Original Article

Improving Diagnostic Safety by minimizing errors in Preanalytical Phase of Laboratory Testing Process

Tahmina Rahman[1], Debashish Saha[2], Rezina Ahmed[3]

1. Deputy General Manager, Quality Assurance, Evercare Hospital Dhaka
2. Senior consultant, Biochemistry & Coordinator, Laboratory Medicine, Evercare Hospital Dhaka
3. Senior General Manager & Head, Quality Assurance, Evercare Hospital Dhaka

Address for Correspondence:
Dr. Tahmina Rahman
Deputy General Manager,
Quality Assurance,
Evercare Hospital Dhaka
tahmina.rahman@evercarebd.com

Submitted: *11 – Jul - 2024*
Accepted: *15 – Nov - 2024*

ABSTRACT

The role of laboratory medicine is indispensable for the healthcare industry. Laboratory Services is a rapidly expanding field which contributes significantly 60–70% of clinical decisions regarding hospitalization, discharge, and medications of patients. Total laboratory testing is a cyclical process which is divided into three phases: preanalytical, analytical and postanalytical phase. The pre-analytical phase is a complex process and performed outside the laboratory. Available evidence demonstrates that the most common errors occur in the pre-analytical phase (46–68.2% of total errors). User's feedback was collected proactively to find the gaps in the exiting process. Retrospective data was collected from February to July 2023, and it was evident that average sample rejection rate was significantly higher 2.56%, wrong investigation order error was 1.65% and sample transportation time was prolonged (average 160 minutes for inpatient and 79 min for outpatient department) in Evercare hospital Dhaka. Therefore, Laboratory stakeholders and senior leaders of Evercare hospital Dhaka decided to start hospital wide quality improvement project. The objective of this study is to identify the gaps in the preanalytical phase of diagnostic services. It was aimed to minimize the errors by developing and implementing effective quality initiatives and was targeted to decrease sample rejection rate below 2%, reduce wrong investigation input rate below 1% and to maintain IPD sample transportation TAT within 120 minutes and OPD sample transportation TAT within 60 minutes. After implementing multiple effective quality initiatives EHD successfully achieved the target and reduced sample rejection rate 1.5%, reduced investigation order error rate 0.8% and maintained sample transportation TAT for IPD 119.9 minutes and for OPD 59.2 minutes.

Keywords: *Total testing process (TTP), Laboratory errors, Quality parameters, Patient safety, Health care services, Preanalytical, Analytical, Post analytical, Turnaround time (TAT)*

INTRODUCTION & BACKGROUND

Diagnostic service is an integral part of the modern health care industry. Laboratories play a critical role in confirming initial impressions or rule out differential diagnosis. It is a rapidly expanding field which contributes significantly to clinical decision making by supporting prevention, diagnosis, and therapeutic monitoring. According to official data, 60–70% of clinical decisions about hospitalization, discharge, and prescription are based on laboratory results[1]. Delayed, incorrect, missed diagnosis can have a big impact on patient's health. Diagnostic errors can occur at any stage of a patient's journey. Laboratory testing is a cyclical process which is divided into three phases: preanalytical, analytical and postanalytical phase. Errors in any phase of the total testing process generate flawed results which cause delayed, incorrect, missed diagnosis and lead to improper patient treatment. As per International Organization for Standardization (ISO) 22367, laboratory error defined as a "failure of planned action to be completed as intended, or use a wrong plan to achieve an aim, occurring at any part of the laboratory cycle, from ordering examinations to reporting results and appropriately interpreting and reacting to them[2]. Despite advancements in the automation and implementation of Laboratory Information Manage-

ment Systems (LIMS), mistakes can still occur at any stage of the testing process. Laboratory errors are categorized into three critical stages such as preanalytical errors, analytical errors, and postanalytical errors. Currently, available evidence demonstrates that the most common errors occur in the pre-analytical phase (46–68.2% of total errors) and post-analytical phase (18.5–47% of total errors), with less (7–13% of total errors) occurring in the analytical phase[3] (Figure 1).

