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Optimising Diagnostic Turnaround Time without Compromising Analytical Reliability: A Quality Management Framework for Clinical Biochemistry Laboratories

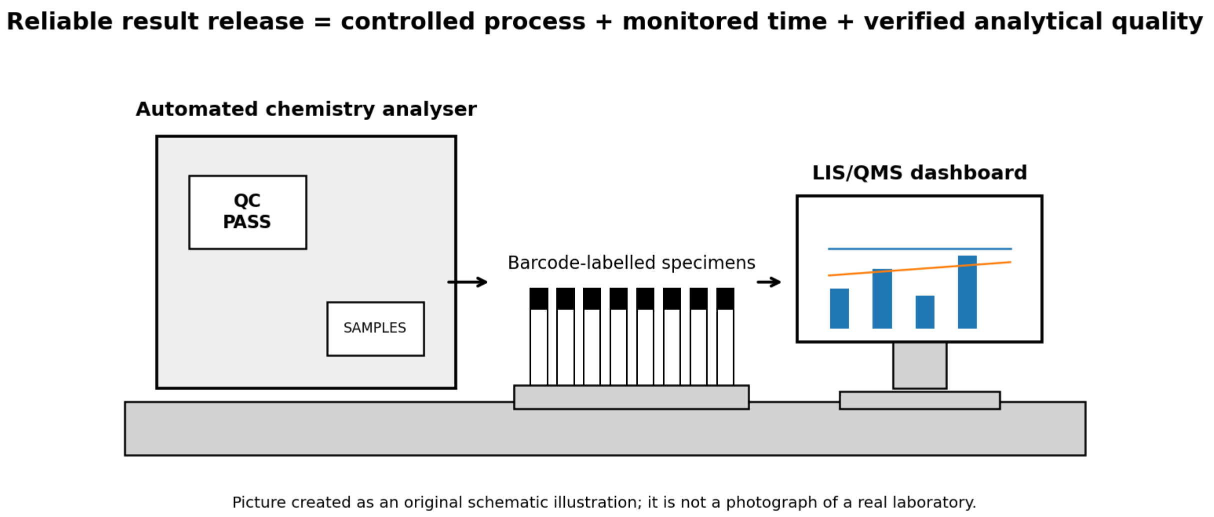
Alasi Bashirat Ololade, Adeyinka Victor Adebayo

University of Cape Town, United Kingdom

ABSTRACT

Clinical biochemistry laboratories are under persistent pressure to release diagnostically useful results rapidly while maintaining analytical validity, traceability and patient safety. In many laboratories, however, turnaround time (TAT) improvement and analytical reliability are handled as separate quality projects: one operational, the other technical. This separation is intellectually weak and managerially dangerous. A fast result that is analytically unreliable is not clinically useful, while an accurate result released too late may lose diagnostic value. This narrative review and quality-improvement framework argues that TAT and analytical reliability should be governed as linked outputs of the total testing process. Drawing on ISO 15189:2022, WHO laboratory quality management guidance, CLSI risk-based quality control principles, and IFCC quality indicator work, the manuscript proposes an integrated model for measuring, analysing, and improving diagnostic TAT without compromising analytical assurance. The framework distinguishes order-to-report, specimen-reception-to-release, analytical, and critical-result TAT; links each interval to pre-examination, examination, and post-examination risk controls; and proposes a dashboard that combines TAT distributions, quality-control performance, specimen rejection, analyser downtime, autoverification performance, and corrective-action tracking. The paper concludes that sustainable TAT improvement requires workflow redesign, competence management, information-system integrity, risk-based internal quality control, external quality assessment and disciplined corrective and preventive action. The contribution is a practical governance model rather than a claim of new empirical causality.

Keywords: clinical biochemistry; turnaround time; analytical reliability; ISO 15189; quality management system; internal quality control; laboratory medicine; patient safety



Picture 1. Original schematic picture of a clinical biochemistry quality-management loop linking specimen processing, analyser control, LIS reporting and dashboard review.

