

Applying the DMAIC Approach to Reduce Pre-Analytical Errors: Evidence from a Moroccan Medical Laboratory Case Study

Application de l'approche DMAIC pour réduire les erreurs pré-analytiques dans un laboratoire médical : Une étude de cas du Maroc

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ABSTRACT

Background: Pre-analytical errors are the most common mistakes in medical laboratories and can directly affect patient safety and the accuracy of test results. Typical problems include hemolysis, mislabeling, and issues with sample transport. In Morocco, few studies have looked closely at these errors or tested structured improvement approaches such as DMAIC (Define, Measure, Analyze, Improve, Control).

Aim: This study aimed to see whether the DMAIC method could reduce pre-analytical errors in a private laboratory in Casablanca, and whether it could provide practical guidance for similar low-resource laboratories.

Methods: We conducted a quasi-experimental study with 324 patients—162 before (September 2023) and 162 after (February 2024) the intervention. Data came from the Laboratory Information System, internal audits, and incident reports. Key indicators included hemolysis, labeling mistakes, and transport problems. We used Pearson's Chi-square test to compare groups, with $p \leq 0.05$ considered significant.

Results: The percentage of patients with at least one pre-analytical error dropped from 43.8% (71/162) to 17.9% (29/162) ($\chi^2 = 24.67$; $df = 1$; $p < 0.001$). Labeling mistakes fell from 29 to 8 cases, transport issues from 24 to 11, and hemolyzed samples from 12 to 3. The sigma level rose from 3.03 to 3.86, showing clear improvement in process reliability. The improvements remained stable over time.

Conclusion: Applying the DMAIC method significantly reduced pre-analytical errors and improved laboratory processes. This structured, step-by-step approach can help similar laboratories improve patient safety and test reliability, even with limited resources.

Key words: DMAIC methodology, Lean Six Sigma, Pre-analytical errors, Process improvement, Medical laboratory

RÉSUMÉ

Contexte : Les erreurs pré-analytiques constituent une source majeure d'erreurs de laboratoire et peuvent compromettre considérablement la précision diagnostique et la sécurité des patients. Les problèmes fréquents incluent l'hémolyse des échantillons, des erreurs d'étiquetage et des problèmes de transport. La méthodologie DMAIC, qui fait partie du cadre Lean Six Sigma, propose une approche structurée et basée sur les données pour réduire ces erreurs.

Objectif : Cette étude a évalué l'efficacité de l'approche DMAIC pour réduire les erreurs pré-analytiques dans un laboratoire médical privé à Casablanca, au Maroc.

Méthodes : Une étude de cas quasi-expérimentale a été réalisée sur 324 patients — 162 avant (septembre 2023) et 162 après (février 2024) de l'intervention. Les données ont été obtenues à partir du Laboratoire Information System, des audits internes et des rapports d'incident. Chaque échantillon a été évalué pour détecter des non-conformités pré-analytiques, notamment l'hémolyse, les erreurs d'étiquetage et les problèmes de transport. L'analyse des causes profondes, utilisant des outils comme les graphiques de Pareto et les diagrammes d'Ishikawa, a guidé les actions d'amélioration. Les statistiques descriptives mesuraient les résultats.

Résultats : Des erreurs pré-analytiques ont été enregistrées chez 43,8 % des patients avant l'intervention, pour chuter à 17,9 % par la suite. Les cas d'hémolyse sont passés de 12 à 3, les erreurs d'étiquetage de 29 à 8, et les problèmes de transport de 24 à 11. Le nombre de cas sans erreur est passé de 91 à 133. Le niveau sigma est passé de 3,03 à 3,86, indiquant une amélioration des performances du procédé. Ces résultats démontrent l'efficacité du DMAIC, en particulier dans des contextes à ressources limitées.

Conclusion : La mise en œuvre de la méthodologie DMAIC a entraîné une réduction substantielle et durable des erreurs pré-analytiques. Cette approche structurée promet d'améliorer les pratiques de laboratoire et de promouvoir la sécurité des patients.

