Research Article

Multicomponent CAPA Programme Incorporating Cloud-Based Laboratory Information System Migration for Post-Analytical Error Reduction in an Accredited Stand-Alone Diagnostic Laboratory: A 13-Month Before-and-After Study

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Article Info

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Keywords

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Abstract

Purpose: Post-analytical errors are under-investigated relative to pre-analytical errors, particularly in stand-alone diagnostic laboratories in low- and middle-income countries (LMICs). We evaluated a multicomponent Corrective and Preventive Action (CAPA) programme — combining process-level controls with two infrastructure changes, migration from a local on-premise laboratory information system (LIS) to a centralised cloud-based LIS and installation of dual-broadband connectivity — for reducing post-analytical errors at an NABL-accredited diagnostic laboratory.

Methods: Single-centre before-and-after observational quality-improvement study reported per SQUIRE 2.0. Failure Mode and Effects Analysis (FMEA) identified six post-analytical failure modes. A six-month pre-CAPA baseline (April–September 2025; 19,898 reports) was compared with a six-month post-CAPA period (November 2025–April 2026; 20,794 reports). October 2025 was designated a priori as an implementation window and excluded from the primary comparison. Outcomes were error count, errors per million reports released (EPMR), and Sigma level. Exact Poisson rate ratios, Fisher's exact test and a bounding analysis for the excluded transition month were performed.

Results: Post-analytical errors fell from 24 (1,206 EPMR; ~4.53σ) to 4 (192 EPMR; ~5.05σ), an 84.1% reduction (rate ratio 0.159, 95% CI 0.040–0.464; Fisher's exact p = 0.00008). The 10 pre-CAPA LIS/software errors arose from two discrete infrastructure incidents, each affecting five reports; no such incident was recorded post-CAPA. Every error category fell. The LIS failure mode was correctly scored low risk on clinical severity and event frequency, yet generated the largest share of observed errors. Bounding analysis indicated the reduction would remain significant unless the excluded transition month contained ≥11 errors, exceeding the highest observed baseline month (7).

Conclusions: A multicomponent CAPA package produced a substantial post-analytical error reduction and a ~0.5 Sigma improvement. The reduction cannot be attributed to any single component. The finding that prospective FMEA classified the dominant failure mode as low risk supports complementing prospective risk assessment with retrospective error logging.

Introduction

Errors in clinical laboratory testing remain a persistent threat to patient safety, with consequences extending from specimen recollection and diagnostic delay to misdiagnosis, inappropriate therapy, and measurable patient harm [1]. The total testing process is conventionally divided into pre-analytical, analytical, and post-analytical phases, and the relative contribution of each to total error burden has been studied for more than two decades [2, 3]. While the pre-analytical phase has historically attracted the greatest attention, accounting for an estimated 60–70% of total errors in most large series [4], the post-analytical phase — result validation, interpretive review, critical value notification, turnaround time management, result transmission, and post-test sample handling — has received comparatively less systematic study [5].

Post-analytical errors are consequential because they occur at the laboratory–clinician interface where corrective opportunities are limited and clinical action is imminent [6, 7]. The IFCC Working Group on Laboratory Errors and Patient Safety has extended its harmonised quality-indicator framework to post-analytical indicators [8, 9], and the 2022 revision of ISO 15189 strengthened pre- and post-examination requirements [10]. Despite this, the evidence base is concentrated in hospital laboratories in high-income countries, with stand-alone diagnostic laboratories in LMIC settings under-represented [11].

Stand-alone diagnostic laboratories in LMIC contexts face distinct operational realities. Specimen collection is often distributed across collection centres, and infrastructure may rely on locally maintained servers rather than centrally managed enterprise information systems [22, 23]. Under such arrangements, server crashes, software hangs, and connectivity disruptions can be recurrent operational events affecting report release [11, 12, 33]. Laboratory information systems in resource-constrained settings frequently lack the redundancy, monitoring and vendor support taken for granted in enterprise environments, and implementation experience from such settings remains sparsely documented [33]. Structured CAPA frameworks anchored in NABL and ISO 15189 offer an institutional infrastructure for systematic improvement, but their application to the post-analytical phase in stand-alone LMIC laboratories is poorly documented [13].

Migration of clinical information systems to cloud-hosted architecture has been advanced as a route to improved availability and reduced local maintenance burden [24, 25], but it redistributes rather than eliminates risk: dependency shifts from local hardware to network availability, vendor service levels, and the security posture of the hosting provider [27, 34]. Health informatics scholarship further emphasises that clinical information systems are socio-technical rather than purely technical entities, and that their safety properties emerge from the interaction of software, workflow and the people who use them [26, 28]. Cybersecurity exposure in healthcare information systems has grown substantially [27], and health information technology implementations frequently fail for organisational rather than technical reasons, including user resistance and inadequate change management [29, 30, 31]. Evidence that health IT interventions improve quality is real but heterogeneous, and effects are strongly context-dependent [32]. These considerations are directly relevant when infrastructure change is proposed as a quality intervention.

Six Sigma methodology, expressed through defect rates and Sigma levels, has been widely adopted for analytical quality monitoring [14] and extended to the pre- and post-analytical phases [15, 16]. Recent work shows that resource-appropriate interventions in stand-alone NABL-accredited laboratories can achieve internationally benchmarkable pre-analytical Sigma performance [17], but corresponding post-analytical evidence is sparse. The present study reports a 13-month before-and-after evaluation of a multicomponent post-analytical CAPA programme combining process-level controls with two infrastructure changes. The aims were to (i) quantify the change in post-analytical error frequency and Sigma performance, (ii) describe the contribution of individual components without attributing the aggregate effect to any one of them, and (iii) compare prospective FMEA risk scoring with observed error frequencies.

Materials and Methods

This quality-improvement study is reported in accordance with the SQUIRE 2.0 guideline [21] (completed checklist provided as Supplementary Information).

