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Research Protocol

Health Management and Policy Section

Efficacy of Newly Developed Unitised Risk Analysis Tool versus Standard Risk Analysis Tool at Clinical Laboratory: A Research Protocol

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ABSTRACT

Introduction: Risk management in medical laboratories is essential for patient safety and diagnostic accuracy. International Organisation for Standardisation (ISO) standards emphasise systematic identification, analysis, and mitigation of risks across laboratory processes. However, many laboratories lack a practical, parameter-specific framework that can effectively eliminate risk factors linked to individual test parameters.

Need of the study: Current risk management models are often theoretical and fail to provide benchmarking tools for severity assessment, leading to poor prioritisation and overlooked risks. The Unitised Risk Analysis Tool (URAT) integrates ISO standards with Failure Mode, Effects, and Criticality Analysis (FMECA) to enable parameter-specific risk evaluation and actionable outcomes.

Aim: To compare the efficacy of the newly developed URAT with the conventional Failure Mode and Effects Analysis (FMEA) tool in a clinical laboratory setting.

Materials and Methods: A prospective observational study will be conducted at Dattatraya Diagnostics Centre, Wardha, Maharashtra, India from May 2025 to April 2026. Data will be collected through real-time audits, structured checklists, interviews, and FMECA scoring. Risk Priority Numbers (RPN) will be calculated for each parameter. Comparative analysis between URAT and FMEA will use paired t-tests or Wilcoxon signed-rank tests, with categorical outcomes analysed by Chi-square or Fisher's exact tests. Reliability will be assessed using Intraclass Correlation Coefficients (ICC) and weighted kappa statistics. Statistical significance will be set at p-value ≤0.05.

Keywords: Clinical laboratory, Compliance, Diagnostic errors, Patient safety, Quality management, Risk assessment

INTRODUCTION

Laboratory test results are central to medical decision-making and continuous patient monitoring. With recent technological advancements, such as fully automated analysers, it has become essential to assess risks across the preanalytical, analytical, and post-analytical phases. Accuracy in laboratory processes depends on the systematic identification, quantification, prioritisation, and mitigation of risks [1]. According to ISO guidelines, risk assessment in medical laboratories plays a crucial role in planning and quality assurance [2]. Risks can be classified as low, medium, or critical depending on their severity, and a robust risk management culture must be embedded into daily practice to proactively identify vulnerabilities, reduce errors, and maintain compliance with international standards [2].

Ensuring a safe working environment for laboratory staff, maintaining the accuracy and reliability of results, and protecting the external environment are all vital aspects of laboratory management. The formulation of quality indicators for each phase of laboratory operations helps reduce risk factors. Impartiality and confidentiality, as emphasised in ISO guidelines, must also be considered in the assessment [3]. Risk assessment involves identifying potential hazards and determining control measures to eliminate or minimise risks to employees, laboratory operations, and the external environment. These standards prioritise clinical risks that directly or indirectly impact patient outcomes, making clinical risk management central to service improvement and error prevention [4].

Laboratories rely heavily on testing equipment, which must detect sample integrity or contamination before processing. Equipment failure or false results due to interfacing errors are also part of laboratory risk management [3]. Despite the existence of frameworks, implementation remains inconsistent, particularly in resource-constrained or high-throughput environments. A major challenge lies in the traditional broad-spectrum approach to risk assessment, which often requires exhaustive evaluations of the entire laboratory system [5].

Once risk identification and mitigation are implemented, laboratories must establish control processes, continuous monitoring, and modify risk statements according to clinical acceptance criteria. This approach, however, can be time-consuming, impractical, and difficult to replicate periodically, especially in high-volume laboratories. There is therefore an urgent need for more efficient, modular risk assessment methodologies that allow continuous improvement without disrupting operations [6].

The methodology integrates elements of FMECA, an inductive bottom-up tool widely recognised for identifying potential failure points in complex systems. Conventional FMEA remains the most widely accepted standard methodology for laboratory risk assessment and therefore serves as the comparator tool in the present study [7]. FMECA prioritises risks by analysing severity, likelihood, and detectability, guiding laboratories to implement effective preventive measures. Integrating FMECA into the URAT framework allows data-driven decision-making and prioritisation of quality improvement initiatives [7].

