

# Pre-Analytical And Post-Analytical Errors In The Clinical Laboratory: A Systematic Review

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DOI: 10.47750/pnr.2022.13.S09.1004

## Abstract

In the present medical scenario, the detection of various diseases is largely dependent on tests performed in the medical Clinical Laboratory. That means a treatment procedure depends largely on the test results provided by the laboratories. There are three phases in any sample testing procedure. These are the pre-analytical, analytical, and post-analytical phases. As human intervention is indispensable, there remains a chance of human error at any phase of the above-mentioned three phases. Although the laboratories work skilfully and use modern tools and equipment, the testing processes are not full-proof. There remains a chance of misdiagnosis leading to wrongful treatment. Laboratories should be safe for patients and health services providers.

Clinical laboratories are focused on the quality of services they impart and quality testing methods to handle the analytical parts of the testing procedures as perfectly as possible. However, several studies and evidence accumulated in recent times have demonstrated that merely focusing on the accuracy of the diagnostic aspects cannot assure the quality and accuracy of laboratory testing results in clinical laboratories. In some more recent surveys on the same subject, it is revealed that mistakes occur more frequently in the pre-analytical and post-analytical phases. Mistakes are comparatively less in the analytical stage.

**Keywords:** analytical errors, Training, post-analytical errors, pre-analytical errors, Rejection of Sample

## I. INTRODUCTION

Modern technology has helped to automate laboratory testing procedures in many ways. Laboratories collect and manage a pool of data through their computerized process of laboratory testing reports. The quality of diagnosis today is largely dependent on the skillful application of modern technologies and the integrity of laboratory data. Remarkable progress has been made in sample

collection, transportation, testing, automation, and report generation. Today the laboratories are operating with more perfection [1], still lots of technical and non-technical issues surface [2, 3].

Laboratory error can be defined as, “A defect occurring at any part of the laboratory cycle, from ordering tests to reporting results and appropriately interpreting and reacting on these” [2, 3].

Conventionally, laboratory practices can be divided into three broad phases – pre-analytical, analytical, and post-analytical. Each of these phases is distinct and can be monitored separately for quality checks. In recent times, it is mentioned in most of the articles in this domain that maximum errors occur in the pre-analytical and post-analytical phases [4]. That error can be anything between 0.1 to 9.3% which can influence outcomes and result in erroneous reports [5].

It is observed that the pre-analytical phase is a huge challenge to laboratory professionals [6]. The study of Plebani M. and Carraro P. shows that the error in the pre-analytical phase ranges between 49-73% while in the post-analytical phase the error remains within 38-66% [7]. The study of Goswami et al. shows that the pre-analytical error remains around 7% while the post-analytical error ranges around 15% [8]. As per some recent articles published across the globe, increasing attention to health care and greater dependency on laboratory results have decreased laboratory errors significantly [9,10].

The right and timely treatment is the primary requirement of a hospital setup. The clinical laboratory plays a vital role in offering the best possible results to hospital patients [11]. Accurate laboratory results are essential for the proper diagnosis of a disease and corresponding patient care or treatment. Error at any phase of laboratory testing may lead to a wrong diagnosis. This has a profuse negative impact on the patients and overall health services of a hospital setup [12].

In a typical clinical laboratory, the complete testing process includes several parts. It starts with the test request and ends with the delivery of the test results. The laboratory testing procedure can be divided into three segments broadly. These are called the three phases of the laboratory testing procedure.

The first phase is called the “pre-analytical phase”. This phase is again segregated into several sub-phases. According to the International Standardization Organization (ISO) 15189:2012, these sub-phases include test requests, sample collection, sample registration, and sample transport to the laboratory.

The second phase is called the “analytical phase”. This phase includes procedural analysis of the sample collected from a patient and targeted tests. The technical validation of the results is also undertaken at this phase.

The third and last phase is the “post-analytical phase”. This phase comprises three sub-phases such as result interpretation, lab manager’s approval, and report delivery to the clinician.

Laboratory errors may occur at any time at any of these phases. Errors can also occur during the analytical phase. The consequence of such errors can be anything such as prolonged hospital stay of the patient, misuse of resources, and inappropriate clinical diagnosis and interpretation [13].

