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Original Research Paper

Effectiveness of FMEA in Preanalytical phase in minimizing laboratory errors

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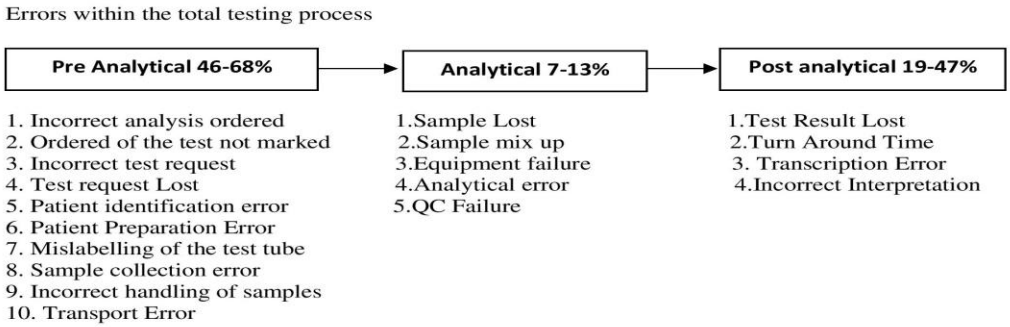
ABSTRACT:
Background: The laboratory 'errors' effects quality of health care . The errors in preanalytical phase account for over 60 percent of laboratory errors.Application of the Failure mode and effects analysis (FMEA) in pre analytical phase of total laboratory testing process, in reducing and eliminating laboratory errors. **Objective**: Effectiveness of FMEA in preanalytical phase .The risks are identifiedand effectiveness of the mitigation process will be evaluated and monitored. Thereby develop quality services to the patient. **Methods:** In identifying the risk, the risk score is calculated in FMEA method by the multiplication of three risk parameters; the probability (P), the severity (S) and the detection (D), in order to produce a risk priority number (RPN = P × S × D). Allowing risk investigation and risk minimization. **Results**: Before Failure Mode Effective Analysis (FMEA) Results in the 2023: Total Number sample rejections: 174 Samples. Total Number of Sample rejections due to LIS Problem: 35 Samples. Total Number of Sample rejections due to Other Causes (Ex: Sample Lyse, Sample Clot, Low Volume, etc): 89 Samples. After Failure Mode Effective Analysis (FMEA) Results in 2023: Total Number of Sample rejections due to LIS Problem: Nil. Total Number of Sample rejections due to Other Causes (Ex: Sample Lyse,Sample Clot, Low Volume, etc): 50 Samples. **Conclusions**: FMEA identifies and rectifies the failure modes of the testing process in the laboratory, which can reduce and eliminate laboratory risks anderrors .This provides accurate and reliable results to the patient and assist in maintaining the continuous delivery of quality patient care in most effective processes. In estimates of risk, along with the 'probability'and ' severity', detectability has significance role. If detectability score is very high we can eliminate and can minimize the lab errors.

Keywords: Risk management, FMEA, Laboratory errors

INTRODUCTION:

Clinical laboratory services in health care system plays a significant role in the decision-making by the clinical doctors in treating the patients. Laboratory tests support about 70% of medical decisions. The turnaround time (TAT) and the accuracy of results are critical to the diagnostic reliability and treatment effectiveness [1]. However the laboratory errors has been reported to be 0.012-0.6 percent of all test results even after corrective actions taken[2]. Even if this error rate in medical laboratories is very low compared to the billions of tests daily performed, it can affect the quality care of the patients. According to survey on laboratory errors, the preanalytical errors account for over 60 percent of laboratory errors [3].



