Quality Management In Point-Of-Care Testing (POCT): The Interface Between Nursing Competency And Laboratory Standards

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Abstract

Point of Care Testing (POCT) has emerged as an essential aspect of contemporary healthcare delivery, especially within primary healthcare, where immediate medical decisions are required. Nonetheless, quality management of POCT is characterized by distinct difficulties, where it occupies an evolving intersection of nursing and analytical standards. Informed by recent consensus-driven perspectives and global standards, this article critically discusses the essential determinants of quality management of POCT, including internal quality control (IQC) schedule, user performance, and device factors. Building on recent consensus-driven perspectives and global standards, this article formulates a comprehensive framework for ensuring quality assurance within POCT, bridging analytical accuracy and pragmatism within resource-constrained settings of primary healthcare delivery. This article integrates contributions from evidence on risk stratification for analyses, device complexity evaluation, and user friendliness analysis, formulating a comprehensive approach for IQC schedule determination. Further, this article critically examines the technological shifts of POCT, including smartphone platforms, continuous monitoring instruments, and molecular diagnostic instruments. Notably, findings from this article illustrate that there is a critical need for device-

specific POCT quality management programs, taking into consideration both analytical accuracy within medical test outcomes, while pragmatically relating POCT analyst activities within non-laboratory settings. This article contributes critical perspectives, guidelines, and policy frameworks for healthcare managers, medical, and nursing professionals charged with POCT quality management programs.
Keywords: point of care testing, quality control, competency of nurses, laboratory standards, primary healthcare, quality assurance

1. INTRODUCTION

Point-of-Care Testing (POCT) is an paradigm shift in the field of lab medicine that allows testing to be done at the location of the patient. The International Organization of Standardization ISO 22870:2016 has defined POCT as follows: "Testing that is carried out near or at the point of the patient with the result interpreted as providing the possible change of the care of the patient" (Gidske et al., 2022). The advantages that come with point-of-care testing are ideal.

The international market for POCT has registered significant growth due to advancement in technology, rising cases of chronic diseases, and the need for rapid diagnostic approaches in various healthcare settings (Fortune Business Inside, 2020). Nonetheless, despite the constant technological improvement and ease of use, the process of POCT continues to encounter various challenges related to quality, training of operators, and standardization of procedures within various healthcare settings (Gidske et al., 2022).

Another difference between POCT in primary healthcare and traditional laboratory tests is based on the operational conditions. For instance, in primary healthcare, tests are mostly conducted by individuals not working in laboratories but rather in healthcare facilities by professionals like registered nurses or medical assistants with one-component analyzers and smaller quantities of samples (Gidske et al., 2022). However, it is noted within most centralized laboratories where most PTCE tests are conducted, most of the errors are in the preanalytical component, unlike in POCT where most PTCE lies in phases (O'Kane et al., 2011).

The intersection of nursing competency and laboratory standards is an area of both opportunities and challenges. It might be difficult for healthcare professionals such as nurses to deal with multiple tasks while performing POCT. According to ISO 15189:2012 guidelines, quality control materials should be inspected periodically depending upon the stability of the process and risk of patient harm due to incorrect results (Gidske et al., 2022). It might be difficult to apply this principle in a practical manner depending upon multiple POCT instruments and settings.

1.1.This paper intends to:

1. Assess the status of the current management of quality in POCT, emphasizing internal quality controls
2. Honest analysis of factors that influence IQC frequency determination in primary health care
3. Assess the competencies needed for non-laboratory staff involved in
4. Present evidence-based recommendations for device-specific protocols for quality control.

