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Risk identification of a hospital laboratory pre-analytics through failure mode and effect analysis

Debdatta Das[1], Krishna Pal[2], Sudip Roy[3], Moushumi Lodh[4]

[1]Sr Manager, Quality & Accreditations, Medica Superspeciality Hospital, Ranchi, Jharkhand, India, [2]Laboratory Technician cum Quality coordinator, Healthworld Hospitals, Durgapur, West Bengal, India, [3]Director Laboratory Services, Medica Superspeciality Hospital, Kolkata & Ranchi, India, [4]Executive Director Laboratory Services, Healthworld Hospitals, Durgapur, West Bengal, India

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ABSTRACT

Background: Implementing an active system to identify, monitor and manage risk from laboratory errors can enhance patient safety and quality of care. **Aims and Objectives:** Failure Mode and Effect Analysis (FMEA) technique allows evaluating and measuring the hazards of a process malfunction, to decide where to execute improvement actions, and to measure the outcome of those actions. The aim of this study was to assess pre analytical phase of laboratory testing, mitigate risk and thereby increase patient safety. **Materials and Methods:** Steps followed in the study were: planning the study, selecting team members, analysis of the processes, risk analysis, and developing a risk reduction protocol by incorporating corrective actions. A Fault Tree Analysis diagram was used to plot the cascade of faults leading to the pre analytical errors. Risk Priority Number (RPN) was assigned. A minimum cut- off 40 RPN was considered for interventions and highest RPN errors were prioritized with corrective actions. Post intervention RPN score was calculated. **Results:** Eight failure modes had the highest RPN. Corrective actions were prioritized against these errors. RPN scores of test ordering error, sample collection error, transport errors, error in patient identification, site selection, urine samples not received, sample accessioning and sample processing errors decreased, post intervention. **Conclusion:** With thorough planning, we can use FMEA as a common standard to analyze risk in pre analytical phase of laboratory testing.

Key words: FMEA; FTA; FRACAS; Failure modes; Risk analysis; Pre analytical

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INTRODUCTION

The impact of laboratory testing in patient care contributes to more than 60% of medical decisions.[1] Laboratory errors have a reported frequency of 0.012–0.6 % of all test results, of which up to 70% occur in pre analytical phase.[2,3] Pre analytical phase errors includes inappropriate test request by physician, inappropriate order entry, patient/specimen misidentification, sample collection errors (hemolysis, clotting, insufficient volume, etc.), inappropriate container, or errors in handling, storage and transportation, sorting and routing, pour-off, aliquoting, pipetting, labeling, centrifugation (time and/or speed).

The ISO 15189:2012 clause no 4.14.6 envisages that the laboratory shall evaluate the impact of work processes and potential failures on examination results, as they affect patient safety. The laboratory shall modify processes to reduce or eliminate the identified risks and document decisions and corrective actions taken.[4]

The aim of this prospectively designed study was to identify the potential hazards involved in the pre analytical phase & quantify their effects by RPN score pre- and post-intervention. We also aimed to identify the risk reduction measures available, and recommend effective interventions to meet the 'low- risk' benchmark requisites, and thereby

Address for Correspondence:
Dr Moushumi Lodh, Executive Director Laboratory Services, Healthworld Hospitals, Durgapur, Pin-713216. West Bengal.
Mobile No: +91-8170052605. **E-mail:** drmoushumilodh@gmail.com

design a more effective and safe patient care process for the laboratory.

MATERIALS AND METHODS

Pre analytical laboratory process of a tertiary care hospital was analyzed by a multidisciplinary team, from Jan to Nov 2019, as part of routine quality work. The team comprised of quality coordinator, lab manager, lab director, IP operations coordinator, ward clinician, deputy medical superintendent, nursing supervisor, infection control officer. The team attended a period training session on FMEA, FTA and FRACAS and analyzed the process through brainstorming, interviews and taking notes during direct observations.

