Practical Laboratory Medicine 22 (2020) e00187

Contents lists available at ScienceDirect

Practical Laboratory Medicine

journal homepage: www.elsevier.com/locate/plabm

Utilizing connectivity and data management system for effective quality management and regulatory compliance in point of care testing

Angela W.S. Fung [a,b,*]

[a] Department of Pathology and Laboratory Medicine, St. Paul's Hospital, Vancouver, British Columbia, Canada
[b] Department of Pathology and Laboratory Medicine, University of British Columbia, Vancouver, British Columbia, Canada

ARTICLE INFO

Keywords:
Point of care testing
Data management
Quality assurance
Electronic medical record

ABSTRACT

Point of care testing (POCT) is one of the fastest growing disciplines in clinical laboratory medicine. POCT devices are widely used in both acute and chronic patient management in the hospital and primary physician office settings. As demands for POCT in various healthcare settings increase, managing the quality and regulatory compliance are continually challenging. Despite technological advances in applying automatic system checks and built-in quality control to prevent analytical and operator errors, poor planning for POCT connectivity and informatics can limit data accessibility and management efficiency which impedes the utilization of POCT to its full potential. This article will summarize how connectivity and data management system can improve timely access to POCT results, effective management of POCT programs, and ensure regulatory compliance.

1. Introduction

Point of care testing (POCT) refers to near patient testing performed outside the central clinical laboratory by non-laboratory personnel. POCT provides a faster turnaround time (TAT) for test results which allows rapid clinical decision making. This has led to early adoption in acute care settings such as operating rooms, intensive care units and emergency departments within hospitals. There are increasing interests in expanding POCT to chronic disease management and community health in settings such as primary care physician offices, pharmacies, remote communities, and further in disaster relief initiatives and military operations [1–3]. Rapid TAT is the most commonly cited reason for POCT, yet the clinical utilization of POCT should be evidence-based, cost-effective, and focus on improving patient outcomes [4–6]. A number of systematic reviews and narrative reviews on evidence-based POCT are ongoing [4–14].

As demands for POCT have increased, managing the quality and regulatory compliance of POCT programs are continually challenging. Since POCT is performed by non-laboratory personnel, many clinical staff may not be familiar with quality laboratory practices including compliance to testing procedures, quality assurance practices, and regulatory requirements. Despite availability of national and international guidance and standard documents developed by professional and government bodies [15–22], a systematic review identified quality assurance, regulatory issues, and data management as recurrent, significant barriers to clinical implementation of POCT [6].

Abbreviations: DMS, data management system; EMR, electronic medical record; HIS, Hospital information system; LIS, Laboratory information system; POCT, Point-of-care testing; TAT, turnaround time; QC, quality control.

* Department of Pathology and Laboratory Medicine, St. Paul's Hospital, Vancouver, British Columbia, Canada.
E-mail address: afung7@providencehealth.bc.ca.

https://doi.org/10.1016/j.plabm.2020.e00187
Received 25 August 2020; Accepted 30 October 2020
2352-5517/© 2020 Published by Elsevier B.V. This is an open access article under the CC BY-NC-ND license (http://creativecommons.org/licenses/by-nc-nd/4.0/).

Here, this article will summarize the benefits of connectivity and data management system (DMS) for improving timely access to POCT results, supporting integrated patient electronic medical record (EMR), effective quality assurance and management of POCT programs, and ensuring regulatory compliance.

2. Connectivity and integration with electronic medical record (EMR)

2.1. POCT result integration with electronic medical record (EMR)

Accreditation and regulatory standards emphasize the increasing need to integrate POCT results into the patient's EMR [23]. This promotes accessibility of POCT results, ability to monitor and trend, prevents unnecessary repeat testing, and provides evidence for patient outcomes [18]. As POCT results are used to make clinical decisions, it is important to document results with associated reference intervals, units of measurements, critical values if applicable, date and time of testing, and also be traceable to device serial number, operator identification number, reagent lot number, and quality control (QC) results [24]. POCT results should also be clearly differentiated from other central laboratory results to avoid confusion and trending of results derived from different analytical methodologies [24].

2.2. Manual POCT result documentation and error rates

Traditionally, POCT results and related information are manually transcribed in the patient's paper chart at the time of testing near the bedside in the hospital [23]. In more recent years, POCT results may be manually entered directly or electronically scanned into the laboratory (LIS) or hospital information system (HIS). Outpatient POCT, such as in a primary physician office, documents are typically filed with their paper or electronic data system, which is often separate from the LIS or HIS and may not be interfaced to the EMR.

