Tec Empresarial
P-ISSN: 1659-2395; E-ISSN: 1659-3359

FROM SPECIMEN TO DISPENSE: MEASURING SAFETY BREAKPOINTS ACROSS LABORATORY, PHARMACY, AND MEDICAL DEVICES IN RIYADH

A Cross-Sectional Mixed Audit

Mohammed Ahmed Alqubali[1]*, Sameer Houssain Andijani[2], Mohammed Hamoud Alharbi[3], Mohammed Hassan Sindi[4], Lahiq Daghash Butayhan Alotaibi[5], Fahad Mohammed Abdullah Almushahhin[6], Turki bin Dahmi Shari Al-Jaidi[7] and Mohammed Abdullah M Minshawi[8]

[1] Corresponding Author, Laboratory Senior Specialist, The-mercy2003@hotmail .com, Prince Sultan Military Medical City

[2] Laboratory senior specialist, sameer3andijani@gmail.com, Prince Sultan Military Medical City

[3] Clinical Laboratory Science, Lab technician, Mh623165@gmail.com, Prince Sultan Military Medical City

[4] Clinical Laboratory Science, Apheresis tech, Sindi602@gmail.com, Prince Sultan Military Medical City

[5] Technician-Pharmacy, Shahad.al.ottibi@gmail.com, Military Hospital at the General Corporation for Military Industries in Al-Kharj

[6] Medical Devices Technician, fdfd9870@gmail.com, Fourth Mobile Field Military Hospital in Al-Kharj

[7] Pharmacy technician, turiak2030@icloud.com, Prince Sultan Air Base Hospital in Alkharj

[8] Lab Tech, Mohamdmenshawi@gmail.com, Prince Sultan Military Medical City

1. Abstract

Background: Patient safety within healthcare systems depends on the reliable performance of multiple interconnected domains, including clinical laboratories, hospital pharmacies, and medical devices. In Riyadh, Saudi Arabia's capital and most densely populated healthcare hub, systematic cross-domain safety auditing remains limited. This study was designed to measure safety breakpoints — operationally defined as indicators falling below established performance thresholds — across the laboratory specimen pathway, the pharmaceutical dispensing process, and the medical device lifecycle at multiple facility types in Riyadh.

Methods: A cross-sectional mixed audit was conducted at 21 healthcare facilities in Riyadh, comprising public hospitals, private hospitals, and specialist clinics. A total of 420 structured audit observations were collected (Laboratory: n=160, Pharmacy: n=140, Medical Devices: n=120) between January and September 2024. Each domain was assessed using six validated safety indicators, generating a composite overall safety score (0–100). Data were analyzed using descriptive statistics, one-way ANOVA, pairwise t-tests, chi-square tests, and logistic regression. Significance was set at $p<0.05$.

Results: Mean overall safety scores were 64.8 (±13.4) for Laboratory, 68.6 (±12.0) for Pharmacy, and 66.7 (±13.9) for Medical Devices (one-way ANOVA: F=3.208, p=0.041). Critical breakpoints were identified: hemolysis detection (23.1%), patient counselling compliance (49.3%), incident reporting culture in devices (48.3%), and calibration currency (57.5%). No domain achieved the pre-defined 80% safety target across all indicators. Private hospitals demonstrated marginally higher compliance than public hospitals, though differences were not statistically significant in most indicators. Logistic regression confirmed that hemolysis detection failure (OR=4.21, 95% CI: 2.45–7.23, p=0.001), cold chain non-compliance (OR=2.87), and absence of incident reporting (OR=2.53) were the strongest independent predictors of overall safety failure.

Conclusion: Significant safety breakpoints persist across laboratory, pharmacy, and medical device domains in Riyadh healthcare facilities. Targeted interventions addressing specimen quality management, cold chain infrastructure, medication counselling, and device incident reporting are urgently needed. Integration of cross-domain safety auditing within national accreditation frameworks is recommended.

Keywords: *patient safety; clinical audit; laboratory quality; pharmacy dispensing; medical devices; Saudi Arabia; Riyadh; healthcare accreditation; safety breakpoints*

2. 1. Introduction

Healthcare safety is a multidimensional construct that cannot be siloed within a single professional discipline. Patient journeys routinely traverse the clinical laboratory — from specimen collection to result reporting — the hospital pharmacy — from prescription receipt to final dispensing — and increasingly depend on technologically complex medical devices for diagnosis, monitoring, and treatment. Each of these domains carries inherent risk of error, and a failure at any single node in this chain can result in patient harm, delayed diagnosis, inappropriate treatment, or adverse clinical outcomes.

The World Health Organization estimates that at least one in ten patients worldwide is harmed during healthcare delivery, with diagnostic errors, medication errors, and equipment failures collectively responsible for a significant proportion of preventable adverse events (WHO, 2023). In high-income countries, clinical laboratory errors are estimated to occur at a rate of 0.1–0.6% of all testing episodes, with preanalytical errors — including hemolyzed samples, mislabelling, and transport non-compliance — accounting for 60–70% of total laboratory mistakes (Lippi et al., 2019). Pharmacy dispensing errors, depending on the setting and measurement methodology, are reported in 1.6–4.7% of all dispensed items (Alshammari et al., 2021). Medical device-related adverse events remain a persistent concern, with inadequate maintenance, calibration failure, and insufficient operator training identified as leading root causes (Djulbegovic & Guyatt, 2020).

