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A DYNAMIC APPROACH TO FMEA-RPN RISK CLASSIFICATION: COMPARING WITH THE CLASSICAL FMEA METHOD

Mufide Narli

Cukurova University, Saricam, Adana, Turkey
Faculty of Engineering, Department of Industrial Engineering

Highlights

- Failure mode and effects analysis (FMEA) assessed neonatal intensive care unit ergonomic risks and calculated risk priority numbers for each failure mode.
- Risk priority numbers yielded contribution rates, percentile ranks, and class labels per failure mode.
- Contribution and percentile classes were fused via an integrated decision matrix.
- Dynamic classes were benchmarked against classical fixed-threshold FMEA categories.
- Robustness was checked with ±1 one-at-a-time sensitivity analysis of occurrence, severity, and detection.

Abstract

Background: Failure mode and effects analysis (FMEA) uses risk priority numbers (RPNs) based on 3 parameters to classify risks. Risk analysis methods use thresholds to determine risk. These class intervals do not account for contextual and system dynamics in high-risk environments such as neonatal intensive care units (NICUs). This study proposes a dynamic classification model that prioritizes risk by integrating contribution percentages and percentile ranks through a decision matrix. **Material and Methods:** This study identified 21 ergonomic failure modes through field observations at a hospital's NICU, interviews with nurses, and a literature review, evaluated a dynamic classification model. The RPN for each failure mode was calculated, and the risks were classified using classical fixed-threshold FMEA. Then, each failure mode was classified using a dynamic model based on a decision matrix that balances risk intensity by its impact contribution percentage and relative importance percentile rank. Model robustness was assessed via a one-at-a-time sensitivity analysis (±1 perturbations in occurrence [O], severity [S], and detection [D]), and agreement was evaluated using weighted agreement measures. **Results:** According to FMEA, risk factors such as "long shift hours" and "constant exposure to alarm sounds" were classified as medium risk. Yet, in the dynamic model, they were classified as very high risk. The model's sensitivity was tested by measuring the effect of a change in the FMEA input ratings (O/S/D) on the results. The model was determined to provide high agreement with practitioners' classifications, with a 93.7% weighted agreement across 63 comparisons between nurse assessments and model results. **Conclusions:** The proposed dynamic framework provides context-sensitive prioritization by integrating each failure mode's contribution to total risk with its position in the unit-specific RPN distribution. When applied to NICU ergonomic failure modes, it produced a different prioritization than classical fixed-threshold FMEA and offers a transparent, reproducible basis for risk-focused improvement planning in high-risk care settings. Med Pr Work Health Saf. 2026;77(2):89–99

Key words: occupational health and safety, risk classification models, dynamic classification, FMEA thresholds, contribution percentage, percentile rank

Corresponding author: Mufide Narli, Cukurova University, Faculty of Engineering, Department of Industrial Engineering, 01330, Saricam, Adana, Turkey, e-mail:mnarli@cu.edu.tr
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INTRODUCTION

Risk analysis and management are crucial not only for protecting healthcare workers and patients but also for improving service quality and making operations more efficient [1]. The basic steps of risk analysis methods involve first identifying potential failure modes within the process, then prioritizing and classifying them. Failure mode and effects analysis (FMEA) is a systematic method commonly used in proactive risk assessment and management [1–3].

Classical FMEA evaluates risks using 3 parameters: occurrence (O), severity (S), and detectability (D) [3]. The risk priority number (RPN) of a risk is calculated by multiplying the values of these factors. Based on the RPN value obtained in a classic FMEA, risks are assigned to risk classes using fixed threshold values [4]. This fixed classification method does not adequately address the systems internal dynamics and contextual needs in critical and sensitive environments, such as intensive care units (ICUs).

This study proposes a dynamic classification model as an alternative to the classical FMEA method. Unlike fixed threshold values, the dynamic model evaluates failure modes based on contribution percentages (share of total system RPN) and percentile ranks derived from the observed distribution of RPN values (i.e., the relative position of each failure mode within the RPN distribution). The results obtained with this approach support decisions for the continuous improvement and development of the risk environment by enabling adaptive, context-sensitive risk prioritization [5].

