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A framework for implementing best laboratory practices for non-integrated point of care tests in low resource settings

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ABSTRACT

The method we respond to pandemics is still inadequate for dealing with the point of care testing (POCT) requirements of the next large epidemic. The proposed framework highlights the importance of having defined policies and procedures in place for non-integrated POCT to protect patient safety. In the absence of a pathology laboratory, this paradigm may help in the supply of diagnostic services to low-resource centers. A review of the literature was used to construct this POCT framework for non-integrated and/or unconnected devices. It also sought professional advice from the Chemical Pathology faculty, quality assurance laboratory experts and international POCT experts from the International Federation of Clinical Chemistry and Laboratory Medicine (IFCC). Our concept presents a comprehensive integrated and networked approach to POCT with direct and indirect clinical laboratory

supervision, particularly for outpatient and inpatient care in low-resource health care settings.

BACKGROUND

Point-of-care testing (POCT), also referred to as bedside testing or near patient testing (NPT), is a field of laboratory medicine that is developing rapidly in terms of analytical quality and clinical reach (1). The POCT solutions provide the clinician with a fast turnaround time of diagnostic results thereby enhancing patient care (2) (3). The technological developments with POCT, such as instrument miniaturization, ease of use and improved accuracy, have not been complemented by a coordinated approach to data management, connectivity and device software interoperability (4). Non-integrated POCT can be defined as a category of POCT that are conducted outside of a traditional laboratory setup but are not integrated into a unified device, system, or LIS. These tests typically rely on test reagent strips/kits and involve the interpretation of visual cues by a healthcare professional. Many clinically useful commercially available POCT devices are non-integrated or have limited interface with the Laboratory Information System (LIS). Some examples of non-integrated POCT include rapid influenza tests, rapid HIV tests, pregnancy tests, rapid malaria tests and SARS-CoV-2 antigen test. An integrated point-of-care test (POCT) device with connectivity is a medical diagnostic tool that can transmit the test results to a centralized database, LIS, or a healthcare provider's electronic medical record system through wireless or wired connectivity. This allows for real-time monitoring of patients, timely interventions, and remote consultations with healthcare providers.

Knowledge in good laboratory practices by POCT end-users, including physicians and allied health professionals working in patient care areas using these devices is limited (5). Furthermore, these end-users must demonstrate a commitment to quality assurance (QA) and quality control (QC) since this is essential for POCT reliability (6) (7). Despite the relative ease of POCT, regulatory bodies such as Joint Commission International (JCI) and the College of American Pathologists (CAP) recommend oversight by the central clinical laboratory for all hospital based POCT (8) (9). The current POCT program for integrated POCT instruments at our institution has strict oversight by the clinical laboratory for both QA and QC (10)(4). Testing performed using POCT devices that lack connectivity to a middleware system or LIS raises concerns regarding reliability. This is because there is no information captured regarding QC performance, the person who performed the testing, transmission of POCT results to the LIS. (11). Furthermore, it is probable that this kind of testing is carried out without standardization of training or supervision by qualified laboratory personnel, which is risky. Subsequently, POCT has not been appropriately utilized in these settings employing non-integrated devices. In order to cater for this crisis, we propose the current framework, considering all regulatory requirements as a practical guide to initiate non-integrated POCT at in-patient and out-patient health care settings. The framework is developed bearing in mind the challenge of POCT-related QA practices and regulatory compliances (12).

