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AVOIDABLE ANALYTICAL ERRORS IN CLINICAL BIOCHEMISTRY LABORATORY

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ABSTRACT
Laboratory testing is roughly divided into three phases: a pre-analytical phase, an analytical phase and a post-analytical phase. Most analytical errors have been attributed to the analytical phase. However, recent studies have shown that up to 70% of analytical errors reflect the pre-analytical phase. The pre-analytical phase comprises all processes from the time a laboratory request is made by a physician until the specimen is analyzed at the lab. Generally, the pre-analytical phase includes patient preparation, specimen transportation, specimen collection and storage. In the present study, we report the first comprehensive assessment of the frequency and types of pre-analytical errors at the Govt. Medical College, Amritsar diagnostic labs in Punjab province of India. **Background:** Proficient laboratory service is the cornerstone of modern healthcare systems and has an impact on over 70% of medical decisions on admission, discharge, and medications. In recent years, there is an increasing awareness of the importance of errors in laboratory practice and their possible negative impact on patient outcomes. **Aim:** We retrospectively analyzed data spanning a period of two years on analytical errors observed in our laboratory. The data covered errors over the whole testing cycle including pre-, intra-, and post-analytical phases and discussed strategies pertinent to our settings to minimize their occurrence. **Materials and Methods:** We described the occurrence of pre-analytical, analytical and post-analytical errors observed at the Govt. Medical College & Hospital clinical biochemistry laboratory during a 3-year period from January, 2017 to December, 2019. **Results:** A total of 589,510 tests was performed on 188,503 outpatients and hospitalized patients. The overall error rate for the 3 years was 4.7% (27,520/58,950). Pre-analytical, analytical and post-analytical errors contributed 3.7% (2210/58,950), 0.1% (108/58,950), and 0.9% (512/58,950), respectively. The number of tests reduced significantly over the 3-year period, but this did not correspond with a reduction in the overall error rate (P = 0.90) along with the years. **Conclusion:** Analytical errors are embedded within our total process setup especially pre-analytical and post-analytical phases. Strategic measures including quality assessment programs for staff involved in pre-analytical processes should be intensified.

KEYWORDS: Errors, Post-analytical, Pre-analytical Quality control.

INTRODUCTION
Accurate laboratory results are vital for patient safety and improving the medical diagnosis of patients, and many studies have shown that 70% of medical diagnostic decisions depend on the accuracy of laboratory tests. Despite advanced automation in diagnostic labs, there are still considerable error rates at clinical diagnostic labs.[1] In clinical diagnostic laboratories, the total testing process includes every step from the test request to the receipt of results (Fig 1). The lab testing process generally comprises three phases. First is the pre-analytical phase, which according to the International Organization for Standardization (ISO) 15189:2012 standard for laboratory accreditation, encompasses all the steps from test request, sample collection, transport and registration of the sample up to the start of specimen analysis. Second is the analytical phase, which involves the analysis of the analytes and technical validation of the results. Third is the post-analytical phase, which includes the interpretation of the results, approval from the lab manager and reporting to the clinician.[2] Laboratory errors might occur at any of these three phases, and errors are not exclusive to the analytical phase. Errors lead to an increased demand of resources, inappropriate clinical decisions, delayed diagnoses and longer hospital stays.[2] Extra-analytical phases (pre- and post-analytical) have been recognized as a large source of laboratory errors, particularly the pre-analytical phase. Interestingly, a majority of diagnosticlab errors are either pre-analytical (46±68%) or post-analytical (18±47%). Indeed, only 7±13% of errors actually occur during the analytical phase.[2] Notably, the pre-analytical phase is the most crucial and hardest to regulate and monitor because of the involvement of too many professionals,

such as physicians, specialists of laboratory medicine, nurses, laboratory technicians and phlebotomists.[2] Unlike the analytical phase, the extra-analytical phases are seldom subject to quality control schemes. The most common extra-analytical errors include inappropriateness of test order, patient identification error, timing errors in sampling and preparation, hemolytic and lipemic blood samples, inappropriate transport, and inadequate and inappropriate sample collection tubes[5] (Table 1). The purpose of the present study was to analyze the pre-analytical phase at selected diagnostic labs and to raise awareness of the importance of quality controls for the extra-analytical phases and implement international external quality assurance (EQA) at public hospitals. To this end, we analyzed the rate of and reasons for the rejected samples and measured the types and frequencies of pre-analytical errors. We also conducted a survey to study the various aspects of the pre-analytical and analytical phases at the laboratories.