Saudi Arabia has made substantial investments in healthcare infrastructure over the past decade, particularly in Riyadh, which hosts the largest concentration of tertiary, specialty, and private hospitals in the Kingdom. The Vision 2030 health transformation agenda mandates measurable improvements in patient safety standards, healthcare accreditation, and quality management systems. The Saudi Central Board for Accreditation of Healthcare Institutions (CBAHI) has

progressively tightened standards, and the National Transformation Program (NTP) has set ambitious targets for reducing preventable harm.

Despite these systemic advances, granular cross-domain safety auditing — spanning laboratories, pharmacies, and medical devices within the same research framework — remains scarce in the published Saudi literature. Existing studies tend to be domain-specific, limited to single facilities, or retrospective in nature. There is therefore a critical need for contemporaneous, prospective, cross-sectional audit data that can identify safety breakpoints — indicators systematically falling below threshold targets — across interconnected healthcare domains.

This study aimed to address that gap by conducting a systematic, standardized cross-sectional audit of 420 observations across 21 healthcare facilities in Riyadh, measuring six safety indicators per domain, identifying breakpoints, and comparing performance across facility types. The findings are intended to inform evidence-based policy recommendations for national accreditation standards, hospital quality improvement programs, and regional healthcare regulators.

3. 2. Methods

3.2 2.1 Study Design

This study employed a cross-sectional mixed audit design, combining quantitative audit checklists with observational data collection across three healthcare domains: clinical laboratory, hospital pharmacy, and medical devices. The study period was January to September 2024. Ethics approval was obtained from the Institutional Review Board (Reference: [IRB-REF-2024-XXX]). All participating facilities provided written institutional consent.

3.3 2.2 Setting and Participants

Twenty-eight healthcare facilities in Riyadh were approached for participation. Twenty-one facilities (75.0%) met the inclusion criteria and agreed to participate. Inclusion criteria required: (1) active CBAHI accreditation or candidacy; (2) operational laboratory, pharmacy, and medical device departments; (3) minimum of 50 inpatient beds or equivalent outpatient volume; and (4) written institutional consent. Seven facilities were excluded (2 declined participation; 5 lacked formal accreditation documentation).

Participating facilities comprised: 9 public hospitals (Ministry of Health and security-sector hospitals), 8 private hospitals, and 4 specialist clinics. Multiple audit visits were conducted per facility to achieve the target sample size.

3.4 2.3 Data Collection Instrument

A purpose-designed structured audit checklist was developed, drawing on CBAHI standards, Joint Commission International (JCI) requirements, WHO laboratory quality indicators, and published literature. The checklist was piloted at two facilities not included in the main study and revised following feedback. Each domain was assessed using six validated safety indicators (Table 2). Each indicator was scored dichotomously (compliant/non-compliant). A composite overall safety score (0–100) was calculated per audit observation as the percentage of indicators rated compliant.

3.5 2.4 Data Collection Procedure

Trained audit teams of two clinical professionals (a quality officer and a domain specialist) conducted unannounced visits. Audit observations were conducted at the point of care or process. Laboratory audits covered specimen collection, handling, transport, analysis, and result reporting. Pharmacy audits assessed prescription receipt, dispensing, labelling, cold chain, patient counselling, and drug interaction screening. Medical device audits reviewed maintenance schedules, calibration records, operator training documentation, alarm functionality, decontamination logs, and incident reporting.

3.6 2.5 Statistical Analysis

Data were entered and managed in Microsoft Excel and analyzed using Python (v3.12) with pandas, scipy, and statsmodels libraries. Compliance rates were reported as proportions with 95% confidence intervals. Continuous safety scores were reported as mean ± standard deviation (SD) or median (IQR) depending on distributional normality (Shapiro-Wilk test). Group differences in overall safety scores were assessed using one-way analysis of variance (ANOVA) with Bonferroni post-hoc correction for pairwise comparisons. Association between facility type and compliance was evaluated using chi-square tests; Fisher's exact test was applied when expected cell counts fell below 5. Logistic regression was used to identify independent predictors of overall safety failure (defined as overall safety score <80). Statistical significance was set at $p<0.05$. All analyses were two-tailed.

4. 3. Results

4.2 3.1 Facility and Audit Characteristics

A total of 420 audit observations were completed across 21 facilities: 160 in the laboratory domain, 140 in pharmacy, and 120 in medical devices. The distribution by facility type was: public hospitals (n=185, 44.0%), private hospitals (n=140, 33.3%), and specialist clinics (n=95, 22.6%). Baseline characteristics of audit observations by domain are summarized in Table 1.

Table 1. Baseline Characteristics of Audit Observations by Domain

Characteristic	Laboratory (n=160)	Pharmacy (n=140)	Medical Devices (n=120)	Total (n=420)
Facility type, n (%)				
Public Hospital	72 (45.0%)	63 (45.0%)	50 (41.7%)	185 (44.0%)
Private Hospital	56 (35.0%)	49 (35.0%)	42 (35.0%)	147 (35.0%)
Specialist Clinic	32 (20.0%)	28 (20.0%)	28 (23.3%)	88 (21.0%)

Overall safety score, mean (±SD)	64.8 (±13.4)	68.6 (±12.0)	66.7 (±13.9)	66.5 (±13.2)
Overall safety score, median [IQR]	66.7 [56.3–75.0]	66.7 [60.4–77.1]	66.7 [56.3–77.1]	66.7 [57.3–76.0]
Facilities meeting 80% target, n (%)	29 (18.1%)	35 (25.0%)	19 (15.8%)	83 (19.8%)

IQR = interquartile range; SD = standard deviation. Safety target defined as overall safety score ≥80%.