The preanalytical errors is a continuous challenge for clinical laboratories in minimizing the risk (the risk of injury or illness associated with the service provided). According to Kumamoto and Henley [4], the term "risk" is defined as a combination of five factors: probability, outcome, significance, causal scenario, and affected population. "Risk" in the laboratory is the probability of a laboratory error which may have adverse outcome such as the factors that threaten the safety of staff, surrounding environment, organization's facilities, financial and operational productivity, and overall quality service [5], [6]. Risk analysis or management is one of the evaluating tool in quality tool box which identify improvement opportunities and aids in reducing errors. The standard related to medical laboratories is the technical specification ISO/TS 22367 "Medical laboratories Reduction of error through risk management and continual improvement" (7) and two Clinical and Laboratory Standards Institute (CLSI) guidelines EP18-A2 "Risk management techniquesto identify and control error sources" (8) and EP23-A "Laboratory quality control based on risk management" (9), now introduce risk management into clinical laboratory and can be used to guide the application of ISO 15189 as a system for reducing laboratory error and improving patient safety (the international standard for accreditation of medical laboratories). The two standards such as revised ISO/IEC 17025 and ISO 9001 has defined for a laboratory to evaluate the severity of threats which helps in achieving improved results and to framework the opportunities to increase management system efficiency[10]. ISO 31000:2018 [11], states risk management as a coordinated activities between the management and an organization in relation to risk. Latest version of standard ISO 15189:2022,has increased emphasis on risk management. The risk-based thinking plays a vital role in understanding and to evaluate activities related risks and finding opportunities to reduce the laboratory errors. FMEA (The failure modes and effects analysis), is to identify potential sources of errors, establish how they could affect the processes under investigation, and implement control measures to detect and eliminate these errors. [12]. The risk assessment in this technique involves identification of potential errors, determining the severity (S), occurrence/probability (O/P) and effects of each error and reviewing the control actions implemented to prevent or detect (D) errors[13]. To identify the errors, a rating scale of 1 to 10 is used (Table 3). Risk Priority Number (RPN) is calculated by multiplying the numbers of three parameters (S x O/P x D). Higher the RPN value,the more recommended actions to be implemented. RPN has it's importance to identify high risk failures modes [14] To address the concern, The Department of Laboratory Medicine, Apollo Hospitals, Visakhapatnam has applied FMEA in sample rejection of preanalytical phase to detect, reduce and eliminate the laboratory errors fromthe period January 2023–December 2023

MATERIALS AND METHODS:

The study was conducted at the Department of Laboratory Medicine, Apollo hospitals, Visakhapatnam. The DLMHV has established sample rejection criteria and monitoring them closely on daily basis. It is one of the quality indicator of DLMHV. On monthly basis the number of rejected samples and reasons for rejections is reviewed. The reason for rejection is recorded in the log book and include allpertinent information. Promptly the concern technician informs the authorized person that the sample is unsuitable for testing and request for fresh sample. The rejected sample will be retained till decision is finalized and in some circumstances it may be necessary to proceed with the testingof a sample that is not optimal. The components of risk management are: a) risk identification - identification and listing of all risks across the entire testing processes covering pre-examination, examination, post-examination risk evaluation based on severity and likelihood of occurrence and detectability of occurrences, prioritization of risks. risk mitigation through preventive actions estimation of residual risk, through monitoring.

RISK IDENTIFICATION:

The causes for sample rejection were listed in fish bone diagram (figure:1)