Failure modes and effects analysis (FMEA) is a step-by-step approach for identifying all possible failures in a design, a process, or a service. Sequential steps followed in our study, as a part of FMEA process were: Planning the study, selecting team members, analysis of the processes using Fault Tree Analysis diagram (FTA), risk quantification by Risk Priority Number (RPN), risk management & developing a risk reduction protocol by Failure Reporting and Corrective Action System (FRACAS) and risk quantification 6 months post corrective actions using RPN.

FTA helps organize the collected errors and assess the interrelationships within the system. RPN is a numeric assessment of risk, assigned to steps of the pre analytical testing process. FRACAS helps us to record in detail, errors and the control measures employed to correct these observed errors.

To identify potential risks, the failures or hazards possible for every step were listed by each of the team members, while assigning their individual score to each failure. 34 such potential failures were identified in the pre analytical phase of laboratory testing process. Risk quantification[5] was done to prioritize the steps where corrective actions needed to be taken at the earliest. The potential effects of these risk steps were rated by the Risk Probability Number (RPN), where RPN =Occurrence (O) X Detectability (D) X Severity (S).[6] The frequency of occurrence of the error ranges from 1 to 5 and its severity ranges from 1 to 4 from least to most frequent/severe. Probability of error detection ranges inversely from 4 (low probability) to 1 (high probability). The limit of this index, from which preventive actions would be taken to prevent risk, minimize it or extinguish it, was forty (40) points. We used Microsoft Office program - Microsoft Excel 2010 for the preparation of spreadsheets and calculations. The overall risk priority number (RPN) was determined by calculating the mean of all RPNs assigned to each failure by the team members. RPN or critical index is a quantitative expression for the evaluation of each failure. Subsequently, the RPNs ranged from 1 (1×1×1) as the "best" score to 80 (4×5×4) as the "worst" one.

FRACAS involves the act of recording the risks, as proposed in Technical Specification ISO/TS 22367, through the creation of a "non-conformity" notice[7], which allows us to investigate on an individual basis, to analyze the cause and the potential harm to the patient, and to take preventive and corrective measures. Results of the indicators were communicated to hospital's quality controllers, and to nursing managers. These activities, together with the laboratory's policy of always rejecting doubtful samples, and in such cases demanding a new sample request and specimen collection, were continued for establishment of a culture oriented toward safety and the recognition of errors committed.

RESULTS

The Process flow map, verification activities, documents checked and team members involved are shown in Figure 1.

The Fault Tree Analysis diagram (Figure 2) allowed us to organize the collected pre analytical errors and to assess the interactions of the faults within the system. It showed us the direct and indirect causes of potential errors or non-conformities. Fault is an abnormal undesirable system element induced by a failure. A connector used to link lower events that are related to an above event. 'OR gate' means either bottom event results in the occurrence of the above event. Basic events lead to intermediate events, which lead to the final event of pre analytical errors. The lower most event that cannot be further developed is called a basic event. Intermediate event or a sub fault is the result of a logical combination of lower-level events. The top event is the target-undesired event (pre analytical errors).

The total number of tests received in the lab during 2019 were analyzed for pre analytical errors No exclusion was done. Risk quantification was done as per Table 1.

Thirty-four modes were identified with RPN ranging from 20 to 80. Preventive interventions would be taken for eight modes whose RPN score was over 40 points. Critical effects occurred where analytical report was assigned to another patient or erroneous results reported, leading to misdiagnosis/incorrect results, as in error in patient identification, in inputting data to the LIS, patient name incorrect on the request form or no specimen/ analytical request traceability. (Table 2)

Major errors were seen in specimen collection. These errors effected analytical quality, caused delay in reporting, led