5. Review emerging technologies and their effects on quality management in point-of-care testing
6. Identification of areas where current practice falls short and strategies for improving quality assurance in POCT

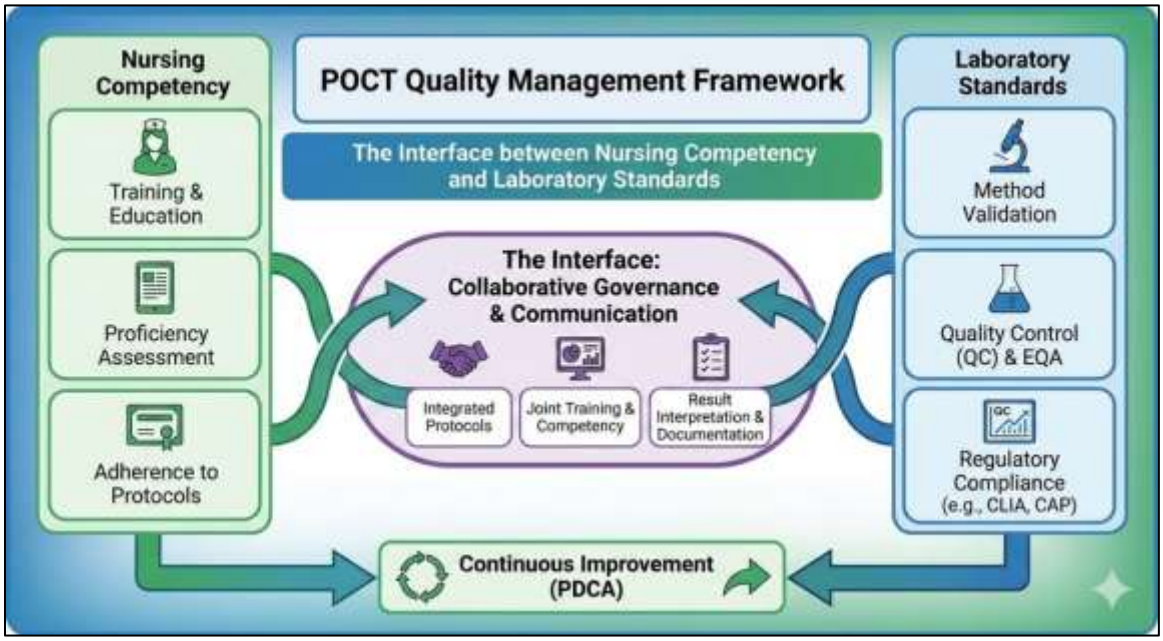

Figure 1: Framework of POCT Quality

2. LITERATURE REVIEW

2.1 Evolution of POCT Technology

There has been a radical change in the landscape of POCT in the past decades. The original POCT analyzers were basic, semiquantitative tests. They included urine dipsticks, pregnancy tests, etc. Modern POCT has progressed to incorporate advanced technologies, which include blood gas analyzers, hematology analyzers, molecular diagnostic analyzers, as well as CGM systems.

St John & Price (2014) have described the existing and evolving technologies in POCT, starting from the humble lateral flow immunoassay to nucleic acid amplification tests and biosensors. The advent of smartphones in POCT instrumentation has enabled the management of data and connectivity to the electronic healthcare record (Liu et al., 2019). The wearable and continuous monitoring systems form the future of POCT, where there is the ability to monitor and manage the parameters of the human body in real time (Dunn et al., 2018).

2.2 Quality Control in POCT

Quality assurance within the context of POCT poses distinct challenges to the traditional approach used by the clinical lab setting. Price et al. (2018) noted that the enhancement of the quality process throughout the stages of POCT, including the selection process, interpretation, and actioning of results, is highly essential. However, the literature base with regard to the frequency of IQC carried out within the context of POCT is very limited (Holt and Freedman, 2016; Gidske et al., 2022).

Internal quality control is essential in ensuring accuracy and precision of analytical processes (Gidske et al., 2022). However, current standards provide inconsistent information concerning IQC rates. Some guidelines for POCT list rates from daily to monthly, or rates in compliance with manufacturers' instructions (Briggs et al., 2008; AACC, 2020). There is, thus, no standard approach for determining IQC rates, which may be problematic without proper frameworks (Nichols, 2014).