Study setting

The study was conducted at a stand-alone clinical diagnostic laboratory in western India, accredited by the National Accreditation Board for Testing and Calibration Laboratories (NABL) under ISO 15189 and operating within a partner-laboratory network arrangement. Across the 13-month study period the laboratory released a mean of 3,393 patient reports per month (range 2,989–3,910) across clinical chemistry, haematology, immunology, serology and microbiology, serving an outpatient catchment through a network of collection centres. Monthly report volumes were extracted retrospectively from the laboratory information system and are reported in full in Table 1; they replace the approximate monthly figure used in earlier internal reporting.

Study design and definition of study periods

This was a single-centre observational before-and-after quality-improvement study spanning a 13-month calendar period (1

April 2025 to 30 April 2026), of which 12 months contributed to the primary analysis: a pre-CAPA baseline (1 April 2025 to 30 September 2025; six months; 19,898 reports) and a post-CAPA observation period (1 November 2025 to 30 April 2026; six months; 20,794 reports). A total of 40,692 patient reports were released across the two analysed periods.

October 2025 (3,419 reports) was designated a priori as an implementation window rather than an observation period, and was excluded from the primary comparison. The rationale was that the LIS migration was executed progressively across the whole month rather than as a single-day cutover; throughout October the information system was in neither its pre-intervention nor its post-intervention configuration, and errors arising during this state are attributable to neither. Consistent with this designation, the laboratory's error log was operated as a phase-locked study instrument and post-analytical errors were not counted during the transition month. Because this exclusion could in principle favour the intervention, a bounding analysis quantifying its maximum possible influence is reported in the Results and the absence of transition-month error counts is acknowledged as a limitation.

Failure Mode and Effects Analysis

Prior to study commencement the quality-improvement team conducted a structured FMEA of the post-analytical phase, adapted from established laboratory FMEA frameworks [18]. The assessment was performed in March 2025 by a four-member team comprising the managing director (quality management), the laboratory head/pathologist, the senior scientific officer, and the quality-improvement coordinator. Six post-analytical failure modes were identified from internal incident records, NABL non-conformity logs, and team discussion.

Each mode was scored on Severity (S) and Probability (P) using five-point scales. Severity anchors were: 1 = negligible, no clinical consequence; 2 = minor, administrative correction only; 3 = moderate, potential to affect a clinical decision; 4 = major, incorrect or delayed clinical action likely; 5 = critical, potential for patient harm. Probability anchors were expressed as expected event frequency: 1 = rare (<1 event/year); 2 = unlikely (1–4 events/year); 3 = possible (5–12 events/year); 4 = likely (13–24 events/year); 5 = frequent (>24 events/year). Risk Priority Number (RPN) was calculated as S × P, with categories Low (<5), Medium (5–8), High (9–14) and Extreme (≥15). Scoring was assigned by group consensus in a single facilitated session rather than by independent rating followed by reconciliation; disagreements were resolved by discussion until consensus was reached. Detectability was not incorporated, since several failure modes were by definition identified only after report release, making a detectability rating uninformative. No formal inter-rater reliability statistic was calculated. These are acknowledged as methodological limitations. The full scoring matrix and anchor definitions are provided as Supplementary Information. A formal post-intervention residual-risk reassessment was not undertaken; this is identified as a limitation.

We note explicitly that in the manuscript as originally drafted, two failure modes scoring RPN 4 (TAT Breach and LIS/Software Failure) were reported as Medium risk. Applied consistently, the categories defined above classify RPN 4 as Low risk. This has been corrected throughout; the correction strengthens rather than weakens the principal FMEA observation reported below.

Operational definitions and error adjudication

TAT Breach (Routine/STAT): any report not released within the laboratory's locally documented turnaround-time targets, attributable to post-analytical workflow factors. The laboratory operates under a franchise arrangement in which locally documented TAT targets, rather than the partner network's centralised TAT key-performance criteria, define compliance for this site; network-level TAT reports generated centrally are therefore not the denominator for this indicator. Critical Value Communication Miss: failure to communicate a critical result within the documented notification window, or incomplete documentation of the attempt; timely communication of critical results is an established post-analytical quality requirement with defined notification expectations [20]. Amended/Corrected Report: any report requiring reissue following identification of an error in the released report. Typographical Error (Manual Entry): error in manually entered demographic, request, or result information identified after release but before clinical action. Sample Retention/Storage Error (Post-Test): failure in post-testing sample storage, including temperature breaches, loss before the retention period, or storage labelling errors. LIS/Software Failure (Report Release Impact): any LIS or related software failure disrupting report release, including server crashes, software hangs, connectivity failures, and data-integrity events requiring manual intervention.

Categories were applied as mutually exclusive. Where an event could satisfy more than one definition — most commonly a report delayed by an LIS outage, which also meets the TAT breach definition — a hierarchical rule was applied: the proximate technical cause took precedence, so such events were classified as LIS/Software Failure and not additionally counted as TAT breaches. Classification was performed by the logging technologist at the point of identification and adjudicated at monthly aggregation by the laboratory head/pathologist, who resolved ambiguous entries. No report contributed to more than one category.

Incidents and affected reports

A single LIS or server failure may delay several reports simultaneously. The laboratory's error log records each such event as one incident line, annotated with the number of reports affected. Both quantities are reported here: the number of discrete incidents, which measures infrastructure reliability, and the number of affected reports, which measures patient-level

impact and forms the error count used for rate calculation. This distinction was not made explicit in the original manuscript and is reported in full below.

