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The Incidence and Evaluation of Quality Indicators for Patient Safety Across the Total Testing Process in the Clinical Laboratory

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Abstract:

- ***Introduction:***

Quality indicators (QIs) are useful evaluation tools that enable the identification of clinical laboratory performance levels and can be used to assess critical healthcare dimensions depending on the objective measures. Standardized and recognized QIs are used to monitor clinical laboratory errors and to manage the risk in diagnostic testing (Grecu et al., 2014, as cited in Alshaghdali et al., 2022).

- ***Aim:***

The aim of this secondary research is to review the frequency of clinical laboratory errors and to determine the need to continually conduct critical research on the analytical stage even in the phase of automation and modern technologies.

- ***Method:***

Literature searches were conducted through Google Scholar, PubMed, Scopus and Scielo to retrieve studies published from 10 years ago but only 9 studies from year 2020 were used for the analysis. Critical Appraisal Skills Program (CASP) tool was used to select the studies based on predefined criteria.

- ***Results:***

The 100 studies retrieved from literature, 30 of them were included in the study and 8 were selected for the review. Most of these studies were excluded because they were studies done on only preanalytical errors. Among the errors found, 57.0%- 98.4% were analytical errors, 0.5%- 8.0%, analytical, and 1.1%-17.9%, post-analytical. Pre-analytical errors showed the highest rates while analytical and post-analytical show variations in their rates. Studies that considered non-conformances in their studies show that preanalytical errors were 18% and 53.3%, analytical were 41% and 43%, and post analytical were 3.19% and 41%.

- ***Conclusion:***

The low rate of analytical errors in these studies has been attributed to high rate of non-conformances in this stage. There is the need for critical documentation of incidents and rigorous research in the analytical stage in order to guarantee quality improvement in the clinical laboratory.

Keywords: *Preanalytical Errors, Analytical Errors, Post-Analytical Errors, Total Testing Process, Non-Conformances, Clinical Laboratory.*

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I. INTRODUCTION

Quality indicators (QIs) are measures that indicate output quality. They are useful evaluation tools that enable the identification of clinical laboratory performance levels and can be used to assess critical healthcare dimensions depending on the objective measures. To monitor clinical laboratory errors and to manage the risk in diagnostic testing standardized and recognized QIs are used. (Grecu et al., 2014, as cited in Alshaghdali et al., 2022). About 60-70% of all diagnosis is made based on clinical laboratory tests and so quality in the laboratory has a significant impact on diagnosis and patient care

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even with minor clinical laboratory errors (Badrick, 2013, as cited in Patel et al., 2026). Laboratory errors has been defined as "failure of planned action to be completed as intended, or use a wrong plan to achieve an aim, occurring at any part of the laboratory cycle, from ordering examinations to reporting results and appropriately interpreting and reacting to them (International Organization for Standardization, 2008 as cited in Abdollahi et al., 2014). Reducing errors and adopting a quality control system is a priority in clinical laboratories since patients' treatments are directly affected by the information reported by clinical laboratories.

World Health Organization (WHO, 2023) has published these key facts that injuries or patient harm occur in every 1 in 10 patients in healthcare. It has been noted that above 50% of harm is preventable and that diagnostic errors are included in the common adverse events that may result in avoidable harm (WHO, 2023). According to Alshaghdali et al. (2022) "studies have shown that pre-analytical errors account for as much as 70% of total laboratory errors, 7% to 13% are analytical errors and post-analytical errors range from 20% to 50%. Apart from increasing health care costs and wastage of resources for laboratories, laboratory errors negatively affect patient satisfaction by influencing quality of patient care" (p.1).

Advancements in science and technology have been reported by Grecu et al. (2014, as cited in Mehndiratta et al., 2021) to have helped significantly to reduce, if not eliminate, the errors occurring in the analytical and postanalytical stages of the total testing cycle in the clinical laboratory, owing to development in automation and related technologies. This has led to global focus on studies on preanalytical and post-analytical errors. However, there must be continuous monitoring since these come with other challenges (Al-Fehaid et al., 2024). The development of external quality assurance programs (EQA) and improved rules for internal quality control (IQC) were provided in reaction to findings from studies that concentrated only on the analytical phase (Plebani et al., 2015).

Biosero, a reputable company that deals in lab automation, highlighted that significant proportion of errors can be made during the analytic stage. (Biosero, 2026). To be followed at all phases are as stated by León Bajaña et al. (2024) are strict quality control protocols, including equipment maintenance and calibration, as well as ongoing staff education (Mohammed (2024) in order to optimize automation.

The objective of the study is to identify the current findings and gaps in studies done to determine the rates of errors in analytical, pre-analytical and post-analytical stages of the total testing process in the clinical laboratory and to determine the need to continually conduct critical research on analytical errors to monitor the analytical stage. Analytical quality has been indicated based on existing evidence to remain a major issue in the phase of automation and modern technologies and that the rate of this error is variable and probably underreported. The low rates in analytical errors could be due to failure to document non-conformances or errors in the clinical laboratory (Pienaar et al., 2024).

