DOI: https://doi.org/10.66206/eduheart.ijnhha.255

Incidence of Pre-Analytical Errors in a Primary Laboratory Clinic in Rodriguez, Rizal: A Basis for a Quality Assurance Plan

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ABSTRACT

Pre-analytical errors are the leading source of laboratory testing inaccuracies and may compromise diagnostic reliability and patient safety. This study determined the incidence of pre-analytical errors in a primary laboratory clinic in Rodriguez, Rizal, as the basis for developing a Quality Assurance Plan. A quantitative retrospective descriptive research design with purposive sampling was employed. Laboratory records with documented pre-analytical errors from January 2024 to December 2025 were reviewed and analyzed using frequency, percentage, mean, cross-tabulation, and the Chi-square Test of Independence. The findings showed that the wrong sample container, particularly the use of foreign containers, was the most common pre-analytical error, followed by contaminated samples, while hemolyzed and insufficient samples occurred at moderate levels. Common diagnoses associated with these errors included common cold, dehydration, diabetes, urinary tract infection, and diarrhea. Significant contributing factors were patient restlessness, difficult specimen collection, improper specimen handling, and incorrect specimen container selection. The study concludes that strengthening laboratory quality management through staff education, competency assessment, adherence to standard operating procedures, and continuous quality monitoring is essential to reduce preventable pre-analytical errors, improve specimen quality, enhance laboratory performance, and promote patient safety.

Keywords: ***P****re-analytical errors, primary laboratory clinic, laboratory quality assurance, specimen collection, patient safety, quality management, Rodriguez, Rizal*

INTRODUCTION

Clinical laboratories play a vital role in healthcare by providing accurate and reliable test results for diagnosis and patient management. However, the pre-analytical phase remains the most error-prone stage of laboratory testing, accounting for approximately 60% to 70% of all laboratory errors (Plebani, 2017). Errors in specimen collection, labeling, transportation, and handling may compromise diagnostic accuracy and patient safety (Lippi et al., 2019). Although laboratory practices have improved, pre-analytical errors continue to occur, particularly in primary laboratory clinics where limited resources and heavy workloads increase the risk of preventable errors. This study determined the incidence of pre-analytical errors in a primary laboratory clinic in Rodriguez, Rizal, and examined their relationship with patients' demographic characteristics. The findings served as the basis for developing a Quality Assurance Plan to improve laboratory performance and patient safety.

Statement of the Problem

1. What is the demographic profile of the patients in the Primary Laboratory Clinic in Rodriguez, Rizal in terms of:
   1.1 Age
   1.2 Gender
   1.3 Diagnosis
2. What is the level of Incidence of Pre-analytical error in the Primary Laboratory Clinic in Rodriguez, Rizal in terms of:
   2.1 Hemolyze Sample?
   2.2 Insufficient Sample?
   2.3 Contaminated Sample?
   2.4 Wrong sample container?
3. Is there a significant relationship between the demographic profile and the level of Incidence of Pre-analytical error in the Primary Laboratory Clinic in Rodriguez, Rizal?
4. What quality assurance plan can be proposed to minimize pre-analytical errors in the Primary Laboratory Clinic in Rodriguez, Rizal?

Scope and Delimitation

This study focuses on the Incidence of Pre-Analytical Errors in a Primary Laboratory Clinic in Rodriguez, Rizal, from January 2024 to December 2025. It excludes errors that happened in the analytical and post-analytical phases of laboratory testing, as well as any data gathered before January 2024 or after December 2025.