Accuracy in the clinical testing procedure is vital for the correct diagnosis and correct treatment procedures for the patients. Several studies have shown that more than 70% of treatments depend on diagnostic results [14]. Modern medical science is mostly evidence-based that focuses on accurate and systematic laboratory tests and reports. With the growth of computerized automated testing procedures in the analytical phase and also in the report generation and delivery (post-analytical phase), errors in the laboratory testing procedure have been reduced to a good extent. However, the focus on accuracy in the pre-analytical and post-analytical phases is lesser than needed. The study of Plebani et al. [14] shows that maximum errors occur in the pre-analytical and post-analytical phases. Several studies have found more than 60% errors in the pre-analytical phase [15, 16].

Keeping this study in focus, this study aims to determine the nature and extent of pre-analytical errors along with the effect of training on phlebotomists.

## II. REVIEW OF LITERATURE

**Table 1: Error types and error rates in the three Stages of the Laboratory Testing Process [17]**

Phase of Total Testing Process	Type of Error	Rates
Pre-analytical	Inappropriate test request	46%–68.2%
	Order entry errors	
	Misidentification of patient	
	Unfitting/ Inappropriate Container	
	Problems in sample collection and transportation	
	Inadequate sample/anticoagulant volume ratio	
	Sample quantity/volume low	
	Categorization and routing errors	
Labeling errors		
Analytical	Equipment malfunction	7%–13%
	Sample mix-ups/interference	
	Unobserved failure in quality control	
	Unauthorized procedure	
Post-analytical	Inappropriate reporting	18.5%–47%
	Erroneous validation of analytical data	
	Inappropriate data entry	

**Table 2: The descriptions of the included studies conducted on pre-analytical and post-analytical errors**

S.N.	Author	Sample size	Year	Pre-A N (%)	Post-A N (%)	Laboratory section
1	Rizk MM, et al [18]	32, 999 demands and 50,440 samples	2014	13,067 (5.2%)	4,540 (16.4%)	Clinical Chemistry

S.N.	Author	Sample size	Year	Pre-A N (%)	Post-A N (%)	Laboratory section
		(252,200 Pre-A and 27,612 Post-A QIs)				
2	Sharaki O, et al [19]	513 RWS (8,436 Pre-A and 1,568 Post-A QIs outcomes)	2014	3,684 (43.7%)	487 (33.3%)	Clinical Chemistry
3	Addis Z, et al [20]	1,533 RWS (21,462 Pre-A QIs)	2015	6,227 (29%)	N/A	Clinical Chemistry and Hematology
4	Wondimagegn MW, et al [21]	754 RWS (7,540 Pre-A QIs)	2016	751 (10%)	N/A	Hematology and CD4
5	Kimengech KK, et al [22]	346 RWS (5,536 Pre-A and 4,844 Post-A QIs)	2017	148 (2.7%)	84 (1.7%)	Clinical Chemistry
6	Ambcahew S, et al [23]	3,259 RWS (948,885 Pre-A and 9,777 Post-A QIs)	2018	3,379 (6.9%)	291 (3%)	Clinical Chemistry
7	Tadesse H, et al [24]	1,633 RWS (17,570 Pre-A and 8,165 Post-A QIs outcomes)	2018	4,337 (24.7%)	104 (1.3%)	Clinical Chemistry
8	Isa HA, et al [25]	15,287 RWS (259,888 Pre-A QIs)	2018	46,413 (17.9%)	N/A	More than 2 Lab sections