1. Risk identification

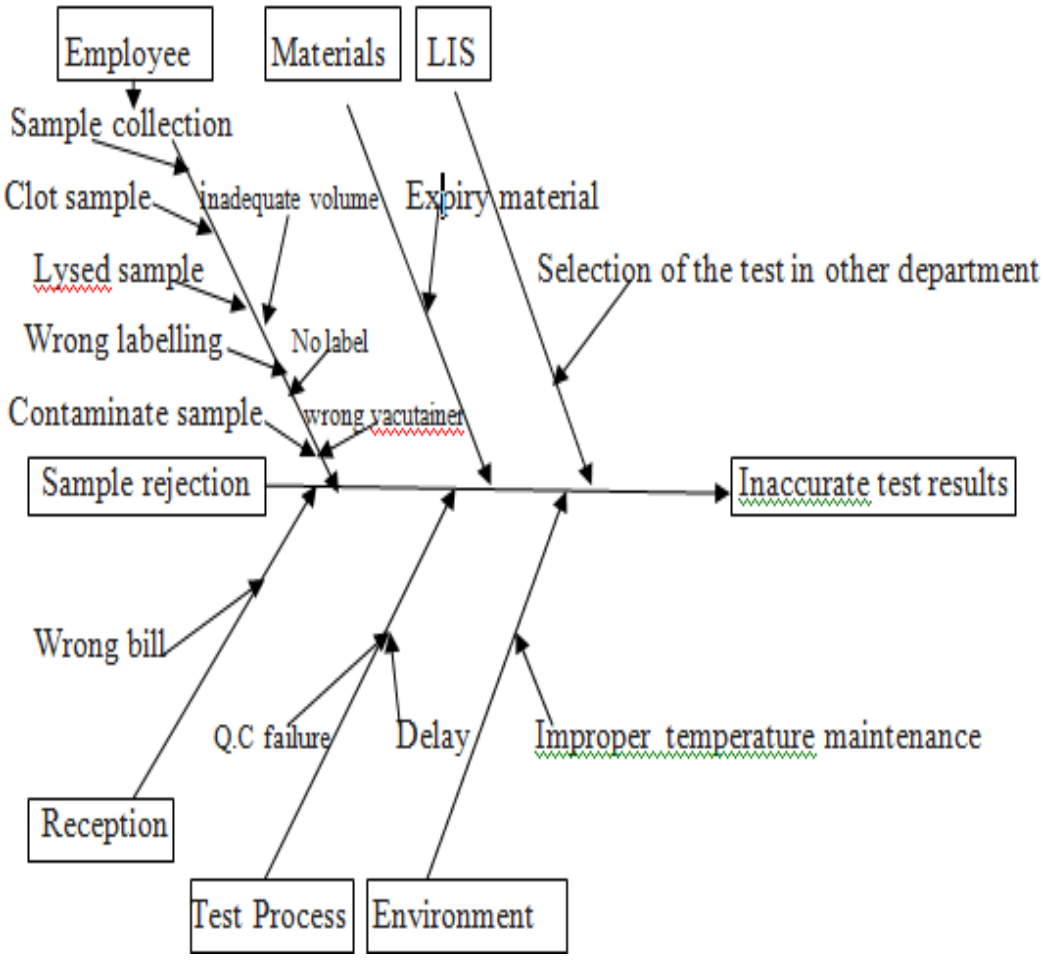


Figure:1

The common causes of sample rejection in our laboratory is sample collection which is preanalytical phase .Among the samples rejection, most common wereclotted sample observed in haematology department. The other cause identified was in post analytical phase, observed in the laboratory information system (LIS).The tests which were raised are notreflecting in the concern department.

Risk evaluation:

The criteria for risk assessment were defined by the nature and types of failures, failure modes, failure effects, failure probability, risk level, and mitigation measures to be taken due to sample rejection was evaluated in FMEA worksheet (Table 1&3)

Department of Laboratory Medicine-Risk Assessment Sheet										
Risk #	**Risk Type**	**Risk Statement**	**Risk Drivers**	**Risk Description**	**Risk Owner**	**Severity(A)**	**Probability (B)**	**Risk Score (A) X (B)**	**Risk Rating L - Low M - Medium H - High** *(ref. Risk Assessment map)*	**Risk Mitigation Measures**
Risk 1	**Operational**	**Sample rejections -Pre analytical phase**	**1 .Incorrect identification of the patient. 2. Mislabelling of samples. 3. Incorrect homogenization of samples. 4. Incorrect blood sampling. 5. Incorrect tube for sampling or incorrect storage. 6. Improper or prolonged transport conditions. 7. Non conformity of serum/plasma-lipemia, haemolysis, Clots. 8. Wrong test identification.**	**1. Repeat samples needs to collect from the patient. 2. Chances of thrombophlebitis is more for the patient. 3. Delay in Treatment 4.Patient and Clinician Dissatisfaction 5.Unnecesary re-dos and repeat testing 6.Unnecessary injury and More pain to the patient.**	**Technologist**	**4**	**5**	**20**	**High**	**1. It is hospital policy to always use 2 patient identifiers (Name and UHID) 2. Induction training for new joiners and regular trainings and competency evaluations of all staff are carried out in the lab. 3. All information about order of draw, quantity of sample required, type of vacutainer,TAT, TAT, TAT etc is readily available in phlebotomy. 4. Samples are barcoded and labelled immediately after collecting the samples and prior to collecting the next patient`s sample. 6. Rejection criteria for wrongly labelled sample is in place.**