INTRODUCTION

Clinical biochemistry results shape decisions in emergency medicine, endocrinology, nephrology, hepatology, cardiology, intensive care and routine outpatient management. The laboratory therefore does not merely produce numbers. It produces clinical time: the time within which diagnostic uncertainty can be narrowed, and treatment can be started, withheld or modified. Turnaround time is consequently a patient-care variable, not an administrative convenience. The usual managerial error is to treat delay as a simple productivity problem and analytical reliability as a separate technical problem. That is poor thinking. A laboratory can reduce reported TAT by pushing unreviewed results through the system, but such speed is not efficient if it increases erroneous reports, corrected reports, or clinician distrust. Conversely, a laboratory can overprotect the analytical phase with poorly designed manual reviews and unnecessary repeat testing, thereby delaying results without adding measurable clinical value. The correct question is not whether the laboratory should be fast or reliable. The correct question is how the quality management system can ensure that rapid reporting is safe, reproducible, and auditable.

ISO 15189:2022 specifies requirements for quality and competence in medical laboratories and applies to the development of management systems, competence assessment and recognition by users, regulators and accreditation bodies [1]. WHO guidance frames laboratory quality management as a comprehensive system encompassing management, administration, and bench-level practice, based on the principles of ISO 15189 and CLSI GP26 [2]. CLSI EP23 similarly moves quality control beyond ritualistic rule-following by recommending risk-based quality-control plans tailored to the measuring system, laboratory setting and clinical application [3]. Together, these sources support a simple proposition: TAT improvement that is not embedded within quality management is fragile.

This manuscript develops a practical framework for improving diagnostic TAT and analytical reliability in clinical biochemistry laboratories. It is not a systematic review, and it does not present original patient data. Rather, it synthesises standards and quality-improvement literature into an implementation model that laboratory managers, quality officers and clinical biochemists can adapt.

Table 1. Turnaround-time definitions that should not be confused in clinical biochemistry

TAT construct	Start point	End point	Primary user	Quality-management interpretation
Order-to-report TAT	The clinician places or confirms the test request	The result becomes visible to the clinician	Clinician/patient pathway manager	Best reflects the clinical pathway, but requires integration of ordering, phlebotomy, transport, laboratory and reporting systems.
Laboratory TAT	Specimen received or accessioned in the laboratory	Result verified or released in LIS	Laboratory manager/quality officer	Most controllable by laboratory operations and useful for internal benchmarking.
Analytical TAT	Sample loaded or analysis started	Analytical result generated	Section head/analyser supervisor	Identifies analyser capacity, reagent, calibration, QC and maintenance constraints.
Critical-result TAT	Critical result generated or verified	Responsible clinician notified and notification documented	Patient-safety lead/clinician	Measures the time-sensitive safety function of the laboratory beyond simple result release.
Corrected-report interval	Erroneous or amended result	Corrected report released and communicated	Risk manager / clinical governance	A reliability and patient-safety indicator, speed is meaningless if corrections are frequent or poorly

	identified		team	communicated.