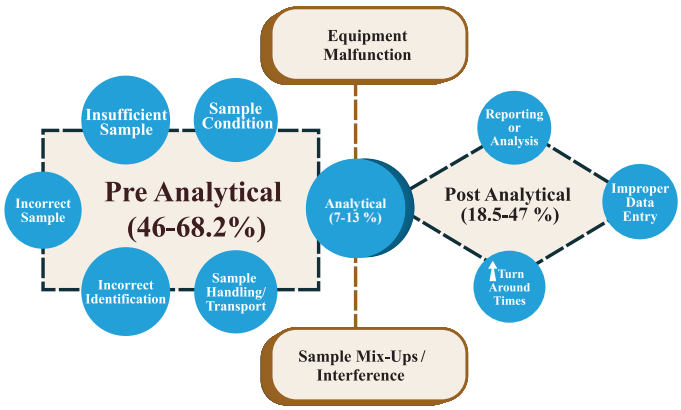


Figure 1: Types and rates of error in the three stages of the laboratory testing process

In the first quarter of 2023, reported diagnostic related incidents were raised in Evercare Hospital Dhaka. During analysis it was observed that most of the incidents had occurred during preanalytical phase of diagnostic services such as misidentification of samples as it was wrongly labelled, insufficient samples were collected from the patient, samples were collected in wrong vacutainer, sample transportation delay etc. Treating physicians repeatedly complained about reporting delays, inappropriate test ordered, loss & misplaced of samples etc. Patients and families showed their dissatisfaction with the reporting delay. Users' feedback was collected to find the gaps in the exiting process of preanalytical phase shown in Table 1. As per official data sample rejection rate was significantly higher (average 2.56%) from February to July 2023 (Figure 2a), investigation order error rate was 1.65% (Figure 2b) and sample transportation TAT (Turn Around Time) was prolonged (for inpatient unit 160 minutes and for sample collection unit 79 minutes) (Figure 2c) in Evercare hospital Dhaka. Therefore, Laboratory stakeholders and senior leaders of Evercare hospital Dhaka decided to start hospital wide quality improvement project to minimize the gaps in existing process of pre-analytical phase in laboratory services to improve diagnosis for patient safety.

Table 1: List of User's feedback

User's Feedback

Laboratory department: Technologist stated their concern about sample collection & dispatch process as they rejected samples due to,

- Incorrect test requests
- Patient misidentification
- Poorly labelled containers
- Using inappropriate containers
- Issues with sample collection and transportation
- Inadequate sample volume ratio or insufficient sample volume
- Collecting a specimen from an infusion route.

Nursing Service: Nursing staff stated their experiences such as

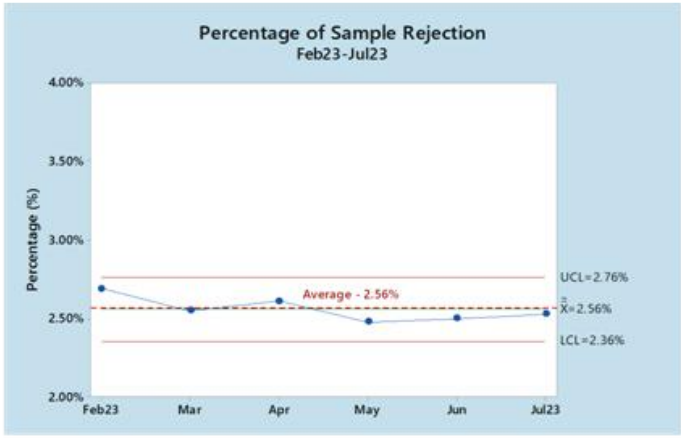
- Doctors delay for ordering investigation input in HIS.
- PCA was not available for sample transportation.
- Multiple order name for investigation in HIS
- New nurses faced difficulties to choose correct vacutainer for the sample
- Loss & misplaced of samples

Medical services: Physicians express their dissatisfaction about delay starting of medical care due to

- Inappropriate test ordered in HIS by staff nurse
- Delay sample collection
- Delay sample transportation
- Inadequate patient preparation

Hospitality Services: Patient Care Attendants also shared their feedback

- There is no dedicated sample receiving area. PCA distributed all the samples to different laboratories which requires extra time.
- There were no Level wise dedicated patient care attendants for sample transportation. So, they face difficulties collecting sample from different location throughout in patient department.

