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RESEARCH INVESTIGATING MEDICAL LABORATORY EXAMINATIONS: QUALITY AND TIMELESSNESS

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ABSTRACT

Modern laboratory medicine can be categorised into two key types, namely central laboratory testing and point-of-care testing (POCT). Typically, centralized laboratory medicine offers high-quality results that can be ensured using effective management programs and training staff. It is the clinical staff who carry out POCT, which enables tests to take place closer to the patient. The key benefit of POCT is that it significantly reduces turnaround time, which is a great benefit to the patient. Nonetheless, the key drawback is that clinical laboratory testing requires staff to have expert skills. Thus, the following factors must be considered when deciding which laboratory testing components will be carried out in central laboratories and which ones will be performed as POCT (in relation to quality and timeliness): medical necessity, medical utility, technological capabilities and costs. POCT is usually the preferable option as long as adequate quality can be guaranteed. This is because it is quick to perform, which is essential when measuring vital parameters. Additionally, POCT is generally preferred in cases where the central laboratory is unable to guarantee that results will be delivered quickly (i.e., within 30-60 minutes).

1. Introduction

The quality of medical care can be defined as the extent to which health care systems generate positive health outcomes for individuals and populations [1, 2]. In terms of laboratory medicine, it is essential that clinical laboratory testing can promptly offer accurate results to ensure optimal medical care. The results of medical analyses must be assessed using laboratory medical tools, such as reference values, predictive value, diagnostic sensitivity and specificity [3]. This is crucial in ensuring that clinicians have the information to diagnose, propose and manage diseases [4]. Effective technological platforms and highly-qualified staff are required to deliver high-quality laboratory analyses [5]. During the 1960s, clinical laboratory testing was based on a patient-oriented approach in which laboratories strongly associated with departments were used (such as emergency units, internal medicine, surgery and paediatrics) [6]. However, automation was minimal in laboratory testing settings, with manual methods being predominant. Given the increasing demands to reduce costs in healthcare systems, new processes for centralising testing in central laboratories were developed. The key objective of this was to enhance the quality of laboratory medicine. This process was driven by the development of large and intricate laboratory analysers. Analysis processes thus moved away from being patient-centred and were increasingly carried out in central laboratories. Nowadays, both types of testing are available to ensure that patients in hospitals and clinical units are covered. At least four factors must be considered to ensure that centralized laboratories can perform tests in an efficient and cost-effective manner, namely:

- Continuous improvements in technology that enhances the quality of automated platforms.
- Establish sample transport systems (such as pneumatic tubes) to connect the laboratory to the patient unit.
- The development of a legal policy for quality assurance is implemented in programs related to quality control, assurance and measurement.
- The computerization of the data transfers within laboratory settings and data transfer between the laboratory and clinical units.

It is crucial that these aspects can be achieved in routine and short-turn-around-time modes. The latter focuses primarily on samples taken in emergency and critical care units. A postgraduate training system for educating laboratory students and technicians was developed to ensure that testing in centralised laboratories is accurate.

2. Errors in Clinical Laboratory Testing

Laboratory medicine errors refer to any "faults" that occur whilst developing a clinical question, ordering an appropriate medical test, interpreting results, and using the information to make patient-related decisions. However, a new paradigm

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of laboratory medicine was created to reduce errors, which has had a significant impact on patient safety [7]. For example, the frequency of errors reduced by approximately 36% over ten years at a university hospital laboratory [8]. The laboratory testing process has traditionally been separated into three stages: pre-analytical, analytical, and post-analytical. This is presented in Figure 1.

