



Practical challenges related to point of care testing

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ARTICLE INFO

Article history:

Received 29 October 2015

Received in revised form

20 November 2015

Accepted 8 December 2015

Available online 9 December 2015

Keywords:

Point of care Testing

Laboratory accreditation

Medical directive

Results documentation

Electronic Medical Record

Transcription error

Connectivity

Positive patient identification

ABSTRACT

Point of care testing (POCT) refers to laboratory testing that occurs near to the patient, often at the patient bedside. POCT can be advantageous in situations requiring rapid turnaround time of test results for clinical decision making. There are many challenges associated with POCT, mainly related to quality assurance. POCT is performed by clinical staff rather than laboratory trained individuals which can lead to errors resulting from a lack of understanding of the importance of quality control and quality assurance practices. POCT is usually more expensive than testing performed in the central laboratory and requires a significant amount of support from the laboratory to ensure the quality testing and meet accreditation requirements.

Here, specific challenges related to POCT compliance with accreditation standards are discussed along with strategies that can be used to overcome these challenges. These areas include: documentation of POCT orders, charting of POCT results as well as training and certification of individuals performing POCT. Factors to consider when implementing connectivity between POCT instruments and the electronic medical record are also discussed in detail and include: uni-directional versus bidirectional communication, linking patient demographic information with POCT software, the importance of positive patient identification and considering where to chart POCT results in the electronic medical record.

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1. Introduction

Point of care testing (POCT) refers to laboratory testing that occurs close to the patient rather than in a central laboratory. POCT is usually performed by non-laboratory trained individuals such as nurses, physicians, respiratory therapists, perfusionists, anesthesia assistants, midwives and paramedics. Patients also perform POCT. Home glucose monitors and home pregnancy tests are examples of POCT performed by patients. POCT results are used to make clinical decisions and the use of POCT requires the implementation of a quality assurance program to ensure the accuracy of results for patient safety. This article describes some of the challenges related to POCT with respect to quality assurance and compliance with accreditation standards. Although the experiences described here relate to POCT performed in a hospital-based setting, issues related to quality assurance will be the same for POCT performed outside the hospital.

Abbreviations: ; POCT, point of care testing; EORLA, Eastern Ontario Regional Laboratories Association; CSCC, Canadian Society of Clinical Chemists; ADT, Admission, Discharge and Transfer; EMR, electronic medical record

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<http://dx.doi.org/10.1016/j.plabm.2015.12.002>

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In a hospital or clinic-based setting, the main advantage of POCT is that it provides a faster turnaround time than testing performed in the central laboratory [1]. A further attraction of POCT is that it generally requires less sample volume than tests performed in the central laboratory. However, these benefits come with a monetary cost, as POCT is generally more costly than traditional laboratory based testing. A study by Nosanchuk in 1995 demonstrated the cost of POCT glucose testing was anywhere from 1.1 to 4.6 times higher than that of glucose testing performed in the central laboratory [2]. There are also many hidden costs to POCT that are often not considered by clinical areas, including reagents for validating instruments, quality control materials and proficiency testing costs. The costs of medical laboratory technologists required to provide support of the quality assurance system for POCT and information system/information technology staff that are instrumental in supporting POCT connectivity platforms also need to be considered. Creating the interface between POCT software or devices to the laboratory information system and/or electronic medical record is also associated with a cost, which can be quite significant [3–5].

There are also quality issues associated with POCT. The assays employed are generally less analytically sensitive than assays performed in the central laboratory and are often more at risk of interferences than traditional laboratory tests. As an example, POCT glucose meter measurements have been shown to be affected by hematocrit levels as well as ascorbic acid present in patients' blood [6,7]. Furthermore, POCT glucose methods often employ enzymes for the measurement of glucose that are not necessarily specific to glucose alone and can be interfered with by other sugars such as maltose or galactose [8]. Despite glucose testing being one of the most widely performed POC tests, neither the American Diabetes Association [9] nor the Canadian Diabetes Association [10] endorse the use of POC glucose measurements for the diagnosis of diabetes due to concerns around the accuracy of these tests. Another example is the use of POCT for measurement of cardiac troponin. These methods lack analytical sensitivity compared to their central lab counterparts, which is especially true now with the introduction of high sensitivity troponin assays to many central laboratory platforms [11].