The research question was: Is there a need to continually conduct critical research on analytical errors to monitor the analytical stage in the clinical laboratory in the phase of automation and modern technologies? Looking into this topic will help in the improvement of safety and quality in the clinical laboratory and will lead to positive effect on overall medical care and patient satisfaction. This study is secondary research which will determine the frequencies of errors across the total testing process from published studies, identify the gaps in current studies using secondary analysis through integrative review, and the need to equally monitor the analytical stage alongside the pre- and post- analytical stages of the total testing process (TTP).

II. LITERATURE REVIEW

Clinical laboratory processes from the reception of the sample to the issuance of the final report is known as the total testing process (TTP) which includes the pre-analytical, analytical and post-analytical stages (León Bajaña et al., 2024). Pre-analytical errors are defined as "errors occurring from physician order to analytic phase, including test request, patient identification, collection, transportation, and preparation for analysis" (Abdollahi et al., 2014). Analytical errors are defined as "errors that occur during the test, and include equipment malfunction, sample mix-ups, interference, undetected failure in quality control, and procedure not followed." (Abdollahi et al., 2014). Postanalytical errors are errors that "happen after the test is conducted, and include failure in reporting, erroneous validation of analytical data, improper data entry, and excessive turnaround time" (Abdollahi et al., 2014).

The goal for patient safety is zero errors, and laboratory professionals having made numerous efforts to reduce errors in the last few decades, "current research into laboratory-related diagnostic errors highlights that errors occur at every step of the TTP, and thus despite the improvement strategies adopted, analytical quality remains a challenge" (Sciacovelli et al., 2016, as cited in Plebani et al, 2021). Despite the benefit obtained from automated systems they are not always reliable, and when automation errs, humans must engage in error management, which is the process of detecting, understanding and correcting errors (McBride et al., 2014).

Current studies are more focused on pre-analytical errors in the clinical laboratory processes which are evident from review of published research. Aita et al. (2017) pointed out the requirement of ISO 15189:2012 to use quality indicators (QIs) to monitor and evaluate all steps of the total testing process. Grecu et al. (2014, as cited in Alshaghdali et al., 2022) and Mehndiratta et al. (2021) also emphasized the need of a comprehensive set of indicators that considers all phases of the total testing process (TTP) and concentrates on the areas that have important effect on patient care and their health outcomes

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to be selected when assessing the quality of the laboratory service for systematic and consistent data collection and analysis. It was shown by Al Naam et al. (2022) that the automated laboratory produced far more tests per staff compared to the non-automated laboratory and in addition to productivity achievements it permitted the use of same number of staff to handle much higher work. This should give staff more opportunities to be able to have good human oversight over automation and to monitor the analytical stage.

Chaudhry et al. (2023) concluded in their study that even though there is increase in automation in the clinical laboratory, errors still occur that can affect patient care and management. The complexity of the clinical laboratory process thus needs a more comprehensive approach that considers a wide range of contributing factors and potential failure points as emphasized by (León Bajaña et al., 2024). The study conducted by Chaudhry et al. (2023) grouped the papers observed into quality improvement (QI) and quality control (QC) and found that the majority of errors in the QI papers were pre-analytical errors, 12 out of 19 papers (63.16%) while the majority of errors in the QC papers were analytical errors, 28 out of 33 papers (84.85%). They attributed this to the QI procedure measured or the focus of the reviewed papers in each group. The QI papers assessed interventions that involve direct human contribution while the QC papers assessed interventions which were more of analytical context.

Another study conducted by Pienaar et al. (2024) at the NHLS in Gauteng, South Africa reported that most non-conformances detected by the study were in the analytical phase which contradicted with several published worldwide findings which concluded that most errors occur in the pre-analytical phase followed by the post-analytical phase (Osegbe et al., 2013, as cited in Pienaar et al., 2024). The findings of their study showed that the findings in other literature could be due to increase in non-conformance documentation in the analytical stage and the retrospective study approach as compared to other studies' prospective and observational approaches. They linked these non-conformances in the analytical phase to the review of internal QC data, adherence to equipment service and maintenance schedules, and problems with administration which supports the findings of Chaudhry et al. (2023). Analytical errors were found by Alghamdi (2024) to be less frequent but critical and were mostly due to equipment malfunctions. Non-conformances occur when there is a deviation from accepted standard methods or protocols across all stages of the TTP and laboratories are mandated by ISO 15189:2022 to identify, document and manage non-conformances (Patel et al., 2026).