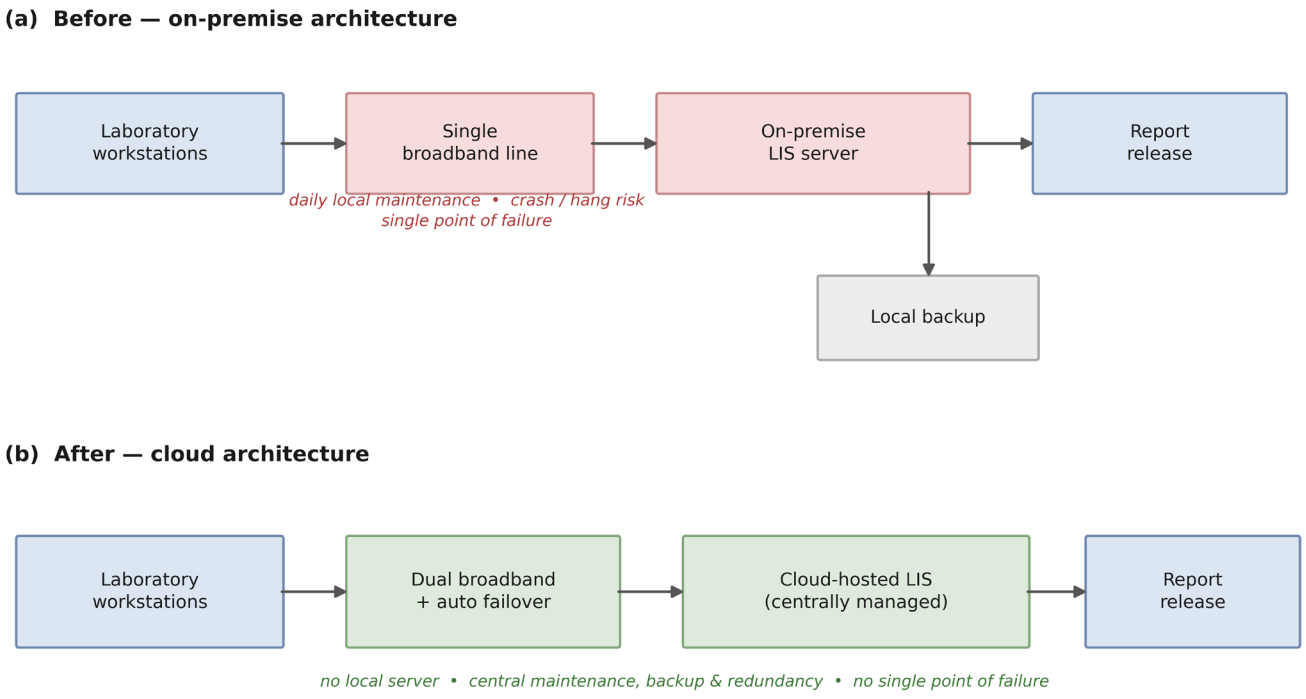
CAPA interventions (October 2025)

Interventions were implemented simultaneously across all six categories within the transitional month, and are described as a single multicomponent package. TAT Breach: a revised turnaround-time protocol with priority routing for STAT/urgent samples and escalation triggers for at-risk reports. Critical Value Communication Miss: activation of a critical-value alert in the LIS with documented notification workflow. Amended/Corrected Report: a structured sample and worksheet review workflow requiring cross-checking of patient history against current results before release. Typographical Error: role-based access control restricting review/authorisation and manual entry to authenticated personnel with audit-traceable actions. Sample Retention/Storage Error: refrigerator calibration and ongoing temperature monitoring with documented daily logs. LIS/Software Failure: the information-system architecture was redesigned through two complementary changes. First, the LIS was migrated from a local on-premise server to a centralised cloud-based LIS connected to the partner-laboratory infrastructure; the previous on-premise server required daily maintenance and was subject to crashes, software hangs and connectivity disruptions that periodically impacted report release. Second, recognising that cloud architecture creates a dependency on continuous internet uptime — under which a single line is a single point of failure — a dual-broadband configuration with automatic failover between two independent providers was installed. The migration was implemented progressively rather than as a single-day cutover. The before-and-after system architecture is contrasted in Figure 1.

Figure 2. Pareto chart of the pre-CAPA post-analytical error distribution (n = 24; April–September 2025; 19,898 reports). LIS/software failures constitute the dominant 'vital few' category, accounting for 41.7% of pre-CAPA errors; the cumulative-percentage line crosses the 80% threshold at the fourth category.

Figure 3. Run chart of monthly post-analytical error rates across the 13-month study period, expressed per 1,000 reports released using each month's actual denominator (printed on the upper axis). Absolute monthly error counts are annotated above each point, and LIS/software-failure errors are overlaid. October 2025, the implementation window, is shaded; post-analytical errors were not counted during that month. Pre- and post-CAPA medians are indicated as dotted lines.

Figure 1: Before-and-after laboratory information-system architecture.



(a) On-premise configuration: a local LIS server reached through a single broadband line, with local backup, requiring daily maintenance and presenting crash, hang and single-point-of-failure risks. (b) Cloud configuration: a centrally managed cloud-hosted LIS with central maintenance, backup and redundancy, reached through dual broadband with automatic failover, removing the local server and the single point of failure.

Because all components were deployed within the same month, their individual contributions cannot be separated. Throughout this report the intervention is therefore described as a multicomponent CAPA package, and the aggregate change is not attributed to the LIS migration alone.

Error logging, outcomes and analysis

Post-analytical errors were prospectively recorded on a standardised Monthly Post-Analytical Error Log by staff at the point of identification (date, accession identifier, category, description, immediate corrective action, logging initials), aggregated monthly by the quality-improvement coordinator, and locked at the end of each phase. The primary outcome was the post-analytical error rate per six-month period, expressed as an absolute count and as errors per million reports released (EPMR = total errors / total reports × 1,000,000).

We use the term errors per million reports released rather than Defects Per Million Opportunities. The opportunity denominator is defined explicitly as one released patient report, which is the unit at which every category in this study was logged. We acknowledge that this treats each report as an equal and independent opportunity for every error type, which is an approximation: critical-value misses can only arise where a critical value is generated, and storage errors only where a sample enters retention. Indicator-specific denominators were not captured prospectively during the study period and could not be reconstructed retrospectively with confidence; category-level rates are therefore reported on the common report denominator and should be interpreted as rates per released report rather than as true opportunity-based defect rates. This is a limitation of the present dataset.

Secondary outcomes were the category distribution pre- and post-CAPA, the Sigma level corresponding to the observed rate (standard conversion incorporating the conventional 1.5σ shift [14]), Pareto analysis of the pre-CAPA distribution [19], and the number of discrete LIS incidents. Monthly error rates, using each month's actual released-report denominator, are displayed as a run chart across the full 13-month period.