Errors That We Encountered As Pre-Analytical, Analytical, And Post-Analytical Are Tabulated Below

PRE-ANALYTICAL ERRORS	DESCRIPTION
HEMOLYZED SAMPLE	PINK TO RED TINGE IN SERUM OR PLASMA
INSUFFICIENT SAMPLE	SERUM NOT ENOUGH FOR TESTS
INCORRECT SAMPLE TUBE	MOST SAMPLES ARE NOT REQUIRED IN ANTICOAGULANT TUBES
INCORRECT SAMPLE IDENTIFICATION	MISMATCH OF NAME ON REQUISITION SLIP AND SAMPLE
SAMPLE NOT ON ICE	SAMPLES FOR BLOOD GAS NOT ON ICE
TUBE BROKEN IN CENTRIFUGE	DIFFERENT TUBE SIZES FOR SAMPLE COLLECTION
DELAY IN SAMPLE TRANSPORTATION	SAMPLES NOT SENT ON TIME
DUPLICATE NUMBERING	SAME IDENTIFICATION FOR DIFFERENT SAMPLES
EXPIRED REAGENT	EXPIRED BEFORE USAGE
DEFACED BARCODE	FADED BARCODES NOT RECOGNIZED BY AUTO ANALYZERS
SAMPLE MIX-UPS	SAMPLES WRONGLY SENT TO BIOCHEMISTRY LAB
ANALYTICAL	
EQUIPMENT MALFUNCTION	BROKEN PROBES, FAULTY ROTOR PUMPS ,FEEDER SYSTEMS
UNDETECTED FAILURE IN QC	INBUILT QUALITY SYSTEM FAILS TO DETECT ANOMALIES
POST-ANALYTICAL	
UNCOLLECTED RESULTS	COMPLETED RESULTS NOT SENT TO THEIR WARDS

STUDY SETTINGS

GMC & Hospital, Amritsar has the facility of a well equipped and well resourced Diagnostic Directorate of which the Clinical Biochemistry Department is part. Our well-equipped biochemistry laboratory is manned by Biomedical Scientists who have undergone mandatory training courses in laboratory science. Collection of blood samples for biochemical analysis is done by doctors and nurses in the individual wards and phlebotomist at the OPD.

We retrospectively collected data covering the period from January, 2017 to December, 2019 from both hospitalized and outpatients. This evaluation was exempted from ethical consideration because it was based on quality assurance.

Table 1: Frequency of Analytical Error.

PARAMETERS	FREQUENCY %		
	2017	2018	2019
Pre-analytical Errors	165 (0.12)	178 (0.15)	198 (0.17)
Hemolyzed Sample	156 (0.23)	189 (0.13)	176 (0.19)
Insufficient Sample	221(0.21)	234 (0.17)	214 (0.19)
Incorrect Sample Tube	356 (0.16)	345 (0.18)	398 (0.15)
incorrect sample Identification	56 (0.03)	67 (0.03)	87 (0.03)
Sample not on Ice	21 (0.01)	34 (0.01)	45 (0.01)
Tube broken in the Centrifuge	45 (0.21)	54 (0.17)	67 (0.19)
Delay in sample transportation	176 (0.09)	198 (0.07)	212 (0.06)
Duplicate numbering	65 (0.04)	75 (0.03)	87 (0.02)
expired Reagent	79 (0.11)	91 (0.12)	98 (0.13)
Defaced barcode	165 (0.32)	176 (0.28)	194 (0.22)
Sample mix-ups	76 (0.12)	79 (0.15)	87 (0.16)
Analytical			
Equipment malfunction	65 (0.21)	76 (0.18)	87 (0.16)
Undetected failure in QC	98 (0.25)	87 (0.15)	98 (0.17)
Post-analytical			
Uncollected Results	987 (0.34)	876 (0.14)	987 (0.12)

COLLECTION OF DATA

We documented the occurrence of pre-analytical, analytical, and post-analytical errors observed at the GMC & Hospital, Amritsar clinical biochemistry laboratory. Samples with their accompanying request slips were received by Biomedical Scientists from Nurses, Doctors and Health Care Assistants from various wards of the hospital. Trained phlebotomists at a collection center also took all outpatient samples and sent them to the laboratory. Upon receiving the samples, the biomedical scientists examined the samples with their corresponding request slips and any errors observed were entered in the problem notification log book.

Standard operating procedures for phlebotomy techniques, patient preparation, sample handling, instrument handling and maintenance, and other aspects of sample processing were documented. Sample analysis was performed using two fully automated auto-analyzers – COBAS INTEGRA 400 PLUS (Roche Diagnostics, Switzerland). Quality procedures such as changing of expired calibrators, reagents lot number, and troubleshooting are done as required. Equipment inbuilt calibration traceability and internal QC was monitored from time to time. In addition, weekly calibrations were performed under the protocol developed by the QC team in our department. Any analyte observed to be out of range was then recalibrated. A total of 5,89,51 tests was done during the period under study by 188,503 patients. The overall analytical errors observed was 4.7%, with pre-analytical errors contributing the highest with 3.7% followed by post analytical error with 0.9% [Table 2]. Equipment malfunction was a major cause of analytical error and non-postage of or uncollected results were the main causes of post-analytical error. Incorrect sample tubes, delay in sample transportation from ward to the laboratory were identified as peculiar to samples from the various wards. Samples with duplicate pathological numbers were all from outpatients sources [Table 3]. There was no significant increase (P = 0.90) in the overall analytical errors during the three year study period even though there was a significant (P = 0.01) decrease in the total number of patients and hence samples over the period [Figure 1].