Cepull (2025) indicated that valid test results of clinical laboratory and its credibility are enhanced when conformance procedures are followed. Cichocki (2025) also added that the checklist for clinical laboratory quality and assurance which involves monitoring and assessment includes the documentation and immediate correction and preventive actions of non-conformance which should be adhered to. The failure to do this could have resulted in limited dataset for current studies as argued by Pienaar et al. (2024).

The Agency for Healthcare Research and Quality (AHRQ, 2025) has therefore highlighted the need to assess the role of technology in influencing rates of wrong diagnoses and to evaluate whether current measurement approaches are adequate to define and assess wrong diagnoses with sufficient accuracy. There cannot be improvement of quality without its measurement in the clinical laboratory although quality improvement has been made routine procedure in the daily clinical laboratory process (De Guire et al., 2026). They related measurement of observed outcomes to the procedure used for collecting data and on staff contribution.

The published studies that were retrieved from literature searches show that analytical errors continue to occur in the laboratory despite the use of modern technologies in the clinical laboratory to improve analytical quality. The difference was however seen in studies that considered non-conformances. Focusing on studies that monitor analytical stage and post-analytical stage in addition to the pre-analytical stage which is currently having global focus, and considering the broader non-conformances could reveal some missed errors which could be corrected and used to improve quality in the clinical laboratory (AHRQ's Patient Safety Indicators, 2025; Alshaghdali et al., 2022; Bajaña et al., 2024; Pienaar et al., 2024 and Plebani et al., 2021).

This secondary research will review and identify the frequencies of errors in the total testing process (TTP) in the clinical laboratory from published studies. The study further seeks to identify the role of health professionals' continuous education and the role of management to minimize laboratory errors, thereby contributing to laboratory performance improvement. It will also provide recommendations for the improvement of quality in the clinical laboratory test. Literature was searched from published studies across the globe using significant databases for secondary analysis, and selection was based on the research question and the inclusion criteria. A relevant appraisal tool was used to perform a qualitative evaluation of the findings retrieved.

➢ *Aim*

The aim of this secondary research is to review the frequencies of analytical, pre-analytical and post- analytical errors in the clinical laboratory using data obtained from published studies on quality indicators for patients' safety in the clinical laboratory and to determine the need to continually conduct critical research to monitor the analytical stage in the phase of automation and modern technologies.

➢ *Objectives*

- To review and determine the frequencies of pre-analytical, analytical and post-analytical errors in the clinical laboratory from published studies.

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- To identify the gaps present in current studies done on errors in the clinical laboratory across the globe.
- To determine the need to continually conduct critical research on analytical errors to monitor the analytical stage in the clinical laboratory despite the implementation of automation and modern technologies.

➢ *Initial Selection Criteria*

The studies chosen to be included in the literature review initially were based on the criteria that they were written in English language, were peer-reviewed original research and published in the last 10 years only.

➢ *Search Strategy*

The databases that were used for the literature search are Google Scholar, Scielo, PubMed, and Scopus. Reference lists of relevant articles were also reviewed. The literature was search by hand. 100 records were initially identified in databases from the review, with 55 from Google Scholar, 40 from PubMed, 2 from Scielo and 3 from Scopus. 70 studies were excluded because they were studies done on only pre-analytical errors or not related to the topic (Figure 1). The selected articles included 30 studies (Figure 2). Google search was used to obtain technical information and expect discussion; 3 articles were retrieved for this purpose.

➢ *Study Selection Procedure*

Various literature sources were searched for secondary analysis using an integrative review that was conducted to gather and synthesize relevant information obtained from studies retrieved from these sources. A deeper insight of the topic was obtained from the diverse data sources. According to Kutcher and LeBaron (2022), the complexity of the search and evaluation in integrative review and the various sources used increases the demand to produce a well written review that can be used to improve medical practices which are based on evidence. The guidance proposed by Kutcher and LeBaron (2022) was used as the process for the integrative review.

The first step of the review was the formulation of the research question: Is there a need to continually conduct critical research on analytical errors to monitor the analytical stage in the clinical laboratory in the phase of automation and modern technologies? The next step was to develop the aims and objectives to guide the stages of the process. A thorough and diverse search strategy was used to identify and include articles. The articles included empirical and observational studies. The inclusion criteria used was a critical one to select the relevant literature. The studies selected were related to the topic, published in English, available in open-access and peer-reviewed. Reference lists of relevant articles were used in addition to the databases used which included Google Scholar, PubMed, Scopus and Scielo.

➢ *Limitations of the Study*

- Inclusion criteria were limited to open access articles.
- Relevant studies that did not meet the criteria used may have been excluded which could cause publication bias.
- The limited databases that were used were Google Scholar, PubMed, Scopus and Scielo. No data was found in Scopus and Scielo relevant to this study.
- Decrease in the universality of the results obtained due to the difference in laboratory practices across the globe.