2.3 Risk-based Approaches to Quality Control

There have been a number of thinkers who have proposed risk-based strategies for the frequency of IQC. Cooper et al. in 2011 pointed out that those tests with a greater risk of causing harm to patients should be subjected to frequent quality control. Martin in 2008 and Holt and Freedman in their proposal in 2016 grouped POCT equipment on the basis of their complexity and said that more frequent IQC should be performed on more complex equipment due to their vulnerability to analytical errors.

The idea of individualized quality control plans, or IQCP, transpired as an alternate view that replaced the traditional fixed-frequency strategies or traditional plans, as proposed by CLSI in 2011, as well as centers for disease control and prevention in 2013; however, the implementation of these plans may be resource-intensive, which might make it impractical for small primary healthcare labs, as cited in Gidske, Støy, and Røyset in 2022.

2.4. Operator Competency and Training

Competency in healthcare providers is an essential consideration in POCT quality. ISO 22870:2016 has been identified to encompass a set of competency requirements in relation to sampling practice, understanding clinical utility and limitations, technical procedure knowledge in analytical procedures, reagent storage conditions, quality control processes, understanding technical limitations, proper follow-up after obtaining out-of-range results, infection control processes, and documentation (Gidske et al., 2022).

According to Meier and Jones (2005), incompetence of the operator and failure to adhere to procedures were significant sources of error with POCT. Nichols (2011) emphasized the sources of errors occurring with blood glucose meters due to lack of proper training and non-adherence to the manufacturer's instructions. The problem is further exacerbated in the primary health care setting because the nurse's handling of POCT is but one of the many aspects they attend to.

Bukve et al. (2016) have shown that involvement in quality improvement activities, including regular IQC analysis, as well as continuous staff training, was related to better analytical quality concerning POCT analyzers for the measurement of hemoglobin, C-reactive protein, and glucose. This is consistent with the need to sustain competence.

2.5 Regulatory and Accreditation Requirements

2.5 Regulatory and Accreditation Requirements

POCT quality management should be practiced under different and often complex regulatory frameworks, which vary internationally. In the United States, laboratory testing, including POCT, is based on requirements issued by the Clinical Laboratory Improvement Amendments (CLIA) - CMS.gov, 2020-. The European Union issues medical device regulations and accreditation standards through the European Accreditation, such as EA-4/20 G:2014.

The World Health Organization, 2011, provided comprehensive guidance on laboratory quality management systems applicable in the POCT setting. Guidelines

have been developed at a country level by national organizations, such as National Pathology Accreditation Advisory Council requirements in Australia (2021), and guidelines from the National Near-Patient Testing Consultative Group in Ireland (2021).

These are minimum regulatory requirements for the quality management of POCT but usually are not detailed enough to include device-specific requirements; therefore, most often, local interpretation and implementation of these broad regulatory principles by healthcare organizations into their particular POCT repertoire and operational environment become necessary.

3. MATERIALS AND METHODS

3.1 Quality Management Framework Development

The article tries to synthesize findings from a systematic literature review and consensus-based approach developed by the Norwegian Organization for Quality Improvement of Laboratory Examinations. The general methodology Gidske et al. present in 2022 serves as a general framework, augmented by international guidelines and published research on the POCT quality management.

3.2 Literature Search Strategy

Literature searches were performed systematically using PubMed, combining the following key words and phrases: point-of-care, point-of-care testing, point-of-care systems, quality assurance, quality control, internal quality control, and quality control issues in point-of-care testing. The search covered publications from the year 2000 up to 2021, mainly those discussing evidence-based approaches for quality management in POCT.

After de-duplication and non-English publication removal, the relevant studies were identified by abstract screening and full-text review. Further to this, international standards and guidelines from organizations like ISO, CLSI, WHO, and national regulatory bodies were also included.

3.3 Consensus Development Process

The framework presented here is based on a consensus development process over a period of 14 months with laboratory medicine specialists, researchers, and laboratory advisors who have comprehensive POCT experience. The working group consisted of medical specialists in laboratory medicine, biomedical laboratory scientists, and researchers focused on quality improvement in primary health care.

The Road to Consensus: Iterative review and refinement through several stakeholder meetings, including presentations to laboratory advisors and medical specialists, were part of the consensus process. Practical feasibility considerations were informed by the input from frontline users of the POCT systems in primary healthcare settings.