Risk 2	Operational	Sample rejections - Analytical phase	1. Procedural non conformity. 2. Errors of equipment or reagents. 3. Discrepancies in the results of the internal control. 4. Delay in analysing the samples.	1. Repeat samples needs to collect from the patient. 2. Chances of thrombophlebitis is more for the patient. 3. Delay in Treatment 4.Patient and Clinician Dissatisfaction 5.Unnecesary re-dos and repeat testing 6.Unnecessary injury and More pain to the patient.	Technologist	3	3	9	Medium	1. Induction training for new joiners and regular trainings and competency evaluations of all staff are carried out in the lab. 2. Strict adherence to the PM Policy of equipment's by the Biomedical Team. 3. Policy adherence by the laboratory staff on Quality controls. 4. Periodical Trainings and discussion on all the Lab QI to the laboratory staff by the Laboratory director.
Risk 3	Operational	Sample rejections -Post Analytical phase	1. Incorrect results. 2. Results entered incorrectly in the system. 3. Report result sent to a different to the patient. 4. Ambiguous way of communicating the result. 5. Lack of information about the limits concerning the results interpretation.	1. Repeat samples needs to collect from the patient. 2. Chances of thrombophlebitis is more for the patient. 3. Delay in Treatment 4.Patient and Clinician Dissatisfaction 5.Unnecesary re-dos and repeat testing 6.Unnecessary injury and More pain to the patient.	Technologist	5	1	5	Very Low	1. Induction training for new joiners and regular trainings and competency evaluations of all staff are carried out in the lab. 2. Strict adherence to the PM Policy of equipment's by the Biomedical Team. 3. Policy adherence by the laboratory staff on Quality controls. 4. Periodical Trainings and discussion on all the Lab QI to the laboratory staff by the Laboratory director.

Ranking of potential failures is done by using 5x5 L Type Matrix Method in the order they should be addressed(Table 2)

RISK MATRIX

Risk Assessment Matrix Level of Risk					
PROBABILITY	IMPACT				
	Very Low 1	Low 2	Medium 3	High 4	Very High 5
Very High (5)	5	10	15	20	25
High (4)	4	8	12	16	20
Medium (3)	3	6	9	12	15
Low (2)	2	4	6	8	10
Very Low (1)	1	2	3	4	5

Value	Probability	Definition
5	Very High	At least once in a Day
4	High	At least once in week
3	Medium	At least once in a month
2	Low	At least once in 6 months
1	Very Low	At least once in a year or Rarely Occurs

Value	Impact	Description
1	Very Low	Little/No impact on testing activities or the personnel performing the activity
2	Low	Low Impact due to changes in work environment which may create delays in testing activity
3	Medium	Medium Impact due to changes in work environment (or equipment) which may lead to ambiguous testing results
4	High	High Impact due to personal grievances or pressure on the personnel performing the test which may lead to compromised test results or falsified report ultimately lead to high financial loss > 500000
5	Very High	Very high Impact due to illegal activity / Bribery case / compromise/change in report for personal gains

The calculation of the risk in FMEA method includes the multiplication of threerisk parameters; the Probability (P), the severity (S) and the detection (D), in order to produce a risk priority number (RPN = P× S × D). Based on the RPN numbers, recommended actions are identified. Corrective actions are designed or process changes are made to lower severity or occurrence.