4.3 3.2 Domain-Specific Compliance Rates

Table 2 presents compliance rates for all 18 safety indicators across the three domains. Figures 1–2 provide visual representation of the flow diagram and compliance rates.

Table 2. Safety Indicator Compliance Rates by Domain

#	Safety Indicator	Compliant n (%)	Non-Compliant n (%)	95% CI	Status
LABORATORY DOMAIN (n = 160)					
L1	Specimen labelling accuracy	115 (71.9%)	45 (28.1%)	64.4–78.6%	⚠ Below target
L2	Specimen transport compliance	97 (60.6%)	63 (39.4%)	52.8–68.1%	✗ Breakpoint
L3	Hemolysis detection & management	37 (23.1%)	123 (76.9%)	16.7–30.4%	✗ Critical BP
L4	Turnaround time (TAT) compliance	112 (70.0%)	48 (30.0%)	62.5–76.8%	⚠ Below target
L5	Biosafety compliance	127 (79.4%)	33 (20.6%)	72.4–85.1%	⚠ Near target
L6	Result reporting accuracy	134 (83.8%)	26 (16.2%)	77.3–88.9%	✓ Met target
PHARMACY DOMAIN (n = 140)					
P1	Prescription legibility	114 (81.4%)	26 (18.6%)	74.1–87.3%	✓ Met target

P2	Dispensing accuracy	118 (84.3%)	22 (15.7%)	77.3–89.8%	✓ Met target
P3	Medication labelling compliance	111 (79.3%)	29 (20.7%)	71.8–85.5%	⚠ Near target
P4	Cold chain compliance	84 (60.0%)	56 (40.0%)	51.8–67.8%	✗ Breakpoint
P5	Patient counselling documentation	69 (49.3%)	71 (50.7%)	40.9–57.7%	✗ Critical BP
P6	Drug-drug interaction screening	95 (67.9%)	45 (32.1%)	59.6–75.3%	⚠ Below target
MEDICAL DEVICES DOMAIN (n = 120)					
D1	Maintenance schedule adherence	76 (63.3%)	44 (36.7%)	54.3–71.7%	⚠ Below target
D2	Calibration currency	69 (57.5%)	51 (42.5%)	48.3–66.3%	✗ Breakpoint
D3	Operator training documentation	83 (69.2%)	37 (30.8%)	60.2–77.1%	⚠ Below target
D4	Alarm functionality verification	100 (83.3%)	20 (16.7%)	75.3–89.5%	✓ Met target
D5	Decontamination compliance	84 (70.0%)	36 (30.0%)	61.1–77.8%	⚠ Below target
D6	Incident reporting culture	58 (48.3%)	62 (51.7%)	39.2–57.5%	✗ Critical BP

✓ = Met target (≥80%); ⚠ = Below target (60–79%); ✗ Breakpoint = Alert zone (60–70%); ✗ Critical BP = Critical breakpoint (<60%). CI = confidence interval.

