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BRIDGING THE GAP: ENSURING QUALITY ASSURANCE, REGULATORY COMPLIANCE, AND DATA INTEGRATION IN DECENTRALIZED HOSPITAL TESTING UNITS

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ABSTRACT

Background: Decentralized hospital testing has become an integral component of healthcare delivery by providing rapid diagnostic information at the point of patient care. But maintaining a consistent quality assurance, regulatory compliance and electronic data integration within a decentralized testing units is still difficult. Poor quality monitoring, staff skills, and information systems interoperability can impact diagnostic accuracy and patient safety.

Objective: To assess quality assurance practices, regulatory compliance, and data integration among decentralized hospital testing units and examine their associations with operational performance.

Materials and Methods: The study was conducted as an analytical cross sectional study in Armed Forces Institute of Pathology (AFIP), Rawalpindi, Pakistan over the period of January 2023 to August 2024 in 77 decentralized hospital testing units (DHTUs). The quality assurance indicators were standard operating procedures, internal quality control, external quality assessment, equipment calibration, staff competency and documentation of corrective action. Structured assessment criteria was used to evaluate regulatory compliance and connectivity with laboratory information system. SPSS version 26 was used to analyze data. Categorical variables were presented by frequencies and percentages, associations between the categorical variables were calculated with Pearson's chi-square test and statistical significance was set at $p<0.05$.

Results: The analysis included 77 testing units, of which 49.4% met the higher quality assurance compliance category, 31.2% achieved high regulatory compliance, and 41.6% had automatic data integration. Regular staff competency assessment was associated with higher quality assurance compliance (65.2% versus 25.8%; $p<0.001$). Automatic data integration was associated with greater documentation completeness (84.4% versus 53.3%; $p=0.005$) and timely result availability (78.1% versus 37.8%; $p<0.001$).

Conclusion: Effective quality assurance, regulatory oversight, personnel competency assessment, and electronic data integration are essential components of decentralized hospital testing services. Strengthening standardized quality management procedures and digital connectivity may contribute to improved documentation, diagnostic reliability, operational efficiency, and patient safety.

KEYWORDS: Point-of-care testing; Quality assurance; Regulatory compliance; Data integration; Laboratory information systems; Patient safety.

INTRODUCTION

Decentralized hospital testing has transformed contemporary diagnostic medicine by allowing laboratory investigations to be performed near the patient rather than exclusively within centralized laboratory facilities. Point-of-care testing (POCT) provides immediate diagnostic evaluation in ED, ICUs, operating theatres, outpatient units and general hospital wards. Portable analytical devices, automated testing platforms and rapid diagnostic technologies have increased the number of bedside analyses (such as glucose monitoring, blood gas analysis, electrolyte measurement, selected infectious disease testing). The trend towards decentralized testing highlights the need for timely clinical decisions, shorter diagnostic delays, and increased availability of critical laboratory services. However, careful consideration of analytical performance, clinical relevance, institutional resources and integration into current clinical workflows is required for the successful implementation of these technologies [1-3].

Accuracy, reliability and reproducibility of diagnostics produced outside of the laboratory setting are central to quality assurance. Decentralized testing adds to the operational challenges as investigations are often conducted by healthcare personnel with different backgrounds in lab training and technical skills. Patient identification, specimen collection, device operation, quality control assessment, result interpretation, and documentation can all

lead to errors. These mistakes can have negative consequences in both clinical practice, and especially if a diagnosis is needed in a timely fashion. Therefore, there should be a comprehensive quality approach that covers all the steps in the testing process (preanalytical, analytical and postanalytical). To reduce preventable risks and enhance patient safety, errors need to be systemically monitored, quality indicators need to be standardized, and performance needs to be evaluated on an ongoing basis [4, 5].

The effectiveness of decentralized testing is also impacted by the availability of trained personnel and the use of standard operational procedures. Consistency at testing locations is achieved with regular competency assessment, equipment verification, monitoring of quality control and the appropriate documentation. The variability of all operators and different diagnostic platforms used in POC testing is an important concern. The aim of the quality improvement activities should be to pinpoint a common source of error, establish greater operator responsibility, and ensure proper laboratory management. Recurrent auditing and corrective action systems may help identify early problems in operations and aid in ongoing improvement of diagnostic efforts [6-8]

Regulatory compliance offers an extra layer of assurance for the safe and sound operation of decentralized testing services that meet the standards of laboratory practice and professional excellence. Good governance involves having clear organisational roles, validated testing procedures, staff training, equipment maintenance, risk assessment and regular internal review. Traceability, patient safety and continuous quality improvement are also highlighted by accreditation and regulatory systems. There may be differences in the technical infrastructure, personnel arrangements, clinical workloads and institutional resources at various decentralized testing sites, however, creating consistent regulatory oversight can be difficult. For this to work well, there must be cooperation between the laboratory, the clinical departments, hospital management and regulatory bodies. The adoption of new diagnostic technologies can be supported by a structured governance system while strengthening accountability [9-11].