In the authors' experience, laboratory QA/QC instruction for non-integrated POCT devices in Chemical Pathology curricula in the national residency programs in Pakistan or most other countries is scant. This creates problems in educating future chemical pathologists on how to establish, evaluate and maintain the quality of in-clinic or inpatient POCT testing using such instruments. Furthermore, the clinical laboratory receives frequent requests for initiating POCT by devices which are not integrated. Acknowledging this void, this framework is outlined given the numerous POCT tests that can

be performed on non-integrated POCT instruments i.e., standalone devices with no IT connectivity and result transmission. This POCT framework for non-integrated and/or unconnected devices was created through a review of the literature using popular search engines such as PubMed, Cochrane, Embase, and Web of Science. It also sought expert consensus from the Chemical Pathology faculty, the CAP director of Aga Khan University (AKU), Karachi Pakistan, the POCT coordinators, the QA team at AKU and international POCT experts from International Federation of Clinical Chemistry and Laboratory Medicine (IFCC). Our model proposes an extensive approach to POCT that has direct and indirect supervision by the clinical laboratory especially for outpatient and inpatient care in low resource health care settings.

SCOPE

This framework predominantly applies to handheld POCT non-integrated devices measuring single or multiple analytes in hospital and outpatient NPT settings. This model may also be used in fieldwork, research settings, in rural or low resource settings. Along with "direct" bedside testing it can be established in a "satellite laboratory" located close to an emergency unit or units for acute care. After several debates and consultations amongst authors the framework was drafted, the prospective framework was distributed amongst the authors for comment. Revisions were made to address each comment, and the final guidance document was approved prior to publication. As additional scientific studies become available and POCT instruments and analytical performance capability evolve, this framework may change; revision is anticipated approximately every two years. This framework is not intended to be all-inclusive; rather, it provides a minimum standard for maintenance of these non-integrated POCT instruments in the clinical setting.

NON-INTEGRATED POCT MANAGEMENT AND RESPONSIBILITIES

Hospitals with a competent POCT coordination should provide organizational and administrative structures for POCT test/device selection, method validation, data management, quality control, continuous trainings, and competency assessments (13). Like all other POCT program the non-integrated POCT devices must be linked to the existing or new POCT program of the hospital or academic medical centre.

Although the end users of POCT may be familiar with its routine administration and delivery of results, the clinical laboratory director or, ideally, a chemical pathologist with training in this area, must bear overall responsibility for the programme. All non-integrated POCT should be managed by central laboratory's POCT team managed by a POCT coordinator, an experienced medical technologist or scientist from a clinical laboratory (7). The POCT coordinator should provide leadership to all POCT users and POCT sites in the following four domains: POCT test introduction, quality assurance, education, and administration. The minimal objectives of providing oversight should be as follows:

- To provide high quality (accurate and precise) of all non-integrated POCT devices
- To assess the need of non-integrated POCT devices before introduction into clinical practice
- To ensure that non-integrated POCT devices are cost-effective
- To train and assess the competency of POCT users
- To provide written policies and standard operating procedures for POCT devices being used at those ancillary sites
- To provide faster turnaround times with minimal inconvenience to the patient

- To outline the billing system on POCT sites
- To ensure all logs are maintained even if interface with LIS is missing (quality control logs, temperature logs, maintenance logs)
- To ensure compliance with policies and procedures by conducting audits. For non-integrated POCT more frequent audits and visits to POCT sites are recommended

For a new non-integrated POCT device to be induced in a clinical setting and practice the test must be reviewed and approved by the POCT interdisciplinary committee (14). This committee would be led by the laboratory director and chemical pathologist (trained POCT expert) and should have members from various sections and departments such as microbiology, haematology, molecular pathology, blood bank and transfusion services. Requests and demands for new non-integrated POCT must be made through this committee. Attention must be paid to need assessment and whether the non-integrated POCT meets quality standards (15). The committee must ensure that it meets the safety and security requirements in relation to protecting data, patient confidentiality and risk management. Once the non-integrated POCT is in place and the responsibility of ongoing problems and compliance issues can be handled by the POCT end user committee (led by the POCT coordinator with pathologists or subject experts, POCT site supervisors, nursing managers, IT, and biomedical experts as members). Nurse directors or nursing managers qualify as POCT site supervisors. POCT site supervisors need to be vigilant for non-integrated POCT (16). They must be made responsible to establish and maintain a system where audits are performed to ensure quality control is being performed and documented and corrective action is being done for outlier results, according to written policies. In the event of a lack of IT connectivity, it is also necessary to manually update employee listings and training and competency records into a spreadsheet (17). Request for training and for competency assessment can be made to the POCT coordinator through these POCT site supervisors. POCT site supervisors should be made responsible for POCT in-house inventory and for administration of the daily operation of POCT at their respective site. Furthermore, audits should be performed to determine if critical results are being documented into patient charts and handled appropriately.