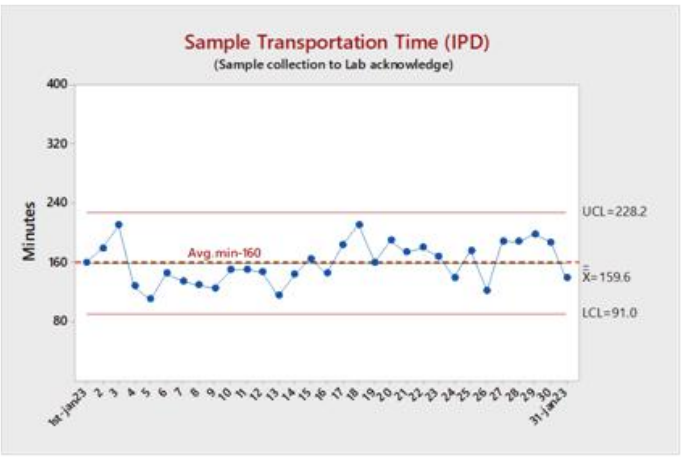


Feb23	Mar	Apr	May	Jun	Jul23
2.69%	2.55%	2.61%	2.48%	2.50%	2.53%

(a)

Feb23	Mar	Apr	May	Jun	Jul23
1.73%	1.98%	1.57%	1.67%	1.82%	1.15%

(b)



(c)

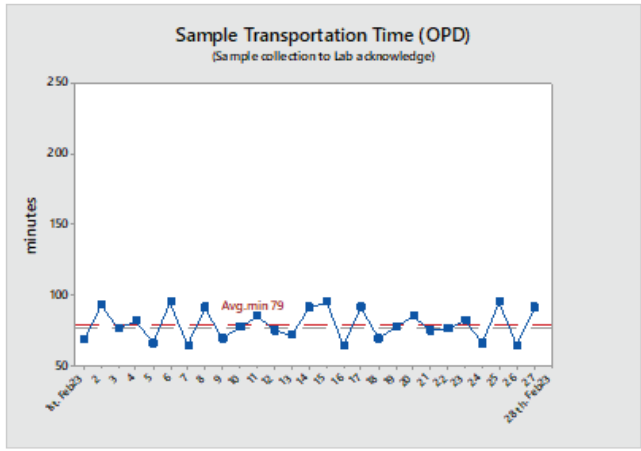


Figure 2: (a) sample rejection rate (b) percentage of wrong investigation order (c) Sample transportation time IPD & OPD

OBJECTIVES

The objective of this study is to identify the gaps in the preanalytical phase of diagnostic services. It was aimed tominimize the errors by developing and implementing effective quality initiatives throughout the hospital within the first quarter of 2024. It was targeted to reduce sample rejection rate below 2%, to reduce wrong investigation input rate below 1% and to maintain sample transportation TAT for impatient unit within 120 minutes and for sample collection unit within 60 minutes and increase user satisfaction rate by 10%.

METHODOLOGY

Activity

Hospital wide quality improvement project was initiated from August 2023 and continued till October 2023. A multidisciplinary team was formed engaging delegates from Quality Assurance, Laboratory medicine, Medical, Nursing and Information technology (IT) departments. Retrospective data was collected from February to July 2023. In this time frame a total of 561954 tests were performed. Among them 115 samples were rejected due to various factors listed in (Table 1) and it was observed that the average sample rejection rate was 2.56%. A total of 139 wrong inputs were given in HIS (Hospital Information System) for laboratory test and investigation order error rate was 1.65% from February to July 2023. An internal audit was conducted by the quality assurance along with laboratory department to monitor sample transportation time. In January 2023, 260 samples (per day 10 samples) were tracked in multiple locations of the