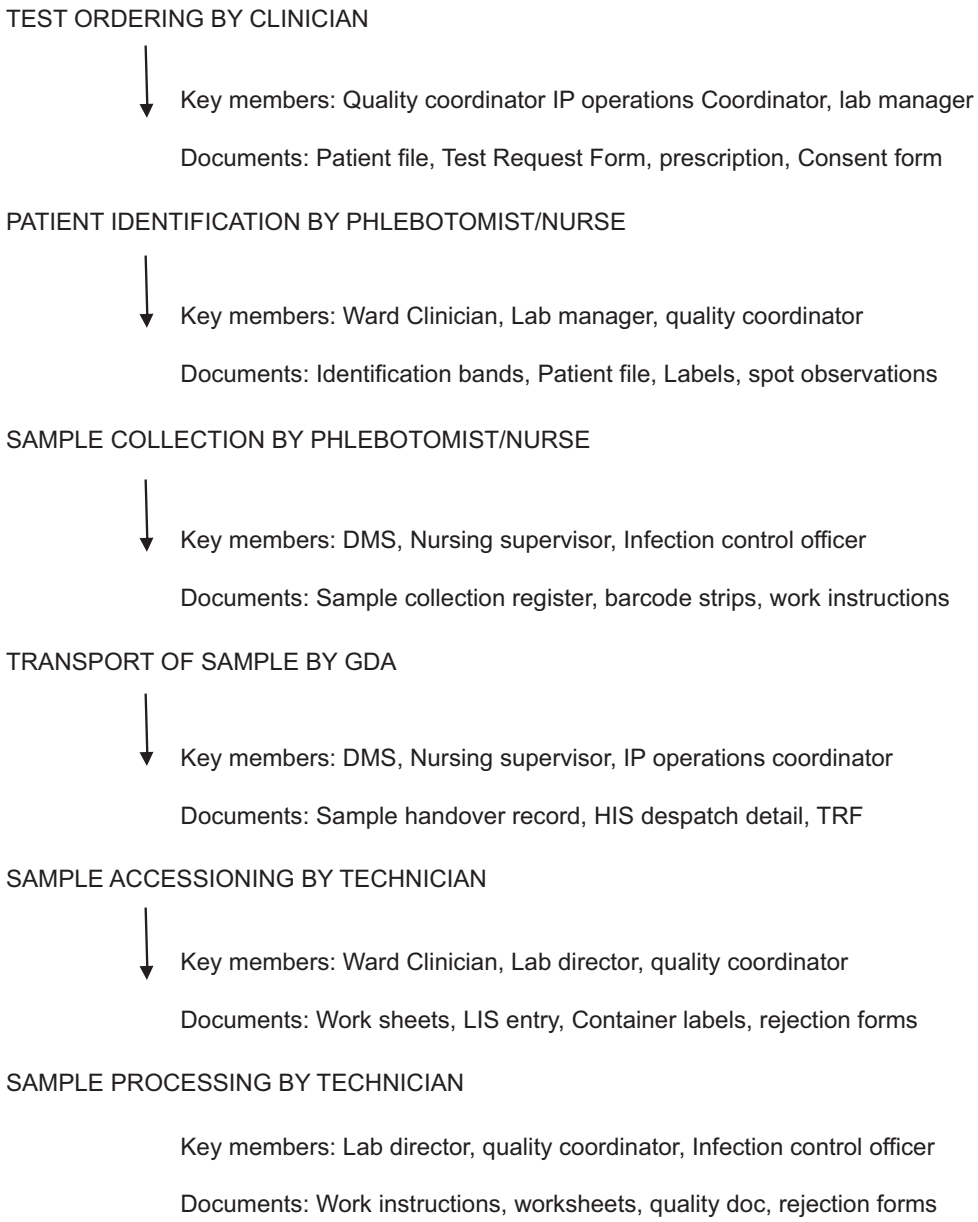

Figure 1: Process flow map & verification activities involved
DMS: Deputy Medical Superintendent; HIS-Hospital information system; LIS: Laboratory information system; GDA: General duty assistant

Table 1: Risk quantification

Effect severity (s)		Failure occurrence (o)		Failure detection (d)	
Score	**Severity description**	**Score**	**Occurrence characteristics, occurrence probability**	**Score**	**Description of detection mechanisms**
4	Severe	5	Continuous, daily	4	Existing mechanisms won't identify
3	Moderate	4	Frequent, Weekly	3	Partial controls available
2	Mild	3	Occasional, monthly	2	Current controls will detect only immediate failures
1	Insignificant	2	Rare, May occur within 1 to 6 weeks	1	Certain of detecting failure before patient is effected
		1	Remote, It may occur annually		

to repeat analyses and increased costs. Available control measures were identified and corrective measures taken. Table 2 also shows RPN improvement as calculated after 6 months of taking interventions.