SELECTION AND EVALUATION OF NON-INTEGRATED POCT

Before bringing any non-integrated POCT into the POCT Program a clinical needs assessment should be conducted. A standard approach must be carried out for every new request of non-integrated POCT by answering some basic questions:

- What is the diagnostic caveat that clinicians are anticipating solving by using this non-integrated POCT?
- Is this non-integrated POCT cost-effective?
- Based on clinical requirements, what is the unacceptable turnaround time for each non-integrated POCT under evaluation?
- What are the potential risks to the patients because of non-integration with LIMS?
- How will the clinical laboratory control these risks?

Waived tests are excluded from method evaluation under Clinical Laboratory Improvement Amendment of 1988 (CLIA), although it is acceptable laboratory practice to confirm the manufacturer's declared performance standards. However, CAP does not entirely adhere to the CLIA way of categorizing tests and instead uses the POCT checklist to ensure compliance with CAP requirements. The CAP defines POCT as waived and nonwaived tests that are only

performed close to the location where the patients are. In comparison to moderately complex tests, waived tests have distinct requirements for quality control, reagents, competency assessment, and calibration. Both waived and moderately complicated tests must meet the same standards for proficiency testing, quality management, procedure manuals, specimen handling, results reporting, POCT instruments, personnel training and certifications, and safety (18).

The protocol for non-integrated POCT method validation according to CAP and CLIA'88 standards must include accuracy, precision, verification of cut-offs, reportable range and analytical measuring range, POCT inter-instrument comparison and comparison with bench top analyzers placed in the central laboratory(19) (20) (21). Reagent shipments and lot numbers must be validated (22). To determine the appropriate use of non-integrated POCT, an evaluation of each test is necessary to establish the unacceptable turnaround time based on clinical requirements. POCT tests, such as beta hCG and SARS-CoV-2 antigen test are recommended to have a turnaround time of no more than 20 minutes in emergency situations. This allows healthcare professionals to make timely and informed medical decisions.

Management of consumables and reagents should be procured in a cost-effective manner for each POCT site. POCT costing must include the fixed capital cost (instrument, proficiency survey cost, service contract for vendor, ancillary infrastructure, etc.) and variable cost (reagent consumption, internal controls, consumables, cartridges) (10) (23).

POCT POLICIES AND PROCEDURES FOR NON-INTEGRATED POCT

As per CLSI guidelines, a quality management system (QMS) approach must be followed for the development of standards and policies for non-integrated POCT. The laboratory director or designee should take responsibility for QC, QA, and test utilization of non-integrated POCT. Every POCT site that performs non-integrated POCT must have written policies and procedures available at the testing sites. The POCT training curriculum should be outlined for every non-integrated POCT by the pathologists or the subject experts and shared with POCT interdisciplinary committee for approval and feedback. Every non-integrated POCT at the institute, as well as its adherence to legal requirements, must be handled by the central laboratory. The central laboratory is responsible for ensuring that the necessary training, quality control (QC), proficiency testing (PT), and validation processes are carried out, confirmed, and documented initially and then on a regular basis.(24).

It should be ensured that the purpose of POCT, i.e. prompt results for prompt patient management, must not be lost and the processes should be simple and easy to follow (25). As noted by Harvey, the mean turnaround time expected by clinicians managing patient in in critical care areas ranges from 5-15 minutes(26). Hence the policies and processes need to be carefully designed keeping this challenge of turnaround time in mind.