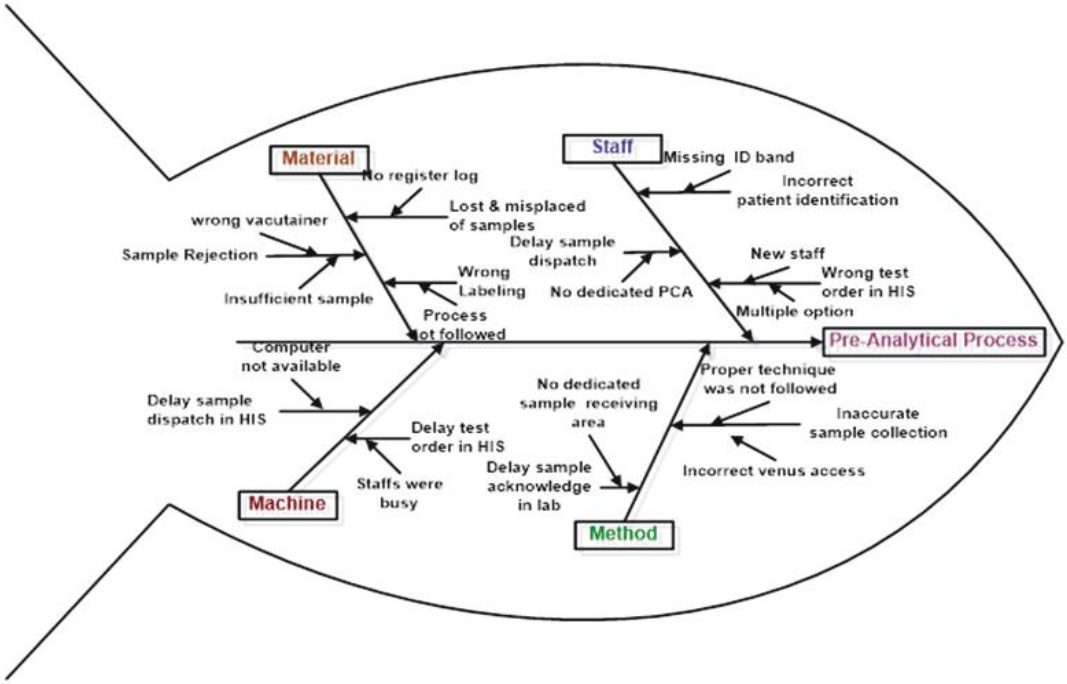


Figure 3: Cause-and-Effect Analysis (Fish Bone Diagram) of Preanalytical process

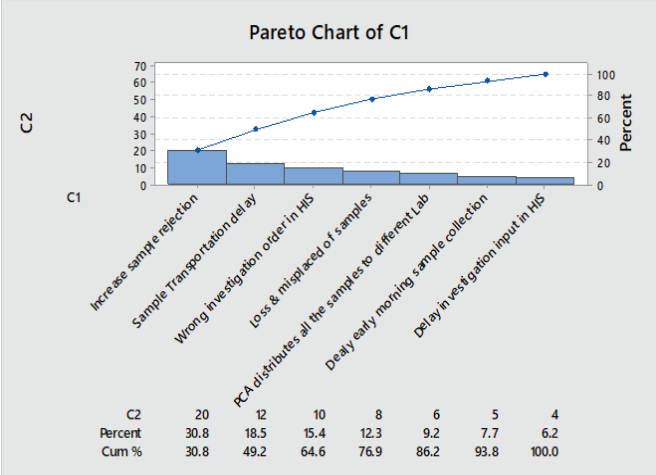


Figure 4: Pareto Chart of Preanalytical process

inpatient department, and it was observed average sample transportation TAT from in patient unit to laboratory area was 160 minutes.

In February 2023, 390 samples (per day 15 samples) were monitored in sample collection unit, and it was found average sample transportation TAT from sample collection unit to laboratory area was 79 minutes. User feedback was also collected to find the gap in the existing process which was listed in Table 1. After that the existing process flow was designed. Multiple Quality tool was used for