The integration of electronic data has gained more and more significance in decentralized diagnostics in hospitals. While point-of-care devices can deliver rapid analytical results, the usefulness of the results may be limited by manual recording or when the results are not linked to a hospital information system. Handwriting can lead to patient identification problems, incomplete records, missed communication and duplicate testing. Electronic connection between diagnostic devices, lab information systems, HIS and EMRs allows results to be transmitted more efficiently and increases the availability of diagnostic information. In addition, integrated digital platforms enable audit trails, operator identification, quality monitoring and post-experimental analysis of testing performance. Therefore, standardized connectivity arrangements and effective information governance become key to maintaining an accurate, traceable, secure and accessible diagnostic result for healthcare professionals [12-14]

Despite technological progress, decentralized testing services continue to face challenges in achieving consistent quality assurance, regulatory compliance, and information system interoperability. Inadequate coordination between clinical departments and central laboratory services, limited personnel training, inconsistent quality monitoring, and fragmented electronic reporting systems may affect diagnostic reliability and operational efficiency. Although these components are closely related, their combined assessment within hospital testing networks remains important for identifying institutional weaknesses and developing targeted improvement strategies. Therefore, the present study was designed to evaluate quality assurance practices, regulatory compliance, and data integration among decentralized hospital testing units at AFIP, Rawalpindi, and to examine their associations with documentation completeness, timely result availability, and overall operational performance.

MATERIALS AND METHODS

Study Design and Setting

This study was designed as an analytical cross-sectional investigation to evaluate quality assurance practices, regulatory compliance, and data integration in decentralized hospital testing units. The study was conducted at the Armed Forces Institute of Pathology (AFIP), Rawalpindi, Pakistan, over a period of 20 months, from January 2023 to August 2024. The study focused on the quality management and operational characteristics of decentralized testing services, particularly point-of-care testing (POCT), including blood glucose monitoring, blood gas analysis, electrolyte testing, and other bedside diagnostic investigations. The principal objective was to assess adherence to laboratory quality standards, identify gaps in regulatory compliance, and examine the relationship between electronic data integration and operational performance.

Study Population and Sample Size

A total of 77 decentralized hospital testing units constituted the study sample. The unit of analysis was the individual testing unit instead of the patient. Eligible units were decentralized testing facilities in emergency departments, intensive care units, general medical and surgical wards, outpatient departments and operating theatres. Units conducting routine diagnostic investigations, but not at the central laboratory, qualified for evaluation. The site was excluded if the testing facilities were not working or insufficient documentation of the existing testing facilities was available. The sampling technique used was the judgemental sampling or purposive sampling. The final sample consisted of 77 quality assurance arrangements, regulatory preparedness, and laboratory information management practices evaluated units.

Data Collection Procedure

A structured assessment checklist was used to collect data on organizational characteristics, quality assurance procedures, regulatory documentation, personnel competency and electronic information management. The checklist has been created to align with the principles and requirements of ISO 15189:2022 for quality management, and also incorporates the relevant requirements for point of care testing. Data was gathered by the review of available quality control records, equipment maintenance registry, standard operating procedure, competency evaluation documents, audit documents, and laboratory information management system. Operational characteristics recorded were location, primary diagnostic modality, availability of central laboratory supervision and the presence of a dedicated POCT coordinator.

Assessment of Quality Assurance Practices

Indicators used to assess quality assurance were the availability of standard operating procedures, internal quality control measures, involvement in external quality assessment programs, equipment calibration, preventive maintenance, staff competency assessment and documentation of corrective actions. Each indicator applicable was judged based on the compliance of the testing unit to the indicator. A percentage (overall quality assurance compliance score) was determined by the proportion of applicable requirements that were met. A score was utilised to describe the performance of quality assurance and to examine the relationship between the score and organizational and operational characteristics.