NON-INTEGRATED POCT DATA CAPTURE

Healthcare regulatory bodies and accreditation agencies, such as the CLIA'88, the JCI, CAP, emphasize the importance of monitoring POCT operator competency and instrument quality as these will lead to reliability of results (20) (27) (28). These regulations stress the need for laboratory oversight and review of POCT QC and patient data. The labour and resources that must be devoted to the POCT locations in order to achieve regulatory compliance with quality assurance, including record keeping, archiving,

billing, and data entry into the electronic medical record or LIMS, will increase with manual, non-integrated POCT devices (29).

The advantages of POCT are multiplied when patient and QC results are directly downloaded into a LIMS with minimal human intervention (30) (31). For accreditation and patient safety, trail (manual or electronic) must link each patient result to the POCT user, user's training and competency records, the reagents or cartridges utilized and its validation, and the device validation and maintenance even if manual entries or manual logs must be kept (32). Where possible connectivity of POCT device to POCT data management system and to the LIMS need to be established. Before bringing non-integrated POCT into practice evaluation of data security, processes, risk assessment must be carried out and reviewed by the IT support and POCT teams.

STAFF TRAINING AND COMPETENCY ASSESSMENT

For all non-integrated POCT, a thorough POCT training plan and curriculum will have to be developed in line with the CLIA'88 and CAP standards by the subject experts (for example by chemical pathologists for Beta- Human Chorionic Gonadotropin testing). *"Evaluating the competency of all testing professionals and ensuring that staff maintains their competency to perform test procedures and report test findings promptly, accurately, and competently"* are two CLIA'88 requirements for competency evaluation (33). The purpose of the curriculum would be to identify and control potential serious medical errors attributable to non-integrated POCT. Training curriculum must include all phases of the testing process and consist of (not limited to) the following:

- Direct observation of routine patient test performance
- Testing previously analyzed specimens, internal or external QC samples
- Recording and reporting of patient test results
- Recording and reporting of QC results
- Interpretation of patient test results, QC results
- Demonstration of POCT device maintenance
- Assessment of problem-solving skills

Training and certification of all POCT users on non-integrated devices with no interface with LIMS must be done separately from integrated POCT. The record of training and certification must be available from the POCT coordinator and site supervisors. If possible barcoded identification must be provided to the certified POCT users in the institute. Competency assessment should be performed annually for waived tests or for non-waived tests, after 6 months from the first test on hire and then annually thereafter. Records of competency must be maintained via the online connectivity server or in the form of manual logs.

INDIVIDUALIZED QUALITY CONTROL PLAN (IQCP)

The analytical goals for non-integrated POCT are equivalent to those used for the central laboratory. In order to ensure that the use of non-integrated POCT does not compromise standard of patient care and clinical decision-making, Individualized Quality Control Plan (IQCP) ought to be outlined and followed (34). The proposed IQCP aims to provide clinical laboratories with the framework to implement it when appropriate and offer flexibility to design a QC plan that meets the needs of the laboratory. A process to identify and mitigate errors will be required by each POCT site using the non-integrated POCT devices. The overall intent of IQCP at POCT sites for non-integrated POCT is to help ensure that

clinical laboratories and hospitals remain in compliance with regulations (35). The proposed IQCP covers includes risk assessment, quality control plans and quality assessment monitoring. It demonstrates how laboratories providing oversight to non-integrated POCT can perform a risk assessment to evaluate and record their current quality activities using the IQCP guide, create a quality control plan (QCP) from the risk assessment information, and establish a QA for the test system being evaluated for an IQCP.