The accuracy of POCT measurements is also related to the fact that POCT is generally performed by busy members of the clinical team and not by laboratory trained individuals. Non-laboratory trained individuals often lack an understanding of the importance of quality control and quality assurance. Additionally, the focus of these individuals is on taking care of the patient and quality procedures associated with POCT often add additional burden to an already hectic role. Implementation of POCT to a clinical unit impacts the workflow for staff that have to integrate processes related to POCT such as daily quality control testing, instrument maintenance and troubleshooting issues with POCT devices [12,13]. An alternative to POCT performed by clinical staff is the model of a satellite POCT laboratory staffed by Medical Laboratory Technologists [14]. This model is less burdensome to busy clinical staff and has been demonstrated to allow for the availability of a larger and more complex POC test menu. A satellite laboratory, where trained laboratory staff performs POCT also makes it easier to comply with accreditation standards related to quality assurance, which will be discussed later. However, there is an added cost for having Medical Laboratory Technologists staff a satellite laboratory rather than having the testing performed by nursing staff. This cost may be inhibitory for small hospitals or clinics. A satellite laboratory may also not be practical in situations where results are required immediately at the patient bedside for clinical decision making.

POCT is laboratory testing and must be treated as such, which includes an understanding of the entire testing process from the pre-analytical phase to the post-analytical phase for anyone performing testing.

Just as with any laboratory test, errors can occur at any point in the testing cycle. A recent study compared the error rates for pre-analytical, analytical and post-analytical factors between testing performed POC and in the central laboratory. A higher rate of pre-analytical errors was found to be associated with POCT compared to central laboratory testing. In particular, the pre-analytical error identified most often was related to positive patient identification. Operators failed to confirm two patient identifiers for 45% of POC tests performed. The rate for this error occurring in the central laboratory was 0.02% [15]. In a study by O'Kane et al. [16], the most common error related to POCT glucose testing was a delay in testing due to an operator not being certified to perform testing. The same study found operator unwillingness or inability to perform minor maintenance, leading to a delay in analysis, as the most common error associated with POCT blood gas analysis [16].

In Ontario Canada, POCT performed in the Hospital falls under the responsibility of the laboratory and is subject to laboratory accreditation requirements. This poses a great challenge for laboratories as the testing being performed is largely out of their hands but still, the laboratory is accountable for ensuring that the testing is performed in compliance with laboratory accreditation standards. The Ottawa Hospital is a large tertiary care academic healthcare centre located in Eastern Ontario, Canada. The hospital is spread over three campuses and operates several satellite clinics. The laboratory services for The Ottawa Hospital are provided by the Eastern Ontario Regional Laboratories Association (EORLA), an organization made up of 16 member hospitals. These hospitals include a mix of large academic healthcare centres, urban community-based hospitals and rural community hospitals. As the laboratory service provider for The Ottawa Hospital, EORLA oversees the POCT programs in each of its member hospitals. In Ontario, it is mandatory that licensed laboratories be accredited by the Institute for Quality Management in Healthcare (IQMH). IQMH requirements are largely based on ISO standards 15189 and 22870 and consist of over 500 standards (www.iqmh.org). Approximately sixty of these standards are directly related to POCT, based on ISO 22870:2006 [17] and address the following: oversight and governance, document control, process improvement, equipment, purchasing and inventory, quality assurance, personnel policies and training, pre-analytical processes and analytical processes.

In 2014, a survey was conducted by the POCT Interest group of the Canadian Society of Clinical Chemists (CSCC). The survey was aimed at gathering information regarding hospital POCT and survey respondents included POCT coordinators and Medical/Scientific directors for POCT from seventeen Canadian hospitals ranging in size from 100–1300 beds. When

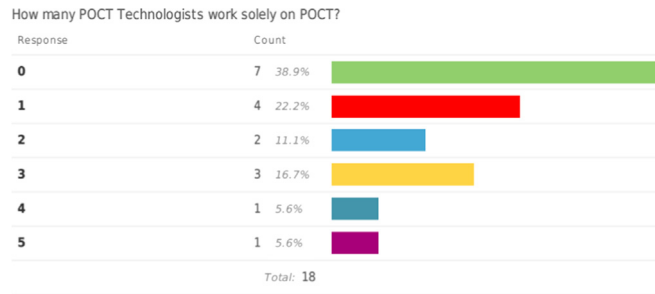


Fig. 1. Summary of results from a national survey by the Canadian Society of Clinical Chemistry POCT interest group on the question of how many technologists work solely in POCT.

asked what the biggest challenge facing POCT was for their institution, more than half of respondents cited a lack of staff to support their POCT program. Of the seventeen institutions that responded to the survey, seven indicated that there are no Medical Laboratory Technologists who are solely dedicated to support of the POCT program at their institution (Fig. 1).