Neonatal intensive care units (NICUs) are areas where multiple critical interventions are performed simultaneously and where the physical and mental workload is intense. Employees working under these conditions are exposed to various ergonomic risk factors [6,7].

The ICU was specifically chosen because it is a clinically critical and sensitive area. In this study, possible failure modes that pose ergonomic risks to nurses providing healthcare services in intensive care were identified, and the FMEA method was applied to them. First, RPN values were calculated using the FMEA method, and classical fixed-threshold classification was performed [4,8]. Dynamic classification was performed using the same RPN values; the results were tested, and the 2 approaches were evaluated.

Miller et al. [9] highlighted the limitations of fixed-threshold systems by demonstrating that an 80% threshold for classifying health data can yield a misclassification rate >20%. This finding can be interpreted as a limitation of classical FMEA applications that rely on classification based on predefined fixed thresholds, because rigid, absolute cut-offs may fail to empirically reflect the risk distributions across different units and operational contexts, thereby undermining the validity of prioritization decisions [4].

In response to these limitations, dynamic and context-aware classification approaches have gained traction. Bertolini et al. [10] introduced the percentage contribution method, which calculates each failure modes RPN as a share of the total system RPN, enabling prioritization based on system-level risk burden rather than absolute RPN magnitude alone. Similarly, Moore et al. [11] developed a model based on relative risk contribution percentages to more objectively identify high-risk areas. In parallel, adaptive modifications to RPN-based assessment have been proposed in healthcare to better differentiate and prioritize failure modes under varying organizational or process-specific risk preferences [5]. Systematic reviews further emphasize that conventional RPN-based prioritization may be insufficient in complex settings and that more robust, multi-criteria, and context-sensitive approaches are needed. At the same time, practical and transparent integrations remain limited [1,4].

This study advances the literature by contributing value ranks to a decision matrix, thereby presenting a multidimensional, distribution-sensitive classification approach. While Zhang and Chu [12] used percentiles, they did not incorporate them into a decision matrix. Chu and Hung [5] in 2014 improved failure-mode discrimination through an adaptive RPN formulation; however, operational integration of complementary indicators into a clear decision-matrix structure remains uncommon in applied healthcare-oriented FMEA studies. Liu et al. [4] emphasized the need for multi-criteria models beyond RPN; however, practical examples of integration remain rare in applied, routine implementations. Accordingly, by jointly leveraging a system-centric indicator (risk contribution) [10] and a data-centric indicator (distributional position) [13]. The proposed framework aims to enhance the robustness of risk-class assignment and to support more consistent prioritization in dynamic risk environments.

Furthermore, methods such as fuzzy logic, technique for order preference by similarity to ideal solution and analytic hierarchy process have been incorporated into FMEA to enhance decision-making [3], and address uncertainty in the assessment of O, S and D [8,14].

Hybrid multi criteria decision analysis based risk assessment frameworks have also been applied in hospital settings to support structured prioritization and improvement planning [15]. However, despite these advances, few studies have operationalized contribution information and distribution-based ranking together within a single decision-matrix mechanism that remains straightforward to implement and interpret in routine, team-based practice.

This integrated approach provides a flexible, unit-adaptable classification model suited to dynamic risk settings, such as manufacturing and healthcare services. By grounding prioritization in both system-level risk contribution and the observed distribution of RPN values from field assessments, it encourages context-specific adjustments aligned with continuous improvement-oriented practices and supports the continuity of risk management. In line with this aim, the present study applies the proposed framework to ergonomic risk-related failure modes among NICU nurses. It evaluates the resulting risk profile in the context of the unit's RPN distribution. In addition, using the same RPN values, it compares dynamic classification outcomes with classical fixed-threshold classification. It presents practical implications for risk-focused improvement planning in high-risk care settings.

A dynamic risk classification framework based on FMEA-derived RPNs is presented. The framework integrates each failure mode's contribution to total system risk and its percentile rank through a decision matrix to assign a final 4-level risk class. Robustness is evaluated using one-at-a-time (OAT) sensitivity analysis (±1 perturbations of O, S, and D), and model outputs are compared with field assessors' classifications using exact and weighted agreement measures.

