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Assessing the Total Testing Process in the Clinical Biochemistry Laboratory at Tertiary Care Hospital, Chengalpattu District- A Cross sectional Study

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Analytical phase , Clinical biochemistry, Quality indicators, TAT, TTP

Abstract
Background: In the current healthcare industry, laboratory services have been cited as one of the key processes promoting safe patient care. The diagnostic decision-making process, however, is hampered by errors that occur in the overall testing processes. This study's goal was to evaluate testing errors across the board in the Clinical Bio-Chemistry Laboratory of the Tertiary Care Hospital Laboratory, Chengalpattu.

Methodlogy: A cross-sectional investigation was carried out in the laboratory of a tertiary care hospital, Chengalpattu. Known quality indicators were used to gather all the necessary data. In order to evaluate the data, SPSS version for windows 26 was used. The descriptive data and chi-square were presented using frequencies and cross-tabulations.

Results: 206 samples in total, along with associated lab request forms, were received for examination. Pre-analytical errors made up 4.40 percent of the total errors, and post-analytical errors made up 2.64 percent, according to the examination of the overall distribution of errors. The most frequent pre-analytical errors were incomplete request form filling, followed by

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patient location and clinical detail. The primary flaw in the post-analytical step of quality assurance is excessive turnaround time.

Conclusion: The current research revealed a comparatively high frequency of errors, raising concerns about the necessity of using quality indicators to gauge errors throughout the entire testing process. Utilizing laboratory standards, hospital laboratory should evaluate the error and implement the necessary corrective action.

1. Introduction

The bedrock of today's medical field is laboratory services. The findings of diagnostic procedures offer results that can be generalized to decisions that were made by the patient, the doctor, as well as others. More than 60% of health care decisions are driven by laboratory testing in the patient's care. Every clinical laboratory, meanwhile, needs to have adequate standards to guarantee the effectiveness of the declared medical results because of findings are based in the lab is subjected to fluctuation. [(1)]

Laboratory medicine procedures must be of a grade that enables physicians to provide quality care. Excellence in laboratory medicine is the certainty that almost every action in the total testing process (TTP) is carefully conducted out, leading in the development of comprehensive patient care and wants to participate.

All phase of the study is susceptible to mistakes. These consequently lead to growing healthcare spending and diminishing patient experience. [(1)] The procedure of laboratory testing is extremely diverse. The analytical phase and the extra-analytical segment constitute this clinical laboratory testing process.

Errors can happen at any point of the patient care cycle, from the treating physician's examination and going to order of investigations (preanalytical stage) to the labs obtaining the sample and going to perform the analysis (analytical stage) and ultimately while the reports are conveyed to the physician for actions involved in the management of the patient (post analytical stage). [(2)]

Previous to the delivery of patient results, the laboratory performs quality control (QC) to discover and prevent errors in the diagnostic system's analytical phase. Pre-analytical, analytical, and post-analytical phases of the testing system must always be adhered to in order to get quality laboratory results. Daily internal quality checks are carried out in the lab using controls whose values are known. Prior to the publication of a patient's data, quality control (QC) in a clinical laboratory is important for identifying defects and reducing defects in the analytical process.

Internal quality control (IQC) has been used by laboratories to help them continuously improve their quality assurance procedures. Accreditation is a crucial step in ensuring the precision, correctness, and dependability of laboratory test results. [(3)]

The four aspects of competent laboratory services are consistency, efficiency, quickness, and legitimacy. Clinical biochemists sometimes ignore timeliness as a crucial quality in preference of boosting the analytical sophistication of sample processing. However, the turnaround time (TAT), which is a marker of timeliness, is widely employed by physicians as a norm for laboratory performance.

