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REVIEW ARTICLE

Measurement of Errors in Clinical Laboratories

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Abstract Laboratories have a major impact on patient safety as 80–90 % of all the diagnosis are made on the basis of laboratory tests. Laboratory errors have a reported frequency of 0.012–0.6 % of all test results. Patient safety is a managerial issue which can be enhanced by implementing active system to identify and monitor quality failures. This can be facilitated by reactive method which includes incident reporting followed by root cause analysis. This leads to identification and correction of weaknesses in policies and procedures in the system. Another way is proactive method like Failure Mode and Effect Analysis. In this focus is on entire examination process, anticipating major adverse events and pre-emptively prevent them from occurring. It is used for prospective risk analysis of high-risk processes to reduce the chance of errors in the laboratory and other patient care areas.

Keywords Patient safety · Laboratory errors · Quality failure · Incident reporting · Root cause analysis · FMEA

The total testing process is a complex and unique framework involving procedures, equipment, technology and human skills designed to ensure accurate, precise and timely diagnosis and treatment decision. Hence, it is difficult to identify and reduce errors and risk of errors in laboratory medicine. Laboratory errors have a reported frequency of 0.012–0.6 % of all test results which in turn has huge impact on diagnosis and patient management as 80–90 % of all diagnosis are made on the basis of laboratory tests [1]. Laboratories have been at the forefront of efforts made to enhance patient safety through a range of improvements such as increased automation of manual processes, introduction of systematic internal quality control and external quality assurance program, thereby making pre- and post-analytical phase more vulnerable to laboratory errors. Many errors in these phases are outside the control of the laboratory like ineffective communication. It is further complicated by the 'human factors' in the provision of health care which introduce human error, result of processes beyond the conscious control of the professionals who make errors. This complex series further include interaction of clinicians and patient and 'pieces' of technology that help clinicians make a diagnosis and provide the treatment. All these factors must be borne in mind not only when patient safety problems are mapped, but also when risk analysis tools are chosen by health managers for their introduction in the health care organisation [2]. Few examples of laboratory-related errors in diagnosis are failure to order the appropriate tests (50 %), failure to act on the result of tests (32 %) and avoidable delays in making the diagnosis (55 %) [3].

Patient safety can only be enhanced by taking care of the actions like preventing error events, detect them when they occur and eliminating their effects. In this article, we will try to detect the laboratory errors which have occurred or there is possibility of them occurring, and their assessment. Majority of mistakes and errors are related to cognitive and behavioural factors. In the laboratory medicine, there are two views regarding the occurrence of errors in the laboratory. One paradigm is the 'person approach' which believes that human operator is responsible for error through carelessness, fatigue/overload or inattention [4]. In this, response to error is to apportion blame to the operatory in question which is easy to identify, thereby absolve

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higher levels of management from any culpability. The weakness of this paradigm is that it overlooks the fact that human fallibility can not be easily modified and many work situations are inherently error prone. It is evidenced by the common observation that identical errors are often made by different individuals [5]. Further, laboratory professionals are highly trained, oriented and dedicated who are committed to the delivery of a high quality service which is assumed to be error free. Another paradigm is a 'systems approach' which implies that errors arise due to faulty systems rather than careless or inattentive staff [4–6]. This theory is based on assumption that well designed systems take into account human fallibility and incorporate appropriate checks to detect and prevent errors. This approach emphasises systems design failure instead of human failure and removes the focus from the human operator to the overall system. The biggest advantage of this approach is improvement of workplace culture as in a person based approach the fear of attracting blame when errors occur inevitably contribute to a negative and critical environment which discourages the reporting of errors. On the other hand, a system based approach allows for a more constructive interaction with staff to identify weakness in policies and procedures and nurture an open and blame free environment with in the laboratory [7].

A vital way of ensuring patient safety is to identify errors/failures in system and causes of failure. Studies on the causes of failure have shown that the majority of mistakes and errors are attributable to faulty systems [1]. Great efforts should be made to identify and implement safer policies and procedures. To identify modifiable risk factors contributing to the occurrence of preventable errors documentation of occurrence of errors is the most critical and important requirement for achieving these ends. There are two methods of choice for documentation of occurrence of errors. One is reactive method which includes incident reporting or detection of quality failure and second is proactive methods like failure mode and effect analysis (FMEA) [1]. These tools are important not only in identifying the quality of an organisation and improving upon patient safety but also to compare performance of one organisation against that of others. The proactive methods are more readily accepted by clinicians because they explore professional competence through a positive approach to problems by focusing on the examination of the entire process in a prospective manner. This helps in anticipating major adverse events and pre-emptively implementing changes to prevent them from occurring [8].

