Research article

Targeting Sample Reception Errors: A Failure Reporting Analysis and Corrective Action System (FRACAS)-Based Laboratory Quality Improvement Study

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Abstract

Introduction: Approximately 70% of clinical decisions depend on laboratory test results, underscoring the critical importance of examination accuracy. Among the phases of the total testing process, the pre-examination phase accounts for the highest proportion of errors; therefore, interventions aimed at reducing these errors can significantly enhance overall laboratory quality. This study aims to evaluate the effectiveness of risk assessment and corrective strategies through the implementation of the Failure Reporting, Analysis, and Corrective Action System (FRACAS) by comparing Risk Priority Number (RPN) scores before and after implementing corrective strategies.

Methodology: This retrospective observational quality-improvement study obtained approval from the institutional ethics committee. It analyzed two years of data from a clinical biochemistry laboratory. A total of 573 samples were rejected in a NABL-accredited, ISO 15189-compliant tertiary-care hospital in South India. Each nonconformance (NC) was categorized, and its frequency, percentage distribution, and RPN were calculated for both study periods. The effectiveness of risk assessment and corrective strategies was evaluated by comparing pre- and post-corrective RPN values and percentage reductions in NCs.

Results: Data from 573 rejected samples (216 pre-corrective in 2021; 357 post-correctives in 2022) were analysed. Mean RPN decreased from 18.0 ± 16.1 to 10.9 ± 15.3 (mean difference 6.0, 95% CI 2.0–24.0, p = 0.041); paired Bayesian t-test showed BF10 = 1.15, evidence for effectiveness. Four NCs were eliminated; however, three new NCs emerged post-STAT lab launch.

Conclusion: FRACAS-guided interventions reduce pre-examination NCs and lower RPNs for high-risk processes, supporting their use for pre-examination quality improvement.

Introduction

Accurate clinical laboratory testing is fundamental to effective patient diagnosis, treatment, and monitoring. In healthcare settings, approximately 70% of medical decisions are based on laboratory test results, highlighting the critical importance of timely and accurate reporting. The total testing process (TTP) in clinical laboratory medicine comprises three phases: pre-examination, examination, and post-examination [1]. Optimal management of each phase is essential to ensure the generation of precise and reliable laboratory results [2].

Advances in laboratory automation and technology have substantially reduced errors in the examination and post-examination phases. In contrast, the pre-examination phase, largely influenced by human factors and frequently occurring outside the laboratory, remains the predominant source of errors within the TTP and therefore requires focused improvement. The pre-examination phase encompasses all processes from the clinician's test request to the initiation of sample analysis [2]. Errors may occur at any stage of the TTP; however, pre-examination errors account for the majority, representing approximately 46–68.2% of total laboratory errors, compared with 7–13% for examination errors and 18.5–47% for post-examination errors [3]. Consequently, laboratory leadership bears the responsibility of maintaining risks at clinically acceptable levels. Quality improvement initiatives include systematic identification, evaluation, corrections, and continuous monitoring of errors [4]. Within the pre-examination phase, errors most commonly arise during patient preparation and specimen collection, underscoring the need for a skilled phlebotomy workforce and ongoing training of personnel involved in pre-examination activities [4,5]. Quality indicators (QIs) play a pivotal role in continuous quality improvement by enabling monitoring and reduction of errors across all phases of the TTP [6].

Risk identification and analysis can be effectively performed using the Failure Reporting, Analysis, And Corrective Action System (FRACAS), which categorizes nonconformances (NCs) based on their Risk Priority Number (RPN). The RPN is calculated as the product of occurrence, severity, and detection scores and facilitates risk prioritization and stratification [3]. Failure Reporting Analysis and Corrective Action System is widely recognized as a robust and systematic approach to risk management. Within FRACAS, every reported failure initiate a thorough investigation. After the root cause is determined, corrective actions are implemented to resolve the immediate issue. Preventive measures are subsequently introduced to reduce the likelihood of recurrence, often through updates to procedures, enhanced training, or modifications to equipment configuration [7]. Ensuring patient safety is a primary objective of healthcare systems, and initiatives aimed at reducing diagnostic errors directly contribute to improved patient outcomes [8]. Data on FRACAS-driven risk assessment specifically targeting sample reception areas of the pre-examination NCs in Indian tertiary-care biochemistry laboratories are limited. This study aims to demonstrate the application of risk management principles and targeted corrective strategies in clinical laboratories to prevent or reduce errors, with particular emphasison the sample reception area of the pre-examination phase, thereby enhancing the overall quality of patient care.