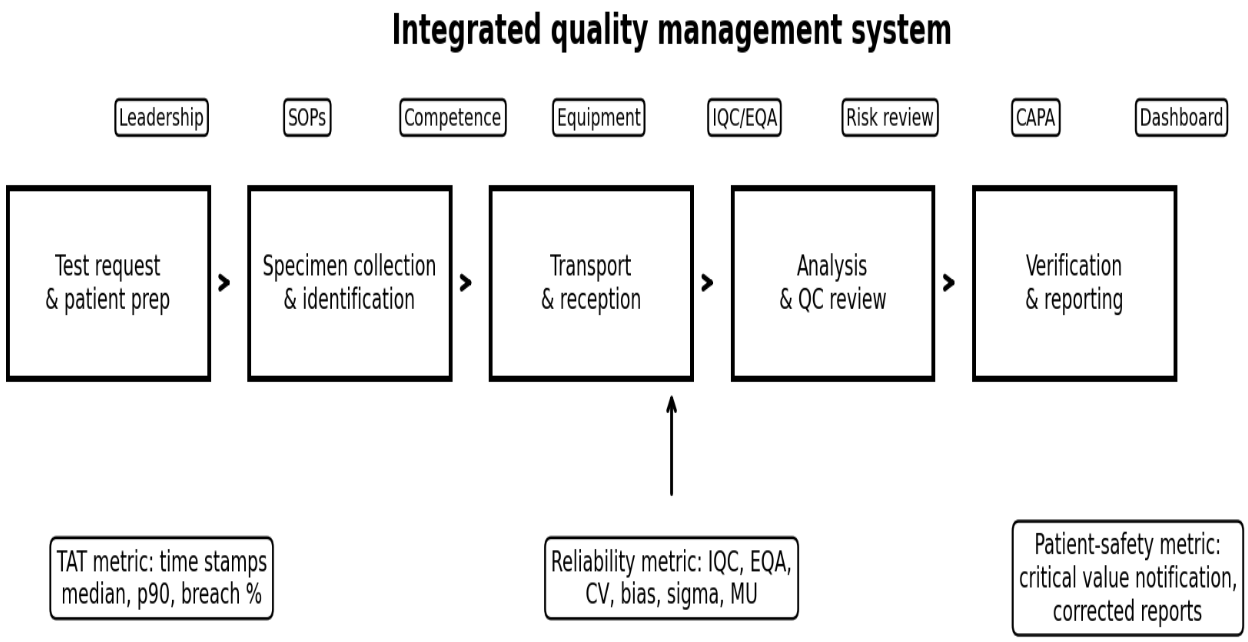


Figure 1. Total testing process map showing where TAT, analytical reliability and patient-safety indicators should be measured together.

METHODOLOGICAL APPROACH

The manuscript uses a narrative review and framework-development approach. The evidence base was selected from international standards and guidance documents, including ISO 15189:2022, WHO laboratory QMS resources, CLSI risk-based quality-control guidance, and IFCC quality-indicator publications, supplemented by peer-reviewed literature on total testing-process errors, sigma metrics, biological variation, and laboratory performance benchmarking. No formal meta-analysis was attempted because the purpose is not to estimate a pooled intervention effect. The purpose is to develop a coherent implementation model for laboratories seeking to improve both speed and reliability.

The framework follows three analytical assumptions. First, clinical biochemistry quality is a property of the total testing process rather than the analyser alone. Second, TAT is a distribution, not a single average; therefore, median, percentile and breach-rate monitoring are superior to isolated mean values. Third, analytical reliability should be demonstrated using multiple safeguards, including validation and verification, internal quality control (IQC), external quality assessment (EQA), method comparison, measurement uncertainty where relevant, competence assessment and nonconformity management.

Table 2. Core quality indicators for an integrated clinical biochemistry dashboard

Process phase	Indicator	Numerator/denominator	Interpretation	Action trigger
Pre-examination	Specimen rejection rate	Rejected specimens / total specimens received	High values indicate problems with collection, labelling, transport, or	Exceeds agreed monthly target or clusters by

			anticoagulation.	ward/phlebotomist.
Pre-examination	Mislabelling or unidentified specimen rate	Mislabelled specimens / total specimens	Direct patient-safety risk should be treated as a serious nonconformity.	Any confirmed event, especially a repeated source location.
Pre-examination	Transport delay rate	Specimens exceeding transport target / total transported specimens	Separates laboratory delay from ward, courier or pneumatic-tube delay.	Persistent breach or temperature-sensitive analytes affected.
Examination	IQC acceptance rate	Accepted QC events / total QC events	A crude but useful high-level signal; must be interpreted with rule design and assay risk.	Falling trend, repeated rejection, unexplained shifts or unstable imprecision.
Examination	Sigma metric by assay	(TEa - |bias|) / CV	Links allowable error, bias and imprecision to QC design and patient-risk tolerance.	Low sigma assay or deterioration from baseline.
Examination	Analyser downtime	Downtime minutes / scheduled analyser time	Identifies equipment, maintenance, interface or reagent-supply constraints.	Downtime affects TAT or creates unacceptable manual workarounds.
Post-examination	Result verification delay	Verified late results / total results	Identifies bottlenecks in manual review, delta checks or specialist authorisation.	Large manual queue or avoidable repeat testing.
Post-examination	Critical-result notification compliance	Documented notifications within target / critical results	Patient-safety indicator beyond routine result release.	Any undocumented notification or repeated target breach.
Cross-cutting	Corrected report rate	Corrected reports / total reports	Reliability indicator and marker of residual diagnostic risk.	Any clinically significant corrected report; rising monthly trend.

WHY TURNAROUND TIME FAILS: THE TOTAL TESTING PROCESS PROBLEM

TAT failure rarely has a single cause. The common causes are banal, cumulative and therefore often invisible: incomplete requests, difficult phlebotomy rounds, wrong tubes, insufficient sample volume, haemolysis, transport batching, centrifugation queues, analyser downtime, QC failure, reagent shortage, interface failure, excessive manual verification and delayed critical-value communication. A laboratory that only measures reception-to-release TAT sees only part of the problem. That is operationally convenient but analytically incomplete. WHO explicitly recommends that laboratories determine TATs for examinations and continuously monitor adherence, as delayed laboratory results delay diagnostic and treatment decisions [4]. This point should not be softened. In acute care, a potassium, creatinine, troponin, glucose, lactate, or liver function result is not merely late; it may be clinically late. The dashboard must therefore distinguish between routine and urgent streams, high-volume and low-volume tests, in-hours and out-of-hours performance, and laboratory-controlled and extra-laboratory delays.