The specific terms that were used for the searches included:

- Types and causes of adverse events that are particularly harmful to patients in the clinical laboratories.
- Quality indicators to evaluate errors in clinical laboratory phases.
- Laboratory errors and patient safety.
- Current publications on the evaluation of analytical laboratory errors.
- Laboratory analytical errors in the face of automation and modern technologies.
- “Analytical errors” in the clinical laboratory.

Filter for publication date was used to select current years.

An intensive review of the articles was done to determine which one met the inclusion criteria. Study design where applicable, results consistency and clinical applicability were used in the assessment criteria.

Data retrieved from the selected findings was critically evaluated to determine their relevance. The quality of the studies was assessed using Critical Appraisal Skills Programme (CASP) checklist. Reduction, visualization, comparison, and analysis of the results were used in the data analysis.

The results were finally presented in a structured manner: Percentages of pre-analytical, analytical and post-analytical errors and non-conformances. A table was used to document the study selection process, showing the number of studies identified, included, and excluded, and the reasons for exclusion (Table 1).

A Table were created that include the general information of each article (Figure 2).

The data collection and evaluation were done by hand. The findings were organized, evaluated and represented by hand in integrative review extraction tables (Table 3 and Table 4). Selected studies for the analysis were grouped into themes to organize them for analysis. (Table 4). Due to limited current research involving all the stages of the TTP, the studies that were organized into themes for the analysis were 9 because they were the only studies that show the rates of errors/NCs in all the three stages of the TTP, analytical, pre-and post-analytical errors/NCs.

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Stage-specific error evaluation and comparative synthesis were used in the analysis of the data extracted from the studies, to identify patterns in laboratory errors across the total testing process.

Table 1. Summary of the Selection Process of the Study

Study Identification			
Selection Process	**Identification**	**Revision**	**Included Studies**
Articles Identified	N = 100 Google Scholar n = 55 PubMed n = 40 Scopus n = 3 Scielo n = 2		
Studies not included in the review	n = 30		
Reviewed Articles		n = 50	
Studies not included after the review (they were not relevant to the study)		n = 20	
Studies included in the review			n = 30

III. FINDINGS

The general information on studies retrieved from the searches was organized in a table as shown in Table 2.

Table 2. General Information on Studies Retrieved from the Searches

Authorship	Country	Year	Database/ Search Engine	Title	Study Method
McBride et al.	USA	2014	Google Scholar	"Understanding human error in automation: A review of error management strategies" (McBride et al., 2014)	Narrative review
Abdollahi et al.	Iran	2014	Google Scholar	"Types and Frequency of Errors during Different Phases of Testing at a Clinical Medical Laboratory of a Teaching Hospital in Tehran, Iran" (Abdollahi et al., 2014)	Descriptive, cross-sectional study
Al-Faraeh & Ababneh	Jordan	2018	Google Scholar	"The detection and prevention of errors in clinical laboratory by Al-Faraeh & Ababneh, 2018" (Al-Faraeh & Ababneh, 2018)	Technical review
Roy & Das	India	2019	Google Scholar	"An evaluation of the errors occurring in pathology and microbiology laboratories of a tertiary care teaching hospital and their root cause analyses" (Roy & Das, 2019)	Descriptive observational study
Plebani et al.	Italy	2020	Google Scholar	"Patient Safety in Laboratory Medicine" (Plebani et al., 2020)	Narrative review

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Mehndiratta et al.	India	2021	PubMed	"Quality Indicators for Evaluating Errors in the Preanalytical Phase" (Mehndiratta et al., 2021)	Descriptive observational, cross-sectional
Alshaghdali et al.	Saudi Arabia	2022	PubMed	"Detecting Preanalytical Errors Using Quality Indicators in a Hematology Laboratory" (Alshaghdali et al., 2022)	Retrospective observational
Al Naam et al.	Saudi Arabia	2022	Google Scholar	"The Impact of Total Automaton on the Clinical Laboratory Workforce: A Case Study" (Al Naam et al., 2022).	Comparative observational
Bhalkar et al.	India	2022	Google Scholar	"Detection and learning from clinical laboratory errors: A performance improvement methodology" (Bhalkar et al., 2022)	Retrospective Observational
Kutcher, & LeBaron	USA	2022	Google Scholar	"A simple guide for completing an integrative review using an example article" (Kutcher, & LeBaron, 2022)	Methodological guide
Sodavadiya et al.	India	2023	Google Scholar	"Impact of developing and implementing nonconformance management system at clinical biochemistry laboratory section of tertiary care hospital run by Government of Gujarat, India" (Sodavadiya et al., 2023)	Descriptive observational
van Moll et al.	Netherlands	2023	PubMed	"The Nature, Causes, and Clinical Impact of Errors in the Clinical Laboratory Testing Process Leading to Diagnostic Error: A Voluntary Incident Report Analysis" (van Moll et al., 2023).	Retrospective study
WHO	Switzerland	2023	Google Scholar	Patient safety	Global WHO fact sheet
Chaudhry et al.	Japan	2023	PubMed	"Quality analysis of the clinical laboratory literature and its effectiveness on clinical quality improvement: a systematic review" (Chaudhry et al., 2023)	A systematic review
Kouser et al.	Pakistan	2024	Google Scholar	"Review of key performance indicators in a hematology laboratory: A preventable source of error" (Kouser et al., 2024)	Cross-sectional study
Mohammed	Not indicated	2024	Google Scholar	"Advancements in diagnostic technology: The role of automation in modern medical laboratories" (Mohammed, 2024)	Narrative Review
Al-Fehaid et al.	Saudi Arabia	2024	Google Scholar	"Factors affecting the accuracy and reliability of laboratory test results" (Al-Fehaid et al., 2024)	Analytical descriptive
Mishra & Beena	India	2024	Google Scholar	"A Bibliometric Analysis of Errors and Mistakes in the Medical Laboratory" (Mishra & Beena, 2024)	Bibliometric analysis