3.4 Development of Scoring System

A scoring system was developed to determine IQC frequency based on four critical factors:

Factor A: Risk to patients in case of harm, depending on the importance of the analyte for diagnosis and monitoring

Factor B: Type of POCT device considering complexity and potential sources of error

Factor C: Ease of use by intended operators D. No. of patient samples analyzed over given periods of time

For each POCT device, numerical scores were assigned for factors A, B and C. The sum of these scores determined the general recommended IQC frequency. Factor D allowed adjustment of frequencies for individual practices, based on testing volume.

4. RESULTS

4.1 Scoring System for IQC Frequency Determination

The consensus-based scoring system provides a structured approach to determining IQC frequency based on multiple dimensions of quality risk. Complete scoring framework with point allocations and interpretation guidelines are given in Table 1.

Table 1: Scoring System Framework for Determining IQC Frequency in POCT

Factor	Category	Score	Description
A. Analyte Risk	Moderate-risk	2 points	Analytes supporting clinical decisions but with lower immediate harm potential
	High-risk	4 points	Analytes essential for critical diagnostic or monitoring purposes
B. Device Type	Qualitative test	1 point	Visual reading, simple strip-based tests (e.g., pregnancy tests)
	Strip-based with automatic reading	2 points	Automated readers for strip tests (e.g., glucose meters)
	Single cartridge	3 points	Single-use cartridge systems (e.g., HbA1c analyzers)
	Larger bench-top	4 points	Automated bench-top instruments (e.g., blood cell counters)
C. User-friendliness	Easy	1 point	Minimal procedural steps, intuitive operation
	Moderately difficult	2 points	Multiple steps, requires attention to detail
	Difficult	3 points	Complex procedures, multiple potential error sources
Total Score	10-11 points	-	**Daily IQC** recommended
	7-9 points	-	**Weekly IQC** recommended
	5-6 points	-	**Monthly IQC** recommended
	4 points	-	**Occasionally** (before new batches, unexpected results, maintenance)

Additional IQC Requirements (All Devices):

•Before new reagent/test batch
• After unanticipated results of investigations
• When suspecting error
• After any instrument repair or maintenance

4.2 Device-Specific IQC Recommendations

All 17 analytes and 134 different POCT devices (153 analyte-device combinations) used in Norwegian primary healthcare were evaluated by the scoring system. Scores and recommendations for commonly used POCT devices are presented in Table 2.

Table 2: IQC Frequency Recommendations for Common POCT Devices

Analyte	POCT Device (Manufacturer)	Factor A Score	Factor B Score	Factor C Score	Total Score	IQC Frequency
Cholesterol	Afinion (Abbott)	2	3	1	6	Monthly
CRP	QuikRead (Aidian)	2	3	2	7	Weekly
	Cobas h 232 (Roche)	2	3	2	7	Weekly
	HemoCue (HemoCue)	2	3	2	7	Weekly
D-dimer	QuickVue InLine Strep A (Quidel)	2	1	1	4	Occasionally
Glucose	Afinion (Abbott)	4	2	2	8	Weekly
HbA1c	Diaquick H.Pylori (Dialab)	4	1	1	6	Occasionally
Hematology	MicrosEmi CRP (Horiba)	4	4	3	11	Daily
Hemoglobin	HemoCue (HemoCue)	4	2	2	8	Weekly
INR	CoaguChek (Roche)	4	2	2	8	Weekly
Mononucleosis	Diaquick Mononucleosis (Dialab)	2	1	1	4	Occasionally
Occult blood	Hemo-Fec (Diag Nor)	2	3	2	7	Weekly
Pregnancy	Alere hCG Cassette (Abbott)	2	1	1	4	Occasionally
SARS-CoV-2	Panbio COVID-19 (Abbott)	2	3	2	7	Weekly
Troponin T	Cobas h 232 (Roche)	4	3	2	9	Weekly
Urine albumin/ACR	Afinion (Abbott)	4	3	2	9	Weekly
Urine test strip	Multistix/Clinitek (Siemens)	2	2	2	6	Monthly

4.3 Volume-Based Adjustments to IQC Frequency

Testing volume is a major determinant of the number of potentially erroneous results released before detection through IQC. Table 3 offers suggested modification of general IQC frequencies in relation to sample volume in individual practices.