The practical implication is simple: laboratories should build time stamps into the workflow. At a minimum, the LIS should capture request time, collection time, receipt time, centrifugation or processing time, analyser start and completion, where possible, verification/release time, and critical-value notification time. Without timestamps, TAT improvement becomes an anecdote.

Table 3. Common TAT failure modes and quality-management countermeasures

Failure mode	Likely location	Typical evidence	Countermeasure	Governance owner
Incomplete or inappropriate request	Ward/clinic ordering	High cancellation/add-on rate; calls for missing information	Electronic order sets, rejection criteria, clinician education, feedback reports	Laboratory director with clinical service leads
Specimen misidentification	Collection and reception	Mislabelling events, unidentified specimens, corrected reports	Two-identifier policy, barcode collection, incident review, retraining	Quality manager and phlebotomy lead
Transport batching delay	Courier/pneumatic tube process	Long collection-to-receipt intervals, ward-specific delay clusters	Scheduled transport review, urgent stream, point-of-care escalation rules	Operations manager
Centrifugation bottleneck	Sample preparation	Receipt-to-analysis lag, queue during peak arrivals	Peak-load staffing, additional centrifuge, smarter batch release, queue display	Section head
QC failure or calibration hold	Analytical bench	QC rejection, calibration failure, repeat runs	Risk-based QC plan, root-cause review, reagent lot verification, maintenance compliance	Senior biomedical scientist / clinical biochemist
Manual verification queue	Post-analytical review	Analysis completed, but unreleased results	Autoverification rules, delta-check refinement, review prioritisation	Clinical biochemist and LIS lead
Critical value not communicated promptly.	Post-reporting clinical interface	Unacknowledged critical alerts, undocumented calls	Escalation protocol, closed-loop notification, audit of call logs	Patient-safety lead

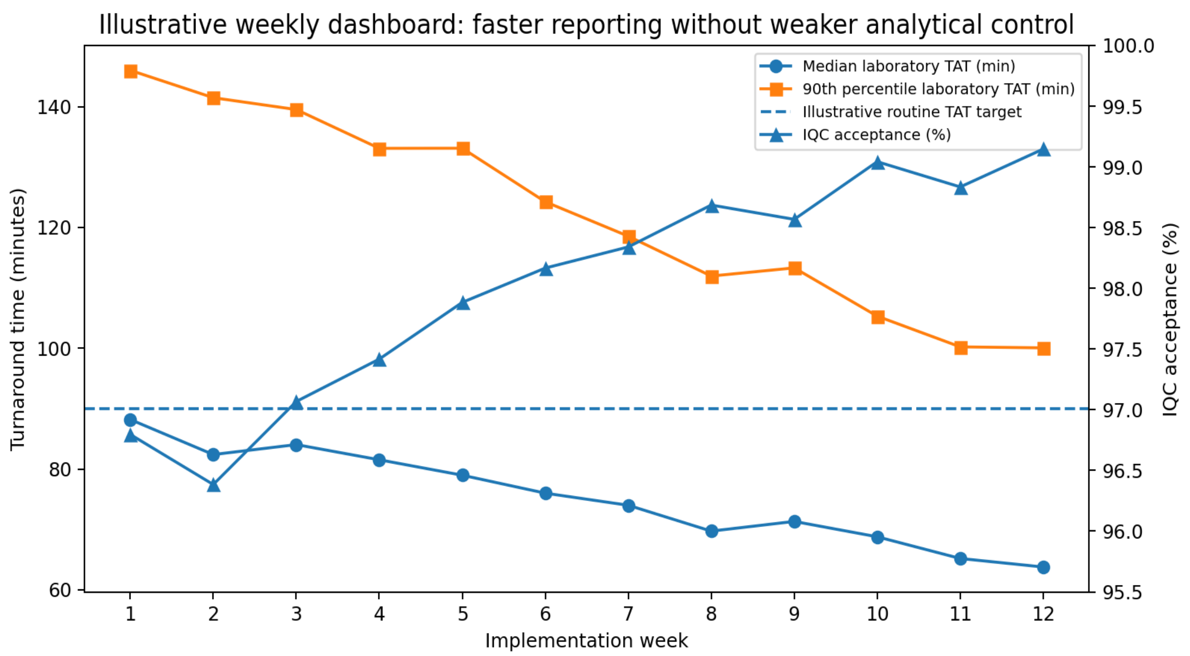


Figure 2. Illustrative synthetic weekly dashboard showing concurrent improvement in TAT and IQC acceptance. Values are for demonstration only, not empirical patient data.