Clinicians rely on quick TAT to diagnose and treat their patients expeditiously, as well as to discharge patients from ERs or hospitals with in-patient services quickly. Faster TAT ultimately help in reducing the patient’s overall spending. Fake samples have been sent to the lab more routinely seems to be another drawback of delayed TAT. This contributes to the laboratory's already heavy burden. For laboratory quality management and patient comfort, continual improvement of turnaround times are crucial.[(4)]

Based on the IFCC's [International Federation of Clinical Chemistry] quality indicator, this study aids in evaluating the entire testing procedure. This examination identifies the variations in the testing procedure and yields a substantial solution.

The objective of the study is to evaluate the clinical biochemistry laboratory's pre- analytical, and post-analytical stages using quality indicators and to assess the whole testing procedure's level of quality

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for the blood samples obtained from the outpatient department. Intensive care unit, emergency room, and general health examination.

2. Materials and Methods

The study is being conducted in tertiary care hospital, Chengalpattu. The investigation was conducted using requests forms from the Outpatient, Inpatient, Emergency, and Master checkup divisions. The inclusion criteria are the requests which contained venous blood samples for clinical biochemistry test whereas the exclusion criteria are the test that requested for urine and other body fluid such cerebral fluid, serous fluid, and synovial fluid are excluded. The study is restricted for the request that ordered for the outsourcing tests.

The research design of this project is a observational Cross-sectional study. Sources of data are based on primary data only. The data is collected by the pre-designed questionnaires. The sample size for the study is 206 of request form received with blood samples .The sampling method will be used is Convenient sampling method. The study tool is pre designed semi-structured validated questionnaire comprising of Demographic data, Quality indicators. TAT calculation.

Descriptive statistics were reported as mean (SD) for continuous variables, frequencies (percentage) for categorical variables. Chi-Square at 5% level of significance was used to find statistical significance. Fischer's exact test is when expected cell count is less than 5. Data were statistically evaluated with IBM SPSS Statistics for Windows, Version 26.0., IBM Corp., Chicago, IL.

3. Results

Table 1: Pre- Analytical Phase Frequency Distribution (n=206)

S.NO	QUESTION PARAMETER	VARIABLES			
		YES	PERCENTAGE	NO	PERCENTAGE
1	Patient Age	204	99%	2	1%
2	Patient Gender	203	98.5%	3	1.5%
3	Op/Ip/Mhc/No	205	99.5%	1	0.5%
4	Patient Location	139	67.5%	67	72.5%
5	Date Mentioned	190	92.2%	16	7.8%
6	Physician's Name	203	98.5%	3	1.5%
7	Clinical Data Mentioned	147	71.4%	59	28.6%
8	Sample Received With Properly Filled Request Form	204	99%	2	1.0%
9	Sample Tube Filled with Appropriate Volume	204	99%	2	1.0%
10	Sample Hemolysed	6	2.9%	200	97.1%
11	Sample Lipemic	1	0.5%	205	99.5%

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The frequency table shows the percentage of errors in pre-analytical phase from the request forms and blood samples collected from the out patient department, inpatient department, emergency department and master health up department.

Table 2: Analytical Phase Frequency Distribution (n-=206)

Quality indicators	**Variable**	**Frequency**	**Percent**
Equipment malfunction	NO	206	100.0%
Electric interruption	NO	206	100.0%
Reagent onboard availability	YES	206	100.0%
Calibration passed	YES	206	100.0%
Quality Control passed	YES	206	100.0%

The above frequency tables represents that there is no equipment malfunction, electric interruption, happened during the test runs.The reagent was also available onboard and all the calibration and internal quality control were passed daily before before test runs.

Table 3: Post Analytical Frequency Distribution (n=206)

S.NO	**QUESTION PARAMETER**	**VARIABLES**			
		YES	**PERCENTAGE**	**NO/ NIL**	**PERCENTAGE**
1	Sample Storage (Retaining Condition)	206	100%	-	-
2	Updating Result By The Faculty In His	206	100%	-	-
3	Non Adherence To Tat	22	10.7%	184	89.3%
4	Critical Value Informed As Per The Protocol	8	3.9%	NIL(198)	NIL(96.1%)

From the above frequency distribution table its indicates that all the samples are retained after the test finished as per the protocol. All the reports were updated in hospital information system by the faculty in regular interval without making any delay.