Materials and methods

This retrospective record-based study analysed documented pre-examination NCs focusing on the sample reception area of the laboratory, from January 2021 (pre-corrective baseline) to December 2022 (post-corrective) in the Department of Biochemistry NABL-accredited, ISO 15189-compliant tertiary-care hospital in South India. The study was conducted after obtaining approval from the "Institutional Research Committee (IRC)" and "Institutional Ethics Committee" (IEC 360/2023). The study included documented data on NCs from the laboratory's sample reception area from January 2021 to December 2022 and excluded data on examination and post-examination non-conformances in the clinical biochemistry laboratory.

Data collection

A complete enumeration of data from January 2021 to December 2022 was taken; each NC event was counted once, irrespective of the number of analytes ordered on that specimen. Data were compiled and categorised to quantify the frequency of each pre-examination NC reported in the lab. The total number of tests processed increased from 2,619,345 in 2021 to 3,268,618 in 2022, indicating a rise in workload during the latter year. Similarly, the number of sample collection tubes received in the laboratory increased from 187,096 in 2021 to 233,472 in 2022. The total number of pre-examinations NCs recorded was 216 in 2021 and 356 in 2022. When calculated relative to the total number of samples received, the rejection rates were 0.115% in 2021 and 0.152% in 2022, demonstrating a slight increase in the proportion of pre-examination errors in 2022. Data between January 2021 and December 2021 were considered as the baseline (pre-correction period) for comparative purposes. Specimens included in the study comprised those obtained from outpatient departments and all the wards of the hospital.

Design

The reported NCs were categorised into 18 distinct pre-examination NC types based on their frequency of occurrence for both study years. Severity rate (SR), occurrence rate (OR), and detection rate (DR) were assigned (1-5 scale) by a multidisciplinary team (laboratory director, quality manager, senior biochemist) using ISO 22367:2020 criteria via consensus. Risk Priority Numbers were calculated as RPN = SR × OR × DR, and RPN bands were defined: ≥40 high risk, 10-39 moderate, <10 low.

Training: Training is a continuous process in laboratory practice. As part of the corrective strategy implemented in this study, targeted training programs were conducted for all pre-examination NCs identified in 2021. The identified errors were systematically communicated to the respective wards, phlebotomy units, or reception areas. Section in-charges were informed and instructed to provide appropriate training addressing the specific errors and to maintain records of the corrective actions undertaken. Training was conducted during the monthly review meeting of the laboratory for approximately 30minutes, involving an

average of 10 technicians. The session focused on discussing errors identified in the sample reception area, analyzing their root causes, and outlining mitigation strategies to minimize such errors in the future. For the NC of "sample mislabelled," the root cause analysis identified factors such as skipping double-check steps due to high workload, inconsistent practices among technicians, and multitasking during peak hours. The mitigation plan included implementing mandatory double-check procedures, displaying standardized protocols in the sample reception area, ensuring uniform adherence to procedures by all technicians, and optimizing workload distribution during peak periods. Similarly,standardized procedures were prepared for all the other NCs, and training was conducted to follow them.

Improvements were quantified by calculating percentage reductions using the 2021 RPN values as the baseline. The RPN analysis provided insight into prioritizing areas requiring intervention to eliminate or minimize pre-examination errors. Comparison of pre- and post-corrective RPN values enabled evaluation of the effectiveness of the implemented risk assessment and corrective action plans.

Each NC was assessed in terms of severity, occurrence, and detection. Scores ranging from 1 to 5 were assigned for each parameter based on predefined criteria, as detailed in Table 1 [9].

Table 1: Severity rate, Occurrence rate and Detection rate scoring details.

Level	Term	Description
Severity Rate Score		
5	Critical	Significant adverse clinical outcome: Life-threatening injury/death.
4	Serious	Moderate adverse clinical outcome: Irreversible bodily damage.
3	Significant	Minor adverse clinical outcome: Temporary physical damage or disability can be remedied with medical treatment.
2	Marginal	No negative clinical outcome: Transient physical damage or impairment, can be reversed without medical intervention.
1	Insignificant	No adverse clinical outcome: Unchanged patient management.
Occurrence Rate Score		
5	Frequent	Happens each day. Very likely to happen soon, with consistent exposure.
4	Reasonably Likely	Each week. Probable to happen soon, with routine exposure expected.
3	Occasional	Each month: Possible to happen at some point in the predictable future, occasional exposure is possible.
2	Remote Each year	Each year; Unlikely to happen in the foreseen future
1	Unlikely	Less than once a year. Will happen only in rare or extraordinary situations.
Detection Rate Score		
5	Very low	The detection rate is minimal, indicating that the current controls are unlikely to identify the presence of the failure mode.
4	Low	There's a low likelihood of identifying the presence of the failure mode with the current controls.
3	Moderate	There is a possibility of identifying the presence of the failure mode with the current controls.
2	High	There is a strong likelihood of identifying the failure mode with the current controls.
1	Very high	It is almost certain to identify the failure mode with the current controls.