With limited human resources available to support POCT programs and a general lack of knowledge or understanding for quality management by clinical users of POCT, it can be challenging for laboratories to maintain compliance with POCT accreditation standards. The three largest areas of challenge encountered in our institution were in relation to POCT accreditation standards were: POCT orders documentation, POCT results documentation and training/recertification of POCT operators. Below, the difficulties encountered in each of these areas will be discussed along with strategies used to overcome these challenges.

2. POCT orders documentation

A review of the practices within our institution indicated that, in practice, POCT is rarely performed as the result of a direct physician order. The testing is often performed in emergency situations to facilitate rapid clinical decision making and often the choice to perform POCT is made by the nurse or other clinical team member in the moment. This speaks to the situation in a hospital-based setting and will likely differ for POCT performed outside of the hospital, for example in physician offices.

At The Ottawa Hospital, the majority of POCT is performed under Medical Directive. The Hospital for Sick Children in Toronto defines a Medical Directive as an indirect physician order, used to expedite patient care by competent health professionals (www.sickkids.ca/medicaldirectives/101/definition/).

Medical Directives are designed for specific patient populations and are to be enacted when patients meet specific criteria as laid out in the directive.

It is important that Medical Directives specify when laboratory testing is to be performed by POCT and when specimens should be sent to the central laboratory for analysis. Inclusion of these specifications in Medical Directives also allows the POCT program to meet accreditation standards with respect to there being defined procedures for the ordering of POCT. For example in a Medical Directive for the prevention and management of hypoglycemia in diabetic patients in the Emergency Department at The Ottawa Hospital, it is stated that diabetic patients with symptoms of hypoglycemia should have a capillary glucose measurement by POCT upon presentation. Documentation that a medical directive has been initiated must be included in the patient chart by the individual performing testing prescribed by the directive. In our institution, there is a corporate policy on medical directives that states 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.

3. POCT results documentation

POCT results are used to make clinical decisions and therefore it is important that these results appear in the patient chart with corresponding units of measurement, reference intervals and critical values. Accreditation standards also require that laboratory results be traceable to the individual who performed the testing and the same applies to POCT. It is important that POCT results be clearly differentiated from central laboratory results in the patient chart to avoid confusion and caution trending of results performed by different methodologies. Appropriate charting of POCT results can be challenging, especially in the absence of connectivity between POCT instruments and the Laboratory Information System.

3.1. Paper charting

In the 2014 survey conducted by the POCT Interest group of the Canadian Society of Clinical Chemists (CSCC), most respondents indicated the use of paper charting in their institutions when asked how POCT results are recorded in patient

charts. Paper charting of POCT results lends itself to a lack of consistency and is prone to transcription errors. One study of an audit of POCT glucose results reported that approximately 30% of results were transcribed incorrectly in the patient chart. This study also found that 12% of POCT glucose results were never recorded in the patient chart [18]. When POCT results are not available in the patient chart, repeat testing is often performed which leads to increased costs and added patient discomfort [19]. Avoiding inconsistencies with paper charting requires agreements with clinical units to specify where and how POCT results will be charted for their patients. At The Ottawa Hospital, our experience was that POCT results were not charted consistently and that paper charting did not meet accreditation standards. Implementation of specific forms for POCT result charting that contained all of the necessary information, for example reference intervals, critical values and units of measurement, can be helpful. However, clinical units often have forms already in-use and want to avoid double charting. Working with the clinical units to modify existing forms and ensure they contain the necessary information for POCT results charting has been successful at The Ottawa Hospital. For example, nursing assessment forms in the emergency department were revised to include specific areas for the charting of POCT results that included reference intervals and the correct units of measurement. We discovered that the operating room, POCT results were already being charted in an electronic record that was linked with the patient electronic medical record (EMR). Working with the Anesthesia group, we were able to modify the electronic record in-use to contain units of measurement, reference intervals and critical values. Working with clinical units to modify their existing charting processes avoids the need for double charting, reducing the chance of transcription errors. It also encourages the clinical users to take ownership over the charting of POCT results, which in our experience led to greater compliance.