Assessment of Regulatory Compliance

Documentations and practices related to laboratory quality management were assessed for regulatory compliance, such as internal audits, staff competency records, equipment validation, biosafety measures, patient safety incident reporting and corrective action systems. The level of compliance was evaluated according to the relevant institutional and Laboratory Quality Requirements, taking into account the following standards: ISO 15189:2022. A percentage overall regulatory compliance score was determined based on the percentage of applicable requirements met. Low, moderate and high levels of compliance were placed into the score based on a predetermined assessment criteria. Compliance with each quality requirement was treated separately from the accreditation status.

Assessment of Data Integration and Operational Performance

Laboratory information systems connectivity and hospital information system integration was evaluated by the availability and usefulness of LIS connectivity and HIS integration; electronic medical record availability, automatic result transmission, electronic audit trails, real-time result availability, and data security procedures. The indicators of result documentation completeness and timely availability of the diagnostic findings were used to evaluate the operational performance. The association of electronic integration with documentation completeness and timely reporting was studied to assess if there is a relationship between electronic integration and a better testing performance in the decentralized environment.

Statistical Analysis

The data was entered and analyzed in IBM SPSS Statistics 26. Categorical variables were presented as frequencies and percentages and continuous variables, if applicable, were presented as means and standard deviations or medians and interquartile ranges, depending on their distributions. Pearson's chi-square test was used to assess the associations between categorical variables, and whenever expected frequencies were too low, Fisher's exact test was used. The association between regular staff competency assessment and the compliance of quality assurance was analyzed, as well as the associations between automatic data integration, documentation completeness and timely availability of results. P value < 0.05 was significant.

RESULTS

The research comprised 77 decentralized hospital testing units spread throughout various clinical departments. The majority of testing units were located in emergency departments (26.0%) followed by intensive care units (23.4%), general medical and surgical wards (22.1%), outpatient departments (15.6%) and operating theatres (13.0%). The most frequently used tests were blood glucose monitoring (41.6%), blood gas analysis (24.7%) and electrolyte tests (20.8%). The percentage of units with central laboratory supervision was 63.6% and there was a point of care testing coordinator in 37.7%. The results indicate that the testing activities were dispersed throughout various clinical environments and that either there was a lack of dedicated supervisory arrangements or that they were poorly developed.

Table 1. Baseline characteristics of decentralized hospital testing units (n=77)

Characteristics	Frequency (n)	Percentage (%)
Testing unit type		
Emergency department	20	26.0
Intensive care unit	18	23.4
General medical/surgical wards	17	22.1
Outpatient department	12	15.6
Operating theatre	10	13.0

Primary testing modality		
Blood glucose monitoring	32	41.6
Blood gas analysis	19	24.7
Electrolyte testing	16	20.8
Other POCT investigations	10	13.0
Central laboratory supervision		
Available	49	63.6
Not available	28	36.4
Dedicated POCT coordinator		
Available	29	37.7
Not available	48	62.3

Evaluation of quality assurance practices showed differences in the implementation of the key laboratory quality assurance standards. 74.0% of testing units had SOP and 68.8% of the testing units conducted regular internal quality control. Sixty-six percent of units had equipment calibration compliance records and 61 percent had records of equipment preventive maintenance. But external quality assessment programs participation was still relatively small (46.8%). Fifty-nine percent (59.7%) of units conducted regular staff competency checks, and 55.8% of units kept documentation of corrective actions. Overall, 49.4 per cent of units were in the higher quality assurance compliance category, offering scope for further development of quality management in decentralised testing facilities.

Table 2. Quality assurance practices among decentralized hospital testing units (n=77)

Quality assurance indicator	Compliant n (%)	Non-compliant n (%)
Standard operating procedures available	57 (74.0)	20 (26.0)
Regular internal quality control	53 (68.8)	24 (31.2)
External quality assessment participation	36 (46.8)	41 (53.2)
Equipment calibration compliance	51 (66.2)	26 (33.8)
Preventive maintenance documentation	47 (61.0)	30 (39.0)
Regular staff competency assessment	46 (59.7)	31 (40.3)
Corrective action documentation	43 (55.8)	34 (44.2)
Higher overall QA compliance category	38 (49.4)	39 (50.6)

The results of the regulatory compliance assessment indicated that 31.2% of the testing units had high compliance, 45.5% had moderate compliance, and 23.4% were at low compliance. Internal audits were carried out in 50.6% of the units and full personnel competency records existed in 54.5%. Units documented equipment validation in 62.3% and 58.4% had patient safety incident reporting systems in place. The scores for biosafety requirements were highest (79.2%). However, a documented corrective action procedure was only available to 55.8% of the testing units. The results in this study reveal that there is a variation in internal readiness in the regulation in terms of internal auditing, personnel documentation and corrective action system.