Table 1. Classical failure mode and effects analysis (FMEA) risk classes based on risk priority number (RPN) score ranges [3]

Classical FMEA risk class	RPN score range
Low	1–100
Medium	101–200
High	201–500
Very High	501–1000

MATERIAL AND METHODS

Ergonomic risk assessment began with identifying physical and organizational factors that may pose ergonomic risks within NICU clinical workflows. This systematic assessment includes direct field observations, a review of current literature, and contributions from key clinical stakeholders. Input was obtained from 3 experienced NICU nurses (N = 3), including the nurse-in-charge, all working in the same university-hospital NICU and each with ≥15 years of NICU experience. Prior to data collection, a brief standardization session on ergonomics and the FMEA approach was conducted with the nurse team to establish shared operational definitions of "ergonomic risk" and "failure mode."

A triangulation-based assessment was conducted using team interviews, field/ward observations, and the literature review. The nurse team performed a step-by-step task analysis of routine NICU activities. For each task, potential ergonomic exposures were documented and discussed, including posture, repetitive movements, static loading, force requirements, and manual patient handling. The draft list was iteratively refined by recording additional risks noted during routine practice and ward observations, and the final set of ergonomic failure modes was derived by triangulating:

- literature review findings,
- field/ward observations,
- stakeholder feedback.

The workflow of this study is summarised as follows. After completing the FMEA and obtaining the RPN values for each failure mode, the dynamic risk classification was carried out in 3 steps. First, each failure mode's share of the total system risk (contribution) was computed from the RPN distribution and mapped to a 4-level contribution class (low, medium, high, very high) using predefined contribution thresholds. Second, RPNs were ordered by rank to derive a percentile rank for each failure mode; ties were handled using a mid-rank approach, and the resulting percentile ranks were converted to the same 4-level percentile class using predefined percentile thresholds. Third, the contribution class and percentile class were jointly evaluated using the decision matrix to assign the final dynamic risk class for each failure mode. Model robustness was assessed via a OAT sensitivity analysis, perturbing each FMEA parameter (O/S/D) by ±1 while holding the remaining parameters constant, and tracking changes in the final class assignments. Finally, model-derived classes were compared against field assessors' classes in the same 4-level format, and agreement was reported using exact and weighted agreement measures.

Classical FMEA framework

Classical FMEA is a systematic and proactive risk analysis method used to identify potential failure modes and analyze their effects. Each failure mode is assessed using 3 fundamental parameters. For each failure mode, these parameters are scored on a scale 1–10. The parameter values determined for each failure mode according to this scale are multiplied to calculate the RPN, denoted as RPN_i for the i-th failure mode for i = 1, 2, 3, ..., n, as shown in Equation 1. The RPN_i value in FMEA ranges 1–1000. The resulting RPN_i value is mapped to a risk class according to the ranges reported in Table 1 [3].

$$RPN_i = O_i \times S_i \times D_i \quad (1)$$

where:
RPN_i – the RPN value of the i-th failure mode,
O_i – occurrence, the probability of the failure occurring for the i-th failure mode,
S_i – severity, the degree of impact of the failure on the system for the i-th failure mode,
D_i– detectability, the likelihood of detecting the failure mode before it occurs for the i-th failure mode,
i – index of the failure mode.

In risk analysis, the classification of failure modes directly affects the interpretation of assessment results and the accuracy of decision-making. Therefore, defining the

Table 2. Contribution-class thresholds based on percentage contribution to the total system risk priority number (RPN)

Contribution class	Contribution to total system RPN [%]
Very high	≥15
High	5–14.9
Medium	2–4.9
Low	<2

class intervals used to determine risk levels is essential. In this study, both statistically based contribution percentages and percentile ranks were used to set risk class threshold values, and a decision matrix approach was also employed. Several studies in the literature have demonstrated that classification based on fixed RPN threshold values is not context-sensitive and can mislead decision-makers [4,12].