Severity scale (scale 1 [least severe] to 10 [most severe] for each effect)					
Minor (1)	**Low (2,3)**	**Moderate (4-6)**	**High (7,8)**	**Very high (9,10)**	
The minor nature of this failure will not have a significant effect on the patient or the choice of treatment	Because of this failure, the patient experiences only a minor injury or a minor discomfort	Failure can lead to patient dissatisfaction, which may include discomfort or failure	Dissatisfaction with the nature of the failure leads to serious disruption and risk to the patient's health	This failure affects safety or increases mortality. This may endanger the patient's life	
(I)					
Probability scale (scale 1 [least frequent] to 10 [most frequent] for the occurrence)					
Remote (1)	**Very low (2)**	**Low (3,4,5)**	**Moderate (6,7)**	**High (8,9)**	**Very high (10)**
Failure is unlikely; This failure was never observed	Only a few separates failures have ever been observed or reported	Isolated failures have been encountered	Occasional minor failures have been encountered	Failure is often encountered	Failure is almost inevitable
(II)					
Detection scale for occurrence (scale 1 [always detected] to 10 [never detected] for each occurrence)					
Very high (1,2)	**High (3,4)**	**Moderate (5,6)**	**Low (7,8)**	**Very low (9)**	**No detection (10)**
It is almost certain to detect the failure mode	There is a good chance of detecting the failure mode	One may detect the existence of the failure mode	There is a poor chance of detecting the existence of the failure mode	One probably will not detect the existence of the failure mode	The existence of the failure mode will not or cannot be detected

RISK mitigation & **Estimation of residual risk**:
Mitigation action was effective as no residual risk was identified in eliminating error due to laboratory information system (LIS).Whereas residual risk still persist in sample collection, as shown inthe below table .

cause of sample rejection	Existing control measures	Detectability	Probability /occurrence	Severity	RPN	Corrective action	ctability	bability	Severity	RPN	esidual risk
LIS problem Improper usage of bar-coding & Test not reflecting in LIS	No	9	8	7	504	Training given to the nursing staff proper usage of bar code and Correction rectified in LIS. **Refer to table**	1	1	1	1	Nil
2. Improper Sample collection Clotted sample Lysed sample Wrong vacutainer improper filling of citrate sample	No	1	9	8	72	1 Training and practical workshops being conducted to the nursing staff and junior phlebotomist **Refer to table1**	1	3	2	6	Low

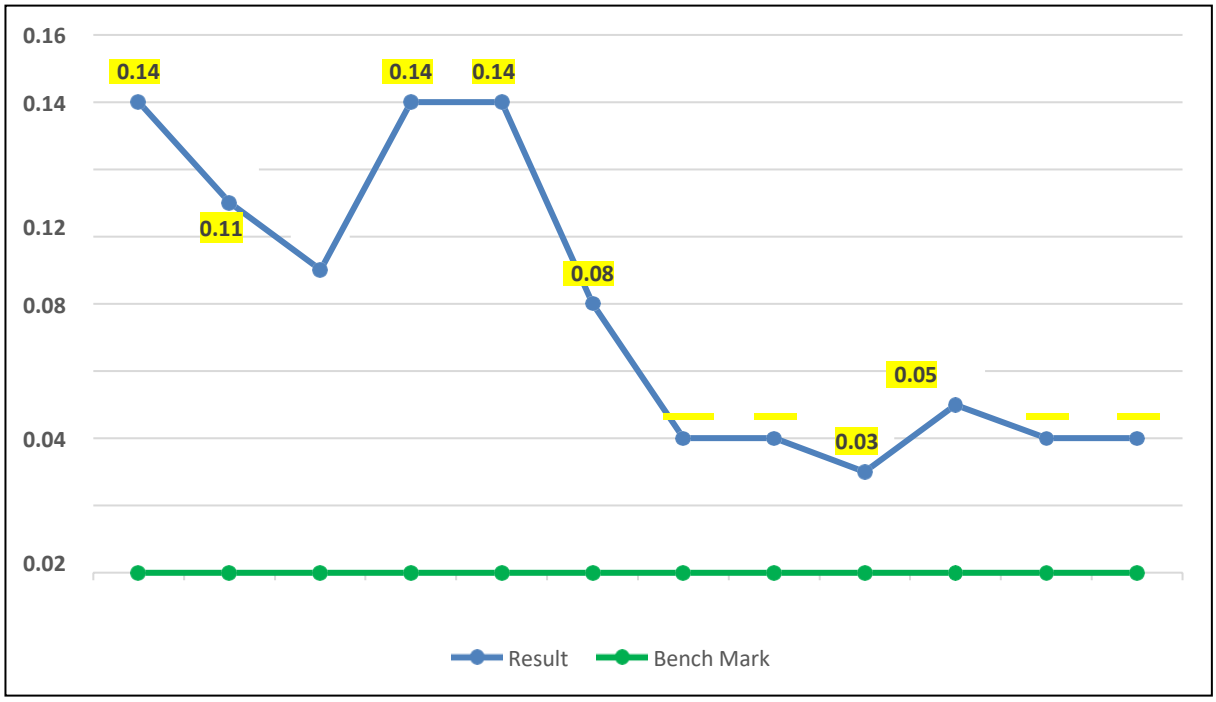
RESULTS:

Total number of samples rejected in a month. (TABLE 4, Graph: 1)

Indicator calculation: Number of samples rejected /Total number of samples accepted inthat month x 100

Sample Rejections Data-Lab TABLE 4		
	Number of samples rejected	**nples accepted in thatmonth**
Jan-23	24	16790
Feb-23	19	17410
Mar-23	17	19517
Apr-23	24	17519

May-23	25	18200
Jun-23	15	19164
Jul-23	8	20475
Aug-23	9	21823
Sep-23	6	20951
Oct-23	10	19560
Nov-23	8	19937
Dec-23	9	21958
TOTAL	174	2,33,304



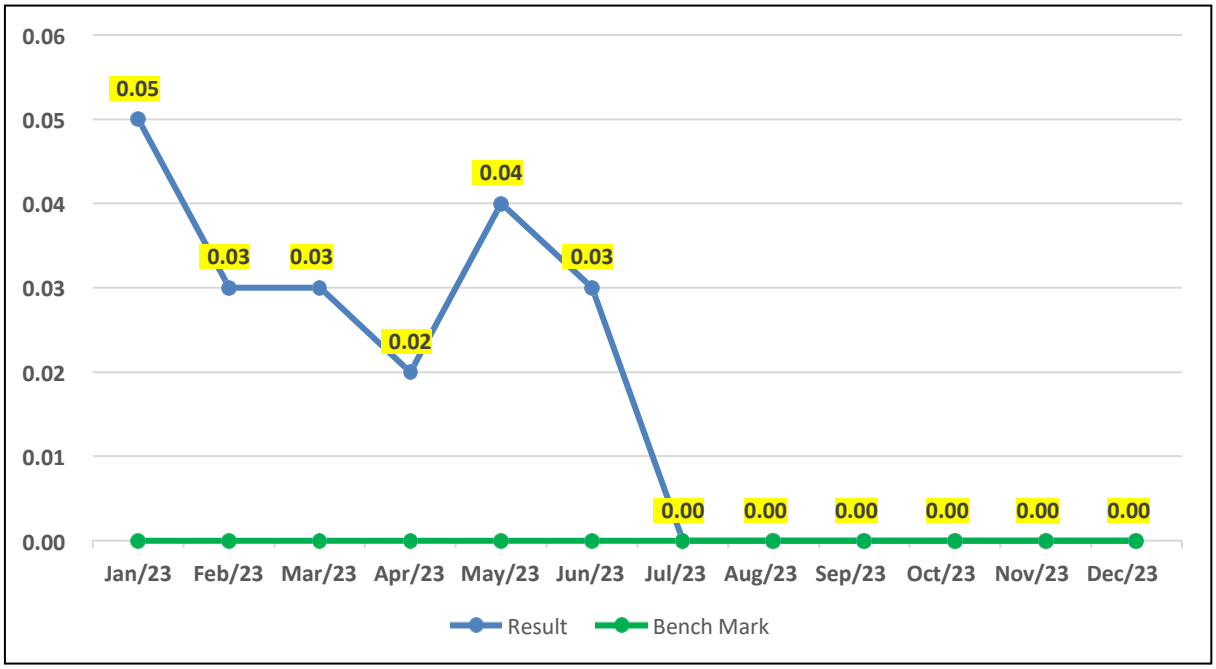
Graph 1

Sample Rejections Data Due to Wrong Raising of Test: **LIS problem(TABLE 5,Graph-2)**

<u>Indicator calculation</u>: Number of samples rejected /Total number of samples accepted inthat month x 100

