.5.1. Position

The CSCC recommends that all POCT follow a recognized accreditation standard. This entails conformance with the standard, formal recognition for compliance in the POCT setting, and an assessment protocol to assure compliance.

1.6. Personnel who perform POCT

1.6.1. Position

CSCC recommends that those performing POCT act within the scope of practice defined by their professional college and that only appropriately trained and competent individuals perform POCT. For individuals who are not regulated, the governing body should determine the qualifications for those performing POCT according to clinical need, training requirements, and accountability. A medical directive may be required to perform licensed acts, including the ordering and interpretation of tests.

1.7. Training

1.7.1. Position

CSCC recommends the development of initial and ongoing competency programs for POCT that includes the proper device operation, QA quality assurance and appropriate actions based on test results. Safe practices should include infection prevention and control. Competency of the user must be successfully demonstrated prior to certification of an operator and ongoing competency assessment is required at regular intervals.

1.8. Device selection

1.8.1. Position

CSCC recommends selection of POCT devices based on local (e.g. site, region, and province) validation studies supported by the clinical laboratory, as well as input from clinical end-users. Consultation with a clinical laboratory professional and availability of external assessments can provide valuable information on the suitability of a device for procurement.

1.9. Validation

1.9.1. Position

CSCC recommends that POCT devices be validated for their analytical performance before they are implemented for patient care. The validation protocol should be based on accepted guidelines and include defined criteria that reflects the intended use.

1.10. Connectivity

1.10.1. Position

CSCC recommends that the ability to connect POCT devices to the existing laboratory information system(s) or electronic health record(s) be an important consideration in device selection. Connectivity will improve compliance with QA requirements, support the interfacing of test results with other applications used by clinicians and/or patients, and allow for timely access to stored results. Standards of data validity and security must be ensured with connectivity.

1.11. Quality assurance

1.11.1. Position

CSCC recommends that all POCT devices are part of a robust QA program. QA practices include quality control and external quality assessment (proficiency testing); they are necessary to ensure that the POCT device is providing reliable results.

1.12. Documentation

1.12.1. Position

CSCC recommends the development of, and compliance with, good documentation practices for POCT programs. This includes complete documentation of all activities of a POCT program, including the life cycle of the device, operator records, patient testing, consumables and other QA practices.

1.13. Patient and provider safety

1.13.1. Position

The CSCC recommends safe practices whenever POCT is performed. This includes the suitability of collection, minimizing the risk of harm to the patient and healthcare staff, prevention of the spread of infectious diseases, and taking appropriate action for critical events. An incident reporting system should be implemented to investigate events when safety is compromised.

1.14. Ethics

1.14.1. Position

The CSCC recommends that POCT be conducted in an ethical manner that balances effective patient care and available resources. Financial and personal gain should not be primary motivators. Ethical conduct also includes patient consent to the sharing of information derived from the POCT test, and ensuring the privacy and confidentiality of patient information.

2. Discussion

2.1. Governance of POCT within organizations

A multidisciplinary POCT committee should have overall responsibility for the provision of.

POCT. This includes an assessment of clinical needs, accountability and outcomes. The team should include representatives from laboratory, administration, information systems, procurement and clinical programs. This group will ensure that the delivery of a POCT program includes all aspects as described in the sections below [1]. The necessary support from the laboratory should be formalized in a service level agreement to ensure that specific roles are delineated and required resources are aligned to uphold POCT accreditation standards.

2.2. Appropriateness of POCT

Improved patient care is the ultimate goal when introducing POCT.