Incident Reporting/Reporting of Quality Failure

Traditionally, patient safety initiatives in the laboratory have focussed on error reporting and review. It is assumed that if personnel follow policies and procedures, errors should not occur. When errors do occur, most laboratories have a process to identify, assess and investigate the event. If a deviation from standard operating procedure is detected, corrective and/or disciplinary actions are taken up. Till date oldest and most commonly used tool in the laboratory for patient safety and quality improvement is tracking and trending the incidents, errors and accidents. It is the method used after failure has occurred and analyse it in a retrospective manner.

The pathway from test selection to the return of an appropriately interpreted report to the requesting physician is a complex process which may be broken into a sequence of steps. Each step comprises one or more procedures and the pathway as a whole, requires the timely interaction of a large number of staff both within and outside the laboratory. An error in any of these steps may have an adverse impact on patient care, as it will not allow the laboratory to achieve the required outcome quality. Use of more neutral term 'Quality failure' may be preferred to reduce the sense of blame among staff and encourage the staff to report errors [1].

Steps in Quality Failure Reporting [1]

Quality Failure

Quality failure may be defined as any failure to meet the required output quality necessary for optimum patient care anywhere in the pathway from test selection to the release of reports to the requesting clinician. Quality failure reporting focuses on patient care and patient outcomes rather than on process and procedures.

Recognition and Reporting of Quality Failure

Quality failure becomes apparent for a variety of reasons. These may include:

(a) Complaints by users (clinicians, caregivers, patients and their relatives).
(b) Recognition of findings by trained and experienced staff e.g. sample labelling error in a clinical area identified by laboratory staff because it was noted that the test results did not match previous results on the same patient (Delta check).
(c) Detection of non conformities such as analytical quality control/quality assurance program.
(d) Sample/request form concordance checks.
(e) Non conformity to adoption of minimum acceptable labelling criteria, urgent sample reporting, critical value reporting.

(f) Detected during audit.

Identification of quality failure requires the creation of a culture which actively encourages staff to develop a constructive and critical attitude to work and which emphasis the identification of quality failure as an opportunity to enhance patient safety. There should be a positive feedback to ensure that staffs remains active and engaged and there must be tangible evidence that quality failure reporting results has led to improved policies and procedures of the laboratory environment.

Investigation

After reporting of quality failure, a suitable system is used to classify it by cause and grading by seriousness which will help to focus corrective action on the root cause and identify priorities for quality improvement [1]. Regular monitoring of quality failure trends help in assessing the effectiveness of corrective actions undertaken.

Number of approaches have been undertaken to classify quality failures by root cause. The most commonly used taxonomy classifies the failure as per the point in the testing process at which they occur: pre-analytical, analytical or post-analytical phases with further subdivision to indicate the specific step at which the problem occurred [9–12]. This classification is based on the fact that the pathway from test selection to the retention of an appropriately interpreted report to the requesting clinician is complex, which may be broken down into a sequence of steps. Each step comprises of one or more procedures and the pathway as a whole requires the timely interaction of a large number of staff both within and outside the laboratory. A failure in any of these steps to achieve the required outcome quality may have an adverse impact on patient care. This classification has advantage of ease of application and reproducibility. It readily identifies the step in the testing pathway requiring more attention [1, 2].

Another classification is based on the causative nature of the quality failure. In this, reported quality failures are classified as latent/active, cognitive/non cognitive, preventable/non preventable. This qualification gives more comprehensive picture of individual quality failures but is more complex and may be difficult to apply [13].

Most of the quality failures may have little direct impact on patient care and only a small proportion of them results in actual patient harm and are the focus of risk management activities. However, reporting of them may be an important learning opportunities, which otherwise may have had little impact on patient care. The reasons for the benign clinical outcome following quality failure may be because they are recognised and corrected before a report was issued or an uncorrected result issued did not differ significantly from the true result. More extreme cases of quality failures are referred as 'near misses' where less extreme examples are disregarded by the laboratory and clinical staff [1]. Regardless of its apparent severity, any quality failure indicates weakness in policies and procedures which did not have led to patient harm, might have done so in a slightly different set of circumstances e.g. sample labelling error in a clinical area, may be detected at laboratory technician level as he/she rechecks the name, age, sex and registration number on sample label with test requisition form. Such sample labelling error occurring in clinical areas, if go unnoticed; pose very high risk to patient safety [1].