Statistical analysis. Contrary to the original submission, inferential analysis was performed. The pre- versus post-CAPA rate ratio was estimated with exact Poisson methods using the conditional binomial approach, with 95% confidence intervals; the two-sided Fisher's exact test was applied to the corresponding contingency table. Exact (Garwood) confidence intervals are reported for individual period rates. A bounding analysis was performed to quantify the maximum possible influence of excluding the transition month, by assigning hypothetical error counts to October 2025 against its actual denominator and identifying the count at which the reduction would cease to be statistically significant. Analyses were performed in Python 3 (SciPy 1.x). Given six observations either side of the intervention, no interrupted time-series model or statistical process control chart with formal control limits was fitted; the run chart is presented descriptively, and this constraint is acknowledged as a limitation.

Results

Monthly volumes and overall error reduction

Monthly released-report volumes and error counts across all 13 months are given in Table 1. Across the 40,692 reports in the two analysed periods, 24 post-analytical errors were recorded pre-CAPA (1,206 EPMR; ~4.53σ) and 4 post-CAPA (192 EPMR; ~5.05σ) — an 84.1% reduction and an improvement of approximately 0.5 Sigma levels.

The exact Poisson rate ratio was 0.159 (95% CI 0.040–0.464), corresponding to an 84.1% reduction (95% CI 53.6–96.0%); Fisher's exact test gave p = 0.00008. Exact 95% confidence intervals for the period rates were 0.76–1.79 per 1,000 reports pre-CAPA and 0.05–0.49 per 1,000 reports post-CAPA.

Table 1: Monthly released-report volumes and post-analytical error counts, April 2025 – April 2026.

Month	Phase	Reports released	Errors (n)	Rate /1000
Apr 2025	Pre-CAPA	3,100	2	0.65
May 2025	Pre-CAPA	3,024	2	0.66
Jun 2025	Pre-CAPA	3,620	7	1.93
Jul 2025	Pre-CAPA	3,231	3	0.93
Aug 2025	Pre-CAPA	3,542	4	1.13
Sep 2025	Pre-CAPA	3,381	6	1.77
Pre-CAPA total		**19,898**	**24**	**1.21**
Oct 2025	Implementation	3,419	Not counted	—
Nov 2025	Post-CAPA	3,520	1	0.28
Dec 2025	Post-CAPA	3,440	0	0.00

Month	Phase	Reports released	Errors (n)	Rate /1000
Jan 2026	Post-CAPA	3,713	1	0.27
Feb 2026	Post-CAPA	2,989	0	0.00
Mar 2026	Post-CAPA	3,910	2	0.51
Apr 2026	Post-CAPA	3,222	0	0.00
Post-CAPA total		**20,794**	**4**	**0.19**

Volumes were extracted from the laboratory information system. October 2025 was designated a priori as an implementation window; post-analytical errors were not counted during this month.

Bounding analysis for the excluded transition month
Because errors were not counted during October 2025, the effect of the exclusion was bounded rather than measured. Assigning hypothetical error counts to October against its actual denominator of 3,419 reports, and adding the month to the post-CAPA period — the most conservative treatment, attributing all transition-associated errors to the new configuration — the reduction remains statistically significant at the 5% level unless October contained 11 or more errors. The highest monthly count observed at any point during the baseline period was 7. The conclusion is therefore robust to the exclusion across the plausible range, though this analysis bounds rather than resolves the uncertainty.

FMEA risk scoring
Table 2 summarises the prospective FMEA. Four of six modes were High risk (RPN 9); TAT Breach and LIS/Software Failure scored RPN 4 and are correctly classified as Low risk under the categories defined in Methods.

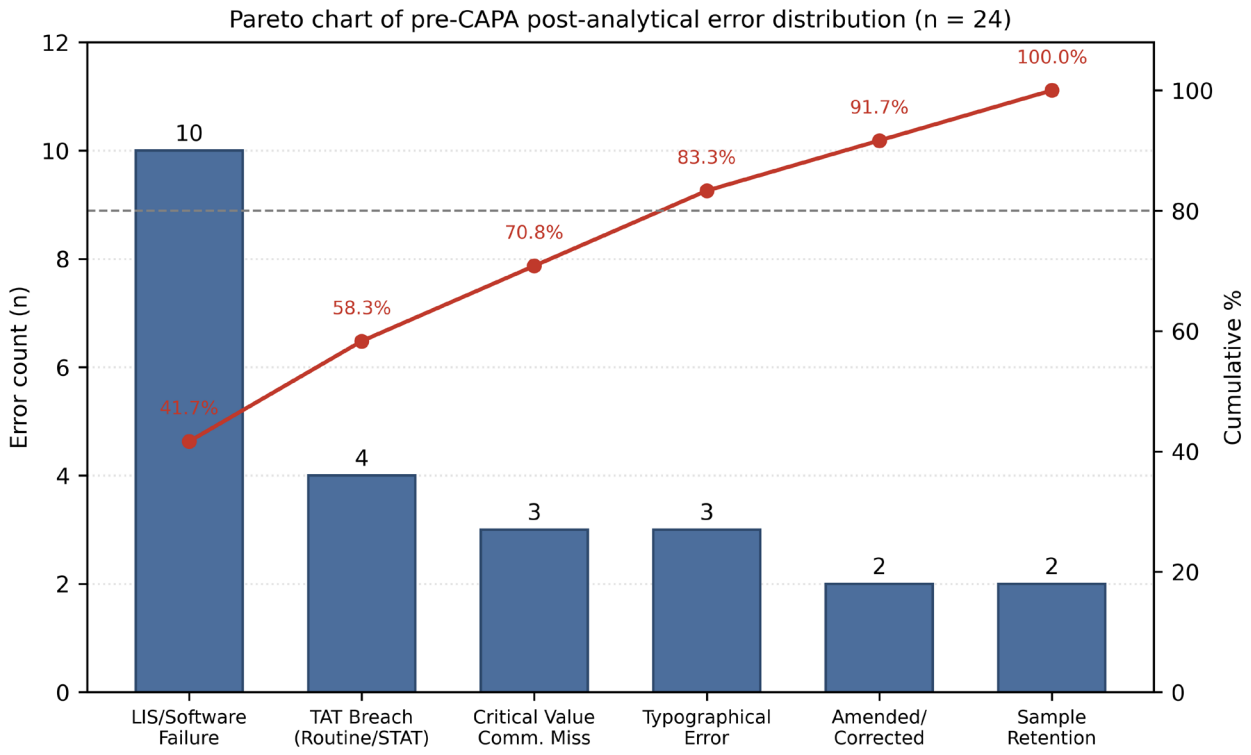
Table 2: FMEA risk scoring of post-analytical failure modes, performed March 2025 prior to study commencement.