ANALYTICAL RELIABILITY: THE NON-NEGOTIABLE BOUNDARY CONDITION

Analytical reliability in clinical biochemistry is established before, during and after routine testing. It begins with method selection, verification, and validation; continues through calibration, maintenance, IQC, and EQA; and is reinforced by staff competence, document control, lot-to-lot verification, uncertainty awareness, and corrective action systems. The analyser is not the quality system. It is only one controlled element within it. Risk-based QC is especially important because not all assays carry the same clinical risk and not all measuring systems behave similarly. CLSI EP23 recommends quality-control plans tailored to the measuring system, laboratory setting, and clinical application, with monitoring to detect trends, identify corrective actions, and support continual improvement [3]. A high-volume sodium assay, a low-volume therapeutic drug assay, an emergency potassium assay and a tumour-marker assay should not be governed by identical QC logic simply because identical rules are easy to remember.

Analytical sigma metrics can help laboratories connect imprecision, bias and allowable total error to QC design. Sigma metrics are not magic; they are only as credible as the selected performance specification and the underlying estimates of bias and imprecision. Still, when properly used, they support rational differentiation between robust assays that require efficient QC and fragile assays that need tighter surveillance. Biological-variation resources and analytical performance specifications can also guide the selection of quality goals. Still, laboratories must choose specifications appropriate to clinical use rather than mechanically copying targets from tables.

Table 4. Analytical reliability controls and their relationship to TAT

Reliability control	Purpose	How can it improve TAT	How can it harm TAT if it is poorly designed	Good-practice principle
Method verification/validation	Confirm method performance before routine use	Prevents downstream repeats, complaints and corrected reports	Overly delayed go-live without risk-based acceptance criteria	Match verification depth to method change and clinical risk.
Internal quality control	Detect analytical instability during routine use	Avoids reporting unreliable batches and reduces repeat investigations	Excessive false rejection creates unnecessary reruns and delays	Use risk-based QC rules and review false-rejection burden.
External quality assessment	Compare performance against peer or reference groups	Builds confidence in long-term comparability	Delayed response to EQA failure leaves persistent risk	Investigate unacceptable performance promptly and document CAPA.
Autoverification	Release safe results without unnecessary manual review	Reduces verification queues and standardises decision logic	Unsafe rules may release implausible or clinically risky results	Validate rules, audit overrides, and monitor corrected reports.
Delta checks	Detect implausible patient-result changes	Targets manual review to higher-risk results	Poor thresholds create excessive review queues	Tune thresholds by analyte, population and clinical setting.
Competence assessment	Confirm staff can perform and interpret assigned tasks	Reduces avoidable errors and rework	Tick-box training consumes time without risk reduction	Assess competence against actual failure modes and high-risk tasks.

Equipment maintenance	Prevent breakdown and analytical drift	Reduces downtime and emergency troubleshooting	Maintenance during peak workload may worsen delays	Schedule maintenance around demand and monitor the impact of downtime.

INTEGRATING TAT AND RELIABILITY THROUGH A DASHBOARD

A proper dashboard does not merely display attractive charts. It disciplines the laboratory to answer five questions every week: What is late? Why is it late? Is speed being achieved at the cost of analytical control? Which failures are recurring? Did corrective action actually work? These questions are elementary, yet many laboratories do not answer them because data are dispersed across the LIS, analyser middleware, QC software, incident logs and staffing records. The dashboard proposed here has four linked panels. The first panel shows TAT distribution by test, priority, location and time of day [15]. The second shows analytical-control status by assay, including QC rejection, EQA performance, sigma metrics, calibration issues and reagent lot changes. The third shows operational constraints such as analyser downtime, pending verification queues and staffing gaps. The fourth shows patient-safety consequences, including compliance with critical-result notification, specimen rejection, and corrected reports. The dashboard is useful only if it is reviewed by a responsible group with authority to implement corrective actions.