IQCP-RISK ASSESSMENT STRATEGY

A risk assessment strategy is required for non-integrated POCT devices with no interface with LIS (36). The process of identifying and evaluating the potential failures and errors has been laid down that could occur during all the phases of POCT testing in Tables 1-3 (37). Risk is, by definition, the product of two factors: the likelihood that harm may occur and its seriousness (38). The goal of the risk assessment is to examine every step of the non-integrated POCT process, from preanalytical to analytic to post analytic, and identify any potential points of error that could endanger the patient if they are not caught. It includes evaluation of the five components of POCT testing: specimen, test system, reagents/cartridges, POCT site environment and POCT users or testing personnel. The table 1 describes the risk assessment including some common sources of errors and solutions encountered in non-integrated POCT program before the actual analysis.

Specimen preparation, reagent handling and test analysis (Table 2) present its own set of risks and problems, which must be identified and mitigated in order to assure the overall safety and reliability of the POCT process. By implementing approaches to reduce the risk of errors and inconsistencies in analysis, POCT can help enhance patient outcomes.

Table 1 Risk assessment for non-integrated POCT in pre-analytical testing phase

Risk Assessment Components	Possible sources of error	Risk Mitigation: Manage/Prevent Errors from Occurring
Patient or specimen identification	Wrongly identified throughout the testing process A functioning barcode reader is not available in the test system to ensure positive patient identification Erroneous patient/specimen information entry	• Train POCT users to follow dual identification criteria and ensure correct patient, correct side and correct POCT • Outline criteria for specimen rejection • Provision of barcoded samples. System should be in place with barcodes to create entry of patient information and test request on LIMS
Specimen collection	Insufficient specimen volume	• POCT system will not perform the test if the specimen volume does not meet the minimum volume requirement
	Incorrect vacutainer or POCT cartridge Wrong labelling Criteria for specimen rejection is missing	• Train POCT users to the correct selection of vacutainer or POCT cartridge • Ensure specimen rejection criteria is present in policy and processes and is taught and assess to POCT users

Table 2 Risk assessment plan for non-integrated POCT in analytical testing phase

Risk Assessment Components	Possible sources of error	Risk Mitigation: Manage/Prevent Errors from Occurring
Testing Personnels' Training and Competency	Not trained POCT user Not competent POCT user Improper training or expired competency records Proper POCT technique/ system maintenance /QC not being accurately followed	• Central laboratory to provide proper initial training and competency • Competency assessment frequency to be decided based on risk assessment • Compliance monitoring • Follow established policies and procedures • Testing personnel training and competency records • Traceability of POCT users
Test system- Calibration	Calibration omitted Calibration out and patient results reported There is no mechanism, such as an operator lockout, to ensure only trained personnel use the test system	• Ensure POCT users follow standard operating procedures through trainings, competency assessment, audits • Test process flow charts • POCT user manual/ electronically shared QC and calibration records with POCT coordinator
Test system- Maintenance	Maintenance procedures not consistent with manufacturer's instructions	• Train POCT users for POCT device maintenance
Test system- Reagent	Expired reagents Wrong lot of reagents	• Train POCT users to check reagent expiry prior to use • Manufacturer's instructions to be followed for reagents storage
Test system- QC	Expired QC Wrong lot of QC Unable to interpret QC Unable to trouble shoot if QC is out	• Prevent QC degradation during storage and use • Training of POCT users on interpreting QC before release of patient results • Maintain QC logs (manual if electronic not possible) • Assure POCT user review each QC before patient result release – through trainings • Training of POCT users on troubleshooting
Environment-room Temperature	Room temperature not appropriate	• Daily room temperature logs • POCT coordinator to sign off logs periodically
Environment- Storage conditions	Sample / reagents/ cartridge/ strips storage conditions not appropriate	• Daily refrigerator temperature logs where POCT items are stored. • POCT coordinator to sign off logs periodically