Table 3: IQC frequency adjusted individually for volume of testing

General IQC Frequency	0-3 tests/month	1-2 tests/week	3-50 tests/week	>50 tests/week
Occasionally	Before patient sample	Before patient sample	Keep occasionally	Keep occasionally
Monthly	Before patient sample	Decrease to occasionally	Keep monthly	Increase to weekly
Weekly	Before patient sample	Decrease to monthly	Keep weekly	Increase to daily
Daily	Before patient sample	Decrease to weekly	Keep daily	Keep daily

For very low-volume testing (0-3 samples per month), IQC should be performed before each patient sample to ensure system performance, regardless of general frequency recommendation.

4.4 Distribution of Recommendations by Analyte Risk Category

Finally, analysis of the 153 analyte-device combinations showed distinct patterns according to the risk classification of the analytes:

High-Risk Analytes (4 Points)

- Total devices: 74
- Daily IQC: 14 devices (19%)
- Weekly IQC: 57 devices (77%)
- Monthly IQC: 3 devices (4%)
- Occasional: 0 devices (0%)

Moderate-Risk Analytes (2 points):

- Total devices: 79
- Daily IQC: 0 devices (0%)
- 39 devices - Weekly IQC - 49%
- Monthly IQC: 15 devices (19%)
- occasional: 25 dispositions (32%)

All blood cell counters (n=14) had recommendations for IQC daily, as per high complexity (4 points for the device type) along with high-risk analytes (4 points). All glucose meters of different manufacturers fell under the umbrella of weekly recommendations in IQC. INR devices were most variable: CUBE and SimpleSimon PT received daily recommendations, while CoaguChek, iLine microINR, and Xprecia Stride received a recommendation for IQC once weekly due to differences in user-friendliness scores.

4.5 Impact Analysis of the Implementation of the Scoring System

Results from the Noklus EQA surveys carried out in November 2019 gave an indication of the number of laboratories likely to adjust their current IQC practices. Table 4 summarizes the likely changes.

Table 4: Expected Shift in IQC Frequency following the Implementation of a Scoring System.

Analyte	POCT Device	Need to Increase Frequency n (%)	Need to Decrease Frequency n (%)	No Change Required n (%)	Total Participants
CRP	QuikRead (Aidian)	250 (28%)	54 (6%)	592 (66%)	896
Glucose	HemoCue (HemoCue)	189 (42%)	21 (5%)	238 (53%)	448
HbA1c	Afinion (Abbott)	308 (41%)	36 (5%)	413 (55%)	757
Hematology	MicrosEmi CRP (Horiba)	89 (35%)	12 (5%)	154 (60%)	255
INR	CoaguChek (Roche)	156 (38%)	28 (7%)	227 (55%)	411
Overall	-	992 (37%)	151 (6%)	1,624 (57%)	2,767

•For each of the analyzed devices, 37% of laboratories would require an increase in IQC, 6% could reduce IQC, while 57% already met the proposed recommendations. The findings suggest that an increase would be necessary for a significantly high percentage of primary health care laboratories.

4.6 Multi-Assay Analyzer

Multiassay analyzers introduced new challenges as different analyzers on the same equipment required different IQC suggested frequency levels. Variability is evident in Table 5 below.