Table 3. Regulatory compliance and accreditation readiness among decentralized hospital testing units (n=77)

Regulatory indicator	Frequency (n)	Percentage (%)
Overall regulatory compliance category		
High compliance	24	31.2
Moderate compliance	35	45.5
Low compliance	18	23.4
Regulatory and documentation indicators		
Internal audit conducted	39	50.6
Complete personnel competency records	42	54.5
Equipment validation records available	48	62.3
Patient safety incident reporting available	45	58.4
Biosafety requirements fulfilled	61	79.2
Documented corrective action procedures	43	55.8

The availability of electronic laboratory information management systems (ELIS) varied greatly when the data was evaluated for integration. Laboratory information system connectivity was documented in 41.6% of testing units and hospital information system integration was documented in 37.7% of testing units. Access to EMR was

available in 45.5% of units and automatic forwarding of laboratory test results in 41.6%. Thirty-nine percent of units had electronic audit trails and 49.4% had real-time access to results. 66.2% of the units had data security procedures in place. Overall, the results indicate that electronic information exchange and automated reporting did not occur as widely as did basic data security practices, which may reflect a lack of interoperability between decentralized testing units and centralized hospital information systems.

Table 4. Data integration and laboratory information management among decentralized hospital testing units (n=77)

Data integration indicator	Yes n (%)	No n (%)
LIS connectivity	32 (41.6)	45 (58.4)
HIS integration	29 (37.7)	48 (62.3)
Electronic medical record access	35 (45.5)	42 (54.5)
Automatic transfer of test results	32 (41.6)	45 (58.4)
Electronic audit trail	30 (39.0)	47 (61.0)
Real-time result accessibility	38 (49.4)	39 (50.6)
Electronic data security procedures	51 (66.2)	26 (33.8)

Results from the analytical assessment showed statistically significant relationships between organizational practices and operational quality indicators. Units that regularly assessed staff competency had a higher proportion of satisfactory quality assurance compliance (65.2%) than those units that did not assess staff competency on a regular basis (25.8%), and this difference was statistically significant (χ^2=11.51, p<0.001). Likewise, the frequency of complete result documentation was much higher for testing units with automatic data integration than for those without automatic data integration (84.4% v 53.3%; χ^2=8.06, p=0.005). Seven hundred and eighty-one percent of the electronically integrated testing units had results available soon compared to 37.8% of the non-integrated units, which was statistically significantly associated (χ^2=12.28, p<0.001). The results indicate that structured competency assessment/s and electronic integration may relate to better performance of decentralized laboratory testing.

Table 5. Association of staff competency assessment and electronic data integration with quality assurance and operational performance (n=77)

Variables	Exposed group n (%)	Comparison group n (%)	χ^2	p-value
Regular competency assessment and higher QA compliance	30/46 (65.2)	8/31 (25.8)	11.51	<0.001
Automatic data integration and complete result documentation	27/32 (84.4)	24/45 (53.3)	8.06	0.005
Automatic data integration and timely result availability	25/32 (78.1)	17/45 (37.8)	12.28	<0.001

Statistical test: Pearson chi-square test. p<0.05 was considered statistically significant.