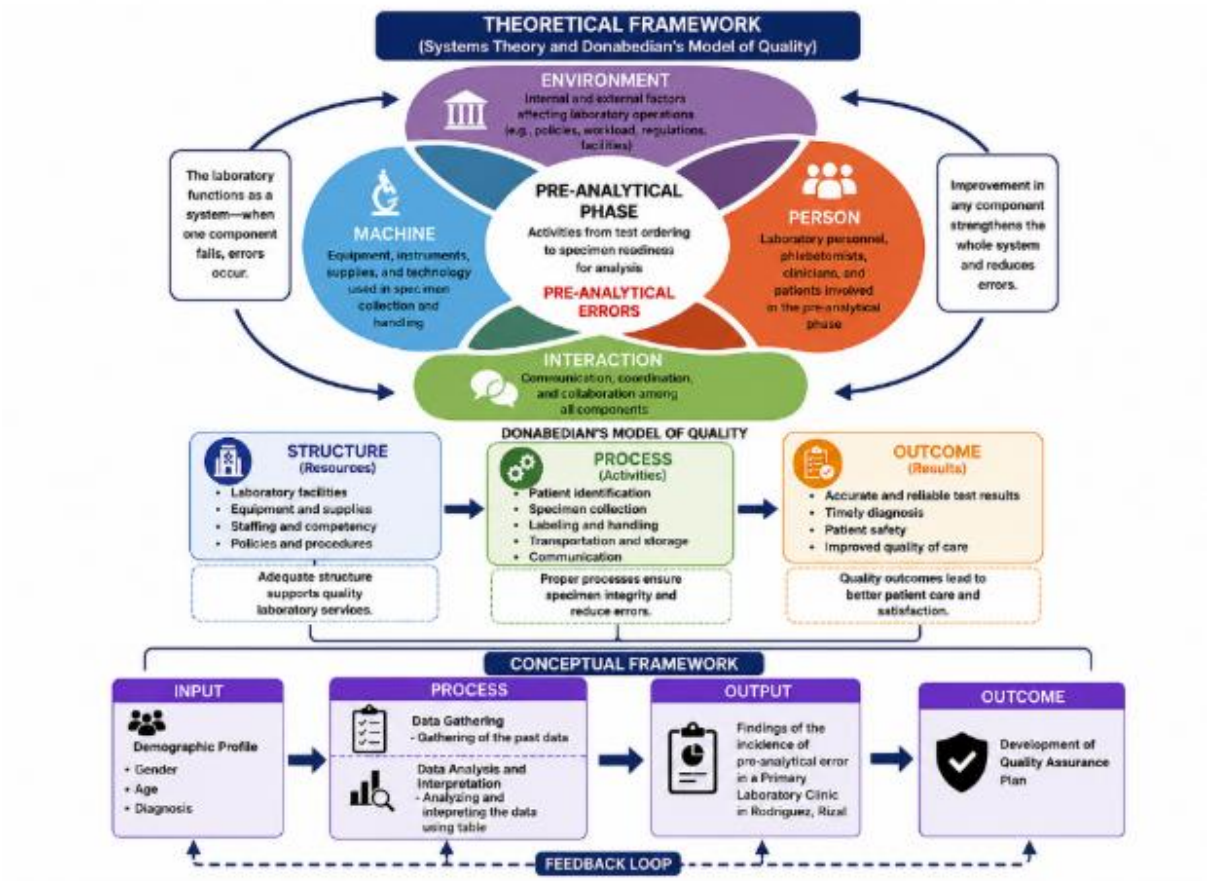
Review of Related Literature

Previous studies have identified the pre-analytical phase as the most error-prone stage of laboratory testing, with errors such as hemolyzed specimens, contaminated samples, insufficient sample volume, and incorrect specimen containers affecting diagnostic accuracy and patient safety (Lippi, 2025; Nordin et al., 2024). Although quality assurance programs can reduce these errors, evidence from primary laboratory clinics in the Philippines remains limited, justifying the need for this study.

Theoretical Framework

This study is anchored on **Systems Theory** and **Donabedian's Model of Quality**. Systems Theory views the clinical laboratory as an interconnected system in which personnel, equipment, and procedures work together to ensure accurate laboratory results. Failures in any component, such as inadequate staff training or improper specimen handling, may result in pre-analytical errors (Bertalanffy, 1968; Plebani, 2019). Complementing this, Donabedian's Model explains quality through **structure**, **process**, and **outcome**, emphasizing that adequate resources and standardized laboratory procedures contribute to accurate test results and improved patient safety.

Conceptual Framework



RESEARCH METHODOLOGY

This study employed a quantitative retrospective research methodology to determine the incidence of pre-analytical errors in a primary laboratory clinic in Rodriguez, Rizal. Laboratory records were reviewed to identify the occurrence of pre-analytical errors, examine their relationship with patients' demographic characteristics, and provide the basis for developing a Quality Assurance Plan.

Research Design

This study employed a quantitative retrospective research design to determine the incidence, types, and causes of pre-analytical errors in a primary laboratory clinic. Quantitative data from laboratory records were analyzed using descriptive and inferential statistics to identify patterns and trends, serving as the basis for developing a Quality Assurance Plan to minimize future laboratory errors.

Research Steps

The study was conducted in four phases: (1) securing ethical approval and institutional permission, (2) retrieving laboratory records with documented pre-analytical errors through purposive sampling, (3) organizing and classifying the collected data, and (4) analyzing the data using descriptive and inferential statistics to develop a Quality Assurance Plan.

Data Collection and Sample Selection

Purposive sampling was used to select laboratory records with documented pre-analytical errors from January 2024 to December 2025. Records with complete demographic and laboratory information were included. Data on age, sex, diagnosis, and types of pre-analytical errors were extracted, anonymized, and used solely for research purposes.