Mots clés: Méthodologie DMAIC, Lean Six Sigma, Erreurs pré-analytiques, Amélioration des processus, Laboratoire médical

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INTRODUCTION

Medical laboratories are essential to healthcare because they help diagnose diseases, guide treatments, and prevent illness. About 70% of medical decisions rely on laboratory test results (1). However, accurate results depend not only on the tests themselves but also on what happens before testing. The “pre-analytical phase” includes patient preparation, sample collection and labeling, and transport and storage (2). Errors during this phase can compromise patient safety and increase healthcare costs.

The global healthcare community recognizes the need to strengthen quality management during the pre-analytical phase, which accounts for 60–70% of laboratory errors (3,4). Common problems include specimen mishandling, patient identification errors, hemolysis, and transport delays. While many laboratories implement quality assurance systems, these often focus on analytical steps, leaving pre-analytical processes under-managed.

To address this gap, laboratories worldwide are increasingly adopting Lean Six Sigma (LSS) methods. Central to LSS is the DMAIC model (Define, Measure, Analyze, Improve, Control), which provides a structured, stepwise approach to identify inefficiencies and reduce errors (2,5). Studies have shown that applying DMAIC in laboratory settings can reduce pre-analytical errors and shorten turnaround times by targeting root causes and implementing sustainable improvements (6–8).

Despite global evidence supporting DMAIC, its practical application remains limited in Moroccan laboratories, where most reports rely on aggregated process indicators rather than patient-level data. This study addresses that gap by monitoring pre-analytical errors for individual patients before and after a DMAIC intervention. A total of 324 patient records (162 pre-intervention, 162 post-intervention) were reviewed in a private laboratory in Casablanca. This allowed the team to assess the frequency and types of non-conformities, such as hemolysis, labeling errors, and transport issues, and to evaluate the impact of targeted corrective actions. Following DMAIC implementation, the overall error rate dropped from 43.8% to 17.9%, with notable reductions in hemolysis and labeling and transport errors.

Research question: How can Moroccan laboratories systematically reduce pre-analytical errors using patient-level evidence? More specifically, can DMAIC provide a reliable and sustainable approach for improving pre-analytical workflows in this context?

General objective: To reduce pre-analytical errors in a Moroccan medical laboratory using the DMAIC methodology.

Specific objectives:

- Identify the most frequent pre-analytical errors.
- Investigate their root causes using quality improvement tools such as Pareto charts and Ishikawa diagrams.
- Design and implement targeted interventions.
- Evaluate the effectiveness of these interventions using key performance indicators, including sample rejection rates and overall error rates.

Background

Lean Six Sigma (LSS) is a widely used method that combines two effective strategies: Lean, which aims to reduce waste and improve efficiency (originally from the Toyota Production System), and Six Sigma, developed by Motorola in the 1980s to minimize defects and enhance quality. A key component of Six Sigma is the DMAIC cycle (Define, Measure, Analyze, Improve, and Control) a structured approach that helps teams improve processes and reduce errors over time (9,10).

The DMAIC model has its roots in the work of early quality pioneers like W. Edwards Deming, Joseph Juran, and Walter Shewhart, who emphasized the importance of continuous improvement, data-driven decisions, and meeting customer needs (11). Over the years, this approach has become an essential tool in healthcare quality initiatives—especially in medical laboratories—where accuracy and safety are critical for reliable patient care (4,5).

In this study, the DMAIC framework is used both as a theoretical model and a practical tool to help reduce pre-analytical errors in a Moroccan medical laboratory. Each step of the DMAIC cycle supports a structured, data-driven approach to lasting quality improvement:

→ **Define:** This phase involves clearly stating the problem and identifying those involved. The pre-analytical process is mapped using tools like the SIPOC diagram (Suppliers, Inputs, Process, Outputs, Customers) to find the stages most prone to errors—such as patient identification, sample collection, labeling, and transport.

→ **Measure:** At this stage, baseline data are collected to understand the current performance. Key indicators like sample rejection rates due to hemolysis, low volume, wrong tube selection, or labeling mistakes are recorded. The process’s capability is evaluated using Sigma level calculations (10).

→ **Analyze:** Here, the aim is to understand why errors are happening. Root causes are identified using tools like Pareto charts, fishbone diagrams (Ishikawa), and the 5 Whys method. These techniques help link issues to factors such as poor staff training, lack of communication, or missing standard procedures.

→ **Improve:** Based on the findings, specific corrective actions are introduced. These may include updating protocols, conducting training sessions, improving how samples are labeled and transported, or using tools like barcodes and color-coded tubes. Pilot tests are carried out to check the success of the changes.