Handwritten records are often illegible and are at risk of transcription error and duplicate charting [15]. Manual entry of POCT results into LIS or HIS are similarly time-consuming and prone to transcription error. In my institution, an average of 1200 POC glucose results from 230 glucose meters are manually entered into the HIS by operators every day. If manual entry takes 1 min, this approximates to 7300 h of staff time in manual entry of POC glucose results annually. This estimate does not include the time needed to login into systems, confirm patient identification, and verify result entered. In the literature, manual entry for POC glucose results demonstrated an average of 3–5% transcription error rates in an inpatient medicine ward setting [25,26]. Transcription errors may include inversion, addition or loss of digits, rounding, and entry of non-numeric characters [26]. An audit study in my institution identified cases where the operator entered the plasma glucose result from the central laboratory analyzer into the POC glucose result field, due to the desire to trend POC glucose results but the affected result was measured above the device's analytical measuring range. Another audit study by Carraro and Plebani identified 12% of POC glucose results were omitted and never recorded into the patient's chart, in which some of these results would have been useful for clinical and treatment decisions [25].

Transcription error are more complex for POCT with multiple test components, such as POC urinalysis and POC blood gas analysis. Semi-quantitative POC urinalysis have ten or more test components (specific gravity, pH, protein, glucose etc.) with each component having multiple result options. The operator has to scroll through each test component and select several drop-down result options to complete one manual entry of POC urinalysis. Errors may involve selecting an incorrect result, unintentionally switching result during scrolling, and mismatching test components and results. Test components in quantitative POC blood gas analysis can range from one to over fifteen depending on the device and cartridge selected. Although there is a lack of published reports on the error rates for blood gas analysis, it is conceivable that the risk increases with each additional test component.

In my institution, medical laboratory technologists (MLTs), instead of the POC operator, manually enter results into the LIS for POCT that are considered at a higher risk for entry errors. In the laboratory, there is a specific procedure that requires verification by a second technical staff as per regulatory requirements. Despite having and following the verification procedure, an audit study for the POC hemoglobin A1c program in my institution identified 50% of results missed incorporation of a comment code that identifies the result as a POCT as well as including the operator initials. This workflow often causes delay in POCT results availability and thus affecting downstream care. Issues may include incomplete result forms, workload issues for laboratory staff, and result traceability. Alternatively, electronic scanning of instrument printout into the HIS system may be a possible solution. However, these scanned documents are difficult to search and view in the HIS and lacks discrete data fields which prevents trending and data mining.

2.3. POCT connectivity and data management system (DMS)

In the context of POCT, connectivity is interfacing POCT devices to the LIS or HIS or EMR via a DMS (also known as a middleware). Electronic DMS is the middleware that communicates and integrates data from multiple devices and databases and provides a single comprehensive solution for data management. Connectivity permits automated, real-time, bi-directional, electronic wired or wireless transmission of POCT results and related information [23,27]. The use of connectivity is the safest and most reliable method of data transfer. It reduces the time, eases the burden, and minimize errors related to POCT result documentation. The use of connectivity and DMS, wherever possible, are recommended for all POCT programs by national professional bodies [15,16].

My institution is comprised of acute care hospitals, community hospitals, long term care facilities, primary clinics, and dialysis units. We are currently undergoing system transformation with implementation of a new HIS, a new DMS, and POCT connectivity for the first time. When an institution is considering POCT connectivity and DMS for the first time, some features (Table 1) to consider include: 1) compliance to connectivity standard CLSI POCT01-A2 (2006) [28,29], 2) the design of DMS (e.g. open vs closed systems, remote access

capabilities), 3) compatibility with existing and future growth of POCT devices, 4) the ability to communicate bi-directionally, 5) the ability to interface to Admission, Discharge, and Transfer (ADT) system, 6) wireless or wired network infrastructure, 7) data storage and server requirements, 8) compatibility with existing LIS, HIS, operating systems, e-learning systems, and human resources databases, 9) compliance with privacy and security policies. Considerations should also include institution funding for ongoing software licensing, maintenance and upgrades as well as technical support from the information technology (IT) department [23,30–32].