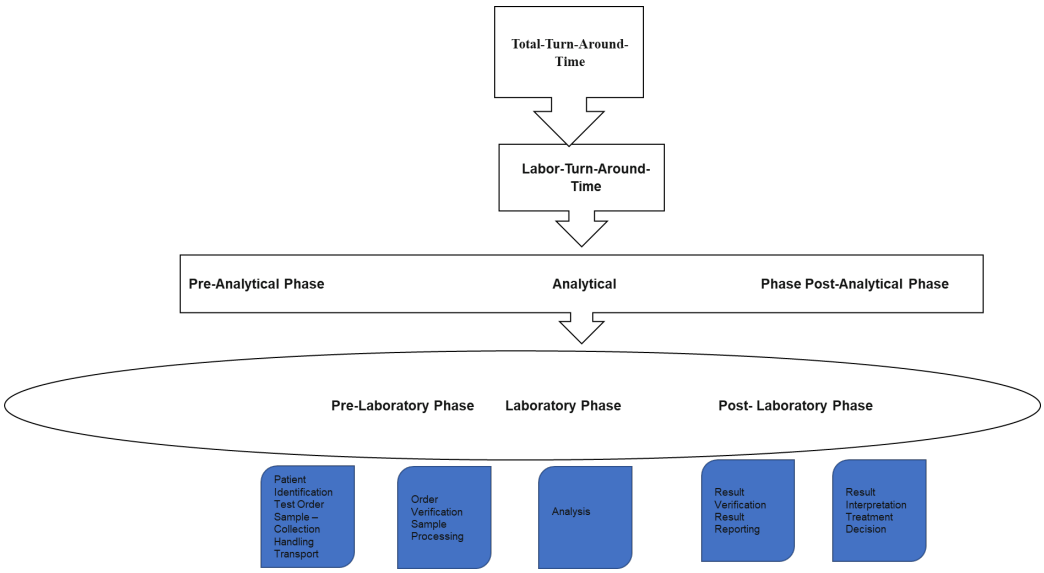

Figure: 1 Medical laboratory testing stages.

The most significant reduction in errors was found during the pre-analytical phase. Additionally, more than 62% of all mistakes investigated in this study occurred during the pre-analytical phase (vs 15% of analytical origin and 23% of post-analytical origin) [8]. According to recent studies, 46-68% of errors were made during the pre-analytical phase, with just 18-47% occurring during the post-analytical phase [9]. Thus, the pre-analytic phase should focus on future quality enhancement. Moreover, identifying the key stages in the pre-analytical phase is crucial in reducing errors and ultimately enhancing patient safety [10]. Interestingly, activities in the pre-analytical phase can be performed outside of the laboratory. Physicians and nurses take the lead role during this phase. They must carry out activities such as documenting patient data, developing clinical questions, ordering tests, collecting samples and preparing samples for transportation [11]. These activities have a substantial impact on the quality of laboratory medicine, which has been revealed in many studies, most of which indicate that most errors occur during the pre-analytical. Phase is related to specimen collection from infusion routes, tube-filling mistakes, the use of inappropriate containers and wrong additives, patient identification errors and errors with requesting procedures [8, 11]. Laboratory staff take charge of the second pre-analytical phase. Errors can also occur at this stage, which involves specimen preparation (e.g., centrifugation, aliquoting, diluting, sorting) to ensure that the sample is sufficiently prepared for analysis. However, the fewest errors seem to occur during the analytical stage, which is evidenced in the low frequency of proficiency testing failures. However, it is still important to note that post-analytical errors can occur, including neglected or incorrectly transmitted results, misinterpretation of results by clinicians and making poor decisions irrespective of correct result transmission and interpretation.

Thus, when it comes to patient safety, quality management programmes must include all processes involved in testing. Moreover, laboratory or clinical staff must be accountable for this [11]. An external comparison with other hospitals is required to accomplish "whole quality management," It enables hospitals to analyse their own performance and identify areas that need improvements to enhance laboratory medicine [12, 13]. This method is now known as "benchmarking." It is thus critical to highlight the importance of laboratory medicine education and training for both laboratory workers and those working in clinical units. Usually, SOPs aid in standardising the analytical process and avoiding common errors caused by incorrect application. This also applies to the newly-developed "point of care testing" (POCT) concept, in which healthcare professionals are required to carry out all stages in the analytical process.

3. Centralised Testing Versus POCT

Aside from quality, the pre-analytical process has a significant impact on timeliness. The majority of ordered tests can be completed with routine priority because the results are not needed to make quick decisions. On the other hand, clinicians are expected to obtain laboratory data as quickly as possible, particularly if they must make important decisions in emergency and intensive care settings. Nonetheless, when unexpected laboratory results are reported, outpatients can expect relatively to receive test results quickly, including those acquired in the ambulance. This is because the physician can consult directly with the patient regarding the effects and any extra medical/laboratory investigations that may be required. Even though there are automated sample transport systems in most modern hospitals, the activities that occur

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during the pre-analytical stage (i.e., sample transport and sample preparation by centrifugation) can be time-consuming. In the late 1980s, a new laboratory testing method called "point-of-care testing" (POCT) was developed. This has also been referred to as "bedside testing" or "near-patient testing" and requires the clinician to return to the patient to perform testing. This method has grown in popularity in recent years for several reasons. The primary reason is that it can significantly reduce the time taken during the pre-analytical phase. Technological breakthroughs have enabled devices to be made smaller. Moreover, micro-computerisation has occurred. These two events served as milestones in the development of POCT. Additionally, due to the development of microchemistry technologies (i.e., biosensor methods, substrate-specific electrodes and ion-selective electrodes) and a focus on analysing blood as sample material, POCT has become increasingly popular in many different medical testing fields [14, 15]. Nowadays, it has a wide spectrum of parameters [10] that is likely to expand in future. As well as being employed for screening, diagnosis and therapy control in hospitals, POCT can also be used in caregivers' offices. Guidelines for laboratory medicine practice were recently established to provide n evidence-based foundation for the use of POCT.