Beyond improving patient safety and diagnostic reliability, effective risk management has economic implications. Diagnostic errors, equipment failures, and non-conformities can lead to repeat testing, delayed treatment, and reputational damage, all of which result in financial losses. Inaccurate cost accounting and failure to manage incremental costs can further jeopardise a laboratory's financial sustainability. By identifying both clinical and financial risks at the parameter level, the URAT framework supports better resource allocation, cost reduction, and strategic planning.

To address these challenges, this study proposes a URAT designed to simplify and streamline risk assessment. Instead of reassessing risk at the macro level each time, URAT focuses on evaluating individual laboratory parameters based on their associated risk severity. This parameter-based approach enables laboratories to pinpoint risks more accurately, apply targeted interventions, and ensure compliance with ISO guidelines in a measurable, reproducible manner.

REVIEW OF LITERATURE

Two key guidelines currently govern laboratory risk management: ISO 15189:2022 [8], which outlines requirements for quality and competence in medical laboratories, and ISO 22367:2019 [9], which provides a framework for comprehensive risk assessment. While these standards are robust, conducting a full risk analysis for every process is often time-consuming and impractical. To address this limitation, the present study proposes the development of a URAT, designed to operationalise risk assessment at the parameter level. By analysing risks for each parameter individually, laboratories can more effectively minimise risk factors and improve overall quality.

Jayamani J et al., developed a practical tool for risk management in medical laboratories using questionnaires, evaluated through laboratory processes, and scored using the RPN via the FMEA tool. Although their study prepared 70 risk identification questionnaires linked to quality assurance activities, the process was lengthy and not parameter-specific. Moreover, their work remained largely theoretical, without practical or qualitative implications. This empirical gap highlights the need for URAT, which applies risk assessment directly at the parameter level [1].

Tziakou E et al., identified risk management challenges across preanalytical, analytical, and postanalytical stages, and proposed quality indicators based on risk statements. Their study emphasised risks related to employee competence, reagent wastage, environmental conditions, test methods, and result reporting. They concluded that most laboratory errors occur in the preanalytical stage and recommended risk-based thinking, standardised procedures, training, and automation to improve safety and reliability. However, while their work recognised important risk domains, it did not provide a practical tool for implementation. URAT addresses this limitation by offering parameter-wise assessment and actionable scoring [3].

Aita A et al., focused on patient safety and laboratory risk management using theoretical applications of FMEA. Although their study highlighted important concepts, it relied on assumptions and did not provide quantitative risk statements. URAT improves upon this by employing FMECA, a modified version of FMEA, to generate measurable and reproducible risk scores. Conventional FMEA has been widely adopted for systematic identification of process failures and prioritisation by RPN scoring, but its application is typically at the overall process level rather than parameter-specific, limiting operational precision in high-throughput laboratories [7].

Eliza DR and Minodora D developed a tool combining FMEA and FRACAS to identify errors based on occurrence and to establish quality indicators and control plans for entire laboratory processes. While comprehensive, their approach was impractical for parameter-wise studies of risk analysis. URAT overcomes this limitation by focusing on individual parameters, making risk assessment more precise and adaptable to routine laboratory operations [10].

This study aims to assess the comparative efficacy of the newly developed URAT against the conventional FMEA-based standard risk analysis tool in a clinical laboratory.

Primary Objective

- To develop and validate a URAT for compliance assessment with respect to RPN thresholds and acceptance criteria in medical laboratories, in accordance with ISO 15189:2022 and ISO 22367:2019 standards [8,9].

Secondary Objectives

1. To identify error-prone laboratory tests using URAT;
2. To evaluate each identified parameter/test using ISO standards and FMECA, thereby generating quantitative risk statements;
3. To minimise identified risk factors based on RPN criteria and implement corrective or preventive actions to reduce Operational Diagnostic Errors (ODS).

Null hypothesis (H_0): There is no statistically significant difference in the mean RPN scores calculated using URAT compared to the conventional FMEA-based standard risk analysis tool in medical laboratories.

Alternative hypothesis (H_1): There is a statistically significant difference in the mean RPN scores calculated using URAT compared to the conventional FMEA-based standard risk analysis tool in medical laboratories.

MATERIALS AND METHODS

A prospective observational study will be conducted at Dattatraya Diagnostics Centre, Acharya Vinoba Bhave Rural Hospital, Sawangi (Meghe), Wardha, from May 2025 to April 2026. The study has received ethical clearance (Approval No. DMIHER(DU)/IEC/2025/203).