Our analyses indicated that the failure risks with the highest RPNs (Table 2) were Test ordering error (RPN 80), sample collection and transport errors (RPN 60), error in patient identification, site selection, urine samples

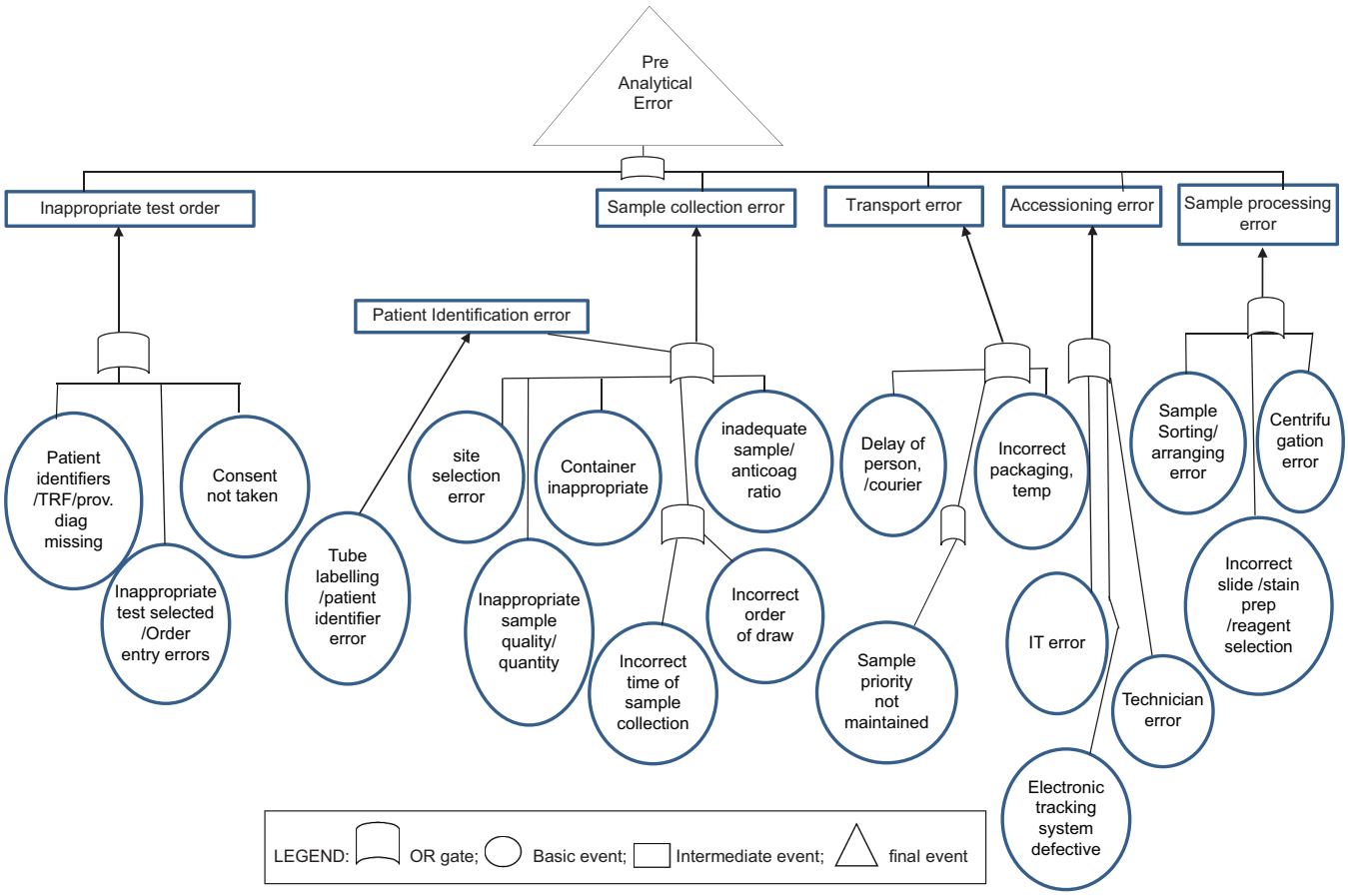

Figure 2: Fault Tree Analysis Diagram for pre analytical errors

not received, sample accessioning and sample processing errors (RPN 48). Based on the risk assessment, action plans were determined to reduce the risks of these eight failure modes. The recommended risk reduction measures (Table 2) were followed for six months and the previous team performed rescoring. This revealed a reduction in the value of all RPNs assigned to potential failures so that RPN scores of test ordering error, sample collection error, transport errors, error in patient identification, site selection, urine samples not received, sample accessioning and sample processing errors decreased to 12,18,12,12,8,12,8,8 respectively (Table 2).Corrective interventions that proved most successful towards improving patient safety were automated labelling and barcoding of blood samples, mandating usage of HIS by clinicians and training and performance monitoring of the responsible staffs and clinicians, to achieve the desired outcomes.

DISCUSSION

Clinical and Laboratory Standards Institute guidelines (i.e., EP18-A2, EP22-A and EP23-A) introduce risk management principles which can be used for driving application of ISO 15189, the international standard for accreditation of medical laboratories as a system for reducing laboratory error and improving patient safety.[8] Marin*et al*[9] noted the commonest pre analytical errors as: haemolysed samples (8.76%), urine sample not submitted (1.66%) and clotted sample (1.41%). Hawkins *et al*[10] defines a pre-pre-analytical (46-68%) phase consisting of inappropriate test request, order entry, patient/specimen misidentification, sample collected from infusion route, sample collection (hemolysis, clotting, insufficient volume, etc.), inappropriate container, handling, storage and transportation and a pre-analytical (3-5%) phase comprising sorting and routing, pour-off, aliquoting, pipetting and labeling, centrifugation (time and/or speed).

Our study was based on a structured, planned and complete mapping of the pre analytical testing process, anticipating adverse events by means of planning and implementation of preventive actions. Many studies show effectiveness of FMEA as a proactive tool for managing risk in healthcare.[11-14] Rezei et al showed that improved RPN scores reassessed by root cause analysis show some variations.[15]