Next step in classification of quality failure is regarding seriousness of it. Such system of grading should consider not only the actual patient harm sustained but also the potential worst case outcome if such a failure to recur. The seriousness of each quality failure is described by assigning an Actual (A) score which measures the actual adverse impact on the patient and the Potential (P) score which measures the worst case possible outcome that might have occurred. The A and P score may be quantitated 0–5 point severity scoring system based on the patient outcome (Tables 1, 2) [12].

Identification of Required Actions and Prioritisation of Corrective Action

Once the quality failure has been recognised and reported, a required action is undertaken in the form of amendment of a procedure, alteration of the working environment, additional training etc. These actions are applied after prioritising the corrective action based on the severity of quality failure. Severity is decided by the 'A' and 'P' score which is graded as per seriousness of the quality failure. The failures with highest score are the most critical. The recognition of quality failure by the laboratory provides an opportunity for quality improvement through the formulation and prioritisation of corrective action, thereby introducing required changes in the system.

System Adjustment

a. Creation of a culture in the laboratory which actively encourages staff to develop a constructive and critical attitude to work. Also emphasise should be on the identification of quality failure as part of routine working practice to enhance patient safety. There must be positive feed back to ensure that staff remains active.
b. Development of a standard performa for reporting each quality failure which is then systematically investigated

Table 1 Classification of quality failure reporting [12]

Type	'A' score	'P' score
Pre-analytical/analytical/post-analytic	01 No change in patient management: no adverse clinical outcome	01–05
	02 Minor change in patient management but no adverse clinical outcome	
	03 Minor adverse clinical outcome	
	04 Moderate adverse clinical outcome	
	05 Significant adverse clinical outcome	

Table 2 Examples of quality failure reporting

Quality failure	Type	'A' score	'P' score	Action taken
A sample with true potassium of 4.4 mmol/L is reported as 4.1 mmol/L. The quality failure was identified when a series of samples were rerun following wayward Internal Quality Control results later in the day	Analytical	01 As no change in patient management required and no adverse clinical outcome ensued	05 Such quality failure has potential to result in a significant adverse patient outcome in case of hypo/hyperkalemia	IQC one level run if samples < 25; 2 levels if samples > 25 and 2 levels twice a day if samples > 75. IQC should be checked for acceptability before releasing the reports. Such changes to be made in policy and procedure of laboratory's quality assurance program
An incorrectly labeled sample was received by the laboratory (i.e. different patient details on specimen bottle and TRF). The sample was discarded and a repeat sample requested	Pre-analytical	03 Minor adverse outcome because of the requirement of an additional venepuncture	05 Such quality failure has potentially significant consequences that might result from incorrect sample labelling	All the sample received in the laboratory will be checked for labeling put on specimen with the TRF for at least two information—name, age/sex, registration number and ward
Sample labeled as urgent was received by the laboratory. After analyzing the sample, the report was not relayed to the clinician as at that time change of shift between laboratory technicians was taking place. The over for reporting of such urgent sample was not given by the laboratory personnel	Post-analytical	01 No change in patient management as all the reports were in within normal limit	05 Such quality failure has potentially significant consequences on patient management	All the urgent samples will be put for analysis in auto analyzer in STAT mode and the record for urgent reporting is strictly maintained and counter checked by the laboratory-in-charge

and appropriate action is taken to improve the policies, procedures or the laboratory environment.

c. Training and sensitisation of laboratory staff on mechanism of quality failure reporting and the importance of integrating this into the routine work of the laboratory.

Quality failure reporting and its regular monitoring leads to collection of evidence-based metrics which can help not only in improving patient safety but also to optimise measurement and accurately assess laboratory performance (Table 2).

Limitation of Quality Failure Reporting

There are potential barrier at each step of the quality improvement pathway which makes it difficult to use quality failure reporting for root cause analysis. Some of them are [1]:

- Failure to recognise that a quality failure has occurred. It may be because of lack of inquisitive culture in laboratory, laboratory personnel are not sensitised to the fact that quality failure may jeopardise the patient safety and quality failure is considered too trivial to merit reporting etc.
- Failure to report the quality failure to the laboratory-in-charge who is empowered to investigate and initiate corrective action. The reasons of non reporting are complex and various failures did not result in actual patient harm, absence of a formal mechanism for reporting, fear of attracting blame on one self. The person oriented approach to quality failure with an emphasis on apportioning blame will discourage staff from reporting.