To ensure that the applied rating scales reflected the variability of ergonomic problems assessed in the NICU, the FMEA parameter anchors (S/O/D) were adopted from the literature [3] and contextualized to NICU ergonomic conditions by specifying NICU-relevant extreme anchor descriptions consistent with the range observed in practice.

Contribution-based classification

In risk analysis, measuring the impact of each failure mode on the overall system provides essential information about the system's relative importance. However, the impact of this effect level on the system is often overlooked [9]. In this section, the total system RPN is calculated using Equation 2, and the percentage contribution of each failure mode to the total system RPN is computed using Equation 3. The total system RPN is calculated as RPN_{total} using Equation 2, where i ranges 1–n.

$$RPN_{total} = \sum_{i=1}^{n} RPN_i \tag{2}$$

$$Contribution_i(\%) = \frac{RPN_i}{RPN_{total}} \times 100 \tag{3}$$

where:
RPN_{total} – the total RPN value of all failure modes,
n – the total number of failure modes.

The percentage contributions are categorised using predefined threshold ranges inspired by the Pareto principle (80/20 rule), as shown in Table 2. This allows for identifying a few failure modes responsible for most of the system risk. This classification scheme highlights the disproportionate impact of specific failure modes, thereby supporting more targeted risk management interventions.

Percentile-based classification

Percentile-based classification is used to identify the relative position of each failure mode within an ordered data set. This approach provides a distributional perspective and supports context-aware prioritization, particularly in systems with varying frequencies and severities of failure modes.

In this study, the percentile rank of each failure mode was calculated using Equation 4 based on the ascending order of RPN values. Accordingly, a percentile rank closer to 100 indicates higher-risk failure modes.

$$\text{Percentile rank}_i = \frac{r_i}{n-1} \times 100 \tag{4}$$

where:
r_i – the rank position of the i-th failure mode after sorting the RPN values in ascending order, equals 0 for the lowest RPN and n−1 for the highest RPN.

Failure modes were ranked in ascending order of RPN, so that higher percentile ranks correspond to higher RPNs (higher risk). Zhang et al. [16] highlighted that the ranking's accuracy significantly affects the precision of percentile-based classification. Therefore, in this study, the ranking was carefully maintained to ensure data integrity and accuracy.

When ties occur, the average-rank (midrank) approach is applied. In such cases, for a given failure mode i, the tie set (T_i) is defined in Equation 5 [17]. The minimum and maximum ranks within the tie set are given in Equation 6, and Equation 7, the midrank is computed in Equation 8, and the percentile rank under ties is obtained using Equation 9.

$$T_i = \{j : RPN_j = RPN_i\} \tag{5}$$

where:
T_i –the set of indices of failure modes having the same RPN value as the i-th failure mode,
j – an index over the failure modes in T_i.

The minimum and maximum ranks within the tie set are given in Equations 6 and 7, respectively.

$$r_i^{min} = \min_{j \in T_i} r_j \tag{6}$$

Table 3. Percentile-class thresholds based on percentile rank

Percentile rank	Percentile class
≥75%	very high
50–74%	high
25–49%	medium
<25%	low

$$r_i^{max} = \max_{j \in T_i} r_j \quad (7)$$

where:
r_i^{min} – the smallest rank occupied within the tie set T_i,
r_i^{max} – the largest rank occupied within the tie set T_i,
r_j – the rank of the j-th failure mode.

The midrank is then computed as follows Equation 8:

$$r_i^{mid} = \frac{r_i^{min} + r_i^{max}}{2} \quad (8)$$

where:
r_i^{mid} – the midrank of the i-th failure mode when tied RPN values occur.

The percentile rank under ties is then obtained using Equation 9.

$$\text{Percentile rank}_i = \frac{r_i^{mid}}{n-1} \times 100 \quad (9)$$

After calculating the percentile rank of each failure mode, the result is assigned to the corresponding percentile class, as shown in Table 3. This method statistically defines the distributional importance of each failure mode within the dataset, helping to differentiate between relatively rare but impactful risks and more frequent but less severe.