→ **Control:** The final phase ensures that improvements are maintained over time. This involves setting Key Performance Indicators (KPIs), performing regular audits, and putting formal procedures (SOPs) in place. Visual tools and feedback systems are used to monitor performance and prevent errors from reoccurring.

The figure below summarizes the DMAIC cycle and its sequential application in quality improvement processes:

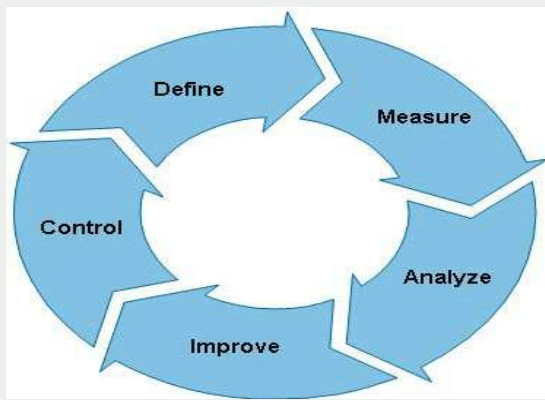


Figure 1. DMAIC Cycle Diagram
(Adapted from (5))

Using the DMAIC approach allows laboratories to move from simply reacting to problems toward a more proactive way of working, where error prevention becomes part of everyday practice. This shift helps improve patient safety, ensures better compliance with regulations, and encourages smarter, more efficient use of resources (4,9).

RESEARCH METHODOLOGY

Study Design

This study used a case study approach along with a quasi-experimental design to compare results before and after the intervention, in order to assess how well the DMAIC method helped reduce pre-analytical errors.

A total of 324 patients were included 162 before the intervention (September 2023) and 162 after (February 2024) enabling a direct comparison of non-conformities at the patient level.

Setting

This study was conducted in a private medical laboratory located in Casablanca, Morocco. The laboratory provides various diagnostic services and uses a Laboratory Information System (LIS) to organize its operations and record data accurately.

Participants

The team engaged in this quality improvement initiative consisted of laboratory technicians, biologists, and quality management staff. Their combined expertise and active participation were crucial for detecting errors, investigating root causes, executing corrective actions, and sustaining ongoing process control.

All biological samples analyzed were linked to identifiable patient records (coded anonymously), allowing for individual-level analysis of conformity before and after the intervention.

Data Sources

To ensure a thorough evaluation, data for this study were

gathered from several sources:

→ The Laboratory Information System (LIS) supplied quantitative data on sample handling and the frequency of errors.

→ Internal audit reports provided valuable information about compliance with procedures and any observed deviations.

→ Incident reporting forms captured detailed accounts of pre-analytical errors as reported by laboratory personnel.

Patient-level tracking allowed classification of each case according to the presence or absence of specific pre-analytical non-conformities.

Key Pre-Analytical Error Indicators

The pre-analytical phase of laboratory testing is prone to errors that significantly affect patient safety and diagnostic accuracy (4). Based on literature and clinical relevance, the following indicators were selected and monitored:

→ Number of Rejected Samples Due to Hemolysis:

Hemolysis, the rupture of erythrocytes releasing intracellular contents, is a leading cause of specimen rejection in clinical labs and can alter test results (1,12). Monitoring hemolyzed samples indicates quality of blood collection, handling, and transport.

→ Number of Mislabeled Samples:

Mislabeled risks patient identification errors and wrong test results (13). This indicator reflects adherence to identification and labeling protocols, a critical control point in quality assurance (14).

→ Number of Samples with Incorrect Transport or Storage Conditions:

Sample degradation due to improper transport or storage compromises analyte stability and test validity (15). Tracking this indicator evaluates compliance with temperature and time guidelines during sample transit (16).

→ Time Between Sample Reception and Entry into LIS:

Delays in sample processing can affect test turnaround time and sample integrity (15). Measuring this interval identifies workflow inefficiencies and potential process bottlenecks.

→ Number of Patients with at Least One Pre-Analytical Non-Conformity:

Each patient record was assessed for conformity on an individual basis, rather than aggregate error percentages alone, allowing a more granular analysis of process impact.