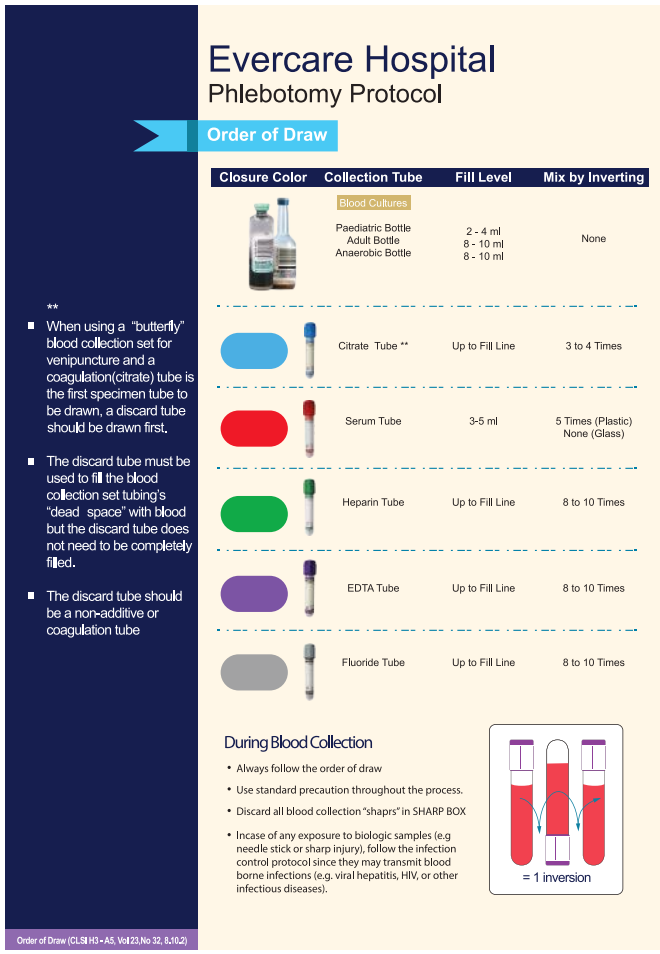


Figure 5: Phlebotomy Protocol Poster

analysis to find the root cause of the problem such as Fishbone diagram, Pareto chart, Flow chart (Figure 3 & 4).

Initiatives

Below mentioned effective quality initiatives were taken by project team members with the help of relevant departments and implemented throughout the hospital such as:

- **Order of Draw/ Phlebotomy protocol poster** was created and made available in all nurse stations and sample collection unit to avoid any sample collection related error (Figure 5)
- **Vacutainers details** (appropriate name & clour of the vacutainers) were incorporated in hospital information system with the help of the IT department, so that staff can choose appropriate container for specimen collection.
- **Investigation input** access was restricted to physicians only, to avoid Inappropriate test ordered.
- **Level wise dedicated patient care attendants** for sample transportation for admitted patients. Ensured hourly dispatch of specimens from the sample collection unit by dedicated PCA for OPD patients.
- **Single point sample** receiving area in the laboratory to receive and verify the samples.
- **Introduce Lab Register** and ensure proper recording of samples. Laboratory staffs document after receiving & verifying the samples.
- **Strengthening training & refreshers training** for nurses regarding sample collection process by laboratory physician