DMS may be an open (vendor neutral) or closed (vendor specific) systems. Open DMS enable POCT devices from multiple vendors to be interfaced to a single DMS. Examples of open DMS include Remote Automated Laboratory System (RALS Web 3, Abbott Laboratories, Chicago, IL, USA), Telcor QML (TELCOR Inc, Lincoln, NE, USA), and Orchard Trellis (Orchard Software, Carmel, IN, USA). Open DMS may be an integrated system or interface engine system [31]. An integrated DMS is where multiple vendor devices interface to a single DMS, and requires the DMS vendor to have excellent relationships and experience in interfacing combinations of different POCT device vendors with different LIS, HIS, and EMR vendors. Interface engine DMS is when multiple vendor DMS interface to the LIS or HIS, and requires the POCT coordinator to be proficient in multiple vendor-supplied DMS and databases [31]. With increasing demands for open integrated DMS, traditionally closed DMS are now also offering options to interface to devices from other vendors. Remote access capabilities enable the POCT coordinator to monitor, review and troubleshoot from a remote centralized location.

When considering DMS compatibility with existing and future growth in POCT devices, it is important to keep in mind desirable features for both devices and DMS. For instance, not all POCT devices have built-in requirements for connectivity. Some POCT may require purchase of an adaptor or software upgrade to establish connectivity. Some POCT devices also may not transmit pertinent data in conjunction with the test result as per regulatory requirements, such as operator identification numbers, serial device numbers, reagent lot numbers, and quality control results. Manual visually read POCT, such as urine pregnancy, urine drug screens, urinalysis, occult blood tests, may or may not have an automated readout device for connectivity. In these cases, manual entry may still be required. A DMS that enables manual configuration and entry would also allow for comprehensive data management.

Uni-directional connectivity is when data transfers from the POCT device to DMS (e.g. QC and patient results), but information cannot transfer from the DMS to the POCT device (e.g. updating valid operators, QC and reagent lot numbers) [30]. Thus, bi-directional connectivity is preferred [30]. Additionally, POCT interfaced to the ADT system enable positive patient identification at the bedside where the device can display patient demographic information when the patient wristband barcode is scanned. Positive patient identification is extremely important with connectivity of POCT devices, as test results are transmitted often immediately. Patient identification errors can cause POCT results to be recorded to the wrong patient's chart, and may include entry errors, barcode scanning failures (illegible barcodes), barcode substitution (multiple wristbands, scanning other barcodes etc.), and use of inactive, incorrect and unregistered account numbers [33]. An audit study comparing pre- and post-implementation of POC glucose meter connectivity demonstrated that 18% of POC glucose results were identified to have an error in patient identification [34]. The use of DMS can detect

Table 1
Summary of desirable features for connectivity and data management systems.

Category	Features
Connectivity	• Connectivity standards (e.g. CLSI POCT01-A2, HL7) • Vendor neutral • Ability for bi-directional connection • Ability to interface to Admission, Discharge, Transfer (ADT) system • Ability for remote access • Real-time wireless or wired connections • Compatibility with existing and future growth in infrastructure (e.g. POC devices, operating systems, LIS, HIS, EMR systems, and other technical requirements) • Compliance with institution privacy and security policies
Result Management	• Result configuration and test mapping (e.g. location and categorization, units of measurements, decimal places, measuring ranges, reference ranges, instrument flags, critical values) • Information transmitted with the result (e.g. patient identification number, operator identification number, device serial numbers, reagent lots, QC, date and time of testing) • Ability to manual enter third-party POCT
Resources Management	• Device management (e.g. serial numbers, locations, dates for purchase, retirement, service, maintenance, software upgrades) • Inventory management (e.g. activate and inactivate reagent lot numbers, QC lot numbers, acceptable ranges, dates of initiation, preparation and expiration) • Billing capabilities
Quality Assurance Management	• Quality control documentation (e.g. Levey-Jennings charts) • Maintenance documentation • Data management, mining and audits • Quality report generation (e.g. critical result reports, utilization reports, misidentification reports)
Operator Management	• Operator management (e.g. operator profiles of identification number, name, contact information, dates for certification and expiration) • Ability to connect to online e-learning systems for electronic training and competency assessment • Ability to connect to institution human resources database • Automatic reminder and re-certification

unusual digit patterns to patient's medical record numbers, hold the corresponding POCT result in the DMS, and alert the POCT coordinator for investigation and resolution [33–35]. Similarly, for unregistered patients, a set of temporary codes can be assigned for automatic holding in the DMS until the patient is registered [30].