DMAIC Methodology Application

The DMAIC cycle comprising: Define, Measure, Analyze, Improve, and Control, served as a structured framework to methodically reduce pre-analytical errors:

→ **Define:** The study's scope and objectives were clearly outlined, with key stakeholders identified. Pre-analytical workflows were mapped using SIPOC diagrams (Suppliers, Inputs, Processes, Outputs, and Customers) to highlight the most error-prone stages.

→ **Measure:** Baseline data on error rates and process performance were gathered from the Laboratory Information System and audit reports. Process capability was evaluated through Sigma level calculations.

→ **Analyze:** Root cause analysis was conducted using Pareto charts to prioritize errors, Ishikawa diagrams to explore causes, and the 5 Whys method to uncover deeper systemic issues.

→ **Improve:** Focused corrective measures were developed and applied, including staff retraining, protocol standardization, enhanced sample labeling, and optimization of transport conditions.

→ **Control:** To maintain gains, Key Performance Indicators (KPIs) were established, Standard Operating Procedures (SOPs) implemented, regular audits scheduled, and ongoing staff feedback encouraged.

Data Analysis

Statistical analyses were performed using IBM SPSS Statistics version 22. Descriptive statistics (frequency and percentage) summarized categorical variables such as the presence or absence of pre-analytical non-conformities per patient.

To compare the proportion of errors before and after the DMAIC intervention, the Pearson Chi-square (χ^2) test was applied. When any expected cell count was below 5, Fisher's exact test was used. Continuous variables such as turnaround time were analyzed with the independent-samples t-test after verifying normality with the Shapiro-Wilk test.

Pareto charts identified the most frequent error categories, and control charts evaluated process stability over time. Sigma-level calculations quantified the capability of the process before and after improvement. A p-value ≤ 0.05 was considered statistically significant.

Timeline

The project was carried out over a five-month period from September 2023 to February 2024, with each phase of the DMAIC cycle scheduled to ensure a systematic and thorough reduction of pre-analytical errors. The timeline below details the activities by month:

Phase	Sep 2023	Oct 2023	Nov 2023	Jan 2024	Feb 2024
Define	X				
Measure		X			
Analyze		X			
Improve			X	X	
Control				X	X

Ethical Considerations

This study was conducted in accordance with ethical guidelines to ensure the protection and respect of the rights of all participants involved. The data collection process maintained strict confidentiality and anonymity of laboratory staff, with all information anonymized to prevent identification. No patient-identifiable data were accessed or used, fully complying with Moroccan Law 09-08 on the protection of personal data. Participation of laboratory personnel was voluntary, and they retained the right to withdraw from the study at any time without any consequences.

Approval for the study was obtained from the management of the private medical laboratory in Casablanca. Given that this quality improvement project posed minimal risk and involved no direct interventions on patients, formal ethical committee review was not deemed necessary. Instead, the study adhered to widely accepted ethical standards applicable to quality improvement and observational research.

Participants were fully informed about the study's purpose and objectives at the outset. Their continued involvement and cooperation were considered as implied consent. The tools and processes used in data collection were designed to minimize any discomfort or disruption to the routine laboratory workflow.

Since the laboratory does not have a formal ethics committee, management authorization was deemed sufficient to satisfy ethical and legal requirements for conducting this study.

Statistical analyses were performed using IBM SPSS Statistics (version 22). Descriptive statistics summarized key indicators before and after the intervention. Analytical methods, including Pareto analysis, control charts, and sigma level calculations, were applied to evaluate the effectiveness of the DMAIC methodology.

RESULTS

Baseline Data (Pre-Intervention)

In September 2023, during the measurement phase, data were gathered from 162 patients to evaluate how often pre-analytical errors occurred. The results showed that 43.8% of the patients (71 out of 162) experienced at least one issue before the analysis phase.

The main problems identified were:

- 12 samples rejected due to hemolysis
- 29 samples with labeling mistakes or missing information
- 24 samples that weren't transported properly
- Some patients had more than one type of error in the same sample

A Pareto chart showed that labeling problems and transport issues made up more than 70% of all the errors. Based on the error rate, the sigma level was estimated at 3.03, suggesting that the process was performing at an average level and could benefit from further improvement.