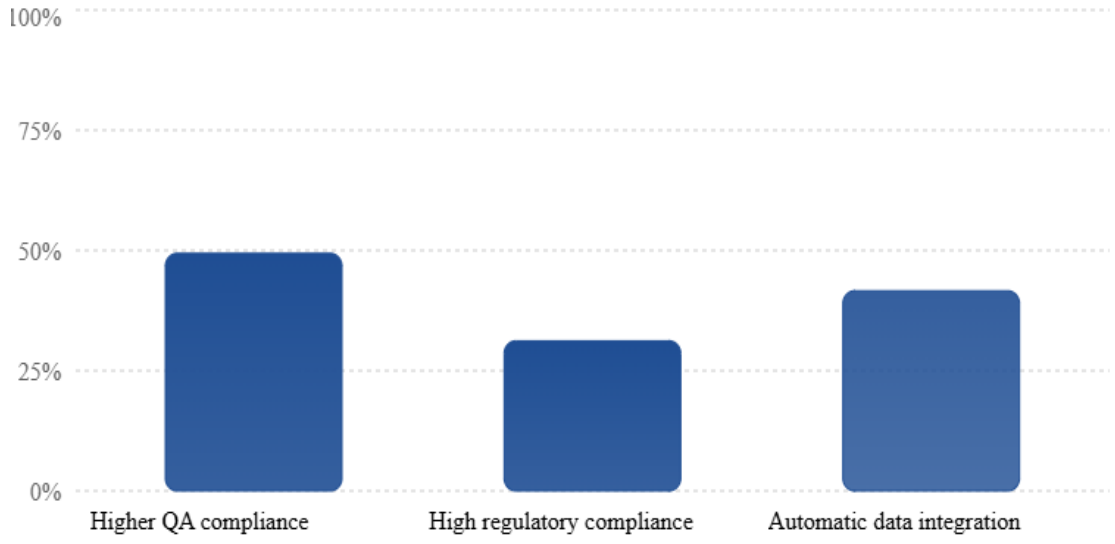


Fig. 1: Distribution of selected quality assurance, regulatory compliance, and electronic data integration indicators among decentralized hospital testing units.

DISCUSSION

Decentralized hospital testing has become an important component of contemporary healthcare delivery by enabling rapid diagnostic evaluation near the patient and supporting timely clinical decision-making. Point-of-care testing is particularly valuable in emergency departments, intensive care units, operating theatres, and other clinical environments where immediate laboratory information may influence treatment decisions. However, the expansion of decentralized diagnostic services introduces challenges related to analytical reliability, professional competency, regulatory oversight, and information management. Maintaining uniform quality standards across multiple testing locations requires coordinated supervision, standardized operating procedures, effective quality monitoring, and integration with existing laboratory services. Contemporary literature emphasizes that decentralized diagnostic testing must operate within a comprehensive quality management framework to ensure that improved accessibility does not compromise analytical accuracy or patient safety [15, 16]

Quality assurance is one of the basic and necessary requirements of any laboratory testing service to be reliable and trustworthy. Point-of-care testing is often conducted by health care practitioners with non-laboratory medicine appointments. Variability in testing performance may be attributable to the differences in professional training, equipment familiarity, workload and adherence to procedural requirements. Therefore, documented standard operating procedures, internal quality control, external quality assessment, equipment verification, equipment maintenance schedules, and systematic corrective actions should be addressed in a comprehensive quality assurance program. These activities are monitored routinely in order to ensure analytical consistency and to help to identify operational weaknesses at an early stage. In 2020–2021, professional recommendations have focused on not only the performance of the instruments but also on the entire testing process, covering preanalytical, analytical and postanalytical activities, for effective quality management [17, 18]

Internal quality control is especially important as it gives ongoing proof that a diagnostic system is performing analytically in a desirable range. The frequency and extent of quality control activities should be related to the clinical use, analytical performance, operational conditions and implications of inaccurate results. However, overall reliability of testing cannot be achieved if only internal quality control is used. Independent performance standards are also used to assess analytical accuracy through external quality assessment, and to detect systematic deviations. Applying a risk-based approach consisting of Internal Monitoring, External Assessment, Equipment Verification and Corrective Action Procedures is therefore necessary to ensure quality in the testing process. Laboratory supervisors can also use structured quality indicators to detect recurring issues, assess improvements and to track adherence to each clinical department [19]

Another key element of decentralized laboratory quality management is personnel competency. All health care workers conducting bedside investigations should have technical knowledge of how to use testing devices, understand the results if they are outside the range, know the quality control warning, and be able to enter the results properly. Initial training should be followed up by regular competency re-assessment, especially in the event of changes in the equipment used, new diagnostic techniques being introduced or new testing errors being identified. Assessment of competency can be made through direct observation, skill analysis of quality control results, and examination of test results. A standardised training structure guarantees consistency of operators and minimises the risk of variation in procedure. It is also important to have a clear delegation of duties within clinical departments, the laboratory, the testing coordinator and institutional management in order to promote effective laboratory oversight [20].

To achieve sustainable quality improvement in decentralized testing environments, regulatory compliance is required as the organizational base. Laboratory accreditation frameworks set out expectations for the management responsibilities, competency of personnel, equipment performance, documentation, risk management, internal auditing and continual improvement. This has been further emphasized by the latest ISO 15189:2022, which includes point-of-care testing in the medical laboratory quality and competence requirements. Written procedures are not sufficient to meet these standards; the institution must ensure that its written procedures are followed, monitored and reviewed. Internal audits, management reviews, incident reporting and documented corrective actions are elements of institutional accountability and readiness for external evaluation. Thus, regulatory compliance needs to be treated as a quality improvement process rather than a process for accreditation [21].