#	Failure mode	S	P	RPN	Risk category
1	TAT Breach (Routine/STAT)	2	2	4	Low
2	Critical Value Communication Miss	3	3	9	High
3	Amended/Corrected Report	3	3	9	High
4	Typographical Error (Manual Entry)	3	3	9	High
5	Sample Retention/Storage Error	3	3	9	High
6	LIS/Software Failure (Report Release)	2	2	4	Low

S = Severity; P = Probability; RPN = Risk Priority Number (S × P). Categories: Low (<5), Medium (5–8), High (9–14), Extreme (≥15). Full anchor definitions are given in Methods and the complete matrix in Supplementary Information.

Pre-CAPA distribution and Pareto observation
LIS/software failures were the single most frequent pre-CAPA category (10/24, 41.7%), exceeding the conventional Pareto 'vital few' threshold; TAT breaches (16.7%) and typographical errors (12.5%) followed (Table 3). A Pareto chart of the pre-CAPA distribution is presented in Figure 2 .

Figure 2: Pareto chart of the pre-CAPA post-analytical error distribution (n = 24; April–September 2025; 19,898 reports).



LIS/software failures constitute the dominant 'vital few' category, accounting for 41.7% of pre-CAPA errors; the cumulative-percentage line crosses the 80% threshold at the fourth category.

Table 3: Pre-CAPA post-analytical error distribution by category (April–September 2025; 19,898 reports).

#	Error category	Count (n)	% of total	Rate /million reports
1	LIS/Software Failure	10	41.7%	503
2	TAT Breach (Routine/STAT)	4	16.7%	201
3	Critical Value Communication Miss	3	12.5%	151
4	Typographical Error	3	12.5%	151
5	Amended/Corrected Report	2	8.3%	101
6	Sample Retention/Storage Error	2	8.3%	101
	TOTAL	**24**	**100%**	**1,206**

Rates are expressed per million reports released on the common report denominator; see Methods for the limitations of this denominator.

Incident-level analysis of LIS failures

The 10 pre-CAPA LIS/software errors did not arise from 10 separate events. The error log records two discrete infrastructure incidents — one on 12 June 2025 and one on 19 September 2025, each documented as a local server failure — with five reports affected in each case. Expressed at incident level, the pre-CAPA rate was two incidents across six months (0.10 incidents per 1,000 reports); expressed at report level it was 10 affected reports (503 per million reports). No incident meeting the LIS/Software Failure definition was recorded during the six-month post-CAPA period.

This clustering explains why an infrastructure-level component contributed a large share of the absolute reduction despite a low underlying incident frequency, and it materially qualifies the apparent frequency of this failure mode. Error logs that count each affected report separately will overstate the frequency of failure modes that cluster around shared infrastructure. We report both quantities so that readers may judge infrastructure reliability and patient-level impact separately.

Post-CAPA distribution and comparison

Post-CAPA, four errors were recorded — one each in TAT Breach, Critical Value Communication Miss, Amended/Corrected Report and Sample Retention/Storage; no LIS/software failures and no typographical errors were recorded (Table 4). Every category showed a reduction, the largest absolute reduction being LIS/software failures (10 → 0).

Table 4: Pre- versus post-CAPA comparison by category and overall Sigma performance. Sigma values calculated from the observed rate using the standard Six Sigma conversion incorporating the 1.5σ shift.

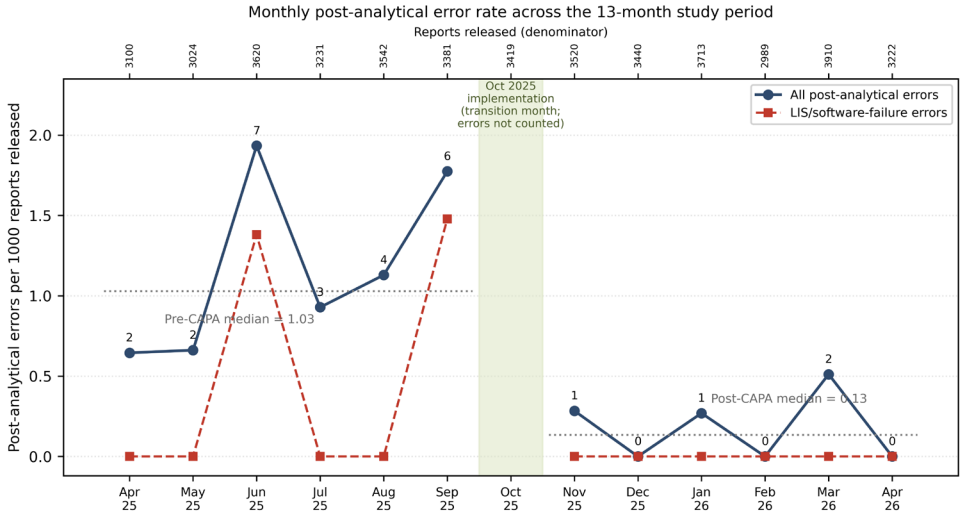
Error category	Pre-CAPA (n)	Post-CAPA (n)	Absolute Δ	% reduction
LIS/Software Failure	10	0	−10	100%
TAT Breach (Routine/STAT)	4	1	−3	75%
Critical Value Communication Miss	3	1	−2	66.7%
Typographical Error	3	0	−3	100%
Amended/Corrected Report	2	1	−1	50%
Sample Retention/Storage Error	2	1	−1	50%
TOTAL errors	**24**	**4**	**−20**	**84.1%**
Rate per million reports	**1,206**	**192**	**−1,014**	**84.1%**
Sigma performance (approx.)	**4.53σ**	**5.05σ**	**+0.52σ**	—

Category-level differences are descriptive; the small post-CAPA counts do not support category-level inference.