Table 1. Baseline Distribution of Pre-Analytical Errors (Pre-Intervention Phase)

Error Type	Number of Cases (n)	Percentage (%)	95% Confidence Interval
≥1 Pre-analytical error	71	43.8%	36.2 – 51.6
Labeling errors	29	17.9%	12.3 – 24.7
Transport issues	24	14.8%	9.8 – 21.2
Hemolysis	12	7.4%	3.9 – 12.5

Root Cause Analysis

In October 2023, the team carried out a root cause analysis during the Analyze phase, using tools like the Ishikawa diagram and the "5 Whys" technique to dig deeper into the sources of pre-analytical errors. Several underlying factors were uncovered:

- Labeling mistakes were linked to the absence of a clear labeling procedure, confusion from handwritten entries, and staff fatigue during busy hours.
- Transport issues stemmed from not using insulated containers for samples that require controlled temperatures, along with no designated person in charge of checking transport conditions.
- Hemolysis cases were often caused by the use of inappropriate needle sizes, poor blood draw techniques, and delays in centrifuging the samples.

When multiple errors occurred together, it was usually due to a disorganized workflow, failure to follow standard procedures, and weak communication between different shifts.

Improvements Implemented

Between November 2023 and January 2024, several improvements were put into place to reduce errors:

- Staff received refresher training on how to properly collect, label, and transport samples.
- Updated standard operating procedures (SOPs) were posted near work areas as quick visual reminders.
- Thermo-resistant containers were provided to ensure proper conditions during sample transport.
- Morning meetings were held daily to remind staff of quality targets and encourage good practices.
- A real-time audit checklist was introduced, allowing staff to track compliance during their shifts.

Post-Intervention Results

In February 2024, during the Control phase, data collection revealed a substantial and statistically significant reduction in pre-analytical errors following implementation of the DMAIC improvement plan.

The overall proportion of patients presenting at least one pre-analytical non-conformity decreased from 43.8 % (71 of 162) before the intervention to 17.9 % (29 of 162) after ($\chi^2 = 24.67$; df = 1; $p < 0.001$; OR = 0.28, 95% CI: 0.17–0.46).

By error category:

- Labeling errors declined from 29 cases (17.9 %) to 8 (4.9 %) ($\chi^2 = 10.86$; $p = 0.001$; OR = 0.23, 95% CI: 0.10–

0.52)

- Transport and storage issues dropped from 24 (14.8 %) to 11 (6.8 %) ($\chi^2 = 4.27$; $p = 0.039$; OR = 0.42, 95% CI: 0.19–0.92)

- Hemolysis incidents were reduced from 12 (7.4 %) to 3 (1.9 %) (Fisher's exact $p = 0.045$; OR = 0.24, 95% CI: 0.06–0.91)

Errors involving multiple non-conformities within the same sample were almost completely eliminated. The calculated Sigma level improved from 3.03 to 3.86, confirming higher process capability.

Control-chart analysis demonstrated that the process remained stable after intervention, with error rates consistently below pre-intervention levels throughout the observation period (Figure 2).

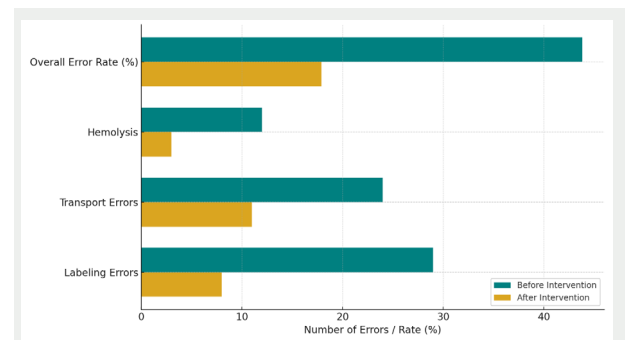


Figure 2. Comparison of Pre-Analytical errors before and after Intervention

Staff Feedback and Sustainability

Informal interviews and team debriefings revealed that staff felt more confident and aware of quality assurance practices. Many expressed that they felt more engaged in their work, largely thanks to the daily briefings.

To keep these improvements going over the long term, several actions were put in place:

- Regular reviews of non-conformities were added to monthly staff meetings
- Phlebotomists and front-desk staff were scheduled for refresher training every three months
- A digital dashboard was introduced to track performance trends and quickly identify potential issues
- A designated quality officer was assigned to each shift to oversee and support adherence to procedures.

