

# Evaluation of issues pertaining to the pre-analytical phase within the Biochemistry laboratory of the National Hospital of Sri Lanka: A case study

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**Abstract-** The National Hospital of Sri Lanka (NHSL) is the largest teaching hospital in Sri Lanka and the country's final referral center consisting of 3280 beds. As biochemical tests are widely used to diagnose diseases and monitor treatments, Biochemistry laboratory plays a significant role in providing health care. The Biochemistry laboratory of NHSL receives more than 1000 tests on average per day. An error that occurs at the laboratory may cause a complete change in diagnosis and the treatment process. Therefore, the quality of service provided by the laboratory should be optimized.

In view of improving the delivered services at the Biochemistry laboratory, this study was conducted to assess the pre-analytical errors and factors contributing to it, using key informant interviews, focus group discussions, and direct observation of samples from handing over to analysis at the biochemistry laboratory.

The study revealed the presence of pre-analytical errors in the biochemistry laboratory. Identified problems were prioritized using the nominal group technique. Problems associated with sample collection and transportation were selected for further analysis using a problem tree. Recommendations were given for further improvement of identified root causes.

**Index Terms-** Biochemistry laboratory, pre-analytical errors, NHSL,

## I. INTRODUCTION

Clinical laboratory services contribute to maximizing the effective delivery of health care to the patients. Appropriate utilization of clinical laboratory services enhances the ability of clinicians to make evidence-based diagnostic and therapeutic decisions for their patients, by using the optimal level of resources and minimizing overall healthcare expenditures. Clinical laboratory services are the most cost-effective, least invasive source of objective health information in disease prevention and diagnosis, to improve patient outcomes while assuring patient safety.

In order to achieve the above goal, the Ministry of Health, Sri Lanka has adopted several strategies. Allocating sufficient personnel to the laboratories, installing new laboratory equipment, managing an adequate stock of consumables and other supplies, and maintaining the quality of laboratory tests are some of them.

The NHSL is situated in Colombo on a 32-acre block of land is the largest teaching hospital in Sri Lanka and the final referral center in the country consisting of 2280 beds. It is the training center for undergraduates and postgraduate medical trainees of the University of Colombo. The nursing training school, Colombo, post basic nursing school, and Schools of Radiography, Pharmacy, Cardiograph, physiotherapy, and occupational therapy are also affiliated with the NHSL.

The biochemistry laboratory plays a significant role in providing health care. The biochemistry laboratory of NHSL receives more than 1000 tests on average per day. It accounts for approximately one-third of all laboratory investigations.

Efficient laboratory service is the cornerstone of modern health care systems. Scientific innovations have contributed to substantial improvements in the field of laboratory science, but errors still prevail. These errors are classified as pre-analytical, analytical and post-analytical, depending upon the time of presentation.

- Pre-analytical phase – This is the stage before the test, outside the laboratory and until the analysis in the laboratory.
- Analytical phase – This is the stage in which the test or measurement is made.
- Post-analytical phase – This is the stage where the test result is transferred to a patient's test report and the clinician makes decisions about the treatment.

Aksoy et al.,[1] said that the vast majority of laboratory errors occur in the pre-analytical and post-analytical phases. Further, they describe that pre-analytical errors are generally observed at

Laboratory services are an essential component in carrying out evidence-based patient care services in order to achieve better health outcomes. Therefore, clinicians rely on accurate laboratory results in their practice. Eventually, a strong laboratory service is an essential element in sustaining a healthy population of a country.

Biochemistry laboratory of the NHSL and to provide recommendations to strengthen the system.

## II. METHODOLOGY

Key Informant interviews were conducted with the Consultant Chemical Pathologist, Superintendent of Medical Laboratory Technologists (MLT), Senior MLT of the Biochemistry lab, other MLTs, and a focus group discussion was conducted among the randomly selected ward sisters in view of identifying the issues associated with the pre-analytical phase. Further, details of 200 rejected blood samples were recorded using a data sheet for each specimen.

Nominal group technique was used to prioritize the identified problems. Three registrars in medical administration, one registrar attached to the biochemistry department and two MLTs of the biochemistry laboratory were the members of the nominal group. Feasibility, Ability to address issues at hospital level, frequency and severity of the problem were used as priority criteria.

Problems associated with sample collection and transportation were identified as the main problem and root cause analysis was done. Problem tree analysis was used to identify the root causes.

## III. RESULTS

Data collection revealed the following pre-analytical errors which need to be addressed to strengthen the system. A total of 6450 samples were received during the observation period and out of them 200 samples were rejected due to the following reasons. The overall rejection rate was 3.1%.