3.2. Electronic charting

Electronic charting of POCT results in the patient EMR is ideal. Achieving this connectivity is, however, not a trivial undertaking. It is expensive and can be quite resource intensive. There are several POCT management software solutions available on the market which function to facilitate the transmission of POCT results from many different types of POCT devices to the Laboratory Information System (LIS), Hospital Information System (HIS) and EMR. These are web based data management solutions that also allow for management of POCT operators and inventory. Examples include RALS Web 3 from Alere Informatics, Telcor QML, UniPOC from Conworx and Roche Cobas IT 1000. When considering connectivity of devices, there are a few factors to consider. The schematic diagram in Fig. 2 outlines the components of a connectivity solution, each of which will be discussed in detail below.

4. Communication between the POCT device and data management software

POCT devices will communicate uni- or bi-directionally with the POCT data management software depending on the

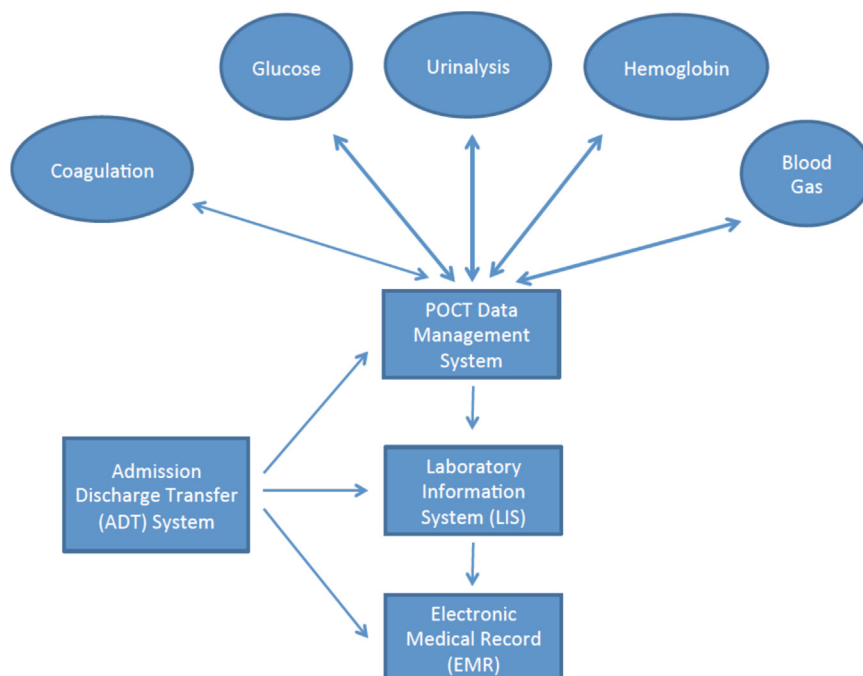


Fig. 2. Schematic representation of POCT device connectivity.

sophistication and functionality of the POCT device. With uni-directional connectivity, quality control and patient results will flow from the POCT device to the data management software but information will not flow from the data management software to the POCT device. For example, unidirectional connectivity means that the list of valid operators for a particular instrument, quality control and reagent lot information cannot be uploaded to an instrument in real-time from the data management software. Instead, these data valid must be entered into the POCT device manually or via separate software specific to the POCT instrument. This process can be quite time consuming and inefficient. Bi-directional communication allows for real-time uploading of operator lists to POCT instruments, which avoids delays between an operator completing their certification training and having access to the POCT device. Bi-directional communication also allows for real-time control of reagent and quality control lot information on individual instruments and can allow for parallel use of multiple lots which can be attractive from an inventory control perspective.

Some instruments have the capability of communicating wirelessly with the POCT data management software and some require a hard-wired connection. Wireless connectivity is convenient, particularly with hand-held devices such as glucose meters, which are frequently in-use. Even with wireless capability, hard-wired docking stations should be considered if there are concerns about interruptions in the wireless signal. Some POCT devices will communicate at specified time intervals with the data management system and others will communicate whenever they are used for testing. In light of this, it is important to remember that the time of data transmission from the POCT device to the data management software may not accurately reflect the exact time the patient test was performed. With wireless transmission of results, operators may not be as diligent at returning the device to the docking station required to maintain the charge of the device. In our experience, a large number of calls to the POCT support team are from operators stating that their device will not function and in many cases, the instrument battery is found to require charging.