Data Analysis Methods

The data were encoded in Microsoft Excel and analyzed using frequency, percentage, mean, cross-tabulation, and the Chi-square Test of Independence to determine the incidence of pre-analytical errors and their relationship with patients' demographic profile. The findings served as the basis for developing a Quality Assurance Plan.

Research Hypotheses and Validation

The study tested the null hypothesis that **there is no significant relationship between patients' demographic profile (age, sex, and diagnosis) and the incidence of pre-analytical errors**. The hypothesis was tested using the **Chi-square Test of Independence** at a **0.05 level of significance**. The decision to accept or reject the null hypothesis was based on the computed *p*-value.

Study Limitations and Ethical Considerations

This study was limited to documented pre-analytical errors from a single primary laboratory clinic. Institutional permission and ethical approval were obtained, and all patient records were anonymized and treated confidentially throughout the study.

RESULTS AND DISCUSSION

SOP 1. The findings revealed that the wrong sample container was the most common pre-analytical error, followed by contaminated, hemolyzed, and insufficient samples. Common diagnoses associated with these errors included common cold, dehydration, diabetes, urinary tract infection, and diarrhea. The leading contributing factors were patient restlessness, difficult specimen collection, improper specimen handling, and incorrect specimen container selection.

SOP 2. The Chi-square Test of Independence revealed significant relationships between patients' demographic profile and the incidence of selected pre-analytical errors. Variations in the occurrence of errors across age groups, sex, and diagnosis suggest that demographic characteristics influence the likelihood of pre-analytical errors.

SOP 3. The findings indicated that deficiencies in specimen collection, handling, labeling, and container selection contributed to the occurrence of pre-analytical errors. These results emphasize the importance of strengthening laboratory quality management through continuous staff education, competency assessment, strict adherence to standard operating procedures, and regular quality monitoring to minimize preventable laboratory errors.

SOP 4. Based on the findings, a Quality Assurance Plan was developed to strengthen laboratory quality management through continuous staff education, competency assessment,

standardized specimen collection procedures, routine monitoring of quality indicators, and implementation of corrective and preventive actions. These strategies are expected to reduce pre-analytical errors, improve specimen quality, enhance laboratory performance, and promote patient safety in primary laboratory settings.

SUMMARY

The study determined the incidence of pre-analytical errors in a primary laboratory clinic in Rodriguez, Rizal, and identified the demographic characteristics and factors associated with their occurrence. The findings revealed that the wrong sample container, particularly the use of foreign containers, was the most common pre-analytical error, followed by contaminated samples, while hemolyzed and insufficient samples occurred at moderate levels. Significant relationships were found between patients' demographic profile and selected pre-analytical errors. These findings served as the basis for developing a Quality Assurance Plan aimed at strengthening laboratory quality management, reducing preventable pre-analytical errors, improving specimen quality, and enhancing patient safety in primary laboratory settings.

CONCLUSIONS

The findings demonstrate that pre-analytical errors remain a significant concern in the primary laboratory clinic, with wrong sample containers, contaminated samples, hemolyzed specimens, and insufficient samples identified as the most common errors. Significant relationships between patients' demographic profile and selected pre-analytical errors indicate that patient characteristics influence the occurrence of these errors. These findings support the implementation of a comprehensive Quality Assurance Plan focused on strengthening specimen collection practices, staff competency, adherence to standard operating procedures, and continuous quality monitoring to improve laboratory performance and enhance patient safety.

RECOMMENDATIONS

Based on the findings and conclusions of the study, the following recommendations are suggested:

- Primary laboratory clinics should strengthen quality assurance programs by providing continuous staff education, competency assessment, and strict adherence to standard operating procedures to minimize pre-analytical errors.
- Laboratory managers and healthcare administrators are encouraged to implement routine monitoring of quality indicators and corrective and preventive actions to improve specimen collection, handling, and overall laboratory performance.
- Future studies should include multiple primary laboratory clinics, larger datasets, and longer study periods to further validate the findings and enhance the generalizability of quality improvement strategies for reducing pre-analytical errors.

ACKNOWLEDGMENT

The researchers sincerely express their gratitude to the management and staff of the selected primary laboratory clinic in Rodriguez, Rizal, for granting permission to conduct this study and for providing access to the laboratory records used in the research. Appreciation is also extended to the research advisers, panel members, and faculty for their invaluable guidance, expertise, and constructive recommendations throughout the completion of this study. Finally, the researchers are deeply thankful to their families, friends, and everyone who offered encouragement, support, and inspiration throughout the research process.

AI DECLARATION

Artificial intelligence (AI) tools were used only for language editing, grammar correction, and formatting during the preparation of this manuscript. AI was not used in the study design, data collection, data analysis, interpretation of findings, or formulation of conclusions. All scientific judgments and academic contributions were made by the authors, who assume full responsibility for the accuracy and integrity of the work.

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