Missing sample and/or test request	8 (4%)
Wrong/missing identification	16(8%)
In vitro hemolysis	15(7.5%)
Undue clotting	100(50%)
Wrong container	4(2%)
Contamination from the infusion route	4(2%)
Insufficient sample	35(17.5%)
Inappropriate blood to anticoagulant ratio	8(4%)
Insufficient mixing of the sample	2(1%)
Inappropriate transport and storage conditions	1(0.5%)
Inappropriate centrifugation condition	2(1%)
Other	3(1.5%)

Discussion with Senior Medical Laboratory Technologist (S/MLT) and other MLTs revealed that pre-analytical errors associated with the sample collection and transportation are more common. The direct observation done on 200 samples (Both

a higher rate because the process is generally not managed by the medical laboratory, and they can only intervene in the process when the sample reaches the laboratory.

As it is said to be more common, pre-analytical errors related to biochemistry laboratory were selected for this study.

The objective of this case study was to identify the key problems associated with the pre-analytical phase related to the

- **Problems associated with patient preparation** – Biological variability, Environmental conditions, Postural changes
- **Problems associated with sample collection** – Patient identification and sample labeling, Type of disposal or collecting blood (e.g., straight needle, butterfly, or cannula), caliber/gauge of the needle, Tourniquet time, Container (e.g., primary tube), Order of draw, Phlebotomy procedure, Contamination from...., Tube/s mixing
- **Problems associated with sample transportation** – Length and environmental conditions, Pneumatic tube systems
- **Problems associated with sample preparation for analysis** – Length, speed, and temperature of centrifugation, preparing aliquots
- **Problems associated with sample storage** – Length, Temperature, Freezing, and thawing

The problem tree revealed many causes contributing to the problems associated with sample collection and transportation. They include, poor knowledge of sample collection and transport, absence of proper sample acceptance method at the laboratory, poor coordination between the wards and the laboratory, lack of minor staff to transport the samples from the ward to the laboratory without delay and lack of supervision.

## IV. DISCUSSION

Contemporary clinical diagnosis heavily relies on accurate laboratory data [2]. Rejection of inappropriate samples contributes to prolonged turnaround times and impacts patient care adversely [3]. The overall rejection rate of the present study was 3.1%. A similar study conducted in a teaching hospital; Sri Lanka revealed a rejection rate of 3.3% which is almost similar to present study [4].

In the present study, out of the total sample rejected 50% (n=100) was rejected due to undue clotting. The same results (60%, n=184) were reported in a study conducted in Sri Lanka [4].

All the relevant stakeholders should get involved in finding the solutions immediately as pre-analytical errors finally affect the quality of healthcare provided to the patients. The Establishment of continuous monitoring and evaluation system and close supervision of the project would strengthen the services provided by the laboratory.

The following recommendations were made based on the findings of the study.

blood and urine) were in favor of the facts they provided. We observed that there were samples sent to laboratory without the request forms, request forms sent without samples, inappropriate labeling of the samples and insufficient samples.

Following analysis of the information gathered, five major sources which give rise to pre-analytical errors were identified.

- Provide in-service training on sample collection and transport to the nursing officers.
- Introducing the barcode technology and laboratory information system (LIS) with adequate technical support will reduce a lot of pre-analytical errors.
- Implementation of a monitoring system to assess the sustainability of the project.
- Arrange instant communication between the laboratory and wards once the missing samples are detected.

## V. CONCLUSION

The overall sample rejection rate of the NHSL biochemistry laboratory was 3.1%. Undue clotting was the major cause for sample rejection.

The most important component of quality in laboratory testing is, that the results are accurate and suitable for clinical practice. An accurate result always begins with a high-quality specimen. Therefore, pre-analytical variability exerts a strong influence on laboratory testing. Restructuring of this crucial phase offers a great potential for improving the total quality of laboratory diagnostics and enhancing the satisfaction of the stakeholders. The most reliable approach includes systematic analysis and identification of the bottlenecks in the system, redesigning the mishandled procedures, identifying the solutions which suits the local environment, continuous process monitoring, continuous training and education by dissemination of reliable recommendations and improved communication between the respective units and the laboratory.

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- Updating the guidelines related to sample collection and transportation and making them available in the wards.
- Introducing a more organized and responsible method of accepting the samples at the laboratory.
- Arranging an adequate number of minor staff for the sample transportation.
- Arranging adequate minor staff members for sample transport at the casualty wards which is not in current practice.

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