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Pienaar et al.	South Africa	2024	Google Scholar	"Analysis of internal audit non-conformances at non-accredited public health laboratories in Gauteng province, South Africa" (Pienaar et al., 2024)	Retrospective observational
León Bajaña et al.	South America/ Ecuador	2024	Google Scholar	"Prevention and control of adverse events in the clinical laboratory process: A literature review" (León Bajaña et al., 2024)	Literature/ Narrative review
Alghamdi et al.	Saudi Arabia	2024	Google Scholar	"Pre-analytical, analytical, and post-analytical errors in clinical Laboratory testing: A systematic review of causes and prevention strategies" (Alghamdi et al., 2024).	Systematic review
Guo et al.	China	2025	Google Scholar	"Analysis and actions after laboratory errors in a Chinese university hospital" (Guo et al., 2025)	Retrospective
Tarekegn et al.	Ethiopia	2025	Google Scholar	"Evaluating the total laboratory testing process and performance via quality indicators in clinical chemistry and hematology laboratories at Pawi General Hospital, Benishangul Gumz, Northwest Ethiopia: a prospective cross-sectional study" (Tarekegn et al., 2025).	A prospective cross-sectional
Lin et al.	USA	2025	Google Scholar	"Pre-analytical phase errors constitute the vast majority of errors in clinical laboratory testing" (Lin et al., 2025).	Retrospective observational
AHRQ	USA	2025	Google Scholar	"Patient Safety Indicators (PSIs): Recommendations to update the PSIs" (AHRQ, 2025).	Technical review and expert consensus process
Cichocki	USA	2025	Google Search	"The Importance of laboratory quality and how to achieve it" (Cichocki, 2025)	Narrative expect Discussion
Cepull	USA	2025	Google Search	"Six Cs of lab quality that ensure reliable testing" (Cepull, 2025)	Narrative expect Discussion
Biosero	USA	2026	Google Search	"How to reduce laboratory errors with automation" (Biosero, 2026)	Technical article
De Guire et al.	Canada	2026	Google Scholar	"Recommendations from the IFCC Working group on laboratory errors and patient safety for the global adoption of an essential quality indicators panel in laboratory medicine" (De Guire et al., 2026)	Expert consensus
Patel et al.	India	2026	Google Search	"Evaluation of non-conformances in the total testing process of a NABL-accredited clinical biochemistry	Descriptive observational

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				laboratory: An observational study" (Patel et al., 2026)	

The following are the findings from literature showing the frequencies of the errors at the different stages of the total testing process in the laboratory.

Pre-analytical errors were 75%, analytical errors 7.1%, and post-analytical errors 17.9% in a performance-improvement study conducted by Bhalkar et al. (2022) in a Clinical laboratory in India.

In a retrospective study involving 600 voluntary incident reports concerning diagnostic testing selected from all incident reports filed at the University Medical Center Utrecht in 2017-2018 three hundred and twenty-seven (327) of the reports were included in the study conducted by van Moll et al. (2023). The findings showed that 77.1% of the errors occurred in the pre-analytical phase,13.5% in the analytical phase and 8.0% in the post-analytical phase (1.5% undetermined).

A cross-sectional study that was performed by Kouser et al. (2023) at the DDRRL Hematology laboratory from October 2021 to September 2022 to assess the key performance indicators and the laboratory errors in the hematology laboratory 414,400 hematology request forms were retrieved from OPD, private wards, IPD and Emergency. Pre-analytical errors were 419 (17.63%), analytical122 (15.13%) and post-analytical 1834 (77.17%) of the 2376 (0.573%) total errors detected in the haematology laboratory.

In a bibliometric analysis of the errors and mistakes in the Medical Laboratory, India, by Mishra and Beena (2024), out of 1240 mistakes from the analysis of 935,896 specimens, pre-analytical errors were 84.52%, analytical 4.35%, and post-analytical 11.13%.