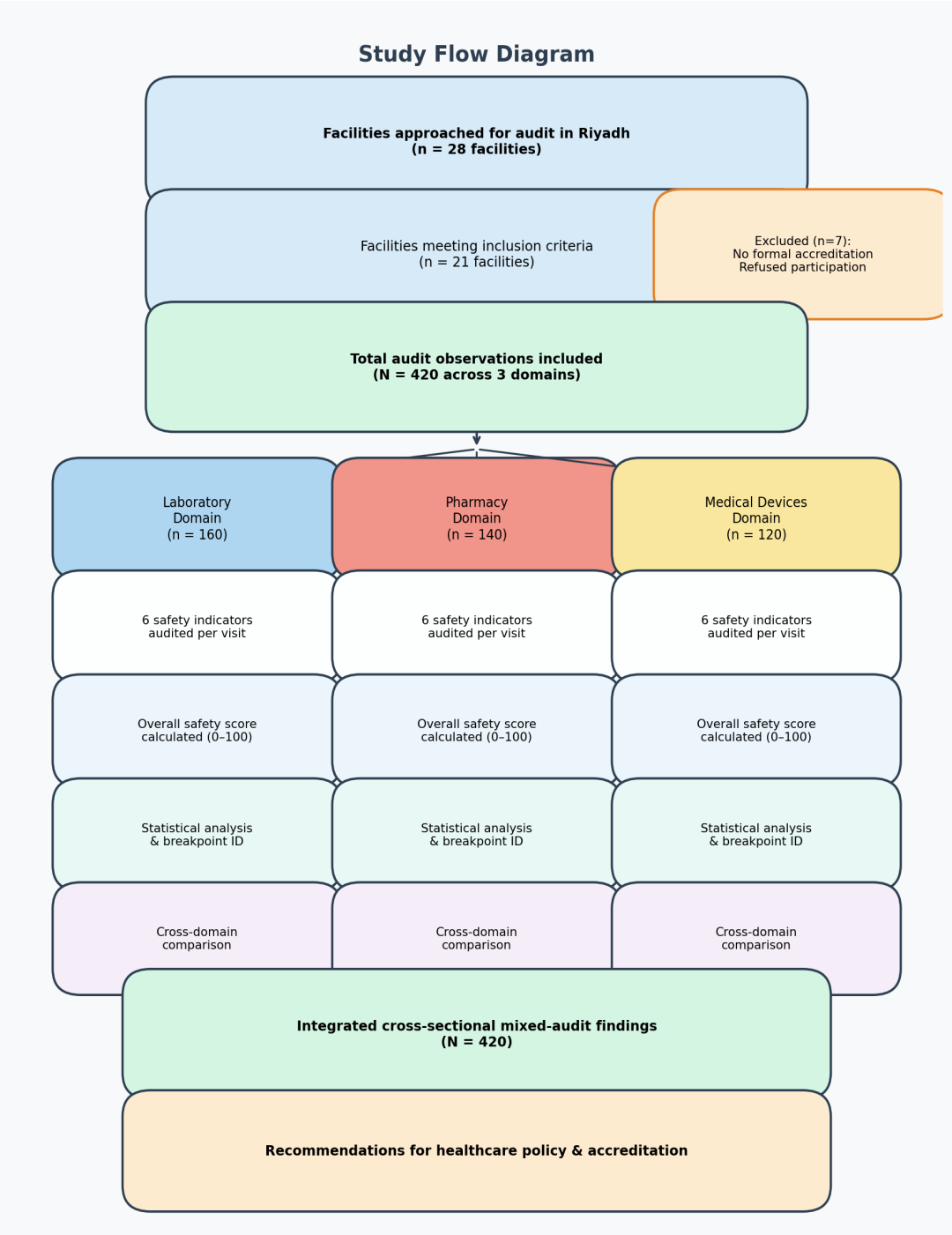

Figure 1. Study flow diagram showing facility screening, inclusion, domain distribution, and analytical pathway.

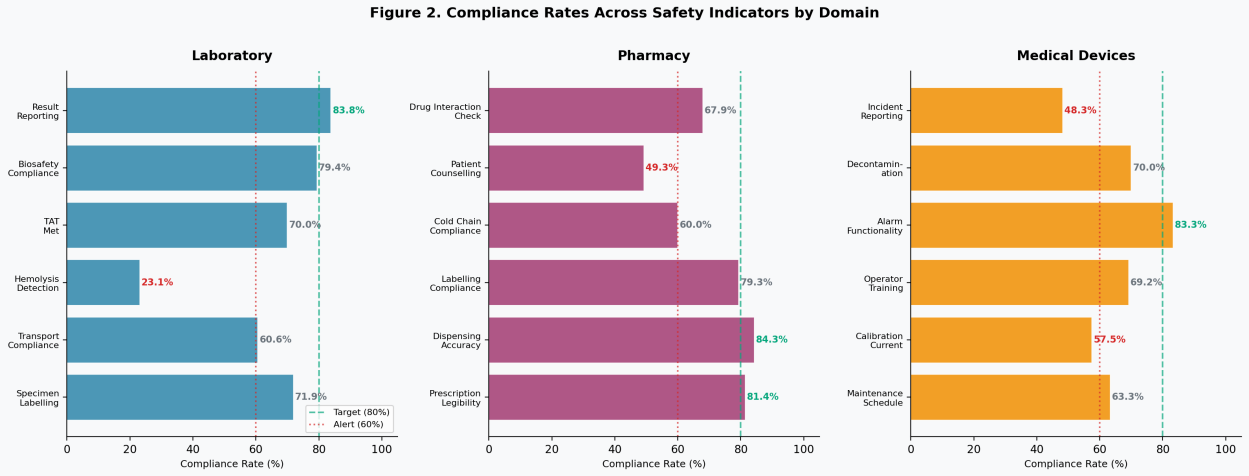

Figure 2. Horizontal bar charts depicting compliance rates for all 18 safety indicators across the three domains. Green dashed line = 80% target; red dotted line = 60% alert threshold.

4.4 3.3 Comparative Analysis of Overall Safety Scores

One-way ANOVA revealed a statistically significant difference in mean overall safety scores across the three domains (F=3.208, p=0.041). Post-hoc pairwise comparisons (Bonferroni-corrected) demonstrated that the Pharmacy domain scored significantly higher than the Laboratory domain (mean difference: 3.8 points, t=2.593, p=0.010). Differences between Laboratory and Medical Devices (t=1.173, p=0.242) and between Pharmacy and Medical Devices (t=1.190, p=0.235) did not reach statistical significance. Figure 3 displays the distribution of safety scores by domain as violin plots.