Table 5. Minimum data fields for a TAT and analytical-reliability dashboard

Data group	Minimum fields	Source system	Reporting frequency	Primary decision supported
Specimen identity and priority	Specimen ID, test code, ward/clinic, routine/urgent/critical status, collector/location	LIS / order-entry system	Daily for operations; monthly for governance	Locate demand and risk concentrations.
Time stamps	Order, collection, receipt, centrifugation/processing, analysis start, analysis completion, verification, report release, critical notification	LIS, middleware, analyser interface, call log	Daily and weekly	Identify delay intervals and target bottlenecks.
Analytical control	QC result, rule violation, calibration status, reagent lot, EQA performance, CV, bias, sigma metric	QC software/middleware / EQA reports	Weekly and monthly	Protect analytical reliability while reducing delay.
Operational capacity	Analyser uptime, queue length, staffing roster, maintenance, reagent stockouts	Middleware, maintenance log, inventory system	Daily and weekly	Distinguish process design problems from resource constraints.
Safety and nonconformity	Specimen rejection, corrected reports, critical-value compliance, complaints, CAPA status	Incident system/quality log / LIS	Monthly governance review	Link laboratory performance to patient-safety risk.

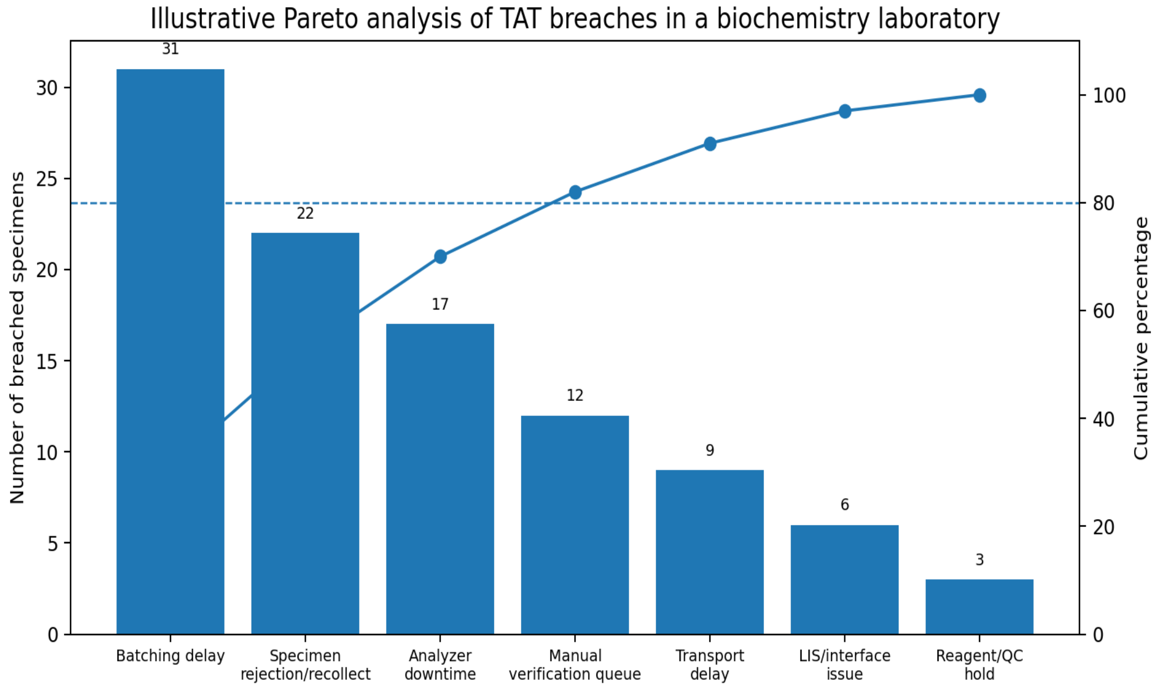


Figure 3. Illustrative Pareto analysis of TAT breaches. The purpose is to demonstrate prioritisation logic, not to report empirical performance.