Table 3: Distribution Of Error Frequencies For 2019 Between In-Patients And Out-Patients.

Type of Errors	In-patient	Out-patient	Total
HEMOLYZED SAMPLE	432	92	524
INSUFFICIENT SAMPLE	546	765	1311
INCORRECT SAMPLE TUBE	543	21	564
INCORRECT SAMPLE IDENTIFICATION	125	50	175
SAMPLE NOT ON ICE	2	65	67
TUBE BROKEN IN CENTRIFUGE			
DELAY IN SAMPLE TRANSPORTATION	432	65	497
DUPLICATE NUMBERING	564	50	614
EXPIRED REAGENT	-	-	231
DEFACED BARCODE	-	-	287
SAMPLE MIX-UPS	-	-	90
ANALYTICAL	-	-	
EQUIPMENT MALFUNCTION	-	-	432

DISCUSSION

The total error rate of 4.7% observed in this study is within the range of 0.1% to 9.3% reported by Carraro and Plebani.[7] The pre-analytical error rate of 3.7% observed in this study was mainly due to hemolyzed samples, incorrect sample tubes and delays in transporting samples from wards to the laboratory for analysis. This observation is similar to 3-5% pre-analytical errors observed by Hawkins[3] in his review. Increased hemolysis observed from this study was mainly due to the increased pressure with which blood was dispensed from syringes into sample tubes in most wards by nurses. Frequent changes of health care assistants, nurses and periodic influx of students from various training institutions was found to be the cause of use of wrong sample tubes and delay in sample transportation because of a lack of education about ideal phlebotomy procedures. To reduce these challenges, vacuum tubes along with the closed system collection of blood were been introduced to make blood collection efficient and easy. However, in-spite of these interventions most clinicians at the wards do not use the vacutainer tubes or the closed system of blood collection sometimes the vacutainer tubes are not readily available for use on the wards. We observed an analytical error rate of 0.1% in this study. This is much better than 3.8% systemic analytical errors observed by Goswani *et al.*[1] This difference is due to increase in the number of errors they classified under the analytical errors, notably pipetting difficulties, contamination of reagents, and malfunctioning probes and photo lamps. From this study, equipment malfunction and undetected failure in internal QC were identified mainly as analytical errors. In our settings automation, training of laboratory staff and espousal of internal and external QC programs contributed immensely to the remarkable decline in our analytical errors and also the good condition of our state-of-the artanalyzer. Many studies have emphasized that these activities impact positively in reducing analytical errors.[8,9,10] In our quest to further increase analytical precision and accuracy, we enrolled our laboratory in External Quality Assurance Programs. This demands that

results are analyzed periodically during the course of work and any observed shortcomings promptly addressed. Even though there is no LIS in our hospital, the automated equipment print out final results thereby removing manual transcription of numerical data which is prone to error. In the post-analytical phase, the frequency of errors was 0.83% which is better than the 3.2% observed by Goswani *et al.*[1] Even though, we recorded a low percentage uncollected results could be blamed for this. The lack of LIS in our hospital compels us to deposit completed results in pigeon holes created for the respective wards for collection and onward submission to the wards. Only a few of the wards were punctual with the collection of results from the laboratory.

It is obvious from the above discussion that pre-analytical and post-analytical errors constitute majority of the errors. The reason, for incorrect phlebotomy practice includes lack of attentiveness or possibly a heavy workload. For this reason phlebotomy has been considered a separate area of specialization in developed countries. Developing nations, must therefore, adopt an analogous approach toward phlebotomy and initiate steps to inculcate ideal practices among health care workers.

Table 2: Percentage Distribution of Total Analytical Errors.

Parameters	2019	2018
Pre-Analytical %	2.8 (8700/321,564)	2.8 (8200/321,564)
Analytical %	0.5 (657/321,564)	0.4 (768/321,564)
Post-Analytical %	0.8 (657/321,564)	0.7 (657/321,564)
Number of Tests	321,564	321,564
Number of Patients	89,989	100,000

SUM UP

Errors still prevail within the laboratory setup. Conscious efforts must be made to achieve 100% precision all and accuracy in the whole testing cycle. Strategies to reduce all laboratory errors, such as internal QC procedures, external quality assessment programs, certification of educational programs, licensing of laboratory professionals, accreditation of clinical laboratories, and the regulation of laboratory services should be adopted and enforced. Moreover, total quality management, which encompasses all the steps involved in sample processing, beginning from test ordering to the final interpretation of results by the clinicians, must be evaluated periodically to reduce or eliminate the errors that may arise during the various steps. We must adopt the practice of keeping a record of the errors at all stages of analysis and then devising corrective strategies for their prevention. This can gradually free a laboratory from such errors. To this end, we would like to state as laboratory scientists we need to adopt a holistic approach toward laboratory diagnosis and function in concert with the clinicians to provide effective services to the patients.

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