Sample rejections data due to wrong identification of the test: LIS problem TABLE 5		
Name Of The Month	**Number of Sample rejected**	**Number of samples accepted in thatmonth**
Jan-23	8	16790
Feb-23	5	17410
Mar-23	6	19517
Apr-23	4	17519
May-23	7	18200

Jun-23	5	19164
Jul-23 (Sample Rejections after correction)	0	20475
Aug 23 (Sample Rejections after correction)	0	21823
Sept 2023 (Sample Rejections after correction)	0	20951
Oct 2023 (Sample Rejections after correction)	0	19560
Nov 2023 (Sample Rejections after correction)	0	19937
Dec 2023 (Sample Rejections after correction)	0	21958
TOTAL	**35**	**233304**

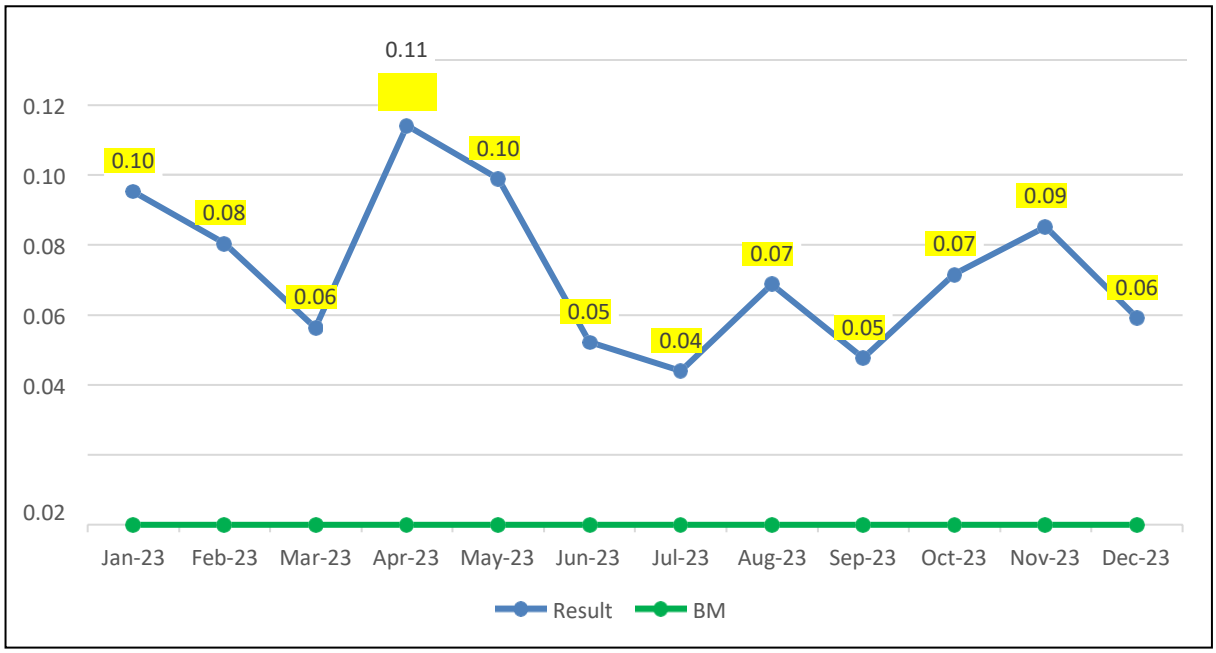


Graph 2

Total number of samples rejected due to other causes (Table: 6, Graph: 3)