Table 3 Risk assessment plan for non-integrated POCT in analytical testing phase

Risk Assessment Components	Possible sources of error	Risk Mitigation: Manage/Prevent Errors from Occurring
Test Results reporting and archiving	Incorrect result reading Incorrect result entry Delay in signing out Data security Data storage loss Patient report lost to retrieval No correlation between initially generated/finally recorded result	• Training and competency of POCT users for result reporting and entry into LIS to be ensured by the central lab • Frequency of competency assessment may be increased • Even if instrument interface with LIS is missing provision of manual entry of results should be given to POCT users • Manual records of all tests be entered in log sheets and signed off by central laboratory on periodically • Provision of LIMS data entry should be limited to the POCT on which the POCT user is certified • Missing data audits to be conducted periodically • Periodic scanning/ digitalization of manual patient results' logs
Reference range or cutoff	Incorrect Reference range or cutoff Incorrect units	• Reference range or cutoff must be verified by the central lab • Reference range/ cutoff must be built in LIS • Units on reports must be checked by the clinical lab, built in LIS
Interpretation	Incorrect interpretation	• POCT report includes interpretation verified by the central laboratory and built-in LIS • Distinction that the test was not done in central lab on patient report
	False positive and false negative results	• The report includes a disclaimer regarding the false negatives and false positive causes to aid clinical interpretation
	Critical results not informed	• Ensure POCT users read/ follow critical results policy • Critical results policy should be readily available at POCT sites

The significance of the post-analytical phase in POCT stems from its ability to influence clinical decision-making and patient outcomes. The accuracy and reliability of the test results are checked during this phase, and the results are interpreted in the context of the patient's clinical history and current state. Incorrect or insufficient interpretation of test data might result in erroneous treatment decisions or therapy delays, both of which can have a detrimental impact on patient outcomes. Table 3 shows the risk assessment plan for non-integrated POCT during post-analytical testing phase.

Once an IQCP is developed and is acceptable with no risk to the patients then the non-integrated POCT should be introduced in clinical areas. Regular IQCP audits and risk management must follow starting with specimen and patient identification, specimen collection, specimen container, transport, etc., and moving through the other components, the lab would identify and list potential places where mistakes could occur, evaluating each one for risk of error. A historical analysis is necessary for the risk management. Risk management for non-integrated POCT can be a proactive project to identify potential flaws in new, altered, or complex processes, a reactive project to respond to an incidence or finding, or a continuous assessment based on daily events and observation. Non-integrated POCTs can involve several complex processes that require specialized knowledge, expertise, and training to ensure accurate and reliable results. Some of such complex processes are as follows:

- Some non-integrated POCTs require specialized knowledge to interpret results accurately, particularly rapid tests for infectious diseases like influenza or COVID-19, which require experience in detecting subtle changes in color or signal intensity to determine positive or negative results.
- For non-integrated POCT devices, such manual QC procedures may add extra work as they may involve manual checks of equipment performance, tracking reagent quality, and regular checks to maintain consistency and reliability of test results.
- POCTs generate significant amounts of data that require management and tracking. This data includes patient identification, test results, quality control data, and instrument maintenance logs. Manual data management is essential in non-integrated POCT
- Complying with these regulations can be more complicated and may require specialized knowledge and expertise, particularly for non-integrated POCT devices.

The manufacturers' package inserts, pertinent policies and procedures, QC, corrected reports, physician complaints, employee training and competency records, PT results, and temperature records are the documents that must be reviewed periodically. Table 4 is an illustration of a practical checklist that can be used, particularly when writing the IQCP for non-integrated POCT. The review of historical non-integrated POCT data will then determine the frequency of occurrence of errors and the impact of harm to a patient.

Table 5 shows a template of the 'Risk Matrix' for the non-integrated POCT that can be followed. This will determine if the non-integrated POCT can be continued or should be removed from the POCT Program.