Monthly trajectory

The run chart (Figure 3) displays monthly error rates against each month's actual denominator. Monthly rates fell from a pre-CAPA median of 1.03 per 1,000 reports (range 0.65–1.93) to a post-CAPA median of 0.13 per 1,000 reports (range 0.00–0.51), with three post-CAPA months recording zero errors. The two highest pre-CAPA months (June and September 2025) coincided with the only months in which LIS/software failures occurred. The post-CAPA series remained at or below 0.51 per 1,000 reports across all six months. With only six observations either side of the intervention, this pattern is presented descriptively; it does not satisfy the requirements for formal run-chart or control-chart rules, and no claim of demonstrated statistical process stability is made.

Figure 3: Run chart of monthly post-analytical error rates across the 13-month study period, expressed per 1,000 reports released using each month's actual denominator (printed on the upper axis).



Absolute monthly error counts are annotated above each point, and LIS/software-failure errors are overlaid. October 2025, the implementation window, is shaded; post-analytical errors were not counted during that month. Pre- and post-CAPA medians are indicated as dotted lines.

Discussion

This 13-month before-and-after study at a stand-alone NABL-accredited laboratory found an 84.1% reduction in post-analytical errors (rate ratio 0.159, 95% CI 0.040–0.464) and an improvement in Sigma performance from ~4.53σ to ~5.05σ following a multicomponent CAPA programme. Seven distinct changes were deployed simultaneously — cloud-LIS migration, dual-broadband connectivity, revised TAT protocols, critical-value alerting, role-based access control, a structured report review workflow, and storage temperature monitoring. Because they were implemented together, the aggregate effect cannot be attributed to any single component, and we make no such attribution. The largest single categorical change was in LIS/software failures, for which no qualifying event was recorded during the post-CAPA period, but all six categories fell, which is consistent with a package effect rather than an isolated infrastructure effect.

A post-CAPA performance of approximately 5.05σ represents strong post-analytical performance relative to Sigma levels typically reported for laboratory quality indicators [15, 16]. It remains, however, materially below the six-Sigma benchmark, and we avoid describing it as approaching that benchmark.

FMEA and observed frequency

A methodologically important observation concerns the relationship between prospective risk scoring and observed error frequency. LIS/Software Failure was scored Severity 2, Probability 2 (RPN 4, Low risk). Both scores are defensible against the anchors defined in Methods: two discrete incidents across six months corresponds to approximately four events per year, matching the Probability 2 band, and the clinical consequence of an affected report was delay in release rather than an incorrect or misleading result, matching Severity 2. Yet this correctly scored low-risk mode generated 41.7% of all pre-CAPA logged errors. The explanation is that the Risk Priority Number quantifies risk per occurrence and contains no term for the number of outputs that a single occurrence affects. A laboratory allocating CAPA resource strictly by RPN would have deprioritised the largest single contributor to its logged error count, and would have been methodologically correct to do so on risk grounds. The practical implication is that prospective FMEA and retrospective error logging measure different quantities — clinical risk per event and operational error burden respectively — and neither substitutes for the other. Low clinical risk and high operational error volume can coexist in the same failure mode, particularly where that mode clusters around shared infrastructure.

Infrastructure, and the risks it introduces

Stand-alone laboratories without enterprise IT typically depend on locally administered servers maintained by laboratory staff, for which crashes, hangs and connectivity disruptions are recurrent rather than anomalous events [12, 22, 33]. Migration to a centrally managed cloud LIS transfers infrastructure maintenance to a specialised team, while dual-broadband redundancy addresses the internet-uptime dependency that cloud architecture introduces.

Cloud migration nonetheless introduces risks that laboratories considering this route must weigh explicitly [27, 34]. Data are hosted outside the laboratory's physical control, raising questions of data residency and sovereignty that differ by jurisdiction. Access control and encryption become contractual rather than local responsibilities. Vendor dependency and the practical difficulty of exporting data constitute a lock-in risk. Provider outages transfer a single point of failure from the local server room to the hosting platform, and dual-broadband redundancy does not mitigate an outage at the provider end. Disaster-recovery arrangements, breach-notification obligations and service-level commitments should be established contractually before migration, and recurring subscription costs replace one-off capital expenditure. In the present study the dual-broadband configuration used two independent commercial providers; whether their physical last-mile routes are fully disjoint was not verified, and shared physical infrastructure would reduce the effective redundancy. None of these risks materialised during the six-month post-CAPA observation period, but six months is insufficient to characterise them.

Operational adoption at other sites

Following the single-site work reported here, the same cloud-LIS migration was subsequently adopted at other laboratories within the partner network. We report this as operational adoption only. No post-analytical error outcomes were measured at those sites, no implementation timelines, technical difficulties, costs, user acceptance or inter-site variation were recorded, and no claim of demonstrated scalability or of equivalent effectiveness elsewhere is made. The original manuscript described the intervention as operationally scalable on this basis; that characterisation overstated what the observation supports and has been withdrawn.

Limitations

This study has substantial limitations, several of which constrain the strength of the conclusions.

Design and confounding. The single-centre before-and-after design cannot exclude secular trends, Hawthorne effects or co-incident operational changes. Contextual variables that could plausibly contribute to the observed change — staffing levels and turnover, test mix, number of collection centres, proportion of STAT requests, operating hours, seasonal workload variation and any concurrent quality initiatives — were not systematically captured across the two periods and cannot be compared. Their potential contribution cannot be excluded.

Excluded transition month. Post-analytical errors were not counted during October 2025. The bounding analysis reported above constrains but does not eliminate the influence of this

exclusion.