Sample Rejections Data Due other causes		
	Number of sample rejected	**Number of samples accepted in that month**
Jan-23	16	16790
Feb-23	14	17410
Mar-23	11	19517
Apr-23	20	17519
May-23	18	18200
Jun-23	10	19164

Jul-23(Sample Rejections after correction)	8	20475
Aug 23(Sample Rejections after correction)	9	21823
Sept 2023 (Sample Rejections after correction)	6	20951
Oct 2023(Sample Rejections after correction)	10	19560
Nov 2023(Sample Rejections after correction)	8	19937
Dec 2023(Sample Rejections after correction)	9	21958
TOTAL	139	2,33,304



Graph 3

Summary of the Results:

Before Failure Mode Effective Analysis (FMEA) Results in 2023:

Overall Total Number sample rejections: 174 Samples. Total Number of Sample rejections due to LIS Problem: 35 Samples. Total Number of Sample rejections due to Other Causes (Ex: Sample Lyse, Sample Clot, Low Volume, Etc): 89 Samples. After Failure Mode Effective Analysis (FMEA) Results in 2023: Total Number of Sample rejections due to LIS Problem: Nil. Total Number of Sample rejections due to Other Causes (Ex: Sample Lyse,Sample Clot, Low Volume, Etc): 50 Samples

DISCUSSION:

Proper sample collection is an important part of good laboratory practice and improper collection can lead to delays in reporting, unnecessary re-draws/retests, decreased customer satisfaction, increased costs,incorrect diagnosis / treatment, injury and occasionally death. Application of FMEA in preanalytical phase can eliminate and reduce the laboratory errors to maximum extent by right patient identification with the right test allows the laboratory to produce the right results in the right time. According to Elkington and Smallman [15], risk identification is the first step in identification and listing of all risks across the entire testing processes covering pre-examination, examination, post-examination Hallikas et al. [16] also state that the identification phase is fundamental to implement risk management, as by recognizing sources of risk, future

uncertainties can be identified, and preventive measures can be taken. Plebani [17] defines risk management as the process by which risk is assessed and strategies are developed to manage it. The target of any risk management activity is to identify, evaluate, mitigate, and reduce the risk to an acceptable level. According to Dikmen et al. [18], risk management involves identifying sources of uncertainty (risk identification), assessing the consequences of uncertain events/conditions (risk analysis), thus creating response strategies based on expected results and, finally, based on the feedback received from the actual results and the emerging risk, the steps of identification, analysis and repetitive response events are performed throughout the life cycle of a project to ensure that the project objectives are achieved. Kang et al. [19], define risk management as an act of classification, analysis, and response to unforeseen risks, which are involved during the implementation of a project.

CONCLUSION:

Failure Modes and Effects Analysis (FMEA) is a systematic, proactive method which helps laboratory services in evaluating a process to identify where and how it might fail and to assess the relative impact of different failures. In identifying and rectifying the failure modes of the process can reduce the laboratory risks and errors. This affect the patient outcome/results and to develop in the continuous delivery of quality patient care in most effective processes. In estimates of risk, along with the 'probability'and ' severity', detectability has significance role. If detectability score is high we can eliminate lab errors. Thereby application of FMEA in preanalytical phase can eliminate and reduce the laboratory errors to maximum extent by right patient identification with the right test allows the laboratory to produce the right results in the right time. Limitation of the risk management is existence ofresidual risk which is still a challenge to the laboratory.Need to create innovation in all services and find the opportunities to eliminate the residual risk.

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