Integration via decision matrix

In this study, contribution percentage and percentile rank are used together to construct a dynamic classification model. Each metric provides distinct but complementary perspective:

- contribution percentage reflects the relative impact of the failure mode on the total system risk (system-centric perspective),
- percentile rank reflects the relative position of a failure mode within the overall distribution (data-centric perspective).

Using these 2 indicators together helps the model identify failure modes that are both highly impactful and highly ranked. This is especially useful for detecting outlier risks that classical fixed threshold approaches might underestimate. The literature suggests that fixed-threshold classification is often insufficiently sensitive and can result in incorrect prioritization. For example, prior studies report substantial misclassification in healthcare settings when fixed thresholds are used [9]. This approach is crucial to ensure that rare but significant failure modes are not overlooked. However, to ensure consistent classification when neither scale is simultaneously high or low, a final decision matrix has been created that evaluates contribution and percentile classes.

Table 4. Dynamic risk classification matrix by contribution and percentile classes

Percentile class	Contribution			
	low	medium	high	very high
Low	low	low	medium	medium
Medium	low	medium	medium	high
High	medium	medium	high	very high
Very high	medium	high	very high	very high

Final classification using the decision matrix. After assigning contribution and percentile classes to each failure mode, the 2 criteria are combined in Table 4 to determine the final risk class. This allows both the impact on the system and the failure mode's priority to be evaluated together. This ensures a more balanced and fair classification.

To ensure full reproducibility of the integration step, the decision matrix in Table 4 was implemented as a deterministic lookup rule. An auxiliary combined score (s_i) was defined as Equation 10:

$$s_i = p_i + c_i \quad (10)$$

where:
s_i – the auxiliary combined score of the i-th failure mode,
c_i – the contribution class type of the i-th failure mode,
p_i – the percentile-rank class type of the i-th failure mode;
$p_i, c_i \in \{1, 2, 3, 4\}$, where low – 1, medium – 2, high – 3, and very high – 4.

The final dynamic risk class (k_i) was then assigned using the following thresholds in Equation 11, which reproduce the predefined 4 × 4 mapping in Table 4 while preserving monotonicity:

$$k_i = \begin{cases} 1, & s_i \le 3 \\ 2, & 4 \le s_i \le 5 \\ 3, & s_i = 6 \\ 4, & s_i \ge 7 \end{cases} \quad (11)$$

where:
k_i – the final dynamic risk class type assigned to the i-th failure mode, where low – 1, medium – 2, high – 3, and very high – 4.

Thus k_i, mapped to low, medium, high, and very high. For example:
- If $c_i = 2$ (medium) and $p_i = 3$ (high), then $s_i = 5$ and $k_i = 2$ (medium), consistent with the (high percentile, medium contribution) cell in Table 4.
- If $c_i = 2$ (medium) and $p_i = 4$ (very high), then $s_i = 6$ and $k_i = 3$ (high), consistent with the (very high percentile, medium contribution) cell in Table 4.

This approach was adapted into a framework supporting the present study, inspired by the classification methods described in the studies by Miller et al. [9] and Bertolini et al. [10].

RESULTS

Findings from model implementation

The proposed classification approach developed in this study was tested in the NICU of a university hospital. The potential ergonomic failure modes experienced by nurses working in this unit were classified both using the classical FMEA method and a dynamic classification model based on contribution percentage and percentile rank. The RPN value for each failure mode was calculated based on the O, S, and D parameter scores.

The RPN values in Table 5 have been assigned to risk classes based on the fixed FMEA class thresholds in Table 1. The O, S, and D scores reported in Table 5 were assigned by 3 experienced NICU nurses (1 nurse-in-charge and 2 experienced NICU nurses) using the predefined 1–10 anchor criteria, and the final values were calculated as the arithmetic mean of their independent ratings. According to the findings, the failure modes with the highest RPN values are "continuous exposure to alarm sounds," "physical strain from lifting/moving devices alone without ergonomic support," and "long shift durations." These failure modes pose high priority risk within the system in terms of both severity and frequency. In contrast, failure modes with lower RPN scores are typically associated with infrequent or minimally impactful operations.