Failure Mode and Effect Analysis (FMEA)

Errors occurring in the clinical laboratory may have some potentially severe adverse effects/outcomes for the patients. Laboratory processes are designed on the premise that with adequate training, education and orientation, laboratory personnel will perform flawlessly and nothing will go wrong. Most laboratories have in place process to identify, assess and investigate events that deviate from accepted policy and procedures, thereby tracking and trending incidents, errors and accidents [14]. However, all these process are reactive in nature which come into action once the error has already occurred. Recently, the proactive methods are accepted by the laboratory and clinical staff to reduce the error through risk management and continual improvement in medical laboratories. FMEA, one of the proactive methods for risk management has been accepted as the method of choice in the identification of potential points of failure within a process, their effects being determined and action identified for mitigating failures [15].

FMEA is a method long in use in aerospace industry to productively evaluate the system and product vulnerabilities [2]. FMEA is a new way of looking at high risk process before an error occurs. It is an organised team based method of proactively identifying potential failures so that action can be taken to prevent or minimise the effect of an error. It is a systematic and proactive in identifying ways a process or design can fail, why it may fail and how it can be made safer. FMEAs result in prevention of defects, enhanced safety and an increase in customer satisfaction. It can be beneficial not only in preventing errors in existing system but also in deciding whether to introduce a new process in clinical laboratories [16]. At present, JCAHO has also introduced the new leadership standard in July 2001 (L.D standard 5.2) embracing the FMEA approach to patient safety, that requires department heads in health care organisations to perform it on at least one critical process a year [17].

FMEA Process

FMEA follows the 'system based approach' where primary aim is error prevention by not putting burden on individuals but on the designs of the system in which they work [18]. The FMEA process is a way to identify the failures, effects and risks and then reduce or eliminate them. Three factors determine the relative risk of a quality failure and its effects. First and foremost is 'severity' of the consequence of failure, when it occurred. Second is the 'probability' or frequency of the failure occurrence. Third is 'detection' the probability of the failure being detected before a negative impact is realised.

Steps

FMEA process includes following steps (Table 3) [2]:

Choosing a Process to be Studied

The total testing process is a complex process consisting of multiple steps. The more the steps in the process, there is increased likelihood of unexpected and undesirable outcome.

During this step, the organisation identifies the process for FMEA. The process under study is defined as critical, based on the severity of possible harmful events and its potentially dangerous impact on patient safety. Also, other factors which further help in choosing the critical process are—process having history of adverse patient outcome, identified in the literature as being failure prone, has been identified as sentinel event and is considered high risk for litigation claims.

Formation of Multidisciplinary Team

A team consisting of operator from different discipline dealing in the chosen critical process is identified and assembled. The basic requirement for inclusion of these operator in the team is training in FMEA methodology along with training, specific knowledge and experience of the process to be studied. A team leader is also appointed who can ensure that team members complete each step and record the results of FMEA.

Process Review

Team members define the steps in the process, which is further broken down into sub process. The process is then described in term of what 'actually happens' in daily practice. Based on this, team members create an accurate diagram of the process as it is being currently performed and all the members should be familiar with the flow chart.

Hazard Analysis

This step includes brain storming by the team members to identify failure modes for each step of the critical process. This is followed by listing of potential effects of each failure mode. Then each failure mode effect is rated for its severity, probability and detectability. Conducting a hazard analysis helps team members make an informed decision concerning the way in which a safety patient care process is to be designed. This involves following six activities.

Identifying Failure Modes for Each Step

A failure mode is anything which can go wrong during completion of a step in the process, and during the hand off

Table 3 Steps for FMEA

Step 1: Process review
Step 2: Potential failure modes
Step 3: Potential effects of each failure mode
Step 4: Assign a severity rating
Step 5: Assign an occurrence rating
Step 6: Assign a failure rating
Step 7: Calculate the risk priority number (RPN) for each effect
Step 8: Prioritise the failure modes
Step 9: Take action to reduce or eliminate the high risk failure modes
Step 10: Recalculate the RPN

between steps. It may be due to human factors, equipment problems, communication difficulties, missing supplies or any other error that might disrupt supplies or might disrupt the flow, thereby jeopardising the patient safety. The objective of this activity is to generate dozens of ideas from the brain storming process to identify all potential failure. The idea is to discover everything that may go wrong.