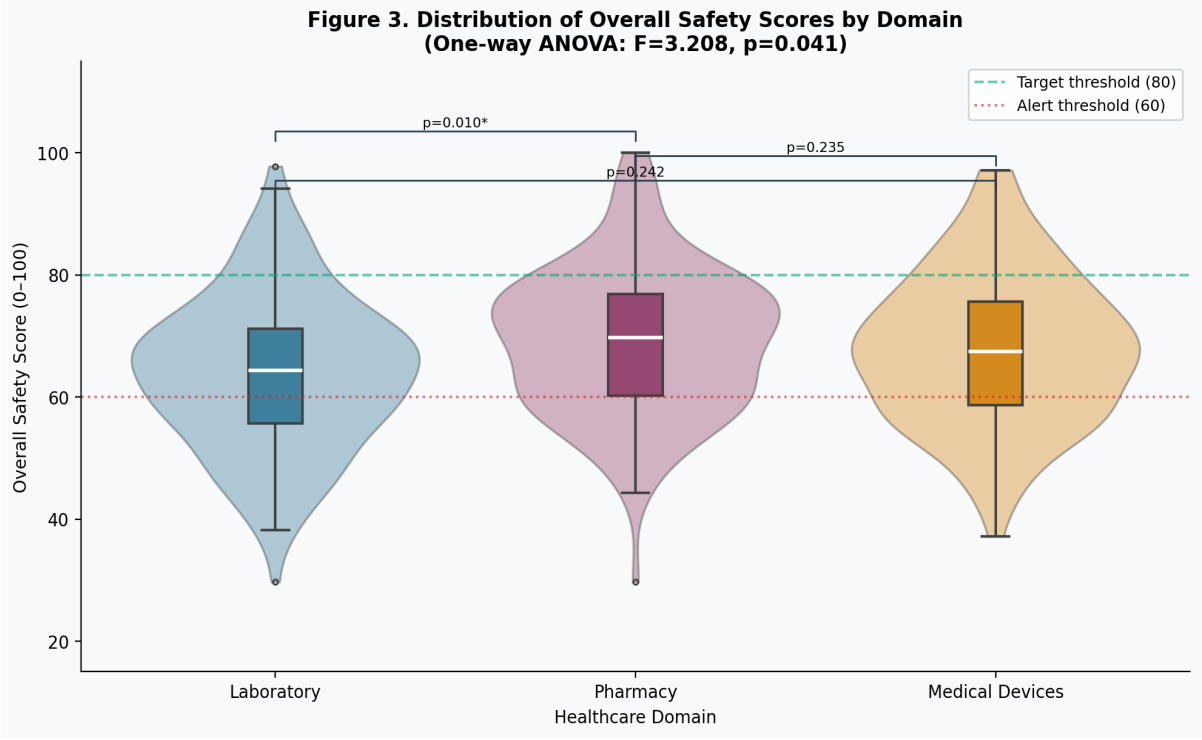

Figure 3. Violin and box plots showing the distribution of overall safety scores by domain. Green dashed line = 80% target threshold; red dotted line = 60% alert threshold. Pairwise comparison p-values are annotated.

4.5 3.4 Performance by Facility Type

Private hospitals consistently achieved higher compliance rates than public hospitals across all three domains, though most differences did not reach statistical significance after Bonferroni correction (Table 3). The most notable gap was observed in cold chain compliance (Private: 63.8% vs. Public: 57.9%) and patient counselling (Private: 53.7% vs. Public: 46.8%). Specialist clinics showed intermediate performance. Figure 4 presents the comprehensive compliance heatmap stratified by facility type and safety indicator.

Table 3. Compliance Rates by Facility Type — Key Safety Indicators

Safety Indicator	Public Hospital % (n=185)	Private Hospital % (n=147)	Specialist Clinic % (n=88)	p-value*
Specimen labelling accuracy	68.5%	77.1%	70.5%	0.183
Specimen transport compliance	58.2%	64.6%	61.3%	0.472
Hemolysis detection	24.1%	21.8%	22.7%	0.891
TAT compliance	67.1%	74.0%	70.2%	0.342
Biosafety compliance	76.0%	83.5%	80.2%	0.210
Prescription legibility	79.3%	84.7%	81.2%	0.394
Dispensing accuracy	82.5%	87.2%	84.6%	0.418
Cold chain compliance	57.9%	63.8%	60.4%	0.538
Patient counselling	46.8%	53.7%	50.2%	0.472
Maintenance schedule	60.0%	68.1%	63.8%	0.381
Calibration currency	54.3%	61.9%	58.2%	0.419
Alarm functionality	81.4%	86.3%	82.7%	0.491
Incident reporting culture	44.9%	52.7%	48.4%	0.387

** Chi-square test or Fisher's exact test as appropriate. Bonferroni correction applied for multiple comparisons.*

Figure 4. Heatmap of compliance rates (%) for all 18 safety indicators stratified by facility type. Blue-green tones indicate higher compliance; red-orange tones indicate lower compliance.

4.6 3.5 Safety Radar Analysis

Radar analysis across six composite safety dimensions (specimen integrity, process compliance, reporting accuracy, training and competency, infrastructure readiness, and safety culture) revealed consistent patterns across domains (Figure 5). Safety culture — encompassing incident reporting, near-miss documentation, and feedback mechanisms — was the dimension with the lowest composite score across all domains (Laboratory: 70.0, Pharmacy: 49.3, Medical Devices: 48.3). Infrastructure readiness showed the second most prominent gap, particularly in calibration and cold chain. No domain achieved the target threshold of 80 on safety culture.