Assessors will be trained on ISO standards, FMECA methodology and URAT application to ensure consistency in scoring and reproducibility of results.

Inclusion criteria: Parameters included in this study will be selected based on their frequency of use in routine laboratory practice, diagnostic importance in clinical decision-making, and susceptibility to errors during preanalytical, analytical, and postanalytical phases.

Personnel included in the study will be laboratory professionals directly involved in testing and risk assessment activities, with a minimum of six months of work experience, and having basic training or orientation in laboratory quality management or risk analysis procedures. Their roles may include laboratory technicians, technologists, quality officers, or supervisors.

Exclusion criteria: Personnel with less than six months of laboratory experience, those not trained or oriented in risk assessment procedures, those not routinely involved in laboratory testing or risk management activities, or those unwilling to participate will be excluded from the study.

Additionally, any laboratory parameters not included in the predefined list of 84 selected tests will be excluded.

The size of the sample to collect the data on the basis of laboratory practices towards risk management with respect to standard checklist of ISO 15189:2022& ISO 22367:2019 [8,9].

URAT will be developed by integrating the FMECA [11] framework with ISO-based clauses [8,9] to ensure parameter-specific risk evaluation. The workflow will proceed in four steps:

1. **Risk identification-** Risk factors will be identified for each parameter across preanalytical, analytical, and postanalytical phases.
2. **Scoring-** Occurrence, detectability, and severity will be scored according to the criteria outlined in [Table/Fig-1].
3. **RPN calculation-** RPN (RPN = O × D × S) will be calculated for each parameter, as shown in [Table/Fig-2].
4. **Action categorisation-** Actions will be categorised based on RPN thresholds, following the criteria in [Table/Fig-3].

Validation of URAT: Prior to full implementation, the URAT will be validated in a pilot study. From the predefined list of parameters, a subset of 10-15 representative tests will be selected, including

coagulation profile assays such as Prothrombin Time (PT) and activated Partial Thromboplastin Time (aPTT), as well as routine biochemistry tests such as glucose, urea, and creatinine. These parameters were chosen because of their high frequency of use, clinical relevance, and documented error rates across the preanalytical, analytical, and postanalytical phases, thereby providing adequate representation of routine laboratory operations.

All assessors will receive structured orientation and hands-on training on ISO 15189:2022 and ISO 22367:2019 standards, the FMECA scoring methodology, and the application of the URAT framework prior to data collection. Standardised scoring manuals and practice exercises will be employed to minimise inter-observer variability. Reproducibility of scoring during the pilot phase will be evaluated using inter-rater reliability statistics. Agreement in categorical risk classification will be assessed using Cohen's kappa coefficient (κ), while consistency of continuous RPN scores will be measured using the ICC.

Probability of occurrence (O)	Score	Criterion
Virtually absent	1	Errors never occurred
Almost absent	2	Very rare errors
Very slight	3	Very few errors
Slight	4	Few errors
Low	5	Occasional errors
Average	6	Some errors
Moderately high	7	Frequent errors
High	8	High number of errors
Very high	9	Very high number of errors
Virtually certain	10	Certain error
Detectability (D)	**Score**	**Criterion**
Virtually certain	1	Controls can detect always the error
Very high	2	Very high probability of detection of the error
High	3	Good probability of detection of the error
Moderately high	4	Moderate probability of detection of the error
Average	5	Average probability of detection of the error
Low	6	Low probability of detection of the error
Slight	7	Slight probability of detection of the error
Very slight	8	Very slight probability of detection of the error
Virtually absent	9	Virtually absent probability of detection of the error
Dangerous effect	10	There are not controls to detect the errors
Severity (S)	**Score**	**Criterion**
No effect	1	No effect on the reporting
Very slight effect	2	Very slight effect on the reporting
Slight effect	3	Slight effect on the reporting
Low severity	4	Error which doesn't require a correction
Moderate severity	5	Error which doesn't compromise the reporting, but correction is necessary
Average severity	6	Altered process, but guaranteed reporting
High severity	7	Important effect on the process needing corrections
Important severity	8	Compromised process
Extreme severity	9	Potentially wrong result
Dangerous effect	10	Wrong result

[Table/Fig-1]: URAT: Criteria for assigning the score for occurrence, detectability and severity.
Scoring criteria for occurrence, detectability, and severity were adapted from established FMECA methodology and ISO 22367:2019 guidelines [7,13].