Table 2: Failure mode and effect analysis

Failure mode	Potential effect	S	Potential Cause	O	Control measures available	D	Pre-intervention RPN	Corrective interventions	Post intervention RPN
Test ordering error	Critical	4	History/ provisional diagnosis/ date/ time/test name missing/ incomplete; name/sex mistake in test request form	5	Manual entry on Request forms. Visual comparison of TRF and prescription by lab personnel.	4	80	✓ Mandate clinicians' entry in Hospital Information System (HIS) directly. ✓ The field for 'history' to be highlighted and mandated in HIS ✓ Training & performance monitoring of clinicians ✓ Availability of user guide in phlebotomy sections and wards level	(2x3x2)=12
Patient identification error	Critical	4	Error in name/UHID/lab ID. Samples collected from outreach clinics do not bear UHID. Staff negativity & complaints of heavy workload	4	Ask patient /check identification band of patient for 2 identifiers (name, UHID)	3	48	✓ Promote 3 patient identifiers usage in lab (name, UHID, Lab number) ✓ Automated barcoding of tubes ✓ Automatic number generation in LIS ✓ Nurses' bedside collection in pre-labelled tubes ✓ Handwritten labels should be stopped & barcoding with alphanumeric codes done ✓ Staff training, incentives for good performance	(2x3x2)=12
Site selection errors	Major	4	Wrong side/lymphedema/ burn restricting approach to vessel/ Drawing from an unacceptable site/Failing to immediately terminate the draw when a nerve has been provoked/ Providing inadequate pressure to the puncture site/Bandaging the site without performing a two-point check	3	Visual check by nurse/ phlebotomist	4	48	✓ Mark sample container as left or right prior to collecting sample in it. ✓ Site marking from ward to be mandatory ✓ Stick leucoplast on wrong side (burn/ lymphedema/ IV drugs) ✓ Hiring experienced personnel for sample collection ✓ Staff training (nursing & phlebotomy)	(2x2x2)=8
Sample collection errors	Major	4	IV channel prick, sample haemolysed by push of sample through syringe, EDTA sample clotted, sample volume error, improper mixing of anti-coagulant/error in timed blood/ urine collection, direct filling sample tube with syringe, wrong container.	5	Rejection of samples from lab	4	60	✓ Training of staff on best practices of phlebotomy, ✓ Mandate use of vacutainer system of collection ✓ Use paediatric sample containers where required. ✓ Allocate phlebotomist, instead of nurses, for drawing ward/inpatient sample	(3x3x2)=18
Sample transport errors	Major	3	Non-compliance with Cold / delay in transport >2 hour/ sample inverted/ container leakage	5	2 container packaging, with ice, carried by General duty attendant	4	60	✓ Triple layer packaging system for samples (primary, secondary, outer) ✓ All collections to reach lab within 2 hours ✓ Ice box to be replenished with ice pack intermittently, if time since sample despatch >2 hour	(2x3x2)=12
Urine samples not sent	Major	3	Patient did not feel the urge/ nurses forgot to collect urine	4	Lab receiver notes in handover register from wards	4	48	✓ Checklist to be followed by nurses in wards for pending samples ✓ handover to be given to next shift nurse to send sample ✓ Lab reception to call ward for pending samples before shift change at 8 a.m., 2 p.m., 8 p.m. ✓ Availability of user guide in phlebotomy sections and wards level	(2x3x2)=12

(Contd...)

Table 2: *(Continued)*

Failure mode	Potential effect	S	Potential Cause	O	Control measures available	D	Pre-intervention RPN	Corrective interventions	Post intervention RPN
Sample accessioning error	Critical	4	Wrong sample sent from ward/ Error in Input data/ Illegible handwriting of nurse on container or writing not correlating with system entry/ knowledge deficit / A large number of samples receipt at the same time	3	Use of Laboratory Information System, Acceptance, rejection criteria though available, not always followed	4	48	✓ Interfacing of instruments ✓ Training of lab technicians ✓ Delta check in LIS by technicians and lab doctors. ✓ Adherence to the sample acceptance and rejection criteria ✓ Effective communication ✓ CAPA of sample rejection rate ✓ Training of staff	(2x2x2)=8
Sample processing error	Major	4	Serum separation time inadequate/less time for centrifuging/ slow speed of centrifuging/	3	Maintain vacutainer manufacturer guidelines for mixing by inversion, centrifugation	4	48	✓ Stand samples at phlebotomy for half an hour, then handover for centrifuging. ✓ Work instructions pasted on walls for correct time and speed for centrifuging different body fluids and paediatric samples. ✓ Centrifuge samples prior to acknowledging, reject if required.	(2x2x2)=8

S: Severity; O: Occurrence; D: Detection; RPN: Risk priority number; UHID: unique hospital identification; CAPA: Corrective & preventive action; TRF: Test Request Form

Misidentification of samples arise when data on sample identification and sample labelling by laboratory or clinical department are not identical to the data entered into the LIS or HIS. Sample hemolysis arises from mechanical trauma to the specimen and sample clotted error is the consequence of inadequate mixing of anticoagulated specimens, both resulting from incorrect collection technique. Test transcription errors arise from error in communicating and recording a test request including order entry in Laboratory Information System or order entry in Hospital Information System.Inappropriate temperature, damage during transport, inappropriate transport containers and conditions, samples missing in transit, lead to pre analytical sample transport & storage errors.