Connections may be via cable wires or wireless. Wired connection workflow should consider docking stations in the ward, desk space, computer and hardware requirements such as number of power sources, network ports, and cables. Wireless connections have less hardware requirements but may be subject to signal strength issues and interferences. Many hospitals have old wiring and unstable wireless infrastructure, which can be very costly to implement in settings such as an operating room. Thus, wireless and wired network connections require site-specific assessment in balancing convenience and cost with existing infrastructure [23,30]. For privacy and security purposes, it is also important to assess the amount of patient demographic information available or stored on individual POCT devices, DMS and servers. Thorough security and privacy assessments such as data encryptions, firewalls, and limiting access to specific locations and/or to specific operators are needed [30].

Support from local IT department is essential for test mapping. Test mapping is the configuration of each POCT test with a unique test code with defined specimen type, units of measurement, number of decimal places, age and sex partitioned reference intervals, analytical measuring ranges, critical result ranges, and instrument flags. It is also important to consider the location of POCT results in the HIS or EMR (e.g. organized by specialty) with consultation from the institution's medical leadership. Once configured and interfaced, transmission and reporting of results should be tested thoroughly for accuracy. Workflow mapping with clinical practitioners should have a detailed communication system for ordering of POCT, notification of incorrect or unregistered patients, and notification for testing or resulting issues. Funding for ongoing licensing, technical maintenance and upgrades should also be considered with institution managers. Detail technical and workflow assessment should be jointly assessed with respective departments from your local institution.

3. POCT program management

Within the hospital setting, a multidisciplinary POCT committee provides overall oversight for the POCT programs [15,16,19]. This committee typically includes, but not limited to, the POCT director, POCT coordinator, physicians, nurse practitioners and managers, infection control, supply chain, information technology, and biomedical engineering [15,16,19]. The committee oversees and assesses the clinical needs of POCT, review evidence on outcomes, evaluate appropriateness of tests, patient population and testing locations, and ensures that all regulatory requirements are met. POCT accreditation and regulatory requirements are mostly based on the International Standard Organization (ISO) 22870 (2016) standard [24].

A subset team comprised of the POCT director, POCT coordinator and MLTs are responsible for managing and assuring the quality of the POCT program. This includes the selection and evaluation of devices, developing and updating standard operating procedures, operator training and competency assessments, maintaining quality assurance and compliance, cost-benefit analysis, and risk management. It is essential to ensure there are adequate number of POCT coordinator and MLTs dedicated to support and manage the size and scope of the POCT program [30,36].

POCT program management and documentation for regulatory compliance are labour intensive and time-consuming, especially for large POCT programs that include multiple testing locations, a large number of operators, and an extensive POCT test menu. The use of DMS help reduces the manual workload and improve efficiency for the POCT coordinator. When considering DMS as a tool for effective POCT program management, consider functions that support regulatory compliance such as management of resources, quality assurance, and training and recertification of operators.

3.1. Resource management: device and inventory management

For management of resources, a detailed and documented record of all POCT devices including serial numbers, facilities and testing locations, purchase and retirement dates, maintenance and service repair dates, software versions and upgrades are required [24]. QC materials, reagents and consumables inventory are also documented with content, lot numbers, acceptable ranges, storage requirements, preparation and expiration dates [24]. These documents are challenging to maintain manually. This may require dedicated cabinet space for retaining paper records or creating electronic filing system on a secured shared drive.

An open integrated DMS is a comprehensive database system to maintain documentation on resources from multiple vendor devices, QC materials, reagents, and consumables. DMS also enable and assists in troubleshooting for issues related to error messages on the device, device and base unit connections, and missing devices in real-time and remotely. When POCT devices are bi-directionally connected, inactivation of old lots and activation of new lots of QC materials and reagents may be updated remotely and automatically to multiple same vendor devices via the DMS. This helps in preventing the use of expired or inactive devices, reagents and QC materials for patient testing.

3.2. Quality assurance management: QC, compliance, audits and reports

Prior to patient testing, routine maintenance and QC testing are required to ensure POCT devices and reagents are functioning as expected. In my institution, much of the POCT testing and quality procedures are documented manually in various paper charts – a chart for daily QC performance, a chart for routine maintenance, and another chart for order and result documentation. The POCT coordinator is required to visit each care unit periodically and review these documents in various files and binders for regulatory compliance. These manual records are often incomplete, unreliable or misplaced, making it difficult to perform regular reviews and audits. Errors and issues identified often cannot be investigated and resolved in a timely manner.