The pilot study demonstrated strong reliability, with Cohen's κ = 0.82 (95% CI: 0.76–0.88) and ICC = 0.88 (95% CI: 0.83-0.92), confirming high reproducibility of the URAT scoring system. ISO clauses relevant to each parameter will be mapped to the identified risk factors to ensure compliance with ISO 15189:2022 and ISO 22367:2019 [8,9].

Standard risk analysis tool: The comparator tool used in this study is the conventional FMEA approach, as described in ISO 22367:2019 and widely applied in clinical laboratory quality management systems [12-14]. FMEA is a structured methodology that identifies potential failure modes within laboratory processes, analyses their causes and effects, and assigns risk ratings based on severity, occurrence, and detectability. In laboratory practice, FMEA is typically applied to evaluate risks across the preanalytical, analytical, and postanalytical phases without parameter-specific unitisation [11,12].

In the standard FMEA model, the RPN is calculated as:

$$RPN = O \times D \times S$$

where O represents the occurrence score, D the detectability score, and S the severity score.

While the conventional FMEA approach provides process-level risk assessment for overall laboratory workflows and quality indicators, the newly developed URAT applies parameter-specific risk assessment directly linked to individual laboratory investigations and corresponding ISO clauses.

A total of 84 parameters across three disciplines will be evaluated using both URAT and the standard risk analysis tool [Appendix 1].

Biochemistry (52 parameters)- e.g., liver function tests, renal function tests, electrolytes, tumour markers, hormones.

Pathology (17 parameters)- e.g., CBC, coagulation profile, ESR, urine examination, sickling test.

Microbiology (15 parameters)- e.g., HIV, HBsAg, HCV, Dengue, Widal, Scrub typhus [Appendix 1].

Primary outcomes: Difference in mean RPN scores between URAT and the conventional FMEA-based standard risk analysis tool across 84 laboratory parameters.

Secondary outcomes will include changes in ISO compliance scores before and after URAT implementation, reduction in parameter-specific high-risk events (RPN > 344) that may lead to diagnostic errors, reduction in financial losses associated with repeat testing and reagent wastage, and an increase in preventive actions implemented per parameter based on RPN categorisation.

Secondary outcomes: Changes in ISO compliance scores before and after URAT implementation [8,9].

Reduction in parameter-specific high-risk events (RPN > 344) that may lead to diagnostic errors.

Reduction in financial losses associated with repeat testing and reagent wastage, and an increase in preventive actions implemented per parameter based on RPN categorisation.

Clause no. ISO STD	Phase	Sub-Phase	Activity	Error	O	D	S	RPN	Action taken description
Only those clauses will be considered which is generating significant risk factors while risk assessment for that parameter	Preanalytical/ Analytical/ Postanalytical	Name of risk factor	Activity in which risk can occur	Risk statement	Occurrence	Detection	Severity	Risk Priority Number (RPN) =O*D*S	Description of action will be based on risk statement and RPN RPN < 125 → Acceptable RPN 126–343 → Corrective action necessary RPN > 344 → Drastic timely action required

[Table/Fig-2]: Activities with the highest RPN value of occurrence index (O), severity index (S), detection index (D).
Scoring criteria for Risk Priority Number (RPN) were adapted from established FMECA methodology and ISO 22367:2019 guidelines.

RPN Score	Criteria	Benchmarking (Ref Table 1)
<125	Acceptable	The O*D*S is 5*5*5 respectively which is below than average risk factors i.e. ODS – Acceptable during each parameter study
126-343	Corrective action necessary	The O*D*S is 7*7*7 which is marginally high risk factors – Corrective action required
>344	drastic timely action is necessary	The O*D*S is more than 344 which is very high risk factor- Need urgent action

[Table/Fig-3]: Criteria for action taken.

STATISTICAL ANALYSIS

Data will be analysed using Statistical Package for the Social Sciences (SPSS) version 31.0. Descriptive statistics such as mean, median, standard deviation, and frequency distribution will be used to summarise RPN scores and compliance measures. Normality will be assessed using the Shapiro-Wilk test. For continuous outcomes, paired t-tests or Wilcoxon signed-rank tests will be applied depending on data distribution, while categorical outcomes will be analysed using Chi-square tests. Effect sizes, including Cohen's d and odds ratios, will be reported with 95% confidence intervals. Inter-rater reliability will be assessed using ICC, and test-retest reproducibility will be evaluated through correlation analysis. Expert agreement will be quantified using weighted kappa statistics. Missing data will be handled by listwise exclusion, with sensitivity analyses performed where appropriate. Statistical significance will be set at p-value≤0.05.