Ascertainment and surveillance bias. Errors were recorded by staff at the point of identification. The log was not subject to independent audit for unreported events, no periodic reconciliation against alternative data sources was performed, staff did not receive formal error-classification training beyond routine induction, and inter-rater reliability was not assessed. Heightened staff awareness during the post-CAPA period could plausibly have increased detection, biasing towards the null, or reduced reporting, biasing away from it. The direction of any such bias cannot be determined from the available data.

Intervention fidelity. The consistency with which each CAPA component was executed was not formally measured. Training completion, SOP adherence, critical-value notification compliance, frequency of manual overrides, broadband failover success rate and the proportion of reports receiving the mandatory cross-check were not quantified. Without fidelity measures it is not possible to state how faithfully the package was delivered.

Objective IT performance. No independent system-reliability data were collected: system uptime, number and duration of outages, latency, failed report-release attempts, backup restoration tests, automatic-failover tests, vendor service-level performance and data-integrity events were not measured. The finding regarding LIS failures rests on the absence of logged report-level errors and should be stated as such: no event meeting the LIS/Software Failure definition was recorded during the six-month post-CAPA period. This is not equivalent to independently verified system reliability, and it does not establish that such events have been permanently eliminated.

Clinical significance. All errors were weighted equally in the analysis, although their potential consequences differ substantially: a typographical error corrected before clinical action is not equivalent to a missed critical-value notification. Error severity, the distinction between near misses and errors reaching the clinician, duration of reporting delays, consequences for diagnosis or therapy, patient harm, and the number of clinicians or patients affected were not recorded and could not be reconstructed reliably. No clinical-significance stratification is therefore presented.

Unintended consequences. Potential adverse effects of the intervention were not systematically evaluated. Report authorisation time, perceived system responsiveness, staff workload, alert fatigue arising from critical-value alerting, workflow interruption from internet dependency, user satisfaction, recurring operating costs, emergence of new error types and increased dependency on central IT support were not measured.

Residual risk reassessment. A formal post-intervention re-scoring of the six failure modes was not undertaken. The FMEA reported here is the prospective assessment performed before the intervention, with the risk-category correction described in Methods; it does not represent current residual risk.

Statistical power and time series. Six observations either side of the intervention are insufficient for interrupted time-series modelling or for statistical process control with formal limits. Category-level comparisons are descriptive only.

Investigator and organisational bias. The corresponding author is the founder and managing director of the study laboratory and was directly involved in implementing the intervention, curating the data, performing the analysis and preparing the manuscript. Error classifications were adjudicated at monthly aggregation by the laboratory head/pathologist, who is a co-author but was not responsible for the infrastructure decision, and error entries were made by front-line staff rather than by the corresponding author. Beyond this, no independent verification of the error log, no audit by a quality officer external to the intervention, and no external validation of the analysis were undertaken. The potential for observer and confirmation bias is therefore mitigated only partially, and readers should weigh the findings accordingly.

Generalisability. The migration is not universally replicable for laboratories without a partner network providing cloud-LIS infrastructure, and the findings derive from a single site.

Transferability

Subject to the limitations above, the approach is expressible as a sequence other networked laboratories could consider: (i) maintain a retrospective post-analytical error log recording both incidents and affected reports, and compare it against prospective FMEA scores; (ii) recognise when interpreting prospective risk scores that the Risk Priority Number quantifies risk per occurrence and does not capture the number of reports a single event can affect, so that a correctly scored low-risk mode may still dominate the logged error count; (iii) evaluate cloud migration together with its governance, security and vendor-dependency implications rather than as a purely technical change; (iv) pair any cloud migration with independent redundant connectivity; (v) sustain process-level controls for non-infrastructure categories; and (vi) monitor the post-analytical error rate against actual monthly denominators.

Conclusion

A multicomponent CAPA programme combining cloud-LIS migration, dual-broadband redundancy and process-level controls was associated with an 84.1% reduction in post-analytical errors (rate ratio 0.159, 95% CI 0.040–0.464) and an improvement in Sigma performance from ~4.53σ to ~5.05σ over a 13-month before-and-after evaluation at a stand-alone NABL-accredited laboratory. Because all components were deployed simultaneously, the contribution of any individual component cannot be isolated. The observation that a correctly scored low-risk failure mode generated the largest share of observed errors — because the Risk Priority Number quantifies risk per occurrence and contains no term for the number of reports a single occurrence affects — supports complementing prospective risk assessment with retrospective error logging.

Multi-centre studies applying standardised post-analytical indicators, with fidelity and system-reliability measurement, are needed to substantiate these observations.

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Conflict of Interest
J.C. is the Founder and Managing Director of Vedant Diagnostic Center, the laboratory at which this study was conducted, which operates within the Agilus Diagnostics partner-laboratory network whose cloud-based laboratory information system infrastructure is described in this work; J.C. is also the Founder and Managing Director of Divyaman Biotech Private Limited. K.B. is affiliated with Vedant Diagnostic Center. These affiliations are disclosed in full. The potential for investigator bias arising from the corresponding author's dual role is addressed explicitly in the Limitations. The authors declare no other conflict of interest.

Additional Declarations

Funding
No funding was received for this work; the study was conducted on a self-funded basis at the study laboratory.

Ethics approval
This study analysed routinely collected operational quality data and involved no patient intervention, no biological sample collection and no analysis of identifiable personal data. In accordance with institutional policy and established practice for quality-improvement activities, formal institutional ethics-committee approval was not required. The work was conducted in compliance with the principles of the Declaration of Helsinki, where applicable.

Data governance
The Monthly Post-Analytical Error Log recorded the laboratory accession identifier for each entry, to permit internal verification and corrective action at the time of logging. Accession identifiers are internal laboratory numbers containing no patient name, contact detail or clinical identifier; they are, however, re-linkable to a patient record by authorised laboratory personnel within the laboratory information system, and we do not characterise them as fully anonymised. Access to the raw log was restricted to the quality-improvement coordinator, the laboratory head/pathologist and the corresponding author. The log is retained within the laboratory's NABL quality-management records for the accreditation-mandated retention period. The dataset used for the analyses reported here comprised aggregated monthly counts by category and monthly released-report denominators only; no accession identifiers or patient-level records were extracted, transferred or analysed for this study.