A retrospective study performed in the ISO 15,189 and CAP-accredited Department of Medical Laboratory at a women and children's hospital by Guo et al. (2025) found that among 51 general laboratory errors, the pre-analytical phase contributed to most of the errors (51.0%), analytical (4%) and post-analytical (18%) phases had fewer errors. The remaining 32 errors were transfusion-related errors. Pre-analytical errors were 98.4%, analytical errors were 0.5%, and post analytical errors were 1.1% of a total of 87,317 errors that occurred affecting billable results and specimens. These were found in another retrospective study conducted by Lin et al. (2025) at a core laboratory from January 2022 to May 2023 using technologist hands-on involvement, documented occurrences by staff and the use of information retrieved from automation reports (Lin et al., 2025).

A prospective cross-sectional study was performed by Tarekegn et al. (2025) at Pawi General Hospital, Benishangul-Gumz Region, Northwestern Ethiopia between October 1 and December 30, 2021 to evaluate the total laboratory testing process and performance through the application of quality indicators in the clinical laboratories. A total of 136,722 quality indicators were assessed from 4140 samples analyzed which showed the occurrence of 24.7% errors, 63.6% being pre-analytical, 1.6% analytical, and 34.8% post-analytical phases.

The rates of NCs due to various laboratory procedures of the TTP identified by Sodavadiya et al. (2023) in a study involving non-conformances were pre-analytical,18%, analytical, 41%, and post-analytical, 41%. The study was a descriptive observational study performed at the clinical biochemistry laboratory of a tertiary hospital from Oct 2011 to Sep 2013 in India. Patel et al. (2026) also documented a total of 439 NCs, pe-analytical errors were 53.30%, analytical 43.51% and post-analytical 3.19% in another descriptive observational study conducted in Clinical Biochemistry Laboratory of a tertiary care teaching hospital located in rural Gujarat, India. This finding supports the findings of Sodavadiya et al. (2023).

The findings from the studies that were selected for the integrative review were organized in a table (Table 3) and those for the analysis were grouped into 3 themes which are pre-analytical errors/non-conformances, analytical errors/non-conformances and post-analytical errors/non-conformances, in order to organize them for analysis. These were visualized with a table as shown in Table 4 including the objectives, study method, study setting/design, study location and study period of each study.

Table 3. Integrative Review Extraction Table

Author	Year	Study Location	Objective	Study Method	Study Setting/ Design	Study Period
Bhalkar et al.	2022	India	To use a structured performance improvement-methodology to identify and evaluate clinical	Performance-improvement methodology	Clinical laboratory	Not reported

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			laboratory errors in the testing process (Bhalkar et al., 2022).			
van Moll et al.	2023	Netherlands	To use data from willingly filed occurrences to examine the nature, causes and effect of errors that occur at the clinical laboratory process (van Moll et al., 2023)	Retrospective study	University Medical Center Utrecht willingly reported incident reports	2017–2018
Kouser et al.	2023	Pakistan	To evaluate the laboratory errors and the key performance indicators in the haematology laboratory (Kouser et al., 2023)	Cross-sectional study	DDRRL Hematology laboratory Hematology request forms were obtained from OPD, private wards, IPD and Emergency.	October 2021 to September 2022
Sodavadiya et al.	2023	India	To give direction to the creation of NMS using the accreditation requirements and to enhance it's understanding (Sodavadiya et al., 2023).	Descriptive observational design	Clinical biochemistry laboratory of a New Civil Hospital, Surat Laboratory Services. Tertiary care hospital	October 2011 to September 2013
Mishra & Beena	2024	India	To methodically outline, measure and evaluate published studies on errors or mistakes in the clinical laboratory (Mishra & Beena, 2024)	Bibliometric analysis	Published literature	From 2000 to 2023
Guo et al.	2025	China	To analyze the process used to address laboratory errors alongside the evaluation of the features causes and results of these errors that happen in a Chinese university hospital (Guo et al., 2025)	Retrospective quality-improvement study	Filed laboratory errors. incident-reports	7 years, 2016 - April 2023

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Lin et al.	2025	USA	To determine the incidence of laboratory errors and to identify the most predominant error in the clinical laboratory (Lin et al., 2025)	Retrospective observational	Reported errors in the TTP	January 2023 – December 2023
Tarekegn et al.	2025	Ethiopia	Using IFCC recommendation to determine performance to analyze the laboratory process occurring in the clinical chemistry and haematology departments in Pawi General Hospital laboratory (Tarekegn et al., 2025)	A prospective cross-sectional study	the clinical chemistry and hematology laboratories, Pawi General Hospital	3 months October 1, 2021 – December 30, 2021
Patel et al.	2026	India	To evaluate the characteristics, rates and causes of NCs in an NABL-accredited clinical biochemistry laboratory connected to a medical college (Patel et al., 2026)	Descriptive observational study	Clinical Biochemistry Laboratory, tertiary care teaching hospital, rural Gujarat, India Filed non-conformances	12 months March 2023 to February 2024