Table 5: Variation Of IQC Frequency Among Multiassay Platforms

Platform	Analyte	Total Score	IQC Frequency	Rationale for Difference
Afinion (Abbott)	CRP	7	Weekly	Moderate-risk analyte (2 pts)
	HbA1c	9	Weekly	High-risk analyte (4 pts)
	Urine ACR	9	Weekly	High-risk analyte (4 pts)
	Cholesterol	6	Monthly	Moderate-risk analyte (2 pts)
Cobas b 101 (Roche)	D-dimer	7	Weekly	Same score across all tests
	Troponin T	9	Weekly	Platform-consistent scoring
	NT-proBNP	9	Weekly	High-risk analyte (4 pts)

QuikRead (Aidian)	CRP	7	Weekly	Consistent across analytes
	D-dimer	7	Weekly	due to device characteristics

5.1 Interpretation of Scoring System Results

The consensus-based scoring system enables a balanced framework for IQC frequency issues in the realm of POCT to be determined. The identification of 96% of high-risk analyte devices distributed in the assessment, comprising 71 out of 74, having daily and weekly IQC recommendations, supports the general requirement that those analytical tests with more possible harm to patients must have more frequent quality checks (Cooper et al., 2011).

The IQC frequency of differentiation based on the complexity of the device takes into consideration the fact that more complex devices simultaneously possess more opportunities for failure (Martin, 2008). The need for complete blood counts with vital healthcare implications justifies blood cell counters that require recommendations on a daily basis. The need to balance between the need for glucose meters of a certain quality and their common use, hence the need to receive recommendations on a weekly basis, justifies glucose meters.

5.2 User-Friendliness as a Quality Factor

The fact that user-friendliness is listed as a distinct criterion for scoring is a significant step ahead of other models that incorporated the complexity of the device and user-friendliness together. The analysis carried out in our study made it clear that there was no direct relationship between user-friendliness and the complexity of the devices. The easy devices included some that were moderately complex because they required interpretation of the results, whereas some smart devices included user-friendly elements.

This result has significant implications for device selection and procurement. It would be important for healthcare settings to choose a POCT device with the right degree of complexity to suit the capabilities of their personnel (AACC, 2020). It would appear that the ease of use component of the proposed framework could help to guide procurement with respect to the need for additional training and quality monitoring because of device complexity.

5.3 Volume-Based Frequency Adjust

The recommendation to vary the frequency of IQC according to the volume of testing satisfies an important missing link in previous documents. For high-volume labs, the more frequent performance of IQC will narrow the potential window of erroneous results being reported before detection. On the other hand, in very low-volume labs (0-3 tests per month), IQC prior to each set of patient samples will help guarantee the analysis system's performance has recently been validated before analysis.

This approach, which is volume based, puts the responsibility on laboratories to track their performance rates of testing and adopt IQC programs that are dynamic. Contemporary POCT connectivity solutions and LAB information systems make it easier for automation of tracking of test volumes and notification of IQC due (Jang et al., 2015; Lewandrowski et al., 2011).

5.4 Competency and Training Implications

The results that 37% of laboratories would require an increase in their IQC intervals indicate a deficiency in competency levels in present practice. However, raising the intervals without improving levels of competency may not translate to desired levels in quality improvement. As shown in the study conducted by Bukve et al. (2016), improvements in quality through organizers with continuous training yield better performance in analyses.

The healthcare institutions using this scoring system should invest in training regarding:Understanding of IQC principles and interpretation

- Recognition of out-of-control situations
- Appropriate responses to IQC failures
- Documentation requirements
- Integration of IQC into workflow

The ISO 22870:2016 competency requirements provide a comprehensive framework, but implementation must be tailored to the specific POCT devices and clinical context of each facility (Gidske et al., 2022).

5.5 Limitations of the Scoring System

However, some limitations exist that must be considered. First, the scoring system relies on consensus rather than scientific research. Even though consensus is a method where input comes from multiple stakeholders with experience, the actual ability of suggested levels to reduce patient risk optimally prior to an error is still subject to evaluation.

Second, the system does not offer device-specific functionality, for instance, self-contained electronic checks, as well as optical verification tools. Some of the device manufacturers assert that the presence of this functionality decreases the importance of conducting traditional IQC, as noted by Holt and Freedman in the year 2016. Nonetheless, the working group indicated that self-contained checks fail to regulate the entire analytical procedure, as noted by Gidske etal. in the year 2022.