The development of POCT has provided the basis for developing a platform that can fulfil test result demands in the quickest possible time. This is, of course, paramount in critical care settings [16]. As well as being used in direct bedside settings (e.g., measuring blood gases, blood glucose in the blood), POCT can also be used in a "satellite laboratory" close to an emergency care unit or other acute care departments [16]. A satellite laboratory can provide a specialised menu of laboratory tests specifically for acute care. Moreover, it brings together the benefits of central laboratory testing (automation, effective quality control, computerisation, expert staff) and POCT (reduced sample transport times which minimise pre-analytical time and quick delivery of results). Table 1 presents the advantages and disadvantages of POCT and centralised laboratory testing. For the most part, the advantages of POCT relate to the reduced turnaround times. However, there are other benefits including a reduction in iatrogenic blood loss and anaemia (this is due to the minimal sample volume that is required in POCT). However, these aspects tend to be less important in some settings, such as paediatrics and neonatology. Nonetheless, a majority of clinical chemistry analysers in centralised testing settings only require small blood samples as well. In terms of neonatal care, studies have shown that POCT phlebotomy results in fewer transfusions, fewer complications and reduced costs [17-19]. On the other hand, the disadvantages are primarily related to the lack of quality assurance, control and management programs, all of which have long been part of centralised laboratory testing systems but are hardly ever applied in POCT. Although laboratory technicians believe that quality assurance and control are key parts of their role, this process is often considered to be tiresome and burdensome for staff in POCT settings. Some such healthcare professionals do not understand the exact nature of the relationship between quality assurance, quality control and the quality of data produced [20]. They thus lack understanding regarding the prerequisites for guaranteeing patient safety.

Therefore, doctors continually expect to see improvements in test result timeliness, even though they do not consider test result quality to be as important. As a result of this disparity, it is expected that medical errors will increase in POCT. Recently, researchers have claimed that there are twice as many analytical errors in POCT as in centralised testing [21, 22]. For instance, studies have identified a discrepancy between the test accuracy claimed by manufacturers and the accuracy attained by POCT end-users. Enhancing laboratory experience and continuous training of POCT amongst end-users are thus critical in addressing POCT quality concerns [23, 24]. In general, POCT results are deemed to be comparable to central laboratory testing results and thus it is reasonable to expect that quality requirements should also be the same, irrespective of the testing site or process employed [14]. Over the last 10 years, POCT programs have been increasingly adopted to enhance quality and management processes. Additionally, such programs are updated based on ISO 22870 point-of-care (POCT) requirements for quality and competence [18]. This entails the following processes:

- Internal and external quality control practices.
- Training schemes for end-users.
- Certification and re-certification of end-users.
- Assessments of new or alternative POCT tools by laboratory medicine experts.
- Assessment and approval of proposals aimed to educate the end-users.
- Maintenance of consumable supplies and reagents.

Another critical factor that has influenced the development of POCT is cost. As previously stated [17, 25], POCT costs more per patient than central laboratory testing. Nonetheless, it is essential to consider whether the benefits of POCT outweigh the cost, as it can significantly enhance the quality of patient care.

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Table: 1 Comparing the advantages and disadvantages of POCT and centralized testing in emergency care settings.

	POCT	Centralized testing
Laboratory turn-around-time:	Faster (< 15 min)	Slower (30–60 min)
Total turn-around-time:	Potentially faster	
Patient benefit:	Potentially higher T-TAT	Potentially higher quality
Sample:	–	–
Serum, plasma:	–	–
Whole blood:	Used predominantly	Used predominantly
Sample handling errors:	More	Less
Sample preparation:	Unnecessary	Necessary
Additional time of physicians and nurses necessary:	Yes	No
Qualification of the staff for laboratory medicine:	Low	High
Continuous education and training of the staff:	No or only to a limited degree	Yes
Quality assurance system based on legal requirements:	Yes but limited	Yes
Integration in the hospital information system:	Under development	Yes
Comparability of the analytical systems:	Limited	Good
Test equipment selection by qualified personal:	No or only to a limited degree	Yes
Equipment maintenance by qualified personal:	No or only to a limited degree	Yes
Frequency of equipment maintenance:	Low	High
Test costs:	Higher	Low

To summarise, the advantages and disadvantages of POCT will be continually revised. When it comes to decisions about new technological developments, the skills and qualifications of end-users must be considered, as well as any relevant legal requirements.