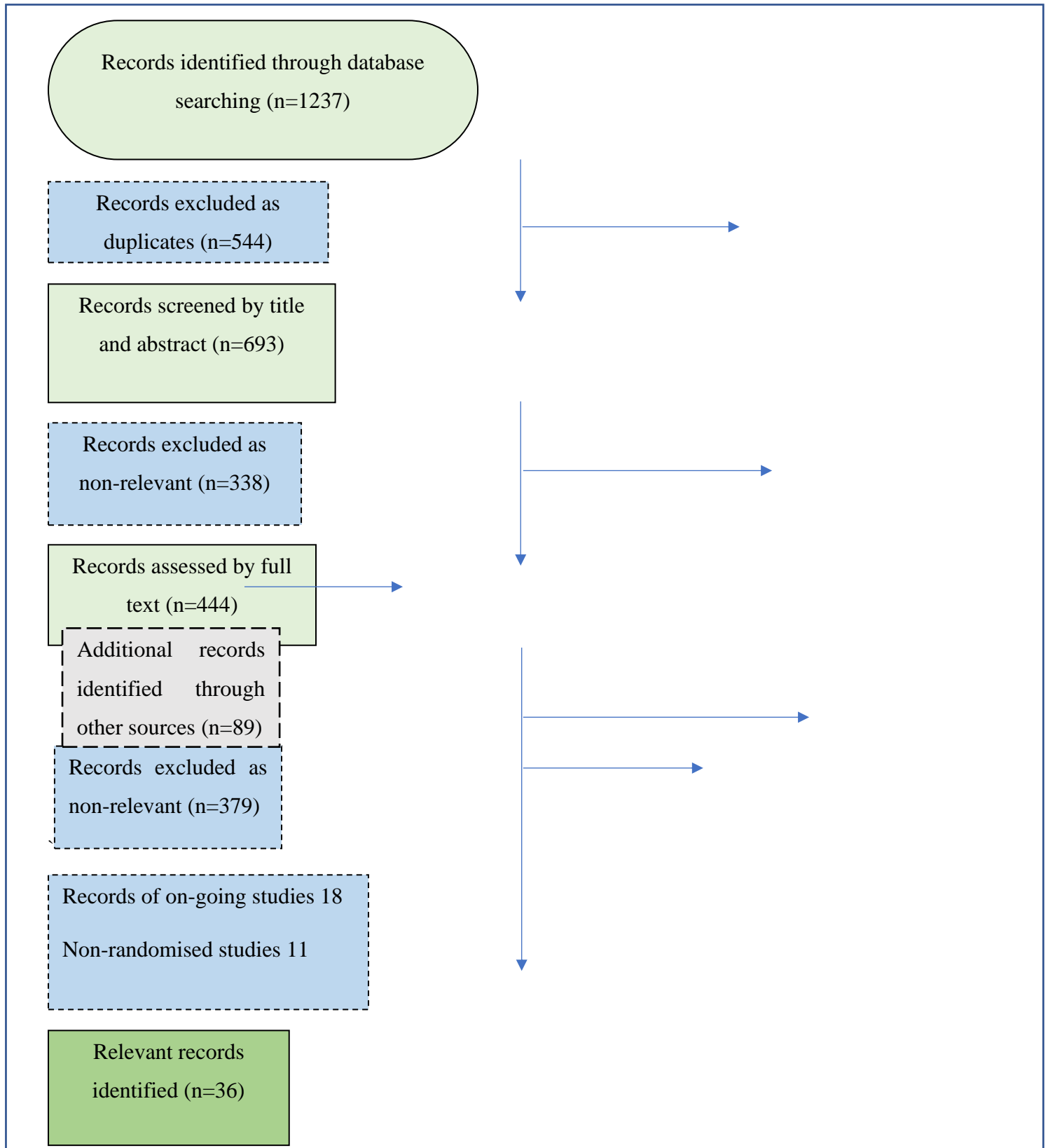
**Table 3: The details of the included studies conducted on sample elimination in clinical laboratories**

S. N.	Author	Year	Study design	Study period	Sample size	Sample rejection N (%)	Laboratory section
1	Jacobsz LA, et al [26]	2011	Retrospective	2 wks.	32,910	481 (1.46%)	Clinical Chemistry and Hematology
2	Rizk MM, et al [18]	2014	Comparative cross-sectional	7 mos.	50,440	2,314 (4.6%)	Clinical. Chemistry
3	Tesfaw HM, et al [27]	2015	Cross-sectional	16 mos.	8,063	116 (1.44%)	More than 2 Lab sections
4	Jegade F, et al [28]	2015	Retrospective	3 yrs.	7,920	22 (0.28%)	More than 2 Lab sections
5	Shiferaw MB, et al [29]	2018	Retrospective	22 days	42,923	221 (0.5%)	More than 2 Lab sections
6	Ambcahew S, et al [23]	2018	Cross-sectional	2 mos.	3,259	123 (3.8%)	Clinical Chemistry

**Table 4: The descriptions of the included studies conducted on LRF (laboratory test request form) incompleteness in clinical laboratories**

S.N.	Author	Year	Sample size	Incomplete LRF	Laboratory section
1	Nutt L, et al [30]	2008	2,550 LTR (38,250 total Qis)	5,818 (15.2%)	Pathology
2	Zemlin AE, et al [31]	2009	482 LTR (3,856 total Qis)	873 (22.6%)	Pathology

<b>S.N.</b>	<b>Author</b>	<b>Year</b>	<b>Sample size</b>	<b>Incomplete LRF</b>	<b>Laboratory section</b>
3	Atewu A, et al [32]	2014	960 LTR (7680 total Qis)	1,434 (18.7%)	More than 2 Lab sections
4	Rizk MM, et al [18]	2014	31, 944 LTR (223,608 total Qis)	10,753 (4.8%)	Clinical Chemistry
5	Sharaki O, et al [33]	2014	514 LTR (3,598 total Qis)	366 (10.2%)	Clinical Chemistry