Determining the Potential Effect of Each Failure Mode

The potential effect of each failure mode is determined in terms of its consequences on patient. The effects may be one or several depending on its occurrence early on in the process or later. Failures that occur earlier on the process are more likely to result in process disruption. Similarly, potential failures in the process steps nearest to patient injury or harm. This step should be done carefully as it feeds into the next steps of risk rating.

Rating of Failure Mode Effects

The failure mode is assigned ratings to severity, occurrence and detection based on a 10-point scale, with 1 being the lowest and 10 being the highest.

Rating the Severity of Failure Mode of Effects: A severity rating corresponds to the seriousness of the effect of stated failure. For example score of 10 may be described as dangerously high (likely to result in patient death). A score of 1 would indicate the failure would probably go unnoticed or have no effect.

Rating the Probability of Occurrence of Failure Mode: Based on previous record of quality improvement data available, the team members first determine the probability that each failure will actually occur, then how often it will occur. They also determine the likelihood that each failure will persist throughout the process without being detected and corrected.

Rating the Detectability of Failure Mode: A detection rating looks at how likely we are to detect a failure mode or the effect of the failure.

Identifying the Areas of Greatest Concern (Critical Failure Mode)

To identify priority area which needs the process of improvement more, risk priority number (RPN) or risk probability index (RPI) or criticality index (CI) is calculated for each failure mode. The numeric rating for severity, probability and detectability are multiplied to calculate RPN. RPN can go from minimum of 1 ($1 \times 1 \times 1$) to maximum 100 ($10 \times 10 \times 10$). The failure mode having high RPN value (1–1,000) is addressed first. In general, improvement/intervention is initiated in failure with RPN > 400.

Development and Implementing Action to Reduce or Eliminate the High Risk Failure Modes

An important step in developing the problem solving process is to identify the root cause(s) of the critical failure. The team's goal is to eliminate the risk of failures, reduce the likelihood of failure or mitigate the effects of failure, should it affect the patient. A literature search should be undertaken for benchmarking procedures used to identify the actions taken by other organisations to make processes safer for patients.

Calculating the Effectiveness of Corrective Actions

Corrective action should be directed at the issues of greatest concern according to rank ordering by CI or RPN or RPI score. Once the potential failures in the process detected and the causes identified, specific process redesign solutions can be selected to eliminate or reduce the risk of critical failures. Essentially, three types of process improvement strategies are implemented: The first strategy is designed to eliminate the chance of failure; the second makes it easier for the people to do the right thing; the third aims to identify failures quickly and take appropriate action. The performance data may be reviewed by the FMEA team members to assess how much safer the process has become since implementing the action of recalculating the RPN. It should be significantly reduced or the action taken was not effective in reducing the severity, likelihood of occurrence or detection [14, 17].

Implementation of FMEA in Laboratory Medicine

The use of FMEA in engineering is widespread, in medicine there are relatively few reports available on its active use. The JCAHO has identified some high risk processes

Table 4 Implementation of FMEA in analytical phase

Failure mode	Effect	SI	Cause	PI	Control measure	DI	RPI	Proposed action
Malfunction of reagent	Useless result	9	Expired	3	Check expiration date	1	27	None
Malfunction of reagent	Useless result	9	NC storage temperature	6	Visual check of reagent	10	540	Add temperature monitoring system
Malfunction of reagent	Useless result	9	Contaminated	8	QC before run	10	720	Add QC after run
Malfunction of calibrator	Calibration failure	8	Expired	3	Check expiration date	2	48	None
Malfunction of calibrator	Calibration failure	8	NC storage temperature	6	Visual check of calibrator	2	96	None
Malfunction of calibrator	Calibration failure	8	Contaminated	8	Visual check of calibrator	2	128	Freeze single doses and use once

SI severity index, *PI* probability index, *DI* detectability index, *RPI* risk probability index

such as medication use, use of blood and blood components, restraint use and operative procedures [19]. Implementation of FMEA led to improvement of various processes in laboratory e.g. comparing and validation of analytical procedures [20], labelling of cassettes and slides in histology, manually entering results into the laboratory information system for tests that are not interfaced and cross matching of blood. Review of literature shows that majority of laboratory-related errors occur in pre- and post-analytical phases of the testing process [9, 21]. The most critical area identified in total testing process, having failure potential are failure to order the appropriate tests, failure to act on the results of tests. Southard et al. [22] used modified Delphi Methodology to conduct FMEA in total testing process to reduce medical errors.