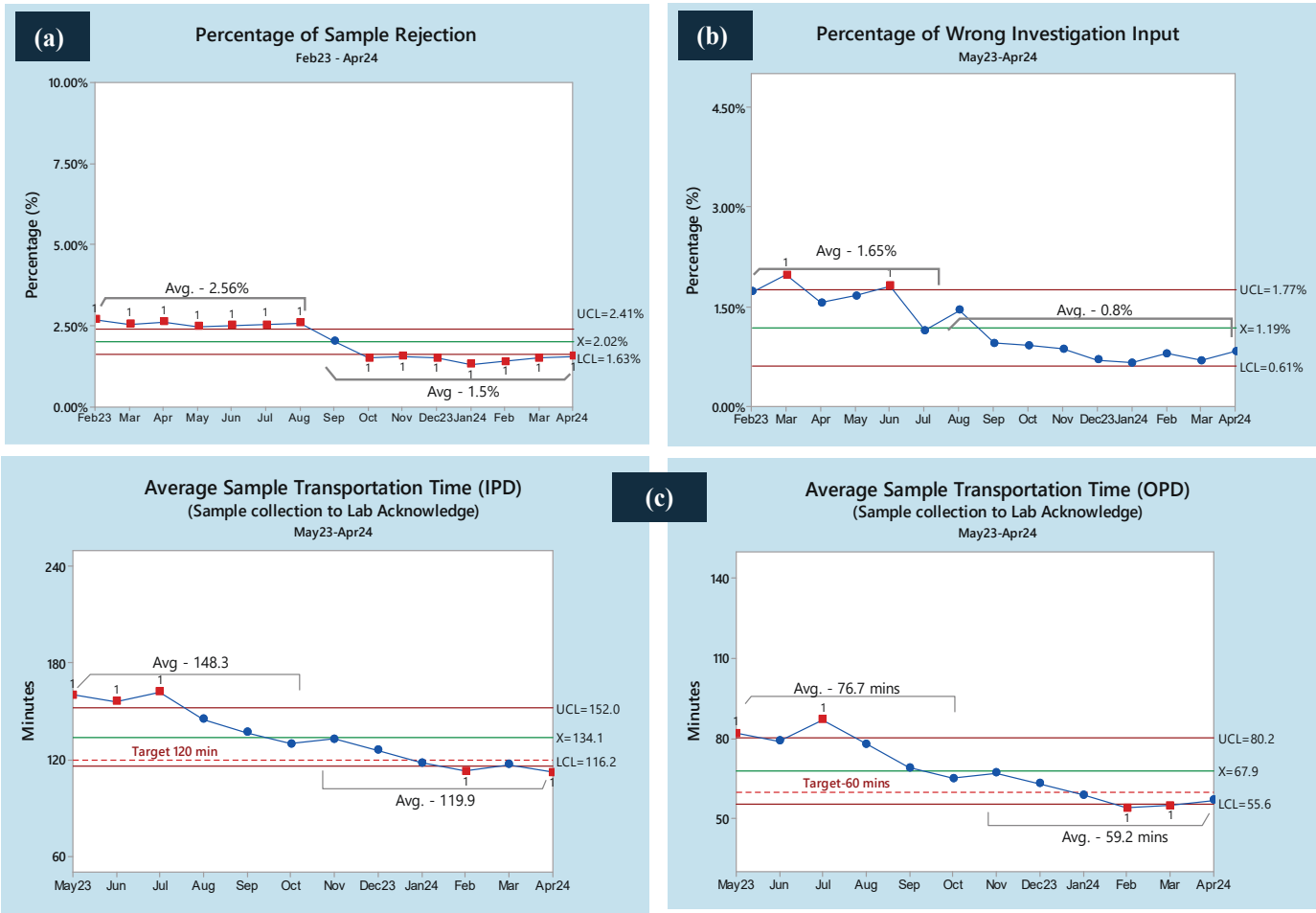


Figure 6: a) sample rejection rate, b) percentage of wrong investigation order, c) Sample transportation time IPD & OPD

RESULTS

The new process was monitored for 6 months from November 2023 to April 2024, and below mentioned outcomes were observed.

- Reduced sample rejection rate from (2.56% to 1.5%) (Figure 6a) as phlebotomy protocol poster was created and made available in all nurse stations and sample collection units for staff educational purposes. "Vacutainers details" (appropriate name & color of the vacutainers) were also incorporated in hospital information system so that staff can choose appropriate container for specimen collection.
- Reduced wrong investigation input related error from 1.65% to 0.8% (Figure 6b) as Investigation input access was restricted. Now only physicians can access for investigation input in HIS.
- Achieved sample transportation TAT 119.9 minutes (Figure 6c) for inpatient department, by ensuring Level wise dedicated patient care attendants for sample transportation for admitted patients.
- Maintaining sample transportation TAT 59.2 minutes (Figure 6c) for sample collection department by ensuring hourly dispatch of specimens by dedicated patient care attendants from the sample collection unit.
- Increase user satisfaction rate 10% by reducing delay as introduced single point sample receiving area in the laboratory to receive and verify the samples and quickly prepare the sample for test and introduced Lab Register for user department to avoid loss and misplaced of samples.