Findings related to dynamic classification and classical FMEA classification are presented in Table 6. This table displays the contribution percentage, contribution class, percentage rank, and percentile class for each failure mode, along with the dynamic risk classifications resulting from integrating these inputs into the matrix. Additionally, the classic RPN class is presented in the same table to facilitate easy comparison with dynamic classification.

In Table 6, the contribution percentage of each failure mode to the total system risk is derived. First, the RPN of each failure mode is computed as Equation 1. The total system RPN is then calculated as Equation 2. The contribution percentage is obtained by Equation 3. Based on this value, failure modes are assigned to contribution classes using Table 2 thresholds: very high ≥15%, high 5–14.9%, medium 2–4.9%, and low <2%.

In Table 6, the percentile column represents the relative position of a failure mode within the empirical distribution of RPN values. Failure modes are ranked in ascending order of RPN_i, and a rank index $r_i \in \{0, 1, 2, ..., n-1\}$ is assigned: $r_i = 0$ for the lowest RPN and $r_i = n-1$ for the highest RPN. The percentile rank is calculated using Equation 4, so that a higher percentile rank corresponds to a higher RPN. Column with percentile class is obtained by mapping Percentile rank$_i$ to the predefined ranges in Table 3: very high ≥75, high 50–74, medium 25–49, and low <25.

For example, for the failure mode "continuous exposure to alarm sounds" with O = 9, S = 4, and D = 4, the RPN is calculated using Equation 1. The contribution percentage is calculated using Equation 3, and is classified as high according to Table 2. As this failure mode lies at the upper end of the RPN distribution, it is assigned to the very high percentile class according to Table 3. The final dynamic risk class reported in Table 6 is then assigned by jointly evaluating the contribution and percentile classes using the decision matrix in Table 4.

Sensitivity analysis

To evaluate the robustness of the proposed multidimensional dynamic risk classification model against small rating uncertainty, a OAT sensitivity analysis was conducted. For all failure modes (N = 21), each FMEA parameter (O/S/D) was perturbed by ±1 pt individually while the remaining parameters were held constant within the 1–10 bounds. This design produced a total of 126 scenarios; the whole classification pipeline was re-executed (RPN, contribution percentage, percentile rank, and the decision matrix), and it was recorded whether the final dynamic risk class of the perturbed failure mode changed relative to the baseline case.

Sensitivity was summarized using the class-change rate (CR), defined as the percentage of OAT scenarios in which the final dynamic class differed from the baseline class for the perturbed failure mode. Across all scenarios, the final class changed in 64 of 126 cases, yielding

Table 5. Ergonomic risk categories, definition of failure modes, parameter values, and risk priority numbers (RPN) scores

Failure mode	O	S	D	RPN score
Postural strain				
standing for a long time and preparing fluids and treatment in a fixed position [18,19]	9	7	2	126
making forced stretching/bending movements during access to the incubator [18,20]	8	4	2	64
working in a fixed bent or twisted position inside the incubator for a long time [21]	8	4	2	64
performing procedures in an improper posture due to the incubator height being non-adjustable or not properly adjusted	7	5	3	105
strains caused by carrying heavy, restless, or active infants in the arms	7	5	3	105
Repetitive movements				
preparation of enteral and parenteral nutrition [22]	6	5	3	90
repetitive wrist movements during fine-motor tasks (opening vials, breaking ampoules, shaking bottles, constant handwashing, etc.) cause strain [19,23]	7	5	3	105
repeated pressing of alarms and setting buttons	5	3	5	75
Lifting/push/pull				
patient transfer in the incubator [24]	7	5	3	105
physical strain from lifting/moving devices alone without ergonomic support	7	6	3	126
physical strain caused by lifting and carrying infants and incubators due to various reasons	6	4	4	96
Environmental ergonomics				
workstation design				
monitors not placed at eye level [20]	6	3	4	72
constant reaching to access monitors or equipment [20]	6	4	5	120
lack of ergonomic equipment (e.g., adjustable chairs, footrest, lumbar supports)	9	4	3	108
narrow or disorganized physical workspaces	9	3	2	54
physical environment				
continuous exposure to alarm sounds	9	4	4	144
inappropriate lighting	5	3	3	45
insufficient heating/cooling systems	9	4	2	72
Organizational factors				
long shift durations [21]	8	4	4	128
excessive workload due to an imbalance between the number of patients and the number of nurses	8	3	4	96
inadequate or lack of implementation of rest breaks [19]	9	3	3	81