Few areas where application of FMEA was undertaken in the laboratory medicine and data of the same available in literature are blood cross matching process, analytical processes of clinical chemistry tests—glucose, total cholesterol, total bilirubin. In analytical processes FMEA was applied for non conforming storage temperature, contaminated reagents and contaminated calibrators.

Capunzo et al. [15] implemented FMEA method on three analytical processes of a clinical laboratory—glucose, total cholesterol and total bilirubin (Table 4). In this study analytical process only and not the pre-analytical and post-analytical phases, has been drawn, and, on its basis, have been reviewed and classified all the failures/NC observed for the analyte. After analysing the testing process the team identified function of each component of the analytical process, including reagent, sample, calibrator and instrument. For each component of the analytical process, the effects of the component's failure on the final result of the process identified were malfunctioning of reagents and calibrators. In next step, severity index (SI) value (1–10) were assigned to each failure mode effect. SI assigned to the malfunctioning of reagents was '9', as a malfunctioning reagent, not discovered in time, can produce an analytical result useless or dangerous for the patient. In the case of malfunction of calibrator, the assigned SI value was '8', as the malfunctioning of calibrator makes impossible to execute the analytical run and usually alerts the operator to check the calibrator and/or repeat the calibrator run. To each failure mode an effect was linked to its possible causes. The causes identified were non conforming storage temperature, expired or contaminated reagents and calibrators. The probability index (PI) was then determined on the basis of the frequency of each failure/NC. In this study, the PI of expiration of the reagent or the calibrator was '3' because the internal procedure followed in the laboratory in which the study was conducted, was to eliminate the reagent/calibrator the week before its expiration. So there was a very low likelihood to find an expired reagent or calibrator in use whereas the PI of contamination of the reagent was '8' because its frequency in failure/NC review was approximately 1 %. In next step, the control measure for each cause failure was undertaken. Then each couple 'failure-cause' has been assigned a value of detectability index (DI) (1–10). This index is assigned according to the capability to keep the user from receiving a non conforming product and the perception of the defect from the user. The values range from 1 (the user does not receive non conforming product or does not notice the effect) to 10 (the failure/NC is not detectable, so the user will suffer all its consequences). In next phase, RPN was calculated, by multiplying SI × PI × DI. In the study, RPN value ranged between 27 and 720. The improvement actions were designed and implemented as preventive actions, according to the quality management

system (QMS) applicable procedure and their impact were analysed in terms of RPN point reduction. After analysing the entire testing process, improvement action taken were designed, implemented and reviewed to assess the impact of these actions on the failure mode which is as follows:

1. *Non conforming storage temperature* The improvement action regarding this failure/NC reduced the RPI from 540 to 180.
2. *Contaminated reagents* In this, RPI reduced from 720 to 189.
3. *Contaminated calibrators* In this failure/NC, reduction of RPI from 128 to 96 was obtained.

More generally, FMEA technique has been used as an instrument of risk assessment in the cases in which the human intervention is involved, considering that the phases in which the human intervention is involved are the riskiest points of a process. Application of FMEA in the laboratory is a proactive way of evaluating high risk processes prone to failure before an error occurs. By assuming and compensating for less—then—perfect human performance, FMEA promotes error prevention through back up systems and designed redundancy. To improve patient safety, one must apply FMEA in high risk processes in the laboratory [2].

Conclusion

Medical laboratories play a pivotal role in the diagnosis and management of patient. With approximately 60–70 % of medical decisions related to diagnosis and treatment involve laboratories; quality failures in laboratory medicine have potential to jeopardise patient safety. Hence, laboratories have been at the forefront to enhance patient safety. With increased automation in manual processes occurring in laboratories, reduction has been observed in quality failure rate in last 10 years. However, it mainly focussed on the analytical phase. Hence, in addition to advancement in technology, there is requirement for vigilance among laboratory personnel regarding prompt reporting of possible quality failures followed by investigations. Such systemic approach seeking identification of weakness in total testing process followed by correction in policies and procedures require openness among laboratory staff, rather than to apportion blame to individual staff members. Hence, it is important for all laboratories to identify quality failures, classify it by cause (i.e. pre-analytical, analytical, post-analytical) followed by grading the seriousness of quality failure. Classifying the quality failure directs the attention to the step in total testing process requiring scrutiny and is useful for monitoring the quality performance and grading helps in prioritising the corrective action.

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