Statistical analysis

The percentage and RPN for each NC were calculated and described in Table 2. Pre- and post-corrective RPN for 15 common NCs (n=15 paired observations) were compared using paired t-tests; normality of RPN differences was checked via Shapiro-Wilk test. The effect of the study was assessed using a Bayesian paired sample t-test with default Cauchy prior. Jamovisoftware (Version 2.3.28) was used to do the statistical analysis. Statistical significance was set at $p < 0.05$, and $BF_{10} > 1$ indicated evidence against the null hypothesis.

Results

In the present study, pre-corrective data (2021) and post-corrective data (2022) were considered.

Table 2: Preexamination NC of 2021 and 2022 in number and percentage.

Non- conformances	2021 Numbers (%)	2022 Numbers (%)
Samples lost/not received	70 (32.41%)	115 (32.21%)
Improperly labelled samples	49 (22.69%)	36 (10.08%)
Sample without requisition slip	19 (8.80%)	11 (3.08%)
Sample received in wrong preservative/ wrong vacutainer	18 (8.33%)	32 (8.96%)
Inappropriate sample	16 (7.41%)	20 (5.60%)
Test not billed	12 (5.56%)	3 (0.84%)
Quantity not sufficient except for NICU	11 (5.09%)	30 (8.40%)
Wrong test billed	6 (2.78%)	3 (0.84%)
Test missed	5 (2.31%)	7 (1.96%)
Improper sample transport	4 (1.85%)	4 (1.12%)
Test request form without label	2 (0.93%)	0 (0.00%)
Delay in sample reception	1 (0.46%)	0 (0.00%)
Unordered repeat sample	1 (0.46%)	0 (0.00%)
Bill cancelled	1 (0.46%)	4(1.12%)
Not an in-house test	1 (0.46%)	0 (0.00%)
Barcode not stuck properly	0 (0.00%)	1 (0.28%)
Clotted sample	0 (0.00%)	79 (22.13%)
TRF duplication	0 (0.00%)	12 (3.36%)
Total	216 (100%)	357 (100%)

As a part of risk assessment, RPN was calculated. RPN provides an insight into the clinical impact of NC in patient care. Pre- and post-corrective strategy RPN is mentioned in Table 3.

Table 3: Pre- and post-corrective strategy RNP scores.

2021 and 2022 non-conformances	OR	DR	SR	RPN 2021	Corrective Strategies	OR	DR	SR	RPN 2022
Sample received in the wrong preservative/ improper(wrong) vacutainer	3	3	5	45	Targeted Training and Competency Assessment	4	3	5	60
Improperly labelled samples	3	3	5	45	Reinforce patient identification protocols (two identifiers) at collection Mandatory bedside/bar code labeling immediately after collection Periodic training	3	2	2	12
Samples lost/ not received	3	3	5	45	Clear handover responsibility between the collection and transport staff	3	1	1	3
Test missed	2	3	5	30	Checking the LIS system for pending or unprocessed tests at the end of each duty shift.	2	1	5	10
Wrong test billed	2	4	3	24	LIS validation checks during billing and staff training	2	4	3	24

2021 and 2022 non-c onformanc es	OR	DR	SR	RPN 2021	Corrective Strategies	OR	DR	SR	RPN 2022
Test not billed	3	3	2	18	Training of a billing clerk	2	3	2	12
Improper sample transport	2	2	4	16	Training -Educate transport personnel on sample stability req uirements	2	2	4	16
Quantity not sufficient except for NICU	3	1	4	12	• Display minimum volume req uirements at collection areas • Phlebotomy training on correct draw volumes	3	1	3	9
Inappropria te sample	3	1	3	9	Display of Sample type and container re quirements LIS prompts for correct sample selection Training	3	1	3	9
Delay in sample reception	2	1	3	6	Monitor delays as a quality indicator	1	1	1	1
Sample without requisition slip	3	1	2	6	• Enforce mandatory requisition at sample acceptance • LIS-based electronic test ordering	3	1	2	6
Test request form without label	2	1	3	6	Training Display of the procedure in the workstation	1	1	1	1