### III. QUALITY STANDARDS

Laboratory medicine needs to uphold the highest standard of medical including clinical practices. The rules and regulations in the healthcare sector are quite procedural and strict. It is based on several aspects such as quality monitoring, certification from

appropriate authorities, monitoring the standard operation processes, and setting standard healthcare. As a result, laboratory employees must strive to minimize mistakes in order to assure accurate and exact report output from the Clinical Chemistry Laboratory. Following data collection, the pre-analytical factors responsible were identified and classified. After considering each variable independently and analyzing the reasons of these mistakes, laboratory employees were advised on how to prevent them [34]

Collecting blood in suitable vacutainers that are immediately recognized by color labeling would help eliminate the possibility of inaccurate results owing to an improper volume of sample reaching the laboratory [35].

#### IV. ANALYTICAL ERROR

The “analytical phase” is composed of several steps such as the preparation of the sample for testing, interpretation of the results received from testing, and verification of the results of testing by an approved laboratory operator.

The tests result in this phase may be affected if the specimen is not processed properly or if there is any unwanted substance present in the assay. Faulty techniques, faulty instruments, reagent contamination, and calibration issues can also interfere with the laboratory testing quality and results.

Several methods are adopted in the analytical phase to verify the authenticity and capability of the testing procedures. These verification procedures can check the precision, accuracy, sensitivity, and linearity of the adopted method for certain laboratory testing procedures.

The “analytical phase” starts when the specimen of a registered patient is prepared for laboratory testing and it ends when the authorized technologist verifies the results and approves.

A specimen needs to be processed properly before the analysis. Detection of substances that can interfere with the assay performance is also important. Establishing a test method and verifying its performance is important in the analytical phase.

Clinical laboratories spent years improving their analytical qualities and adopting the best practices in this domain. They try to establish the “Internal Quality Control” (IQC) and “External Quality Assessment” (EQA) at their best. In this context, the role of “Proficiency Testing” (PT) is worth mentioning. PT helps in establishing the appropriateness of an analytical process, and the competencies and accountability of the service providers. The efficiency of the laboratory professionals is to correctly analyze EQA or PT samples and related reports. They are also accountable for investigating the primary causes of deteriorating performance, detecting the trends or biases that may not be detectable in a single test, and above all finding whether the problem that occurred during verification is affecting the clinical decisions.

#### V. PRE-ANALYTICAL ERROR

Pre-analytical errors are the errors that occur at the pre-analytical phase of clinical testing. It can be during the patient assessment, patient identification, specimen collection from patients, specimen transportation from one destination to another, or specimen registration in the laboratory. Collection test sample from a wrong patient or asking for the wrong tests are not usual either. Other examples of errors in this domain include the misidentification of patients, the use of inappropriate containers, and inappropriate labeling of the containers. The literature review shows that pre-analytical errors range between 31.6% to 75% of total laboratory testing errors. Several strategies have been developed to detect these errors. These strategies include regular training for the health workers, automation of the steps in this phase, improving communication channels, and regular checking of quality indicators.

The pre-analytical phase of laboratory testing is the phase where a maximum number of errors occurred and are detected. A study by Bonini et al. [36] shows that pre-analytical errors predominate the laboratory testing processes and it ranges between 31.6% to 75% of overall testing errors.

Chawla et al. conducted a study in a clinical laboratory for one year from April 2008 to March 2009 to find the extent of pre-analytical errors in the testing processes for both inpatients and outpatients. The study found that pre-analytical error for inpatients was 1.9% while it was 1.2% for outpatients.

A plan to prevent pre-analytical errors possesses five interrelated steps:

1. Developing a comprehensive and clear procedure that is elaborately written in understandable language.
2. Increasing the professional and need-based training of the health care professionals.
3. Automating the functions wherever possible, especially the repetitive functions that would include both support operations and executive operations.

4. Regular monitoring of the key quality indicators.
5. Enhancing the communication processes and communication channels that health care professionals use regularly for professional purposes.

The comprehensive written procedure must clarify the phases and provide unavoidable guidelines to health care professionals. It would indicate the identification procedure for a patient, collection procedure, labeling procedure, and transportation procedure to be followed. The health care professionals being a part of the pre-analytical phase should have a clear understanding of the whole procedure and must follow the written procedures. They should have a clear idea of what could happen if the procedures are not followed and errors occur. There must be regular training for everyone related to the system. At the same time, their competencies need to be assessed from time to time.