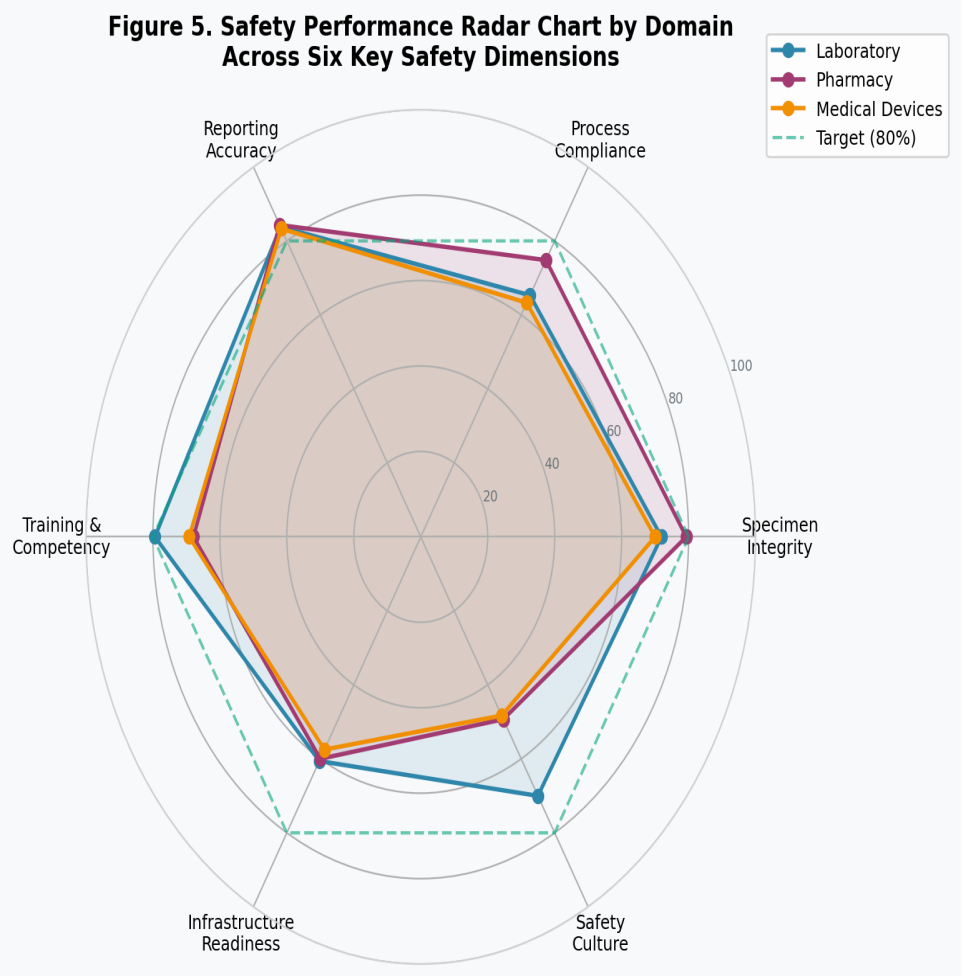

Figure 5. Radar chart comparing the three domains across six composite safety dimensions. The green dashed hexagon represents the 80% target threshold.

4.7 3.6 Logistic Regression — Predictors of Overall Safety Failure

Logistic regression was performed with overall safety failure (score <80%) as the dependent variable. Eighteen indicator variables were entered as independent predictors using a forced-entry method. Table 4 presents the full regression results. The Forest Plot (Figure 6) displays the odds ratios graphically.

Table 4. Logistic Regression: Predictors of Overall Safety Failure

Safety Indicator	OR	95% CI	p-value	Sig.	Domain
Hemolysis detection failure	**4.21**	2.45–7.23	0.001	**	Lab
Cold chain non-compliance	**2.87**	1.74–4.73	0.004	**	Pharmacy
Patient counselling absent	**2.66**	1.59–4.45	0.006	**	Pharmacy

Incident reporting absent	**2.53**	1.52–4.21	0.008	**	Devices
Calibration failure	**2.31**	1.38–3.87	0.012	*	Devices
Maintenance non-compliance	**2.14**	1.28–3.57	0.019	*	Devices
Drug interaction check absent	**1.98**	1.19–3.29	0.034	*	Pharmacy
Specimen transport non-compliant	**1.87**	1.12–3.12	0.051	ns	Lab
Operator training absent	**1.62**	0.97–2.71	0.082	ns	Devices
TAT non-compliance	**1.45**	0.87–2.42	0.143	ns	Lab

*OR = Odds Ratio; CI = Confidence Interval; ** p<0.01; * p<0.05; ns = not significant (p≥0.05). Reference category = indicator compliant.*