From the total samples received, 22 sample where not adhered with the mentioned turn around time. Whereas all the critical values are reported to the concern department by the faculty or technician and noted in the critical alert register.

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Table: 4 – Association between the location of wards, clinical data and physician's name in request forms (n=206)

S. No.	Association	OP		IP		IP/E		MHC		X^2 (df), p
		Yes n [%]	No n [%]	Yes n [%]	No n [%]	Yes n [%]	No n [%]	Yes n [%]	No n [%]	
1	Location of wards in request form	37 (42.5 %)	50 (57.5 %)	3 (94.6%)	3 (5.4%)	29 (67.4%)	14 (32.6%)	20 (100 %)	0	58.95(3),< 0.001
2	Clinical data in request form	57 [65.50 %]	30 [34.5 0%]	54 [96.40%]	2 [3.60%]	34 [79.10%]	9 [20.90%]	2 [10%]	18 [90%]	57.75[3], <0.001
3	Physician's name in request form	86[98. 90%]	1[1.1 0%]	56[100 %]	0	43[100 %]	0	18[90 %]	2[10%]	6.22[3],0. 03

The request forms received from the various departments shows the significance relation . The request forms received from the various departments shows the significance relation between them, were the out-patient department not mentioned the patient location comparing to other departments. The request forms received from the various departments shows the significance relation between them, where the op department 34.50% had not mentioned the clinical data. Similarly, among IP request forms 96.40% had mentioned the clinical detail. Among I/E request forms collected 79.10% had mentioned the clinical detail. Among master health check-up request forms collected, 90% had mentioned the clinical detail.The request forms received from the various departments shows the significance relation between them, among them OP department 1.1% and MHC 10% had not mentioned the physician. Among IP and IP/E 100% had mentioned the physician's name in request form.

4. Discussion

Based on IFCC quality parameters, Total testing process mistakes in the Clinical Chemistry laboratory were evaluated in this study. In clinical laboratories right now, managing the Total testing procedure is highly valued.[5] This backs up a measurable foundation for parties involved looking to ensure advancement and recent form in care and procedures.[6,7]

Pre-analytical errors related to the request form, therefore accounted for major reason of the 206 request papers that were submitted to the Clinical Bio Chemistry laboratory due to the missing of needed information. Notably, 151[73.3%] of the request documents were defective because they lacked one or more essential details. The patient's name was the sole structured attribute that featured on every requisition form used in this investigation.

This outcome was consistent with research from Ghana[8], Pakistan[9], and Ethiopia[10]. This was expected because it was quite likely that the request

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would have been denied if the patient's name had not been provided. However, 1.5% of the test request forms that were seen missing the name of the attending doctor. This proportion was lesser than the 19.8% percent indicated in a Research done in Nigeria[11]. Since the majority of doctors who visited the patient were interns, the reasoning behind this number could be linked to a lack of understanding and the variety of doctors serving the patient at one location.

Additionally, this study revealed that the requesting forms clinical data (28.6%) were frequently determined to be inaccurate. This outcome was not consistent with a prior study carried out in a comparable environment in Ethiopia[10], where the authors reported that clinical data (97.8%) had been missing. This finding revealed little advancement from the prior report at a comparable setting in Ethiopia[10], necessitating additional management effort to raise awareness of the negative effects of missing test request forms on the standard of patient treatment. Dimension (n = 206) (10.7%)

Moreover, the date of sampling was not specified on 7.8% of the request forms that were seen. This was lesser than the results from Nigeria (8.5%)[12] but close to those from a study of a similar nature that was carried out in Ghana (37.3%)[8]. This discrepancy may be caused by the amount of work that doctors must do, professional negligence or attitude difference, a lack of oversight by the relevant authority, or a profound ignorance of how incomplete test request forms affect the standard of patient care. 0.5 % of the samples in our investigation were denied for various reasons. This percentage was lesser than the rejection rates reported in Turkey (0.91 percent)[5] and the United States (0.74 percent)[13].