Together, these steps helped build a stronger culture of accountability and continuous improvement during the pre-analytical phase.

DISCUSSION

The findings of this study clearly demonstrate the effectiveness of the DMAIC methodology in reducing pre-analytical errors in a Moroccan medical laboratory. Following the intervention, the overall error rate declined significantly from 43.8% to 17.9%, reflecting a substantial improvement in quality and operational performance. This reinforces the conclusions of several recent studies that have highlighted the successful application of Lean

Six Sigma tools in clinical laboratories to enhance patient safety and reduce variability in the pre-analytical phase (2,3).

Hemolysis Reduction

Hemolysis remains one of the most common causes of sample rejection globally, compromising the reliability of biochemical tests and leading to repeat sampling (1,3). In our study, hemolysis cases were reduced by 75% (from 12 to 3), largely due to targeted staff retraining, the adoption of appropriate needle sizes, and quicker centrifugation protocols. These findings are consistent with (8), who emphasized that competency-based training and strict adherence to phlebotomy guidelines are crucial in minimizing hemolysis. Furthermore, the introduction of real-time feedback and performance indicators helped sustain these improvements, aligning with the best practices outlined (17).

Mislabeling and Sample Identification

Sample mislabeling can result in serious diagnostic and clinical errors due to patient misidentification (18). In this study, labeling errors dropped from 29 to 8 cases after implementing barcode-based labeling and standardized SOPs. This result mirrors those of (6,7), who demonstrated that automating the labeling process and reinforcing standardized practices can dramatically reduce human error. The synergy of technological solutions and visual management tools contributed to more accurate sample traceability and enhanced patient safety.

Transport and Storage Improvements

Pre-analytical errors related to transport and storage often go underreported, yet they significantly affect sample quality, particularly in settings without strict temperature monitoring (16). Our intervention, which included the introduction of thermo-stable containers and clearer staff roles for monitoring conditions, reduced these errors from 24 to 11 cases. This aligns with studies conducted in resource-limited settings, where structured, low-cost interventions significantly improved sample preservation (2,8).

Turnaround Time and Workflow Efficiency

Workflow Efficiency and Turnaround Time
Although not a primary endpoint, the observed improvements in workflow efficiency were reflected in the reduced number of simultaneous non-conformities and more timely processing of samples. Standardized procedures, daily quality briefings, and the use of audit checklists contributed to smoother sample flow and faster entry into the Laboratory Information System (LIS). Similar gains in turnaround time and workload management have been reported by (6) following Lean Six Sigma implementation.

Staff Engagement and Quality Culture

Feedback from informal staff interviews indicated an increased sense of ownership and awareness of quality procedures. The daily briefings and simplified SOPs helped reinforce a shared understanding of quality objectives. This bottom-up approach to quality assurance aligns with the principles of continuous improvement advocated by ISO 15189:2022 and supported by authors like (19), who noted that active staff involvement is essential for embedding lasting change in laboratory settings.

CONCLUSION

This study showed that using the DMAIC method—part of the Lean Six Sigma approach—can help significantly reduce pre-analytical errors in a medical laboratory in Morocco. After the intervention, the total error rate dropped from 43.8% to 17.9%, with clear improvements in areas like hemolysis, labeling mistakes, and transport issues. These results show how valuable structured quality improvement methods can be, especially in laboratories with limited resources.

Based on what we found, we recommend the following actions:

- Keep training staff regularly on how to properly collect, label, and transport samples
- Use barcode systems or other digital tools to reduce mistakes in sample identification
- Monitor performance using regular checklists and key indicators
- Set clear, easy-to-follow procedures (SOPs) for every step in the process and make them visible to staff

This study has some limits. Since it was done in only one laboratory, the results might not apply everywhere. Also, the follow-up period after the changes was short, so we don't yet know how well these improvements will last over time.

Looking ahead, future studies should involve more laboratories and follow up over a longer period. It may also be helpful to explore the use of artificial intelligence and digital tracking systems to catch and prevent errors more effectively. Finally, studying the costs and benefits of these improvements could help guide national decisions about quality in healthcare.

Applying Lean Six Sigma more widely across laboratories in Morocco could lead to better quality services, safer care for patients, and more efficient daily operations.

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