2021 and 2022 non-c onformanc es	OR	DR	SR	RPN 2021	Corrective Strategies	OR	DR	SR	RPN 2022
Unordered repeat sample	2	2	1	4	Staff education on test ordering protocols	1	1	1	1
Bill cancelled	2	1	1	2	• Clear com munication with patient s/wards before processing	2	1	1	2
Not an in-house test	2	1	1	2	Staff training at reception	1	1	1	1
The barcode is not stuck properly	1	1	1	1	Mandatory visual check before sample dispatch • Training on correct barcode placement	2	2	3	12
Sample clotted	1	1	1	1	Training on correct blood collection technique and mixing	4	1	4	16
TRF duplication	1	1	1	1	Educate staff on avoiding repeat form generation	2	1	1	2

Table 4: List of Non-conformances disappeared in 2022 after corrective strategies.

NCs disappeared in 2022	RPN 2021	RPN 2022
Test request form without label	6	1
Delay in sample reception	6	1
Unordered repeat sample	4	1
Not an in-house test	2	1

Table 5: Comparison between pre- and post-RPN corrective strategies using paired t-test.

RPN	Mean ± SD	Mean difference	SE difference	95% Confidence Interval	95% Confidence Interval	Effect Size	P
Before Corrective Strategy (in 2021)	18±16.1	6	3.69	2	24	0.745	0.041
After Corrective Strategy (in 2022)	10.9±15.3	6	3.69	2	24	0.745	0.041

The clinical relevance of the study was assessed using "Bayesian paired t-test", detailed in Table 6.

Table 6: Showing the confidence interval and Bayser factor.

RPN	Mean ± SD	95% Confidence Interval	95% Confidence Interval	BF	Error %
Before corrective Strategy (in 2021)	18±16.1	9.09	26.9	1.15	0.0242
After corrective Strategy (in 2022)	10.9±15.3	2.42	19.3	1.15	0.0242

The Bayes factor (BF) provides evidence that supports one hypothesis over another [10]. In this study, the alternative hypothesis (H1) states that there is a significant effectiveness noted in the preexamination phase following the implementation of the corrective plan, while the null hypothesis (H0) claims there is no significant effectiveness. BF_{10}=1.15 claims H1 has evidence over H0. BF_{10} and a lower error % of 0.0242 support the study to be clinically significant.

Discussion

The total number of sample collection tubes received in the laboratory increased from 187,096 in 2021 to 233,472 in 2022, accompanied by a rise in pre-examination NCs from 216 to 356. When expressed relative to the total sample volume, the rejection rate showed a slight increase from 0.115% in 2021 to 0.152% in 2022. These findings provide an overview of the trend in pre-examination NCs across the study period.

Failure Reporting Analysis and Corrective Action System-guided interventions were associated with the reduction or elimination of several high-risk pre-examination NCs for e.g., samples lost/not received: High risk RPN to low risk (RPN 45→3); improperly labelled: high risk RPN to moderate risk (RPN 45→12), with overall mean RPN falling significantly (18.0±16.1 to 10.9±15.3, p=0.041). Of 15 common NCs, 9 showed decreased RPN, 4 remained unchanged, and 2 increased. Four NCs disappeared entirely, though three new NCs emerged coinciding with STAT lab launch, highlighting that workflow changes can introduce new error modes. These findings demonstrate that FRACAS-driven risk assessment combined with targeted corrective strategies led to measurable improvement in several pre-examination processes, though persistent and worsening NCs indicate that training alone may be insufficient for complex systemic issues.

The pre-examination phase remains the most error-prone component of the TTP, largely due to its dependence on human factors and processes occurring outside the examination environment [1]. Studies have shown that preexamination errors outnumber examination or post-examination errors by 4 to 6 times in many countries, prompting initiatives for error reduction [12,13,14,15].