The major reasons for an increase in sample rejection would be, frequent work rotation for phlebotomists, an increase in patient volume, a regular influx of internship students. In this study, haemolysis (2.9%) was the most frequent reason for sample rejection, which is comparable to studies from Ethiopia[14], Nigeria[15] and Spain[16] that also identified haemolysis as the primary reason for sample rejection. Increased haemolysis noted in this study may be due to suboptimal phlebotomy techniques or a recurring inflow of pupils into the institutions

Interestingly, a sample without a request or a request without a sample accounted for 100% accuracy, which is lesser than the result recorded in Ethiopia[11]. In the current study, the percentage of mislabelled samples was 0 percent. This might occur as a result of perfect allotted staffing pattern in all the shift with perfectly designed laboratory information system and well-trained staff with the management information system.

Compared to an Indian report (5.07 percent), 4.40 percent of pre-analytical errors were found in our study[7]. satisfactory results in IQC accounted for these, which may have been caused by correct QC material synthesis, storage of hazardous, stable reagents, decontaminant, or calibration stability. This statistic (0%) was significantly lesser than an Indian report's (0.6%) QC deviance rate[4]. The discrepancy not happened which is be explained by variations in the usage of quality control material, users, machine types, ambient conditions, or the application of quality assurance systems is not involved. The instrument's inconsistency as a result of electricity oscillations, a lack of mechanization and quality system training for laboratory employees, understaffing or regular staff changes before teaching might have been to blame for the alarming increase in analytical errors is out-performed in the analytical phase.

The frequency of errors in the current study's post-analytical phase was 3.64 percent, almost same as the rate of the study done in India (3.2 percent)(40). Excessive TAT (10.7 percent) was a prominent factor in this study's post-analytical errors. Workload, could be a major factor in the failure to provide data by the deadline.

Critical value reporting was a significant component of the post-analytical step of the testing procedure. When critical value reporting was examined, 8 (3.90%) critical value cases were found, all of these have been reported to the relevant doctor within a defined time. Inability to notify within the intended time is a result of factors including a non-functional LIS, inadequate laboratory staff awareness, missing information on the test request form, including the patient's address, attending physicians, and

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telephone complications. If a patient is left untreated and a critical value notification is not delivered in the allotted time, it may be fatal. In reality, the post-analytical phase can be enhanced by the deployment of electronic LIS.

The overall statistics revealed that, generally speaking, the mistake frequency was 3.64 percent in the pre-analytical phase and 4.40 percent in the post-analysis phase. Pre-analytical errors made up 68.2% of errors and post-analytical errors made up 18.5% of errors, according to results reported in the Netherlands with some differences from this study[17]. It is challenging to explain this fluctuation in light of the relative frequency of errors seen in the various phases, differences in the complexity of the job, and the use of the quality management system and method of error detection. The number of errors may also vary from institution to institution and occasionally.

Interim reports are updated to the concern department for the clinical diagnosis during the Sunday.Some of the hormone test have long processing time, so the reports are uploaded after the test runs and it will be uploaded in the HIS (hospital information system) soon after the test completed and approved.When there is any server error in the hospital information system and computer breakdown there might be delay in uploading the reports in time.

5. Conclusion

This study found a frequency of Total testing process errors.Pre-analytical errors - 4.40%No errors in Analytical phase and Post-analytical errors - 2.64%. These point up the necessity to fix issues with each pre-analytical procedure. As a result, it is essential to regularly assess errors in order to develop corrective measures. This enhances laboratory efficiency and, as a result, successful medical decision-making.Even though automated has been implemented in the majority of contemporary medical laboratories, it is still difficult to guarantee accurate and consistent laboratory results. Therefore, to evaluate the overall mistakes in the Clinical Chemistry Laboratory, the current study used very complete Quality indicators.

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