Automation is a good choice for reducing pre-analytical stage errors. Modern robotics and IT are effective in reducing errors at this phase. Computerized order entry and sample identification can reduce human intervention as well as errors at this level. An automated phlebotomy tray can carry a set of labeled blood samples. Barcodes on the samples also ease the transportation from one stage to another. It also simplifies the sample tracking process.

Several advances in laboratory-related technology have made serum indices detection easier and faster with complete accuracy. It also eases the hemolysis indexing. Visual identification of hemolysis must be obsolete now. Its sensitivity and reproducibility are low. Lab personnel may ask for a new set of samples when hemolysis is noticed. In absence of new samples, lab personnel may take the matter to the clinician. The serum indices data can be used to observe the features of the sample collection process.

## VI. POST-ANALYTICAL ERROR

The mistakes or fault that happens after the reports have been generated till the time they are delivered to the patients are known as post-analytical errors. Most of the time they happen as a result of mistakes in transcription, giving them to the wrong patients, or even misplacement of reports. This is a very important stage where the results are given to the experts of the clinic so that they can use them to make proper diagnostic findings and decide on best-suited treatment procedures. The post-analytical error can affect the reputation of the laboratory to a huge extent.

The results which are attained out of medical investigation are released to doctors in the clinic where they use them to make a final diagnosis of the condition and determine the medical treatment which must be given to the patient. This is the post-analytical phase.

Piva and Plebani in their article have given a complete review of the several current efforts which are being done to improve the consensus on the notification and definition of the critical values of the laboratory. Currently, efforts are being given to enhance clinical outcomes and also increase the safety of the patients. The article throughout its scope discusses the aspect of automated notification which is much more dependable and can improve the quality and punctuality of communication. This is one of the best ways through which major errors can be avoided.

## VII. INCIDENT REPORTING IN LABORATORY DIAGNOSTICS

On one hand, if major contributions are being made to oversee the pre-analytical phase and offer dependable solutions, it is quite surprising that so far no concrete programs have been initiated for incident reporting. Maximum attention in the context of Healthcare is given to incident reporting in different medical ailments and much less effort is given to translate this important practice into laboratory findings. As a matter of fact, it can be said that due to under-statement related to laboratory finding errors, the revelations from the current statistics show a very small portion of the mistakes which are happening in the medical domain currently. The need to create a policy of recording Errors is really very urgent. It can be done through the process of information support and through 'Laboratory Sentinel Events'. All through the process of testing it will allow us to gain significant data about the grave incident and will also help to bring greater accountability both amongst the stakeholders as well as the providers. This overall process will lead to greater safety for the patients. Many of these have already been recognized which will include an appropriate request for tests and misidentification amongst patients. There have also been instances of very serious analytical mistakes, tests that have been done with unsuitable samples, very poor quality control on lab procedures, and the failure to create critical values in the laboratory procedures. In this context, the ICPS or the International Classification for Patient Safety which is a drafting group of the World Health Organization has come up with a conceptual design that can help to find diagnostic errors.

Experts in the domain have clearly pointed out that TQM or Total Quality Management system and its rigorous implementation is the only effective way through which errors in laboratory procedures can be arrested. In this context, 3 actions have been suggested which include the prevention of adverse course of events, making them as visible as possible, and mitigating the problematic consequences when the error has already occurred.

Certain other approaches can also be taken up to prevent mistakes. The Failure Mode and Effect Analysis is a procedure that has been accepted as an effective risk management approach. It is one of the most systematic procedures which help to identify the potential failures which can happen before they really occur. The main aim here is to eradicate such chances from the very root and minimize the risk factor as much as possible.

## VIII. CONCLUSION

To enhance the safety of the patient greater emphasis must be put on reporting, analysis, and preventing errors which can often result in a very serious course of events. They will not only affect the health of the patient in a very severe manner but such errors can also lead to a big loss of money from both the international and the national economy. Major progress has been made in this domain from the time of the release of 'To Err is Human'. The main thing that has changed is the eagerness to realize the difficulty and not put up a fight related to the numbers. Now greater appreciation is being given to the care that must be given to keep each patient safe and comfortable. This point of view has eventually resulted in major changes in Healthcare organizations as well as their cultures. These changes have now made people realize that medical mistakes are not inevitable but they are incidents that can be realistically streamlined and effectively prevented.

Although major improvements have emerged in this domain we should not become complacent about the whole thing. Even now there is a lot of room for improvement and better quality control procedures.

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