DISCUSSION

Now a days, Clinical care is inevitably dependent on laboratory results for diagnosis, prognosis and/or treatment decisions. Delayed, incorrect or missed diagnosis can prolong illness and sometimes cause disability or even death. Correct and timely diagnosis is the first step to preventative interventions and effective treatment. The accuracy, precision, and speed of laboratory testing are vital components of clinical care. A diagnostic error is the failure to establish a correct and timely explanation of a patient's health problem, which can include delayed, incorrect, or missed diagnoses, or a failure to communicate that explanation to the patient[4]. The magnitude of diagnostic errors is profound, accounting for nearly 16% of preventable patient harm in all healthcare settings[5]. Laboratory testing is a highly complex and multistep process. There are three phases of Laboratory testing process[6] such as

- **Preanalytical phase.** Selecting the appropriate test, obtaining the specimen, labeling it with the patient's name, providing timely transport to the laboratory, registering receipt in the laboratory, and processing before testing.
- **Analytical phase.** Performing the test and interpreting the result.
- **Postanalytical phase.** Preparing a report detailing the result and its interpretation, authorizing the report, and transmitting the report to the clinician so that the clinician can institute appropriate action.

Clinical laboratories have long focused their attention on quality control methods and quality assessment programs dealing with analytical aspects of testing. Therefore, errors inside the clinical lab have decreased significantly over recent years due to the increasing automation of laboratory processes. The more recent surveys on errors in laboratory medicine conclude that mistakes originate more frequently in the pre-analysis stages outside of the laboratory. According to ISO 15189:2007, pre-analytical components are defined as steps "beginning with the clinician's request and including the examination requisition, patient preparation, collection of the primary sample, transportation to and inside the laboratory, and ending when the analytical examination procedure begins"[7]. Each of these steps are inclined to errors that can occur at any stage, which can potentially generate erroneous results and finally endanger patient safety. Errors that occur during the preanalytical phase can significantly impact the accuracy of test results and it starts with physician test request to the beginning of the analysis phase. Preanalytical errors can

happen both within the laboratory and outside the direct control of the laboratory such as:

Outside the laboratory:

- Incorrect test requests
- Patient misidentification
- Poorly labelled containers
- Using inappropriate containers
- Issues with sample collection and transportation
- Inadequate sample volume ratio or insufficient sample volume
- Collecting a specimen from an infusion route.

Within the laboratory:

- Errors in the sorting and routing of specimens
- Mistakes in transferring samples between containers (pour-off errors)
- Labelling inaccuracies

Safe care begins with proper identification of the patient. Incorrect patient identification causes diagnosis error and may result in patient harm. According to International Patient Safety Goals, Joint Commission International, Patients need to be identified before performing diagnostic procedures and at least two patient identifiers are required to identify the patient and to label the elements associated with the patient's care and treatment plan[8]. ID band containing Full name and Unique Hospital Identification Number (UHID) are used as a patient identifier in Evercare hospital Dhaka. EHD provides wrist band to all patients both in IPD and OPD settings. Staff identify the patient with two identifiers before performing diagnostic procedures and providing treatment. Proper sample collection and handling is an integral part of a valid laboratory test result. Specimens must be obtained using proper phlebotomy techniques. There were many incidents reported regarding sample rejection due to inappropriate techniques being used or insufficient samples being collected etc. All blood collection tubes must be filled to the FILL LINE to prevent dilution of blood components. It is important to draw the correct amount of blood (fill the tube up to FILL LINE) to obtain the proper ratio of anticoagulant to blood. Therefore "Order of Draw" / Phlebotomy protocol poster was created and made available in all nurse stations and sample collection unit to mitigate sample collection related error. Nursing staff, mostly new nurses of Evercare Hospital Dhaka complained about facing difficulties to choose correct vacutainer for the samples. They must contact lab personnel to confirm the correct vacutainer for the specimen. It was time consuming and difficult to reach lab personnel. With the help of the IT department "Vacutainers details" were incorporated in hospital information system (HIS) so that staff can choose correct container for specimen to avoid any error. Appropriate name & colour of the vacutainers are visible in system when investigation order is placed in hospital information system (HIS). Sample shall be properly labeled and identified prior to transportation. All specimens received in the laboratory must have a permanently attached label with a minimum of the following information in the form of a computer-generated label:

- Patient's name
- Medical Record Number or UHID number
- Lab Id or Bill no.
- Date and time of collection