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[APPENDIX 1]

S. No.	Parameter Name	Service
1	ABG (Arterial Blood Gas Analysis)	Biochemistry
2	ADA (Adenosine Deaminase)	Biochemistry
3	Alkaline Phosphatase	Biochemistry
4	ALT (SGPT)	Biochemistry
5	Amylase	Biochemistry
6	ANA by IFA	Biochemistry
7	Anti-Nuclear Antibodies (ANA) by ELISA method	Biochemistry
8	AST (SGOT)	Biochemistry
9	Blood Grouping (ABO and Rh Type)	Pathology
10	Body Fluid (Ascitic)	Biochemistry
11	Body Fluid (CSF)	Biochemistry
12	Body Fluid (Pleural)	Biochemistry
13	CSF Exam/Other Body Fluids (Ascites,PL. Fluid, etc.,)	Pathology
14	C4 (Complement Component 4)	Biochemistry
15	C3 (Complement Component 3)	Biochemistry
16	CA 125	Biochemistry
17	CA 19.9	Biochemistry
18	Calcium	Biochemistry
19	CBC investigations on Cell counter with PS	Pathology
20	CEA	Biochemistry
21	Chickunguniya test	Microbiology
22	Chloride	Biochemistry
23	CK (Creatine Kinase)	Biochemistry
24	CKMB	Biochemistry
25	Coagulation profile-BT,CT,PT,APTT	Pathology
26	Creatinine	Biochemistry
27	CRP (QUANTITATIVE)	Biochemistry
28	D-Dimer	Pathology
29	Dengue NS1 Antigen & IgM&IgG Antibodies	Microbiology
30	Direct TIBC	Biochemistry
31	ESR	Pathology
32	FBS-Glucose-Plasma Fasting	Biochemistry
33	Ferritin	Biochemistry
34	Fibrinogen	Biochemistry
35	FT3	Biochemistry
36	FT4	Biochemistry
37	H.I.V. 1	Microbiology
38	Hb%	Pathology
39	HbA1c	Biochemistry
40	HBsAg	Microbiology
41	HCV	Microbiology
42	HIV TEST(TRIDOT KIT)	Microbiology
43	IPTH	Biochemistry
44	Iron	Biochemistry
45	KFT-Ser.Creatinine, Urea, BUN, NA+, K+	Biochemistry
46	LDH	Biochemistry
47	Lactate	Biochemistry
48	Leptospira IgG and IgM	Microbiology
49	LFT-Bilirubin, SGOT, SGPT, ALK.Phos., Total prot. A/G	Biochemistry
50	Lipase	Biochemistry
51	Lipid profile - HDL, LDL, Triglycerides, Cholesterol	Biochemistry
52	Magnesium	Biochemistry
53	NH3 (Ammonia)	Biochemistry
54	*P. falciparum* (Malaria Kit)	Pathology
55	Phosphorus	Biochemistry
56	Potassium (k+)	Biochemistry
57	Procalcitonin (PCT)	Biochemistry
58	PSA.	Biochemistry
59	PT-INR	Pathology
60	RA Quantitative	Biochemistry
61	RBS-Glucose-Plasma Random	Biochemistry
62	Reticulocyte Count	Pathology
63	SCRUB TYPHUS	Microbiology
64	Serum Ionic calcium	Biochemistry
65	Sickling (Early and Late)	Pathology
66	Sodium (Na+)	Biochemistry
67	Stool for Occult blood	Pathology
68	T.3.	Biochemistry
69	T.4.	Biochemistry
70	Total IgE (serum IgE)	Biochemistry
71	Total Bilirubin	Biochemistry
72	Total Protein	Biochemistry
73	TROPONIN-I (Quantitative)	Biochemistry
74	TSH	Biochemistry
75	Uric Acid	Biochemistry
76	Urinary Protein	Biochemistry
77	Urine Exam-(Routine)	Pathology
78	Urine Protein/Creatinine ratio	Biochemistry
79	Urine Osmolality	Biochemistry
80	Urine-(Na+),(K+)	Biochemistry
81	VDRL	Microbiology
82	Vitamin B12	Biochemistry
83	Widal	Microbiology
84	Vitamin D	Biochemistry