D – detectability, O – occurrence, S – severity.

an overall CR of 50.8% (95% Wilson CI: 42.2–59.4%). Parameter-specific results showed that class changes occurred in 16/42 occurrence perturbations (38.1%, 95% CI: 25.0–53.2%), 23/42 severity perturbations (54.8%, 95% CI: 39.9–68.8%), and 25/42 detectability perturbations (59.5%, 95% CI: 44.5–73.0%).

Overall, these findings indicate moderate but threshold-sensitive stability of the model under ±1 pt variations, with class changes observed more frequently under D perturbations than under O perturbations. This pattern is consistent with the multidimensional structure of the framework: small rating changes can propagate through both the contribution-based and rank-based components, and failure modes near class thresholds may cross boundaries and receive an updated final class.

Practitioner-based agreement analysis

An agreement-based assessment was conducted to assess whether the proposed dynamic FMEA risk classification aligns with prioritization in the NICU setting. An evaluation form was prepared for this analysis and was completed by 3 experienced NICU nurses (1 nurse-in-charge and 2 experienced NICU nurses). The nurses independently rated each failure mode using the same

Table 6. Distribution of failure modes by risk priority numbers (RPN), contribution, percentile rank, dynamic risk classes, and classic RPN classes

Failure mode	RPN	Contribution		Percentile		Class	
		%	class	rank	class	dynamic risk	classic RPN
Inappropriate lighting	45	2.27	medium	0.0	low	low	low
Narrow or disorganized physical workspaces	54	2.73	medium	5.0	low	low	low
Working in a fixed bent or twisted position inside the incubator for a long time	64	3.23	medium	12.5	low	low	low
Making forced stretching/bending movements during access to the incubator	64	3.23	medium	12.5	low	low	low
Monitors not placed at eye level	72	3.63	medium	22.5	low	low	low
Insufficient heating/cooling systems	72	3.63	medium	22.5	low	low	low
Repeated pressing of alarms and setting buttons	75	3.79	medium	30.0	medium	medium	low
Inadequate or a lack of implementation of rest breaks	81	4.09	medium	35.0	medium	medium	low
Preparation of enteral and parenteral nutrition	90	4.54	medium	40.0	medium	medium	low
Physical strain caused by lifting and carrying infants and incubators due to various reasons	96	4.85	medium	47.5	medium	medium	low
Excessive workload due to an imbalance between the number of patients and the number of nurses	96	4.85	medium	47.5	medium	medium	low
Repetitive wrist movements in fine motor tasks (opening vials, breaking ampoules, shaking bottles, constant hand washing, etc.) cause strain	105	5.30	high	62.5	high	high	medium
Strains caused by carrying heavy, restless, or active infants in the arms	105	5.30	high	62.5	high	high	medium
Performing procedures in an improper posture due to the incubator height being non-adjustable or not properly adjusted	105	5.30	high	62.5	high	high	medium
Patient transfer in the incubator	105	5.30	high	62.5	high	high	medium
Lack of ergonomic equipment (e.g., adjustable chairs, footrest, lumbar supports)	108	5.45	high	75.0	very high	very high	medium
Constantly reaching to access monitors or equipment	120	6.06	high	80.0	very high	very high	medium
Standing for a long time and preparing fluids and treatment in a fixed position	126	6.36	high	87.5	very high	very high	medium
Physical strain from lifting/moving devices alone without ergonomic support	126	6.36	high	87.5	very high	very high	medium
Long shift durations	128	6.46	high	95.0	very high	very high	medium
Continuous exposure to alarm sounds	144	7.27	high	100.0	very high	very high	medium

4-level ordinal scale as the model. During this step, the nurses were not provided with the computed FMEA outputs (e.g., RPN values or fixed-threshold classes) or the model outputs (dynamic risk classes), and they completed the form independently.