PRACTICAL IMPLEMENTATION ROADMAP

A serious TAT project starts with definition, not enthusiasm. The laboratory must first define which TAT interval matters for which test and which clinical setting. A single blanket target is usually crude. Emergency potassium, creatinine and glucose results may require different targets from routine lipid profiles or endocrine tests. The next step is baseline measurement using time-stamped data over a period long enough to capture weekday, weekend, in-hours, out-of-hours and peak-demand variation. After the baseline measurement, the laboratory should map the process and identify the drivers of delays. The common mistake is to buy capacity before proving where capacity is constrained. More analysers do not solve phlebotomy, transport, centrifugation, LIS, or manual-verification problems. The intervention should be selected only after the bottleneck is shown. Interventions may include demand smoothing, separate urgent streams, staffing redesign, equipment maintenance scheduling, autoverification, revised delta checks, reagent inventory control, ward feedback or phlebotomy retraining.

The final step is governance. Improvements should be reviewed in a formal quality meeting, linked to corrective and preventive action (CAPA), and sustained through audit. If a laboratory reduces median TAT but increases specimen rejection, QC failure, corrected reports or clinician complaints, the intervention has failed. That point is not negotiable.

Table 6. Twelve-week implementation roadmap for improving TAT without weakening reliability

Weeks	Main task	Technical work	Quality-management output	Evidence of success
2-Jan	Define scope and governance	Select assays, clinical settings, TAT definitions and stakeholders	Project charter, RACI matrix, risk register	Approved definitions and accountable owners.
4-Feb	Build baseline	Extract timestamps, QC data, downtime, specimen rejection and corrected-report data.	Baseline dashboard and data-quality assessment	Baseline performance described by median, p90, breach rate and reliability indicators.
5-Apr	Map the	Observe sample flow, review	Process map and Pareto	The top two or three

	process and identify constraints	queue points, and classify delay intervals	analysis	delay drivers are identified with evidence.
8-May	Intervene using PDSA cycles.	Pilot urgent stream, autoverification, batching redesign, staffing adjustment or maintenance schedule	Documented PDSA cycles and risk assessment	TAT improves without deterioration in QC, specimen rejection or corrected reports.
10-Aug	Standardise successful changes	Update SOPs, LIS rules, training materials and escalation protocols	Controlled documents and competence records	Staff compliance and reduced variation across shifts.
12-Oct	Audit and sustain	Audit dashboard, critical-value logs, CAPA closure and user feedback	Quality review report and sustainability plan	Improvement was maintained, and governance actions were closed.

DISCUSSION

The central lesson is that clinical biochemistry laboratories must stop separating speed from quality. TAT is a quality indicator; analytical reliability is another; patient safety is the clinical expression of both. The total testing process provides the correct conceptual frame because most delays and many errors occur outside the narrow moment of measurement. This is precisely why pre-examination and post-examination indicators deserve the same seriousness as analytical indicators. The framework also clarifies why average TAT is a poor metric for governance. A laboratory can have an acceptable mean while repeatedly failing urgent or high-risk cases. Median TAT, 90th-percentile TAT, breach percentage, and critical-result notification compliance provide a more accurate picture. Stratification by test, location, priority and time of day prevents global averages from hiding local harm.

Analytical reliability must remain the boundary condition for speed. Autoverification is an excellent example. Properly designed autoverification can reduce unnecessary manual review and shorten TAT, but unsafe rules can silently release erroneous results. Similarly, risk-based QC can reduce wasteful false rejections while preserving the detection of clinically important analytical errors, but weak QC design can create a false appearance of efficiency. The quality-management system must therefore evaluate interventions based on joint outcomes, not on TAT alone. For resource-limited laboratories, the framework remains applicable. The dashboard can begin with manual extraction of a random sample, as WHO LQSI recommends for quarterly TAT monitoring, and then progress to automated LIS extraction [4]. The important point is not technological sophistication. The important points are disciplined measurement, root cause analysis, and corrective action. A spreadsheet used honestly is better than a beautiful dashboard ignored by management.

CONCLUSION

Improving diagnostic turnaround time in clinical biochemistry is not a matter of working faster; it is a matter of designing a controlled, measured and continuously improved total testing process. Analytical reliability is not an obstacle to speed. Properly governed, it is the condition that makes speed clinically safe. A reputable laboratory should therefore monitor TAT and analytical reliability through a single integrated quality-management framework, supported by time-stamped data, risk-based QC, quality indicators, competent staff, robust LIS processes, equipment reliability, and disciplined CAPA. The laboratory that releases results quickly but unreliably has failed the patient. The laboratory that releases accurate results too late may also have failed. Excellence lies in governing both.

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