Connectivity between POCT data management software and the patient information system for patient demographic information to populate POCT data management software and the instruments themselves, a connection between the data management software and the patient information system, commonly referred to as the Admission, Discharge and Transfer (ADT) system, is required. It is important to consider what amount of patient information can be stored on an individual POCT device at any one time. It may be necessary to map specific devices to specific locations and allow only the patient data for that particular location to flow through to the device from the ADT system. The number of POCT operators that an instrument can store can also be a limitation. This may require that POCT operators only be given access to the instruments within specific locations and this can cause problems if operators move around the institution.

Determining the way in which patients are registered within the ADT system is another important consideration. For example, do all areas of the institution register patients in the same way? Are patients automatically discharged from the system when they are discharged from the institution? Does the patient location in the ADT system truly reflect their physical location in the institution? In our hospital, for example, when inpatients visit areas such as diagnostic imaging or the operating room for a procedure, they are still listed as being in their ward location according to the ADT system. Our POCT devices are mapped to specific locations because mapping all locations to each device would surpass the number of patients that can be stored on each device. The POCT device would not identify inpatients visiting diagnostic imaging or the operating room because they were not listed as being in that location in the ADT system. In our institution, all patients registered in the ADT system are present within the POCT software in-use with a limited number of patients sent to each POCT device based on patient location. In areas such as the operating room, we allow operators the ability to add new patients to POCT devices. This gets around the issue of patients not being present on these instruments however this workaround poses a risk for positive patient identification. To help circumvent this risk, we do not allow for manual entry of patient information into the meter and instead require that a patient medical record number barcode be scanned prior to testing.

5. Positive patient identification

Positive patient identification by a POCT device becomes extremely important with the connectivity of POCT devices. With test results flowing from the device to the LIS and EMR, often immediately, inaccurate patient identification can have serious consequences. Manual entry of patient information into POCT devices will increase the chances of a transcription error or use of invalid patient identification/information. Increasingly, institutions are providing patients with barcoded armbands containing their demographic information. These armbands can facilitate scanning of patient information into the POCT device prior to testing, ensuring the test result will transfer to the correct patient chart. One consideration, however, is whether or not the barcode on the bracelet is compatible with the POCT device(s) in-use. At present, many POCT devices are only able to scan linear barcodes and it therefore important that linear barcodes be included on the patient armband for the purpose of positive patient identification for POCT. Not all POCT devices have the ability to scan patient barcodes and in these instances, manual entry of patient identification will be required.

Positive patient identification may be more difficult for outpatients who may be visiting the hospital for a clinic visit. These patients may not be provided with barcoded armbands as they are expensive and the patients are only visiting for a short time. Alternative solutions have to be considered and developed for these patients. In our institution, barcoded labels containing the patient medical record number have been developed. These labels are printed and included on the patient chart to be used for positive patient identification for POCT when required for a clinic visit.

A

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Sep 03 2015 08:18	*	Na	C	C	136	mmol/L		136-145
Sep 03 2015 08:18	*	K	C	C	5.4	mmol/L	H	3.5-5.1
Sep 03 2015 08:18	*	Cl	C	C	105	mmol/L		98-107
Sep 03 2015 08:18	*	CO2	C	C	23	mmol/L		21-32
Sep 03 2015 08:18	*	Anion Gap	C	C	8	mmol/L		5-12
Sep 03 2015 08:18	*	Urea	C	C	19.2	mmol/L	H	2.1-8.0
Sep 03 2015 08:18	*	Creatinine	C	C	147	umol/L	H	49-93
Sep 03 2015 08:18	*	Albumin	C	C	30	g/L	L	34-46

B

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Biochemistry ▼		Start: Sep 3, 2015 23:59						
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Aug 20 2015 15:59		POCT Urinalysis : Bilirubin Urine	G	G	Negative			
Aug 20 2015 15:59		POCT Urinalysis : Glucose Urine	G	G	Negative			
Aug 20 2015 15:59		POCT Urinalysis : Specific Gravity Urine	G	G	1.025			1.005-1.030
Aug 20 2015 15:59		POCT Urinalysis : Blood Urine	G	G	Trace-lysed		*	
Aug 20 2015 15:59		POCT Urinalysis : pH Urine	G	G	6.0			
Aug 20 2015 15:59		POCT Urinalysis : Protein Urine	G	G	Negative			
Aug 20 2015 15:59		POCT Urinalysis : Urobilinogen Urine	G	G	Normal			
Aug 20 2015 15:59		POCT Urinalysis : Nitrite Urine	G	G	Negative			
Aug 20 2015 15:59		POCT Urinalysis : Leukocyte Esterase Urine	G	G	1+		*	

Fig. 3. Examples of electronically charted POCT glucose (A) and urinalysis (B) results.