IQCP-QUALITY CONTROL PLAN

A QCP should be outlined by the central laboratory for each non-integrated POCT device describing the practices and procedures to reduce the chance of possible failures and errors in the test processes. The QCP must ensure that the accuracy and reliability of test results

Table 4 Checklist for IQCP risk assessment for non-integrated POCT

Review	Available	Not Available	Not Applicable
Need of non-integrated POCT justified			
Process Map			
Manufacturer QC requirements			
Manufacturer or package inserts			
Manufacturer alerts			
QC Certificates			
Calibration			
Method Validation/ Verification			
Policies and Processes			
Historical QC data			
Proficiency survey results and corrective action documentation			
POCT testing personnel Training and competency records			
Instrument maintenance logs			
Temperature charts			
Specimen rejection logs			
Physician/client complaints			

Table 5 Risk matrix example to assess severity of harm from non-integrated POCT

Risk Category	**Occurrence of Errors**	**Severity scale for probability of harm**				
		Negligible	**Minor**	**Serious**	**Critical**	**Catastrophic**
Expired Reagents use	Frequent (Once per week)					
	Probable (Once per month)					
	Occasional (Once per year)					
	Remote (Once every few years)					
	Improbable (Once in the life of the measuring system)					

Key:

Unshaded is Acceptable, shaded is Unacceptable.

Severity scale for probability of harm:

- Negligible: Could result in inconvenience or temporary discomfort
- Minor: Could result in temporary injury or impairment not requiring professional medical intervention
- Serious: Could result in injury or impairment requiring professional medical intervention
- Critical: Could result in permanent impairment or life-threatening injury
- Catastrophic: Could result in patient death

from non-integrated POCT, are appropriate for patient care. The QCP for each non-integrated POCT may at least include, electronic controls, internal QC, external QC or PT, calibration, maintenance and training and competency assessment (6). The main QC requirements must be addressed which include the following:

- Procedure established for internal QC (39)
- Internal QC material procurement
- Correction of nonconformities and availability of trouble shooting guide
- PT processes and policies
- Periodic comparison of results from non-integrated POCT device and the gold standard or working instrument for same analyte placed in central laboratory.
- Comparison of results and performance across different POCT sites
- Sub-optimal performance in internal QC and/ or PT to be brought to the immediate attention of the POCT committees

For analytes for which PT surveys are not available or are not accessible, an in-house scheme can be established using split patient samples (40). In split patient each specimen can be split and analyzed in the same manner with the non-integrated POCT method and then with the central laboratory method or another POCT site or by another POCT user. If findings agree within the analyte's allowed performance range, bias between results can be determined and reviewed for acceptance. Criteria for acceptance can be obtained from literature or published guidelines or using ± 2 or 3 standard deviations from the mean from QC data for quantitative assays (41).

IQCP-QUALITY ASSURANCE

For continuous monitoring of the QCP effectiveness for non-integrated POCT a QA plan should be in place (42). Practices, processes, and resources to consider for monitoring effectiveness of a QCP must include clinical audits and review of the following:

- Policies and standard operating procedures
- Logs of training and competence assessment
- Logs of internal QC reviews
- PT performance reviews
- Turnaround time reports
- Logs of critical results informed
- Complaint reports
- Logs of maintenance
- Logs of breakdowns

All POCT programs need to be observed and evaluated periodically to assure that the program is meeting the needs of patients, testing personnel and hospital. All POCT sites must be periodically audited and assessed for compliance of policy, procedure, and protocols, along with POCT users' knowledge, skills, and practices (43).

CONCLUSIONS

In low resource healthcare settings, our approach to non-integrated POCT involves both direct and indirect supervision by the clinical laboratory. This comprehensive model ensures effective POCT management. Major recommendations included in the current proposed framework are taking a formalized approach to POCT within the facility, use of written policies, standard operating procedures, forms, and logs, POCT end user training, including periodic competency assessments, POCT devices performance evaluation and use of both statistical QC and PT programs, use of properly established or validated reference intervals or cutoffs and ensuring accurate patient results reporting. This paradigm may aid with the delivery of diagnostic services to low resource centers in the absence of a pathology

laboratory and may satisfy the demands of POCT specialists, particularly in developing nations. The suggested framework emphasizes how crucial it is for non-integrated POCT to have clear policies and procedures in place to guard or gatekeep patient safety.

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