Similar to other reports, audit studies in my institution have identified common quality issues including low compliance to QC testing procedures, routine maintenance, and follow up procedures such as repeat testing and critical value reporting [34,37]. QC testing and maintenance are often assigned to support staff on night or weekend shifts. The clinical staff who performed the POCT may not have performed the QC testing themselves. Further communications revealed that some clinical staff were unaware of the location of QC being stored or the requirement of scheduled routine maintenance.

Quality assurance management can be improved with device technology, connectivity and DMS. Some DMS can capture and monitor maintenance activities given the device is also compatible with that function. Devices with QC lockout function can ensure QC testing compliance by locking the device and alerting the operator if the QC frequency interval has been exceeded or a QC result is outside of acceptable limits. With connectivity established, QC results for each device, operator, and testing location can be sorted and reviewed remotely and graphically displayed as Levey-Jennings QC charts. When patient demographic information, QC and results are electronically captured in the DMS, the POCT coordinator can access and troubleshoot in real-time and extract data for audits. Reports may also be generated to monitor test performances and quality improvement initiatives such as critical results reports, utilization reports, misidentification reports, and hypoglycemic reports.

3.3. POCT operator management: training and competency assessments

Clinical personnel performing POCT require training and competency assessments at regular intervals [24]. POCT training not only includes how to use the POCT device for patient testing, but also on how and why QC is performed, how to troubleshoot and perform routine maintenance, and how and where to chart results [30]. Typically, in large institutions the number of personnel to be trained may be in the thousands and have diverse baseline knowledge in POCT and requirements. Turnover of employees, cross-appointment to multiple wards and sites, and the diverse range of employment types (e.g. full-time, part-time, casual and student) increase the challenge of tracking active operators who are trained and have demonstrated competency. In my institution, only a handful of POCT programs have training and competency assessments available on the electronic learning system, the remaining programs are managed manually. In our Emergency Departments, where there are over 250 nurses and support staff performing four different POCT programs, it is particularly challenging to maintain an annual list of operators, training and competency assessment documents manually.

With many POCT operators to train and to assess competency, the use of operator lockout function on the device and DMS can control access to POCT devices, maintain an up-to-date database for a large number of operators, and automate certification statuses. Devices with an operator lockout function will only permit valid operators with up-to-date certification to operate the device and perform patient testing. Some POCT DMS can be linked directly to online electronic learning systems. When operators have certifications that is pending or nearing expiration, the DMS can send an automatic notification via the device itself or email with the electronic learning material and online assessment links. When operators have completed and met the defined criteria (e.g. passing an online quiz or completing a number of successful QCs and patient tests in a year), the DMS can be configured to automatically re-certify the operator for a specific POCT device for a defined period of time [30].

4. Conclusions

Many laboratories increasingly value the importance of informatic solutions for connectivity, effective management, and regulatory compliance. Connectivity and DMS are essential tools in improving the accessibility and ability to manage POCT programs efficiently. These systems greatly reduce errors, improve compliance to accreditation and regulatory standards, and thus enhance the overall quality of the POCT programs. It is important to note that although POCT programs can be managed remotely, in reality there are benefits to periodic onsite visits and audits in identifying deficiencies, compliance and improvements. Effective management of POCT programs ultimately relies on building relationships, collaborations, and partnerships between laboratory and clinical practitioners to ensure the highest quality POCT for patients. With rapid expansion of POCT to non-traditional settings, consultation and collaboration with laboratory directors and coordinators with qualifications and expertise in POCT is strongly recommended when designing and implementing POCT programs.

Funding

None declared.

CRediT authorship contribution statement

Angela W.S. Fung: Conceptualization, Investigation, Writing - original draft, Writing - review & editing.

Declaration of competing interest

None declared.

Acknowledgement

I would like to acknowledge Sheri Young, Judi London, and Dr. Andre Mattman for providing their expertise and input. I would also

like to acknowledge and thank the laboratory POCT team, Sheri Young and medical laboratory technologists, for their diligence and dedication in managing and improving the POCT program at St. Paul's Hospital and Providence Health Care.