Thirdly, the risk stratification of the analyte into two groups (moderate risk analyte and high risk analyte) is prone to subjective analysis. It is difficult to generalize that in some medical settings the analyte is of moderate risk while in some other settings it is of high risk because of the diversity in patient populations.

Fourthly, the proposed system does not account for more advanced methods of quality control of analytical statistics like six sigma principles used in satellite labs (Westgard and Westgard, 2019). Even though these methods have certain benefits in theory, applying them in the context of the primary care environment of POCT encounters considerable difficulties. For example, the complexity of calculations (Gidske et al., 2022).

5.6 Comparison with Alternative Approaches

The Individualized Quality Control Plan (IQCP) approach encouraged by the Centers for Medicare & Medicaid Services in the U.S. was found to be an alternative risk-based methodological approach (Centers for Disease Control and Prevention, 2013). IQCP involves risk assessments of every step involved in the testing processes. Though more specific and adaptable to certain circumstances, IQCP also poses problems when it comes to implementing them in small primary health care labs (CLSI, 2011).

A scoring system like what has been proposed here represents an effective balance between strict and generalized frequency requirements and highly individualized but

complicated IQCP strategies. It is easier for small practices to implement because of their less extensive quality management knowledge.

5.7 Technological Evolution and Future Outlooks

The POCT horizon is changing rapidly with evolving new technologies such as:

Smartphone platforms: The integration of smartphones and POCT analyzers gives rise to smartphone platforms, which enhance data management, expert consultation, and the tracking of automated quality control tests (Liu et al., 2019). They have the potential to support real-time IQC checking and decision Support in interpreting results.

Devices used in continuous monitoring: Devices such as CGM and wearable sensors have huge capacities of data production; thus, innovative methods of quality control should be adopted (Vashist, 2013; Olczuk & Priefer, 2018). Conventional approaches concerning IQC may not be appropriate in such devices; thus, additional measures of quality such as sensor accuracy evaluation need to be used.

Molecular diagnostics: Rapid molecular diagnostic platforms, such as isothermal platforms, are being used more and more in the infectious disease diagnosis setting (Cohen et al., 2015; Babady, 2013). Different molecular platforms could potentially have varying Q/C requirements to ensure nucleic acid integrity, amplification confirmation, and prevent contamination.

Artificial intelligence integration: Machine learning algorithms are being integrated into POCT instruments for interpreting results, evaluating quality, and predictive maintenance. These present the possibility for more advanced, automated quality assessment, but also raise additional issues related to their validation and control.

The framework of scoring system is quite adaptable to new technologies as it evaluates device complexity, user friendliness, as well as risk to healthcare. However, it will be required to be updated from time to time to be relevant to advancing capabilities in POCT.

5.8 Implementation Consider

For successful implementations of the IQC frequency recommendations for specific devices, the following are

Organizational commitment: It will become necessary for healthcare management to commit to IQC material and human resources. Cost-effectiveness clearly supports sound IQC practice in view of the catastrophic outcome of wrong results being disseminated (Florkowski et al., 2017).

Workflow integration: Procedures related to IQC need to be perfectly integrated with clinical workflow to make healthcare providers comply with the process with minimum interruptions. Electronic prompting systems and streamlined documentation procedures may help healthcare providers adhere to the process (Jang et al., 2015).

Connectivity solutions

Modern POCT analyzers with data connectivity allow forIQC performance to be monitored from a central location, automated documentation, as well as trending analysis based on data from several sites (Lewandrowski et al., 2011).

Quality indicators: "Tracking rates of compliance for IQC, rates of occurrence of out-of-control events, and turnaround times for corrective actions can help assess how effective the programs are." It has been observed that companies such as Noklus have been able to prove the need for monitoring quality indicators (Stavelin and Sandberg, 2019).

Regulatory Alignment: Its implementation should cater to regulatory requirements such as CLIA standards, ISO standards, and accreditation standards. The recommendations of the points system should be minimum frequencies because the local regulatory standards may require IQC more frequently.