Data integration has become a key factor in the effectiveness of decentralized testing, and it is vital for safety. Diagnostic tools at the bedside can provide fast analysis data, but the information might not be available in the hospital information system or might have to be entered manually. Manual documentation can lead to transcription errors, incomplete patient records, delayed clinical communication and duplication of testing. Results are transferred automatically and with the correct patient when laboratory information systems, hospital information systems and electronic medical records are integrated with the diagnostic devices. Electronic connectivity also allows for quality monitoring, identification of operators, monitoring of the performance of the devices, and documentation of corrective actions from a distance. Therefore, digital interoperability should be seen as a part of the laboratory quality management system, not just an administrative mechanism [1]

Successful integration of the electronic system relies on the right technology, consistent identification systems, secure data transfer and inter-platform compatibility. In a decentralized testing network, the devices may come from various manufacturers, which can lead to interoperability and communication protocol issues. In addition, the lack of network infrastructure, technical support and staff training can limit the use of automated reporting

systems. Such a coordinated institutional approach, involving laboratory employees, clinicians, information technology specialists and hospital administrators is required to overcome such limitations. Electronic result transmission should also be backed up by access controls, audit trails, data verification measures and measures for detecting failures in the connectivity. A few examples of such integrated reporting in geographically distributed POTWs have been published in 2023, which demonstrated the feasibility, and showed the value of it in timely information exchange and enhanced data completeness [3]

Quality assurance, regulatory compliance and data integration are all geared towards patient safety. Incorrect identification of patients, inappropriate specimen collection, equipment malfunction, inadequate quality control, lack of appropriate equipment operator training, and incorrect documentation are all potential errors in decentralized testing. These mistakes may have a significant impact on clinical interpretation and recommendations for care, including for patients in a critical condition whose condition requires rapid diagnosis. Opportunities are provided for identifying preventable problems through regular clinical audits, reporting of errors, root cause analysis and subsequent corrective interventions. Institutions can measure the effectiveness of improvement strategies using such indicators as testing error rate, the time it takes to have results back, the percentage of documentation completed, and the percentage of compliance to quality control requirements. A learning environment is fostered, as well as a culture of nonpunitive reporting of incidents, which further supports patient safety and promotes ongoing compliance with laboratory quality requirements [22]

Integrating organizational governance, professional development, regulatory supervision, and digital infrastructure is essential to sustainable improvement in decentralized diagnostic services. A multidisciplinary oversight committee, responsible point-of-care testing coordinators, staff competency assessment consistency, and centralized electronic monitoring may help to create consistency across testing sites. Apart from purchase of diagnostic equipments, institutional investment should be given to the resources that are needed for staff training, quality control material, participation in external assessments, information technology maintenance, and continuous evaluation and performance monitoring. Quality indicators can be used to support resource allocation as well as to identify areas in need of corrective action when assessed regularly. The implementation of a QM and connectivity system could be a feasible option for improving diagnostic trustworthiness in low-resource healthcare settings, in three stages.

The principal limitations of cross-sectional evaluations of decentralized testing include their inability to establish causal relationships, potential variation in institutional documentation, and differences in testing procedures across clinical departments. Even if assessments are made in one institution, they may not be generalizable to other hospitals that have a different resource base, laboratory equipment, etc. and have different regulations. Moreover, compliance assessments based on documents may not accurately represent practice or patient actual clinical outcomes. Structured quality assurance and control interventions, standardisation of regulation and automatic integration of data should be assessed in future multi-centre longitudinal studies for their effects on analytical error rates, turnaround time for the diagnosis, cost-effectiveness and patient safety outcomes.

CONCLUSION

Quality assurance, regulatory compliance, and electronic data integration are interdependent components of effective decentralized hospital testing. Standardized operating procedures, regular quality control, external quality assessment, equipment maintenance, continuous staff competency evaluation, and systematic regulatory audits are essential for maintaining reliable diagnostic services. Integration of point-of-care testing devices with hospital information systems can improve result accessibility, documentation accuracy, traceability, and operational efficiency. A coordinated quality management framework supported by laboratory supervision, multidisciplinary collaboration, and appropriate digital infrastructure offers a practical approach to strengthening decentralized testing services. Continued institutional investment in quality monitoring, personnel development, and information system interoperability is necessary to promote sustainable diagnostic performance and patient safety.

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