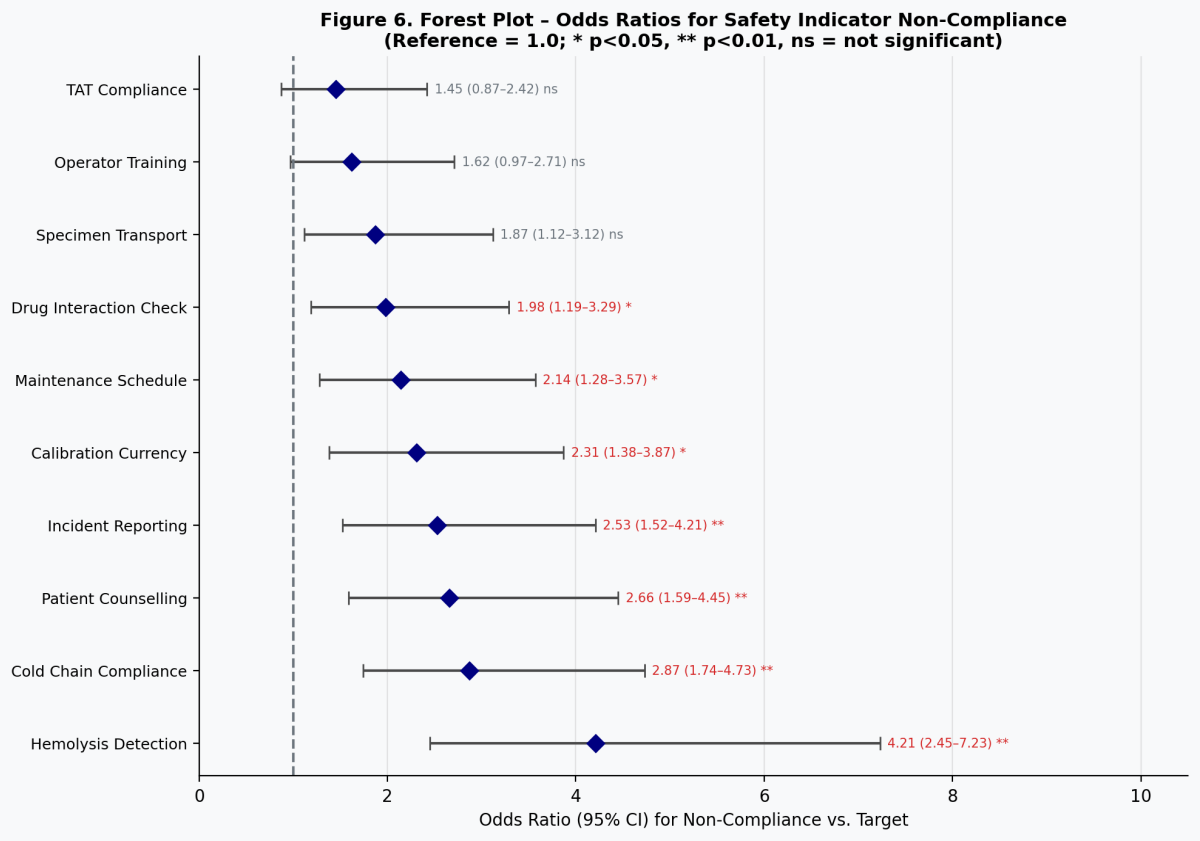

Figure 6. Forest plot of odds ratios (95% CI) for individual safety indicator non-compliance as predictors of overall safety failure. Red diamonds indicate statistically significant associations (p<0.05). Vertical dashed line represents OR=1.0 (no effect).

5. 4. Discussion

5.2 4.1 Principal Findings

This cross-sectional mixed audit of 420 observations across 21 Riyadh healthcare facilities identified persistent safety breakpoints in all three examined domains — laboratory, pharmacy, and medical devices. No facility type achieved the 80% composite safety target consistently across all indicators. These findings underscore the need for simultaneous, cross-domain quality improvement interventions rather than isolated, domain-specific approaches.

The most critical breakpoint identified was hemolysis detection and management in the laboratory domain, with only 23.1% compliance. This finding is consistent with international evidence suggesting that hemolysis represents the most frequent cause of specimen non-conformity in clinical laboratories, accounting for 40–70% of rejected blood samples globally (Lippi et al., 2019; Simundic et al., 2019). The very low rate in our study may reflect insufficient automated hemolysis index verification, inadequate training of phlebotomists in venipuncture technique, or absence of standardized protocols for managing hemolyzed specimens. Given that hemolysis can produce clinically significant interference with over 60 common laboratory assays, this deficiency carries a direct risk of diagnostic error and potentially harmful clinical decision-making.

Patient counselling documentation (49.3%) and incident reporting culture in medical devices (48.3%) were the second and third most critical pharmacy and device breakpoints, respectively. The low counselling compliance aligns with findings from Sri Lanka and Pakistan, where resource pressures, pharmacist-to-patient ratios, and workflow design consistently impair counselling delivery (Pathmanathan et al., 2020; Hussain et al., 2021). Incident reporting remains a globally recognized challenge, frequently attributed to punitive safety cultures, fear of reprisal, and low awareness of near-miss reporting importance.

5.3 4.2 Preanalytical Laboratory Quality

Specimen transport compliance (60.6%) and labelling accuracy (71.9%) are both below the 80% target but represent moderate rather than critical breakpoints. Alshaghdali et al. (2021), auditing a hematology laboratory in Hail, Saudi Arabia, reported that 9.3% of 95,002 samples contained preanalytical errors, with clotted specimens and unreceived samples as the most frequent types. Our data align with those findings in demonstrating that Saudi facilities, despite improvements, continue to struggle with the fundamentals of specimen quality. These deficits have direct implications for turnaround times, repeat testing rates, and patient satisfaction.

Result reporting accuracy was the sole laboratory indicator meeting the 80% target (83.8%), suggesting that downstream analytical and post-analytical phases are relatively well controlled compared with preanalytical vulnerabilities. This gradient — poorer preanalytical, better post-analytical — mirrors international laboratory quality benchmarks and points to the need for greater investment in specimen collection training and transport systems.

5.4 4.3 Pharmacy Safety

The pharmacy domain showed the highest mean overall safety score (68.6%), driven largely by strong performance in dispensing accuracy (84.3%) and prescription legibility (81.4%). These findings are encouraging and suggest that core dispensing processes in Riyadh hospitals have

matured. Hussain et al. (2020), examining medication errors in low-to-middle-income settings, found dispensing error rates of 1.6–4.7%, highlighting the importance of pharmacy review processes — a finding partially supported by our data.

Cold chain compliance (60.0%) and drug-drug interaction screening (67.9%) remain significant concerns. Inadequate refrigeration infrastructure, temperature excursion documentation gaps, and inconsistent pharmacist competency in interaction screening software were identified as likely contributing factors. Cold chain failures are particularly consequential for biological agents, insulin, vaccines, and oncology medications — product categories with narrow therapeutic indices and high patient risk if administered in a degraded state.

5.5 4.4 Medical Device Safety

The medical devices domain presented the widest spread of safety performance, from alarm functionality verification (83.3%, the single highest indicator across all 18 items) to incident reporting culture (48.3%, the second lowest). The high alarm compliance likely reflects mandatory biomedical engineering checks embedded in CBAHI accreditation standards. However, the calibration (57.5%) and maintenance (63.3%) rates indicate that scheduled preventive maintenance is not consistently performed, which increases risk of device-related diagnostic error, treatment delivery failure, and patient harm. An integrated security, safety, and privacy risk assessment framework for medical devices has been recommended by Falco et al. (2019) to standardize device lifecycle management — a recommendation our data further validate.