The integrity of samples is time-sensitive, and they need to be analyzed within a certain period. Proper precautions should follow to maintain the integrity of samples at all stages of transportation. Prolonged turnaround time causes delayed diagnosis and treatment. It may extend hospital stay and increase the cost of health care. Few initiatives were taken to minimize the sample transportation delay. It was decided that samples should be transported to the respective laboratory by the assigned personnel within 2 hours after collection. For In patient department level wise dedicated patient care attendants were assigned to maintain thecompliance. For outpatient department samples are dispatch hourly by dedicated patient care attendants to maintain the sample transportation time within 60 minutes. The sample shall be transported in proper containers with special precaution for leaks, breaks and spillage. Lab Register is introduced to avoid loss and misplaced samples. Laboratory staff ensure proper

documentation after receiving & verifying the samples. In Evercare hospital, there are six different clinical laboratories. Patient care attendant (PCA) distributed all the samples to different laboratories which is one of the contributing factors for transportation delay. There is no dedicated place to receive the samples.

Single point sample receiving area in the laboratory is selected to receive and verify the samples to avoid extra time. Training regarding phlebotomy protocol should be conducted on a regular basis to minimize error in preanalytical phase of laboratory testing process.

CONCLUSION

Laboratory testing is a complex process. Accurate performance of all the steps included test ordering, sample collection, identification, transport, sample preparation, analysis, test reporting, interpretation and action is essential to ensure safe patient care. Unfortunately, each of these steps is vulnerable to errors, which finally jeopardize patient safety. Training, supervision,continuous monitoring of quality measures also helps to minimize the chances of laboratory error significantly. Modern laboratories should voluntarily obtain accreditation from national or international regulatory agencies to maintain the standards for test results. Country's laws and regulations should follow to avoid any legal consequences. Correct and timely diagnosis is the first step to preventive intervention and effective treatments. So, this year world health organization (WHO) selected the theme for world patient safety day 2024 is "Improving diagnosis for patient safety" with the slogan "Get it right, make it safe!" highlighting the critical importance of correct and timely diagnosis in ensuring patient safety and improving health outcomes. On 17th September,2024 Evercare hospital Dhaka celebrated World Patient Safety Day, to raise awareness and foster collaboration between patients, health workers, policymakers and health care leaders to improve diagnosis for patient safety. The role of laboratory medicine is indispensable for the healthcare industry. It is a fundamental component for delivery of safe and quality care to the patient. Strong leadership, qualified staff, modern automated equipment, well-defined standards, training, and responsibilities are required for further developments in the clinical laboratories. Together we can make health care safer for everyone.

LIMITATIONS

Despite recent developments, there are still many challenges. It is difficult to maintain the proper sample collection process due to higher staff attrition rates, especially for nursing staff. Clinical correlations with laboratory reports are not possible sometimes due to unavailability of electronic medical records.Lot of manual work is done which increases the chances of error.

REFERENCE

1. Types and Frequency of Errors during Different Phases of Testing At a Clinical Medical Laboratory of a Teaching Hospital in Tehran, Iran https://www.ncbi.nlm.nih.gov/pmc/articles/PMC4049056/#:~:text=According%20to%20a%20definition%20acknowledged,examinations%20to%20reporting%20results%20and
2. Assessment of laboratory errors and best laboratory practices. https://www.researchgate.net/publication/304612131 Assessment of laboratory errors and best laboratory practices#:~:text=Laboratory%20error% 20is% 20defined%20by, plan% 20to% 20achieve% 20an% 20aim%E2%80%9D.Errors in clinical laboratories or errors in laboratory medicine?
3. https://www.researchgate.net/publication/7052626 Errors in clinical laboratories or errors in laboratory medicine
4. Diagnostic Errors- World health organization https://iris.who.int/bitstream/handle/10665/252410/9789241511636-eng.pdf
5. Improving diagnosis for patient safety" https://www.who.int/campaigns/world-patient-safety-day/world-patient-safety-day-2024
6. Box 11.1Three Phases of Laboratory Testing https://www.ncbi.nlm.nih.gov/books/NBK525286/box/pt4.ch11.sec3.box1/?report=objectonly
7. Assessment of Types and Frequency of Errors in Diagnostic Laboratories Among Selected Hospitals in East Wollega Zone, Oromia, Ethiopia https://www.tandfonline.com/doi/full/10.2147/PLMI.S351851
8. Joint Commission International Accreditation Standards for Hospitals - JCI 8th Edition Manual