Table 4. Integrative Review Extraction Table Showing the Themes Based on Rates of Errors/NCs

Authorship	**Country**	**Year**	**Title**	**Rate of Pre-analytical errors/NCs (%)**	**Rate of Analytical errors/NCs (%)**	**Rate of Post-analytical errors/NCs (%)**
Bhalkar et al.	India	2022	"Detection and learning from clinical laboratory errors: A performance improvement methodology" (Bhalkar et al., 2022)	75	7.1	17.9
van Moll et al.	Netherlands	2023	" The nature, causes, and clinical impact of errors in the clinical laboratory testing process leading to diagnostic error: A voluntary incident report analysis" (van Moll et al., 2023).	77.1	8.0	1.5
Kouser et al.	Pakistan	2023	"Review of key performance indicators in a hematology laboratory: A preventable source of error" (Kouser et al., 2023).	17.63	15.13	77.17

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Mishra & Beena	India	2024	"A Bibliometric Analysis of Errors and Mistakes in the Medical Laboratory" (Mishra & Beena, 2024).	84.52	4.35	11.13
Guo et al.	China	2025	"Analysis and actions after laboratory errors in a Chinese university hospital" (Guo et al., 2025).	57.0	4.0	18.0
Lin et al.	USA	2025	"Pre-analytical phase errors constitute the vast majority of errors in clinical laboratory testing" (Lin et al., 2025).	98.4	0.5	1.1
Tarekegn et al.	Ethiopia	2025	"Evaluating the total laboratory testing process and performance via quality indicators in clinical chemistry and hematology laboratories at Pawi General Hospital, Benishangul Gumz, Northwest Ethiopia: A prospective cross-sectional study" (Tarekegn et al., 2025).	63.6	1.6	34.8
Sodavadiya et al.	2023	India	"Impact of developing and implementing nonconformance management system at clinical biochemistry laboratory section of tertiary care hospital run by Government of Gujarat, India" (Sodavadiya et al.,2023).	18	41	41
Patel et al.	India	2026	"Evaluation of non-conformances in the total testing process of a NABL-accredited clinical biochemistry laboratory: an observational study" (Patel et al., 2026).	53.3	43.51	3.19

IV. DISCUSSION

Although the goal for patient safety is zero errors, and laboratory professionals have made numerous efforts to reduce errors in the last few decades, it has been highlighted that errors still occur at every step of the TTP in the clinical laboratory by current studies, and that analytical quality still remains a challenge even though there has been the implementation of improvement procedures (Sciacovelli et al., 2016, as cited in Plebani et al, 2021). This secondary research aimed at identifying the frequencies of analytical, pre-analytical and post- analytical errors in the clinical laboratory using data obtained from published studies on quality indicators for patients' safety in the clinical laboratory and to determine the need to continually conduct critical research to monitor the analytical stage in the phase of automation and modern technologies.

The total testing process (TTP) process involves a series of measures from the reception of the sample to the issuance of the final report (León Bajaña et al., 2024) which includes the pre-analytical, analytical and post-analytical stages. There is the need for comprehensive testing across the TTP (León Bajaña et al., 2024) that include all these stages. This study however revealed a gap in the current studies although it found a decrease in the frequencies of analytical errors in all the studies retrieved from literature across the globe. The findings of the search did not show many current studies from year 2020 to year 2025 that highlight and compare all three stages of the TTP in the same data collection, which was done in earlier years (2010–2020). Although Aita et al. (2017) pointed out the requirement of ISO 15189:2012 to use quality indicators (QIs) to monitor and evaluate all steps of the total testing process, most of the studies retrieved from literature were studies done on only pre-analytical and post-analytical errors. The reason being that in earlier years focus was on analytical errors and their improvement and neglect of pre-and post-analytical errors

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which led to the high frequency of pre-analytical errors in the clinical laboratory.

The findings of this study show similar rates in all studies done on errors in the clinical laboratory selected for the reviewed (from 57.0%- 98.4% in analytical errors, 0.5%- 8.0% in analytical, and 1.1%- 17.9%). Pre-analytical errors had the highest rates while analytical and post-analytical show variations in their rates in the different studies as indicated by Alshaghdali et al. (2022). Over the years under review there has been a downward trend in the rate of analytical errors across the globe. Studies that considered non-conformances in their studies, however, show that preanalytical errors were 18% and 53.3%, analytical were 41% and 43%, and post analytical were 3.19% and 41%. (Patel et al., 2026 and Sodavadiya et al.,2023). They linked these non-conformances in the analytical phase to the review of internal QC data, adherence to equipment service and maintenance schedules, and problems with management which supports the findings of Chaudhry et al. (2023) who found out that there is a high rate of analytical errors depending on the procedure under focus or the measured objective by the study. Since analytical errors are critical (Alghamdi, 2024) inadequate monitoring or objective measurement can cause more severe harm to patients. To achieve this conformance to procedures in clinical laboratory the checklist for clinical laboratory quality and assurance which involves monitoring and assessment should include the documentation and immediate correction and preventive actions of non-conformances (Cichocki, 2025). The failure to do this could have resulted in limited dataset for research work as was found in the study conducted by Pienaar et al. (2024). Cepull (2025) indicated that valid test results of clinical laboratory and its credibility are enhanced when conformance procedures are followed.