4. Turn-Around-Time

The most significant advantage of using POCT in addition to laboratory testing is the reduced turn-around-time (TAT). TAT can be defined as the time that elapses between commencing and finishing a task. There are two different types of turn-around time (TAT) in medicine, namely laboratory turn-around time (L-TAT) and the total turn-around time (T-TAT). Moreover, many different definitions have been put forward, especially for L-TAT. One researcher defined L-TAT as the time taken for a sample to arrive at the laboratory and deliver the results to the clinical unit. However, it is now understood to include the time it takes to collect a sample and transport it to the laboratory. On the other hand, T-TAT refers specifically to the time that elapses between ordering a laboratory test and a physician's making of a clinical decision based on the final laboratory results. T-TAT has been dubbed the "therapeutic TAT" as it is frequently associated with therapeutic interventions. However, there is little doubt that shortening the L-TAT can, in theory, allow decisions about patient interventions to be made earlier. Thus, it is hardly surprising that physicians prefer to acquire laboratory data as soon as possible. They believe there's a link between longer L-TAT and delayed decision-making, especially in emergency and intensive care settings. [21] Nonetheless, despite technological and organisational advancements in centralised laboratory testing, there is minimal potential for L-TAT times to be further shortened in laboratory settings [26-28]. On the other hand, no sample transportation is required in POCT, whilst whole-blood analysis can also be performed (which reduces the time needed to prepare serum and plasma). Thus, the pre-analytical phase is much shorter in POCT than centralized laboratory analysis. Moreover, the pre-analytical treatment is much simpler (e.g., there is no need for sampling tubes with different additives) and this significantly minimises errors during the pre-analytical phase. POCT is thus considered to have great potential as a testing method, especially in emergency and intensive care settings. Many studies have found that, when POCT is used, there is a significant reduction in L-TAT for parameters such as glucose, blood gases and haematological markers, as well as common markers of clinical chemistry (i.e., potassium, sodium, chloride or urea) . Reduced L-TATs were also identified for hemostatic tests [29, 30] and cardiac marker analysis [31-33]. Nonetheless, the reduced L-TAT is only likely to have a positive impact on patients if it is translated into a reduced T-TAT, as this can enable patient-related decisions to be made at an earlier stage. However, this sometimes causes issues. Thus, it is a critical topic for further investigation. Therefore, findings indicate that, even though POCT reduces L-TAT (and in some cases, even T-TAT), no obvious therapeutic advantage has been identified in terms of shorter patient stays in emergency departments or lower rates of admission and mortality [34]. Nonetheless, evidence suggests that POCT's potency for L-TAT shortening can be translated into clinical benefits, though only for certain individuals [35]. POCT for coagulation monitoring is beneficial [35, 36]. Additionally, individuals suffering from acute chest pain could benefit from POCT. In such instances, POCT-guided cardiac marker testing is permitted in the emergency room to enable early diagnosis of acute myocardial infarction without waiting for the sample to be taken to the central laboratory. Furthermore, a reduction in patient stays in the emergency department or coronary care unit, as well as overall hospital stays, has been revealed. However, when a switch from central laboratory to POCT testing fails to improve patient outcomes, it is important to consider whether ineffective and time-consuming patient management is to blame. In general, this entails issues such as bed availability, as well as other diagnostic disciplines such as radiology,

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MRT, EKG, and echocardiography, which frequently increase the waiting times for results. Clinicians' constant demands for reduced LTATs or switches to POCT generate a significant question, namely how fast is fast enough for laboratory test results? To answer this question, it is important to differentiate between vital parameters and STAT markers. When applying modern POCT platforms to measure vital parameters such as K^+, Ca^{++}, Na^+, glucose, creatinine, blood gases, haemoglobin or hematocrit, NH_3 and lactate, results can be accessed in less than five minutes. Nonetheless, there are still issues associated with translating short L-TATs into suitable T-TATs and ultimately providing optimized patient management to enhance clinical and economical outcomes. For this reason, it has been recommended that POCTs should be used to measure vital parameters rather than a 24-hour central laboratory. On the other hand, a 24-hour central laboratory is preferred for testing hemostatic parameters, acute chest pain differentiation markers (myoglobin, troponin, BNP, D-dimer) and drug screening markers, so long as the sample transportation is quick. However, there is a key requirement here, particularly when it comes to heart markers: the central laboratory must be able to ensure that results can be delivered the same day with an L-TAT of < 1 hour, and optimally < 30 minutes [37, 38]. If not, POCT should be used.

Lastly, when it comes to determining whether laboratory tests should be performed at the bedside, central laboratories or other sites, the dynamic equilibrium between medical utilities, technological capabilities and costs must be considered [46].

5. Conclusion

There are two primary types of testing in modern laboratory medicine: central laboratory testing and point-of-care testing. Nonetheless, results must be accurate and timely, regardless of when and where the tests are performed. In centralised laboratory settings, testing is considered highly high quality. On the other hand, POCT can reduce the time needed to complete a test and deliver results. As long as adequate quality can be ensured, POCT should be considered the method of choice for testing vital parameters given its timeliness. Central laboratories may not deliver STAT marker results in such a short time frame (60 minutes). However, significant laboratories can typically perform other tests cost-effectively and efficiently and show results quickly to ensure optimal patient care.

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