Data availability
The aggregated monthly error-count data, monthly denominators and FMEA scoring underlying this analysis are available from the corresponding author on reasonable request. Patient-level information was not collected and is not part of the analytical dataset.

Author contributions
J.C. and K.B. conceived and designed the study. J.C. implemented the CAPA programme and the cloud-LIS migration, curated and analysed the post-analytical error data, performed the Six Sigma, FMEA and statistical analyses, prepared Figures 1–3, and wrote the main manuscript text. K.B. contributed to the methodology, adjudicated error classifications at monthly aggregation, validated the data, supervised the study and critically revised the manuscript. Both authors reviewed and approved the final manuscript.

Use of generative AI
A large language model was used to assist with language editing, manuscript formatting and verification of statistical computations. The authors reviewed all content, take full responsibility for the work, and approved the final manuscript.

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Supplementary Information

Supplementary Table 1: Failure Mode and Effects Analysis — team composition.
The prospective FMEA was performed in March 2025, prior to commencement of the baseline observation period, by a four-member quality-improvement team:

Role	Function in the assessment
Managing Director (Quality Management)	Facilitation; review of NABL non-conformity records
Laboratory Head / Pathologist	Clinical severity judgement; adjudication of failure-mode definitions
Senior Scientific Officer	Operational frequency input from bench and reporting workflow
Quality-Improvement Coordinator	Incident-record retrieval; documentation of scoring rationale

Supplementary Table 1 FMEA team composition.

Scoring was assigned by group consensus in a single facilitated session rather than by independent rating followed by reconciliation. Disagreements were resolved by discussion until consensus was reached. No formal inter-rater reliability statistic was calculated. Detectability was not incorporated as a third dimension, because several of the failure modes assessed are by definition identified only after report release, which makes a detectability rating uninformative for this phase. These are acknowledged in the manuscript as methodological limitations.

Supplementary Table 2: Rating scale anchors as applied.

Score	Severity (S) anchor	Probability (P) anchor
1	Negligible — no clinical consequence	Rare — fewer than 1 event per year
2	Minor — administrative correction only; report delayed but not incorrect or misleading	Unlikely — 1 to 4 events per year
3	Moderate — potential to affect a clinical decision	Possible — 5 to 12 events per year
4	Major — incorrect or delayed clinical action likely	Likely — 13 to 24 events per year
5	Critical — potential for patient harm	Frequent — more than 24 events per year

Supplementary Table 2 Severity and Probability anchor definitions.

Severity (S) was scored on the clinical consequence of a single occurrence of the failure mode, that is, the consequence to the individual patient whose report was affected. It was not scored on the number of reports a single underlying event might affect.

Risk Priority Number (RPN) = S × P. Risk categories: Low (RPN < 5); Medium (RPN 5–8); High (RPN 9–14); Extreme (RPN ≥ 15).

Supplementary Table 3: Complete FMEA scoring matrix.

#	Failure mode	S	P	RPN	Risk category	Basis for the scores assigned
1	TAT Breach (Routine/ STAT)	2	2	4	Low	Severity 2: report delayed but content unaffected; result neither incorrect nor misleading. Probability 2: internal incident records indicated a small number of qualifying events per year.
2	Critical Value Communication Miss	3	3	9	High	Severity 3: failure or delay in notification can affect an urgent clinical decision. Probability 3: NABL non-conformity records showed recurrent documentation gaps.
3	Amended/Corrected Report	3	3	9	High	Severity 3: an amended report implies the original released result was wrong and may already have been acted upon. Probability 3: consistent with historical reissue frequency.
4	Typographical Error (Manual Entry)	3	3	9	High	Severity 3: manual-entry errors in demographic or result fields can mislead. Probability 3: manual entry was widespread prior to access-control changes.
5	Sample Retention/Storage Error	3	3	9	High	Severity 3: loss or degradation of a retained sample prevents repeat or add-on testing. Probability 3: temperature and retention logs showed periodic excursions.
6	LIS/Software Failure (Report Release)	2	2	4	Low	Severity 2: consequence to the affected patient is delay in report release; the released result is not altered. Probability 2: two to four qualifying infrastructure events per year were anticipated from local server incident history.

Supplementary Table 3 Complete prospective FMEA scoring matrix with rationale, as performed March 2025. Modes 1 and 6 were reported as Medium risk in the originally submitted manuscript; this was an error in the category label applied, not in the underlying S and P scores, and both are correctly classified as Low risk against the categories defined in S2. The correction is applied throughout the revised manuscript.

Supplementary Table 4: Relationship between prospective RPN and observed error frequency.

The table below compares the prospective risk classification with the observed pre-CAPA error frequency. It is presented to support the methodological point developed in the Discussion and does not constitute a residual-risk reassessment.

#	Failure mode	Prospective RPN	Risk category	Pre-CAPA errors (n)	% of pre-CAPA total	Discrete incidents
1	TAT Breach	4	Low	4	16.7%	4
2	Critical Value Communication Miss	9	High	3	12.5%	3
3	Amended/Corrected Report	9	High	2	8.3%	2
4	Typographical Error	9	High	3	12.5%	3
5	Sample Retention/Storage Error	9	High	2	8.3%	2
6	LIS/Software Failure	4	Low	10	41.7%	2

Supplementary Table 4 Prospective risk classification against observed pre-CAPA frequency. For modes 1–5 each logged error corresponds to one discrete event. For mode 6, two discrete infrastructure incidents (12 June 2025 and 19 September 2025) each affected five reports, generating ten logged errors. The Risk Priority Number quantifies risk per occurrence and contains no term for the number of reports a single occurrence affects; a mode may therefore carry correctly assessed low clinical risk while generating a high operational error count.

No formal post-intervention residual-risk reassessment was undertaken. The scoring presented here is the prospective assessment performed before the intervention and does not represent current residual risk. This is stated as a limitation in the manuscript.

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