The real-time manual technologist intervention, incidence reports filed by hospital staff, and retrospective assessment using automated reports from the lab information system (LIS) (Lin et al., 2025) also showed low rates of analytical errors which conform with limitation of the use of retrospective method as argued by Pienaar et al. (2024). The different study methods used by these studies, however, did not increase the incidence of analytical errors in any of the studies nor did the differences in study designs. Most of the studies were, however, found to be conducted at the clinical biochemistry departments of the clinical laboratory. Studies in all laboratory departments should be encouraged. The only study that was conducted in the Haematology alone laboratory found 15.3% of errors to be analytical errors (Kouser et al., 2023) which indicate that all the departments in the clinical laboratory should be included in the rigorous research. The lack of focus and for that matter lack of rigorous research on analytical errors alongside that of pre-analytical and post-analytical errors can lead to hidden occurrences or incidents in the clinical laboratory that can affect patients' safety.

The analytical stage that has been identified by current studies to have the low rate of error due to automation is still prone to errors due to equipment or machine malfunction and lack of adequate human intervention. This was indicated in the examination of QC paper which assessed interventions which were more of analytical context where the rate of analytical errors was the highest, 28 out of 33 papers (84.85%) as was indicated by Chaudhry et al. (2023). There is the need to pay rigorous attention to and to monitor the analytical context especially concerning QC and instrument maintenance (León Bajaña et al., 2024). This strongly suggest that the complexity of the clinical laboratory process needs a more comprehensive approach that considers a wide range of contributing factors and potential failure points for each of the stages of the TTP which is in support of León Bajaña et al. (2024).

There cannot be a guarantee of improvement of quality without its detection and measurement in the clinical laboratory although quality improvement procedures have been made routine procedures in the daily clinical laboratory process. Measurement of observed outcomes could depend on the procedure used for collecting data and on staff contribution (De Guire et al., 2026). Based on this there is the need of staff training (Mohammed, 2024) and management contribution in relation to strict quality control protocols, including equipment maintenance and calibration, to ensure a successful quality improvement and a guarantee of more reliable results in the clinical laboratory, particularly in the analytical stage.

V. RECOMMENDATIONS

- Laboratories must record even small changes in quality control, reagent problems, calibration-related issues, equipment malfunctions and other occurrences of errors.
- Rigorous research should be encouraged in analytical errors alongside that of pre- and post-analytical errors.
- Prospective and observational study approaches in analytical errors should be encouraged rather than retrospective studies. This will give real-time or hands-on intervention on analytical procedures and provide more datasets for the study.
- There is need for continuous education and training of staff to be abreast of new development and to know how to involve real-time interventions in the analytical stage and the entire clinical laboratory processes.

VI. CONCLUSION

Analytical errors still occur in the clinical laboratory even in the phase of automation and advancement in technology to improve quality in the analytical stage of the total testing process in the clinical laboratory. This is evident in published studies. The low rate of analytical errors in these studies has been attributed to high rate of non-conformances in this stage. There is a need for critical documentation of incidents and rigorous research in this stage in order to guarantee quality

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improvement in the clinical laboratory. Rigorous prospective and observational studies involving non-conformances should be encouraged in the analytical stage alongside that of pre- and post-analytical stages in all the departments of the clinical laboratory.

➢ *Abbreviations*

- *AHRQ - Agency for Healthcare Research and Quality*
- *CASP - Critical Appraisal Skills Programme*
- *DDRRL - Dow Diagnostic Reference and Research Laboratory*
- *EQA - External Quality Assurance Programmes*
- *IFCC - IFCC stands for the International Federation of Clinical Chemistry and Laboratory Medicine*
- *IPD - In Patient Department*
- *ISO - International Organization for Standardization*
- *IQC - Internal Quality Control*
- *LIS - Laboratory Information System*
- *NABL - National Accreditation Board for Testing and Calibration Laboratories*
- *NCs - Non-conformances*
- *NMS – Non-conformance Management System*
- *OPD - Out Patient Department*
- *PSIs - Patient Safety Indicators*
- *QC - Quality Control*
- *QI - Quality Improvement*
- *QI - Quality Indicators*
- *TTP - Total Testing Process*
- *WHO - World Health Organization*

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