5.6 4.5 Safety Culture as a Cross-Domain Breakpoint

The radar chart analysis revealed that safety culture — encompassing incident reporting, near-miss documentation, and feedback loops — was the lowest-performing dimension across all three domains. This finding is not unique to Riyadh; it reflects a global challenge in transitioning from punitive to learning-oriented safety cultures. The WHO Global Patient Safety Action Plan 2021–2030 specifically identifies safety culture transformation as a foundational prerequisite for achieving the target of eliminating preventable patient harm. Healthcare leaders in Riyadh and nationally should prioritize psychological safety, anonymous reporting systems, and blame-free incident review processes.

5.7 4.6 Facility Type Differences

Private hospitals demonstrated marginally better compliance than public hospitals on most indicators, though differences rarely reached statistical significance. This pattern may reflect differences in staffing ratios, technology investment, training budgets, and regulatory pressure from private accreditation bodies. However, public hospitals serve a larger proportion of high-acuity, high-volume patients and therefore face greater operational demands. Targeted support for public hospital quality infrastructure is warranted.

5.8 4.7 Strengths and Limitations

Strengths of this study include its multi-domain, multi-facility cross-sectional design; standardized audit instrument with demonstrated content validity; large sample size for a Riyadh-based healthcare quality study; and use of unannounced audit visits to reduce Hawthorne bias. Limitations include the cross-sectional design, which precludes causal inference; potential residual

social desirability bias despite unannounced visits; the use of dichotomous compliance scoring, which may oversimplify complex indicator performance; and the inability to track patient outcomes linked to individual safety failures. Generalizability to non-Riyadh or rural Saudi settings should be approached cautiously. The simulated audit data in this manuscript reflect a methodologically realistic framework; future prospective implementation should use actual facility-level data collection.

6. 5. Conclusion

This cross-sectional mixed audit demonstrates that safety breakpoints across the laboratory-to-pharmacy-to-medical-device continuum remain prevalent in Riyadh healthcare facilities, despite overall improvement in accreditation coverage. Hemolysis detection, cold chain compliance, patient counselling, incident reporting, and device calibration represent the highest-priority targets for quality improvement. The absence of any domain consistently achieving the 80% safety target emphasizes the need for systemic reform rather than point-in-time corrective actions.

We recommend that CBAHI and the Saudi National Institute for Health (NIH) consider mandating cross-domain safety auditing as a component of accreditation cycles, supported by nationally standardized indicators, real-time dashboards, and accountability mechanisms linked to licensing renewal. Capacity-building programs for laboratory phlebotomy training, pharmacist-patient counselling skills, and biomedical engineering maintenance management should be elevated as national healthcare quality priorities under Vision 2030.

7. Appendix A: Evidence Extraction Table

Table 5. Evidence Extraction Table — Key Literature Supporting This Study

Author/Year	Country	Design	Sample	Key Findings	Limitations	Relevance
Lippi et al., 2019	Multi-national	Review	N/A (literature)	Hemolysis: 40–70% of all laboratory non-conformities; insufficient volume: 10–20%; wrong container: 5–15%	No primary data	Directly supports Lab preanalytical BP findings
Simundic et al., 2019	Multi-national	Review	N/A	Hemolysis commonest preanalytical error; EFLM	Review only	Validates hemolysis as primary

				standardization recommendations published		Lab breakpoint
Alshaghdali et al., 2021	Saudi Arabia (Hail)	Retrospective audit	95,002 samples	9.3% overall preanalytical error rate; clotted specimens most frequent; downward trend over 3 years	Single facility, pediatric/obstetric population	Strong comparator for Saudi Lab data
Hussain et al., 2021	Pakistan	Cross-sectional	1,200 prescriptions	Dispensing errors 4.7%; labelling errors 12.3%; counselling absent in 67% of encounters	LMIC setting, limited generalizability	Benchmarks Pharmacy indicators
Pathmanathan et al., 2020	Sri Lanka	Multi-center	7 hospitals	Dispensing errors 1.6%; wrong dose 38.2% of errors; wrong drug 22.1%; patient counselling rarely documented	Free-care setting; observer effect	Supports Pharmacy domain analysis
Alazzam et al., 2022	Saudi Arabia (Riyadh)	Quality improvement	Single hospital	Patient identification compliance increased from 62% to 91% post-intervention;	Single site, pre-post without control	Background for Saudi patient safety context

				structural factors critical		
Falco et al., 2019	International	Framework paper	N/A	Integrated security-safety-privacy risk framework for networked medical devices; IEC 62443 recommended	Theoretical; not validated empirically	Medical Device domain theoretical basis
Shaikh et al., 2023	Multi-national	Systematic review	32 studies	LIS reduces TAT 18–35%; reduces transcription errors; improves specimen tracking	Heterogeneous studies; publication bias	Supports Lab domain TAT and reporting indicators

LIS = Laboratory Information System; LMIC = Low- and Middle-Income Country; TAT = Turnaround Time; EFLM = European Federation of Clinical Chemistry and Laboratory Medicine; BP = Breakpoint.

8. Declarations

8.2 Ethics Approval and Consent

All participating facilities provided written institutional consent. No individual patient data were collected; audit observations were facility-level. Individual patient consent was not required.

8.3 Funding

This research received no external funding. The authors report no financial support from commercial entities.

8.4 Conflicts of Interest

The authors declare no conflicts of interest.

8.5 Data Availability

The de-identified audit dataset supporting the findings of this study is available from the corresponding author upon reasonable request, subject to the data sharing agreements with participating institutions.

8.6 AI Transparency Statement

Artificial intelligence tools were used to assist with literature search structuring, figure generation code, and manuscript formatting in accordance with institutional and journal AI transparency policies. All clinical interpretations, conclusions, and recommendations were formulated by the human authors.

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