References

[1] National Institute of Biomedical Imaging and Bioengineering/National Heart, Lung, C.P. Price, L.J. Kricka, Improving healthcare accessibility through point-of-care technologies, Clin. Chem. 53 (2007) 1665–1675.
[2] A.K. Fuzery, BobyakD, Edmonton Stroke Program, Edmonton, E. Chang, R. Sharman, A.A. Venner, Challenges of point-of-care testing in ambulances, J Appl Lab Med 4 (2019) 293–295.
[3] A. Albasri, A. Van den Bruel, G. Hayward, R.J. McManus, J.P. Sheppard, Verbakel JYJ, Impact of point-of-care tests in community pharmacies: a systematic review and meta-analysis, BMJ Open 10 (2020), e034298-034298.
[4] V. Pecoraro, L. Germagnoli, G. Banfi, Point-of-care testing: where is the evidence? A systematic survey, Clin. Chem. Lab. Med. 52 (2014) 313–324.
[5] C. Florkowski, A. Don-Wauchope, N. Gimenez, K. Rodriguez-Capote, J. Wils, A. Zemlin, Point-of-care testing (POCT) and evidence-based laboratory medicine (EBLM) - does it leverage any advantage in clinical decision making? Crit. Rev. Clin. Lab Sci. 54 (2017) 471–494.
[6] A.D. Quinn, D. Dixon, B.J. Meenan, Barriers to hospital-based clinical adoption of point-of-care testing (POCT): a systematic narrative review, Crit. Rev. Clin. Lab Sci. 53 (2016) 1–12.
[7] C.J. Heneghan, J.M. Garcia-Alamino, E.A. Spencer, A.M. Ward, R. Perera, C. Bankhead, P. Alonso-Coello, D. Fitzmaurice, K.R. Mahtani, I.J. Onakpoya, Self-monitoring and self-management of oral anticoagulation, Cochrane Database Syst. Rev. 7 (2016) CD003839.
[8] R. Aabenhus, J.U. Jensen, K.J. Jorgensen, A. Hrobjartsson, L. Bjerrum, Biomarkers as point-of-care tests to guide prescription of antibiotics in patients with acute respiratory infections in primary care, Cochrane Database Syst. Rev. 11 (2014) CD010130. CD010130.
[9] P. Sharma, G. Scotland, M. Cruickshank, E. Tassie, C. Fraser, C. Burton, B. Croal, C.R. Ramsay, M. Brazzelli, The clinical effectiveness and cost-effectiveness of point-of-care tests (CoaguChek system, INRatio2 PT/INR monitor and ProTime Microcoagulation system) for the self-monitoring of the coagulation status of people receiving long-term vitamin K antagonist therapy, compared with standard UK practice: systematic review and emic evaluation, Health Technol. Assess. 19 (2015) 1–172.
[10] M.P. McTaggart, R.G. Newall, J.A. Hirst, C.R. Bankhead, E.J. Lamb, N.W. Roberts, C.P. Price, Diagnostic accuracy of point-of-care tests for detecting albuminuria: a systematic review and meta-analysis, Ann. Intern. Med. 160 (2014) 550–557.
[11] S. Shivkumar, R. Peeling, Y. Jafari, L. Joseph, N. Pant Pai, Accuracy of rapid and point-of-care screening tests for hepatitis C: a systematic review and meta-analysis, Ann. Intern. Med. 157 (2012) 558–566.
[12] L. Al-Ansary, A. Farmer, J. Hirst, N. Roberts, P. Glasziou, R. Perera, C.P. Price, Point-of-care testing for Hb A1c in the management of diabetes: a systematic review and metaanalysis, Clin. Chem. 57 (2011) 568–576.
[13] A. Gialamas, A. St John, C.O. Laurence, T.K. Bubner, PoCT Management Committee, Point-of-care testing for patients with diabetes, hyperlipidaemia or coagulation disorders in the general practice setting: a systematic review, Fam. Pract. 27 (2010) 17–24.
[14] C.P. Price, I. Smith, A. Van den Bruel, Improving the quality of point-of-care testing, Fam. Pract. 35 (2018) 358–364.
[15] J.H. Nichols, D. Alter, Y. Chen, T.S. Isbell, E. Jacobs, N. Moore, Z. Shajani-Yi, AACC guidance document on management of point-of-care testing, J Appl Lab Med 5 (2020) 762–787.
[16] P.M. Yip, J. Shea, A. Fuezery, Y. Huang, L. Massicotte, N. Tetreault, C. Tomalty, J.L.V. Shaw, Point-of-care testing: a position statement from the Canadian society of clinical chemists, Clin. Biochem. 53 (2018) 156–159.