Among the identified NCs, "samples lost/not received" represented the most significant risk before corrective actions, with a high RPN of 45 in 2021. This finding contrasts with lower rates reported in earlier studies, where the contribution of this error ranged from 1.5% to 13.21% [2,16]. Following the implementation of defined handover responsibilities and improved communication between collection and transport staff, the RPN decreased markedly to low risk (RPN 3) in 2022, indicating a reduction in both occurrence and detectability risk. This underscores the importance of accountability and traceability in sample handling workflows. "Improperly labelled samples" also constituted a major pre-examination error in 2021, with an RPN of 45 indicating highrisk. After reinforcing patient identification

protocols, implementing mandatory bedside labelling, and providing periodic training, the RPN decreased significantly to moderate risk (RPN 12) in 2022. Although the initial rate was higher than those reported in previous studies [2,11,16], the post-corrective strategy reduction aligns with findings from other investigations that demonstrated improved labelling accuracy following targeted staff education [17,18]. This highlights training as an effective corrective strategy for human-factor–related errors.

Errors related to "wrong preservative or improper vacutainer" remained a persistent challenge. Despite a corrective strategy through targeted training and competency assessment, the RPN increased from 45 in 2021 to 60 in 2022, both are in high-risk category due to a rise in occurrences as well as increased samples received in 2022. Similar trends of increased frequency following interventions have been reported in other studies [17], suggesting that this NC may require additional strategies beyond training, such as standardized collection kits, stronger LIS prompts, or visual aids at collection sites. This finding emphasizes that training alone may not be sufficient for certain high-risk errors. Another reason for the increased number of occurrences is improved documentation of the NCs.

Billing-related NCs demonstrated mixed outcomes. "Wrong test billed" maintained a moderate risk RPN of 24 in both years despite a reduction in frequency, reflecting persistent challenges in detection and severity. The "test not billed" issue showed a decrease in RPN from 18 to 12 after targeted training of billing personnel, reflecting improved process reliability. However, the RPN score remains within a moderate risk range. These results indicate that mitigating billing-related risks requires a combination of system-level controls and ongoing staff oversight. Errors related to sample transport and reception showed improvements. "Improper sample transport" exhibited no change in RPN despite a reduction in frequency, consistent with reports that transportation errors can significantly compromise sample integrity if not tightly controlled [19]. In contrast, "delay in sample reception" and "test request form without label" were eliminated following the corrective strategy, with RPNs reduced to one, demonstrating the effectiveness of monitoring these parameters as quality indicators and enforcing standardized procedures.

Certain NCs emerged only after workflow changes. "Clotted samples" appeared in 2022 following the introduction of a short turnaround time (STAT) laboratory service, contributing moderate risk RPN of 16. This finding is comparable to previous studies reporting high rates of clotted samples [11]. Inadequate mixing of anticoagulant tubes after collection is a likely contributing factor [20], highlighting the need for focused phlebotomy training when new services or workflows are introduced.

Overall, this study demonstrates that incorrect techniques, workflow gaps, and communication failures are key contributors to pre-examination errors. Regular monitoring of NCs and RPNs enables laboratories to prioritize risks effectively and evaluate the impact of corrective actions. While training proved effective for many NCs, some high-risk errors persisted or increased, indicating the need for multifaceted interventions that combineeducation, system automation, standardized procedures, and continuous performance monitoring.

Continuous staff training strengthened laboratory–clinical communication, implementation of quality indicators, and routine review of RPN trends are essential to sustaining improvements in the pre-examination phase. Adoption of a structured risk management approach, such as FRACAS, supports proactive error prevention, enhances laboratory efficiency, and ultimately contributes to improved patient safety and quality of care [21,22].

Conclusion

Implementation of FRACAS-driven risk assessment and targeted corrective strategies significantly reduced pre-examination non-conformances and associated risks in the clinical laboratory. Continuous monitoring of RPN enabled effective prioritization of high-risk processes and evaluation of corrective actions. Sustained quality improvement in the pre-examination phase requires ongoing staff training, system-level controls, and proactive risk management to enhance patient safety and laboratory performance.

Limitations

In the study, only the biochemistry laboratory's NCs (573) were analysed. Including all NCs from other laboratories in the hospital could offer a more comprehensive view. The study's scope is restricted to data comprising only two years. Extending the duration of the study could yield further valuable insights.

Declaration of Conflict of interests

We all authors declare no conflict of interests.

Ethics statement

The study was conducted after obtaining approval from the Institutional Ethics Committee (IEC 360/2023). This study used only anonymized laboratory quality-related data and did not involve any direct patient participation or identifiable patient information. The study adhered to the principles of the Declaration of Helsinki.

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Author's Disclosures

Nothing to disclose.

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Data Availability

Data is available with the corresponding author and can be shared upon a reasonable request from the readers.

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