5.9 Global Applicability and Local Adaptation

Although developed within the Norwegian primary healthcare framework, the framework of the scoring system might have further application. In essence, the principles of risk-based frequency of analysis dependent upon the importance of the analyte, device complexity, ease of use, and test volume are generally applicable.

However, local adaptability is necessary. Healthcare systems vary in:

• Existing POCT technologies and instruments
• Regulatory requirements and accreditation standards
• Operator education levels and training opportunities
• Testing volume and practice trends
• Availability of resources for quality management activities

Organizations embracing this framework should set up local working groups to:

1. Ivied POCT technologies operating within their system
2. Scoring criteria with regard to the clinical context
3. Identify volumes at which frequency adjustments need to be
4. Formulation of the implementation plan including training processes
5. Make arrangements for reviewing and revising recommendations from time to time

5.10 Future Research Directions

A number of research priorities that come out from this research are:

Validation studies

Validation studies to evaluate the viability of suggested IQC schedules to ensure appropriate frequency of testing to reach the intended quality outcome and minimize error rates would be a major addendum to present knowledge.

Competency assessment: Development of competency assessment tools that cater to POCT would provide an element of objectivity in competency evaluation among operators. There is potential in linking competency assessment to performance in analytical quality to provide insights into training plans.

Technology assessment: Systematic assessment of the built-in quality verification procedures of modern POCT instruments would determine if these technologies are sufficient substitutes for conventional IQC procedures or if additional procedures are also necessary.

Cost-Effectiveness Analysis: The economic comparison of the different methods of IQC, taking into account the cost of the materials used, personnel time, error rates, and outcomes, will benefit the allocation of resources.

Integration with Other Quality Metrics: The examination of how the frequency of IQC is related to other quality measures (such as turnaround time performance, result usage rate, and performance in proficiency testing) could facilitate the development of more holistic quality management strategies.

6. CONCLUSION

The quality of quality management in point-of-care testing differs from quality in traditional laboratory testing due to the distinct operating features of non-laboratory testing. The set of scores that follows offers a structured approach that aims to address the distinct features of operating the devices and relates to the determination of the frequency of the internal quality controls.

Key conclusions are:

1. Risk stratification is necessary: It is necessary to carry out risk stratification, where high-risk analytes used in crucial medical decisions should be subjected to IQC more often than moderate-risk analytes. Support for this concept emerges from a survey where it was found that 96% of devices used in testing of moderate- to high
2. 2._Minority with specific approaches:_ Device generalization frequency IQC fails to capture real differences in complexity and error-potential among diverse devices and supports user-friendliness parameters for a fair assessment in IQC frequency scoring.
3. The volume of testing has implications: Modifications to the frequency of the IQC are tied to the volume of samples to ensure that high-volume environments are checked more regularly for quality, and low-volume practices are checked before each patient analysis.
4. Competency is basic: Just improving the frequency of IQC would not be helpful unless it was combined with employee competency. Training and improving employee competency through some form of quality improvement program that links training with an ongoing program of IQC has been found to be quite helpful.
5. The need for pragmatic solutions: There is a need to have pragmatic approaches to quality management that can easily be followed by persons other than those in the laboratory in primary health care POCT. Even when statistical approaches to quality control have their merits, simpler models may work.
6. Implementation needs organizational commitment: A commitment by the organizational structure is necessary to ensure that POCT quality is managed in an optimal manner.
7. Ongoing evolution is required: The rate of evolution in POCT technologies requires ongoing assessment and updating of frameworks for the management of quality.

The boundary between nursing competence and laboratory requirements is likely to continue to change as POCT technology improves and the delivery of care continues to change. Improved quality management will require communication between laboratory professionals, clinicians, nurses, and health care administrators to find a solution to this problem.

Organizations introducing IQC cyclic frequencies to suit specific types of devices should see the implementation process as part of the overall strategy of POCT management, including the selection of devices, operator skills, proficiency, and continued improvements. In applying systematic and evidence-based strategies in the management of quality in POCT, healthcare organizations will maximize the advantages of POCT while at the same time minimizing the potential dangers of POCT results to the healthcare of the patient.

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