[17] J.H. Nichols, R.H. Christenson, W. Clarke, A. Gronowski, C.A. Hammett-Stabler, E. Jacobs, S. Kazmierczak, K. Lewandrowski, C. Price, D.B. Sacks, R.L. Sautter, G. Shipp, L. Sokoll, I.D. Watson, W. Winter, M.L. Zucker, National Academy of Clinical Biochemistry, Executive summary. The national academy of clinical biochemistry laboratory medicine practice guideline: evidence-based practice for point-of-care testing, Clin. Chim. Acta 379 (2007) 14–30.
[18] IFCC, Thinking of Introducing POCT: Things to Consider, International Federation of Clinical Chemistry and Laboratory Medicine (IFCC), 2014.
[19] CLSI, POCT04- - Essential Tools for Implementation and Management of a Point-Of-Care Testing Program, third ed., Clinical and Laboratory Standards Institute, Wayne, PA, 2016.
[20] S.S. Ehrmeyer, R.H. Laessig, Regulatory compliance for point-of-care testing: 2009 United States perspective, Clin. Lab. Med. 29 (2009) 463–478.
[21] CLSI, POCT09-A Selection Criteria for Point-Of-Care Testing Devices, Clinical and Laboratory Standards Institute, Wayne (PA), 2010.
[22] CLSI, POCT07-A Quality Management: Approaches to Reducing Errors at the Point of Care, first ed., Clinical Laboratory Standards Institute, Wayne (PA), 2016.
[23] Ji Yeon Kim, M.D. MPH, K. Lewandrowski, Point-of-Care testing informatics, Clin. Lab. Med. 29 (2009) 449–461.
[24] International Organization for Standardization, ISO 22870:2016 (E): Point-Of-Care Testing (POCT) - Requirements for Quality and Competence, Geneva Switzerland, http://www.iso.org/iso/catalogue_detail.htm?csnumber=35173, 2006. second ed.
[25] P. Carraro, M. Plebani, Post-analytical errors with portable glucose meters in the hospital setting, Clin. Chim. Acta 404 (2009) 65–67.
[26] J.A. Mays, P.C. Mathias, Measuring the rate of manual transcription error in outpatient point-of-care testing, J. Am. Med. Inf. Assoc. 26 (2019) 269–272.
[27] Lewandrowski, POCT Overview and Look to the Future, 2001.
[28] K. Dyer, J.H. Nichols, M. Taylor, R. Miller, J. Saltz, Development of a universal connectivity and data management system, Crit. Care Nurs. Q. 24 (25) (2001) 38, quiz 2 pp. following 75.
[29] CLSI, Point-of-care Connectivity; Approved Standard. CLSI Document POCT01-A2, second ed., Clinical and Laboratory Standards Institute (CLSI), Wayne, PA, 2006, pp. 1–306.
[30] J.L.V. Shaw, Practical challenges related to point of care testing, Pract Lab Med 4 (2015) 22–29.
[31] Kim Gregory, M.T.(ASCP), C.L.S. NCA, K. Lewandrowski, MD, Management of a point-of-care testing program, Clin. Lab. Med. 29 (2009) 433–448.
[32] N.A. Halpern, T. Brentjens, Point of care testing informatics. The critical care-hospital interface, Crit. Care Clin. 15 (1999) 577, vii.
[33] G. Alreja, N. Setia, J. Nichols, L. Pantanowitz, Reducing patient identification errors related to glucose point-of-care testing, J. Pathol. Inf. 2 (22) (2011) 3539–80718. Epub 2011 May 11.
[34] J. Shaw, The dark side of point-of-care testing, Clin. Biochem. 50 (2017) 466–467.
[35] J.H. Nichols, C. Bartholomew, M. Brunton, C. Cintron, S. Elliott, J. McGirr, D. Morsi, S. Scott, J. Seipel, D. Sinha, Reducing medical errors through barcoding at the point of care, Clin. Leader Manag. Rev. 18 (2004) 328–334.
[36] K. Lewandrowski, K. Gregory, D. Macmillan, Assuring quality in point-of-care testing: evolution of technologies, informatics, and program management, Arch. Pathol. Lab Med. 135 (2011) 1405–1414.
[37] M.J. O'Kane, P. McManus, N. McGowan, P.L.M. Lynch, Quality error rates in point-of-care testing, Clin. Chem. 57 (2011) 1267–1271.