There will be instances where patients have not yet been registered but require POCT, for example, patients being triaged in the Emergency Department or newborn babies. In our institution, we developed several “unregistered patient” forms to be used in these situations. The form contains a generic barcode that can be scanned into the POCT device prior to testing. Once the patient has been registered, this form must be completed by the operator who completed the test and forwarded to the POCT team. The form includes the patient demographic information, POCT result, date and time of testing. The POCT team identifies the result in the POCT data management system and matches it with the correct patient to ensure the result ends up in the correct patient chart.

6. Location of POCT results in the electronic health record

It is imperative that POCT results be clearly distinguished from results produced in the central laboratory whether paper charts are used or the EMR to avoid confusion for clinicians interpreting results. This is also an ISO accreditation requirement (ISO 22870:2006 clause 5.8.3, 5.8.4) [17]. Analytical bias existing between the central laboratory and POCT methods means that POCT results will not match central laboratory results exactly. It is important that clinicians know where each result came from, particularly when they are trending results over time. In our hospital EMR, laboratory results are separated by specialty; examples include Biochemistry, Hematology, and Anatomical Pathology. In consultation with the medical advisory committee of the hospital, it was decided that POCT results would also be charted according to specialty but would be clearly distinguished from central laboratory results. Examples of POCT glucose and POCT urinalysis results are included in Fig. 3A and B, respectively.

7. Training and re-certification of POCT operators

Individuals performing POCT require training, not only on how to use the instruments, but also on how and where to

chart results, how and why quality control is performed and what to do if something goes wrong with an instrument. Operators also require ongoing assessment of competency through recertification. In 2005, the Centers for Medicare and Medicaid Services (CMS) in the United States performed a National survey of laboratories performing POCT. This study found that 19% of POCT operators had not been trained or evaluated for competency to perform testing. When asked to locate test instructions, 32% of operators could not. They found that 25% of POCT operators did not follow the manufacturer's instructions when performing testing [20].

With many individuals to train and limited human resources to support POCT programs, online training becomes an attractive option. In our institution, we developed online training modules for most of the POCT devices in-use. The modules are available through the Hospital e-learning system and are assigned to POCT operators by the POCT team. There is a quiz included at the end of each module with ten questions. Operators will be certified for use of the device once they have completed the training modules and have passed the quiz. The online training modules are also used as part of the annual recertification process for POCT operators and can be updated to include any changes to POCT policies and procedures on an annual basis.

Some POCT data management software can be linked directly to training material so that operators are automatically certified for use of a device upon successful completion of a training module. Examples include Roche's Cobas Academy linked to the Cobas IT 1000 data management system, online training through Radiometer's Aqure POCT management system. It is, however, important to keep in mind that online training may not be suitable for all learners and does not necessarily allow for a demonstration of competency by the learner. Furthermore, some individuals learn more effectively through active, hands-on training, which should be provided to complement on-line training. Hands-on training also allows for the individual being trained to demonstrate their competency in performing the testing.

POCT operators must be re-assessed for competency at regular intervals to ensure patient safety and to be compliant with accreditation standards. Some POCT software allow for auto recertification of operators simply by virtue of an operator successfully performing a specified number of quality control or patient tests within a defined period of time. For example, in our institution, operators are automatically re-certified on an annual basis if they perform one patient test and set of quality control tests within their annual certification window of one year. As long as operators are performing patient testing at regular intervals, their certification should never expire. For operators that do not meet the auto recertification criteria, they are required to complete the online training module and exam as well as perform quality control testing to regain certification.

8. Conclusions

POCT has become a mainstay in most hospitals, whether they are large academic health centres or rural community hospitals. POCT complements testing performed in the central laboratory and is necessary in certain situations. The conveniences of POCT do come with a price, however, which are not limited to monetary costs alone. The accreditation standards in-place for POCT can be difficult to meet but are important for patient safety. As testing moves away from the central laboratory and closer to the patient bedside, we as laboratorians, have a role to play in ensuring that the quality of results is not diminished.

Acknowledgments

I would like to acknowledge Linda Oliveras and Thomas Moran, two Medical Laboratory Technologists who have put in huge efforts to improve the POCT program at The Ottawa Hospital.

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