The main mechanism for reducing RPNs was to decrease the occurrence of each error. Repeated education & training was given. ISO 15189 requirements and the national recommendations were defined in the primary sample collection manual, and work instructions put up for preanalytical processes with a number of information for collecting primary samples and using proper blood collection equipment as well as a practical training especially for the new staff. All laboratory protocols and educational updates for proper specimen collection were distributed to the personnel outside the laboratory through HIS and in paper form. Surprise audits, feedback collection, strengthening of incident reporting process and repeated training helped in identifying errors in diverse ways.

Skilled manpower recruitment and competency enhancement trainings helped improve sample collection, transport, storage, and other pre analytical testing process. Staff could more effectively identify non conformities, follow operative guidelines and best practice recommendations. The lab could develop more effective error tracking, continuous quality monitoring and reliable detection systems in the lab. Corrective actions became more effective with better teamwork and close cooperation between the skilled laboratory staff and the healthcare workers outside the laboratory.

Along the study process, we recognized that a paradigm positive change came about in staffs, as they understood the process of FMEA and learnt to select proper corrective and preventive actions for potential errors. They performed daily maintenance of primary and back up instruments, reduced risk by sharing information with staffs and clinicians and volunteered to train & improve competency of existing staffs. After implementation of corrective actions, they began to appreciate the process of continuously monitoring lab quality through system

electronic checks, built in controls in instruments, LIS alarms and physician complaints. To detect potential errors, temperature recording of refrigerators, rooms and transport containers were stringently followed as was water quality checking. Error identification and mitigation, helps ensure that patient results are reliable and residual risks are maintained to a clinically acceptable level.

We faced some difficulties in our study. There are very few documented published studies on pre analytical risk assessment and benchmarking processes through FMEA. FMEA is time-consuming and requires organizational commitment. However, with thorough planning, and a trained team, it is efficient for the identification and prioritization of potential risks.

FMEA approach was also used to monitor whether the measures taken succeeded in improving quality. Six months after the implementation of the corrective risk-reducing actions the multidisciplinary team evaluated the specified lab quality indicators. Obtained data showed quality improvement in all steps of preanalytical process with significant decrease in repeat testing, sample hemolysis, misidentification of samples, sample clotting, sample volume error, sample rejection rate, transcriptional errors and increase in safety adherence of staff and reduced turnaround time. Thus, our goal was fulfilled in achieving quality improvement in the preanalytical phase & providing more timely and accurate test results as the most important factors in terms of patient outcome

CONCLUSION

Besides the pre analytical phase, the analytical, post analytical phase, laboratory environment, quality control procedures and measuring systems, communications, document control, record keeping, competency assessment of staff as well as quality of reagents and equipment are all areas where risks of error must be identified and mitigated to lead to correct laboratory results. This will enhance patient satisfaction, reliability of reports and improve quality of lab reporting. FMEA can be considered an effective, proactive systematic approach towards this end. This methodology allows to standardize the evaluation and prioritization of risks in laboratory pre analytics. In future studies we will consolidate this approach and analyze how FMEA can be used to assess and mitigate possible harm to the patient and the inefficiency costs generated by such pre analytical errors.

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Author's contribution:
DD- Concept and design of the study; prepared first draft of manuscript; **KP-** Statistically analysed and interpreted, preparation of manuscript and revision of the manuscript; **SR-** Interpreted the results; reviewed the literature and manuscript preparation; **ML-** Concept, coordination, review of literature and manuscript preparation; All authors read and approved the final manuscript and agree to be accountable for all aspects of the work in ensuring that questions related to the accuracy or integrity of any part of the work are appropriately investigated and resolved.

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Medica Superspecialty Hospital, Kolkata, India.

Orcid ID:
Debdatta Das - https://orcid.org/0000-0001-9348-0952
Krishna Pal - https://orcid.org/0000-0002-5340-0388
Dr. Sudip Ray - https://orcid.org/0000-0003-2267-5458
Dr. Moushumi Lodh - https://orcid.org/0000-0002-9184-0106

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