After data collection, practitioners' ratings were compared with the model's final dynamic risk class for each failure mode. Each assesor-failure mode pair was treated as 1 comparison, yielding a total of 63 comparisons.

The 4 ordinal risk classes were encoded as $g \in \{1, 2, 3, 4\}$, where: 1 – low, 2 – medium, 3 – high, 4 – very high. The absolute class difference d_m was defined as:

$$d_m = \left| g_m^{assessor} - g_m^{model} \right| \tag{12}$$

where:
d_m – the absolute class difference for comparison $m \in \{1, 2, 3, ..., N\}$,
$g_m^{assessor}$ – the assessor-assigned class type for comparison $m \in \{1, 2, 3, ..., N\}$,
g_m^{model} – the model-assigned class type for comparison $m \in \{1, 2, 3, ..., N\}$,
m – the comparison index.

Because the risk scale is ordinal, a simple weighted agreement scheme was used. The weight (w) assigned to each comparison m as a function of d_m was defined as:

$$w(d_m) = \begin{cases} 1, & d_m = 0 \text{ (exact class match)} \\ 0.5, & d_m = 1 \text{ (1-category difference; adjacent-category mismatch)} \\ 0, & d_m \geq 2 \text{ (}\geq\text{2-category difference; non-adjacent mismatch)} \end{cases} \tag{13}$$

And the overall weighted agreement score was computed as:

$$\text{Weighted agreement (\%)} = 100 \times \frac{1}{N} \sum_{m=1}^{N} w(d_m) \tag{14}$$

$$\text{Exact agreement (\%)} = 100 \times \frac{1}{N} \sum_{m=1}^{N} 1(d_m = 0) \tag{15}$$

The "exact agreement" was (87.3%), and the "weighted agreement" was 93.7% across 63 comparisons. Out of 63 comparisons, 55 were exact matches, and 8 differed by 1 risk level; no differences of 2 or >2 levels were observed. Accordingly, the weighted agreement was 93.7%. In particular, agreement was highest in the very high and high categories. Discrepancies between nurse ratings and model outputs were observed in a small subset of comparisons, and these differences were limited to a single-class deviation (±1 level), indicating no systematic directional disagreement across categories. Overall, these results suggest that the model's final risk classes are broadly consistent with practitioner prioritization in this NICU setting. External assessment by independent ergonomics experts could further strengthen generalizability and is recommended for future work.

DISCUSSION

These results demonstrate that the classical FMEA classification method, which typically classifies based on fixed threshold ranges, does not accurately reflect the relative importance of certain failure types. Compared with the classical fixed-threshold classification, the proposed dynamic classification reclassified 5 failure modes that were labeled as low under the classical approach into the medium risk class, while no failure modes were reclassified into the high class. In particular, posture-related ergonomic risks, such as "lack of ergonomic equipment" and "prolonged standing, preparing liquids and treatments in a fixed position," which were assigned to the medium risk class in the classical method, have been classified as very high in the dynamic classification. This demonstrates that the model is more sensitive than the classical FMEA approach in reflecting these classifications. Beyond the comparison with fixed threshold FMEA, the proposed model also differs from single-metric dynamic approaches. Contribution-only schemes emphasize the share of total risk, whereas percentile-only schemes emphasize distributional position. The novelty of this approach lies in a context-sensitive, 2-dimensional decision matrix that jointly integrates contribution (%) and percentile rank and derives prioritization from the system's own risk profile rather than applying generic, fixed cut-offs. The results show that combining these 2 perspectives in a matrix yields a more robust prioritization, particularly when 1 metric is high and the other is moderate or low. This 2-dimensional integration offers a clearer decision rationale than applying either contribution or percentile thresholds alone.

Consequently, while classical FMEA classification provides a general framework, it does not account for contextual differences and variations across the system. The dynamic classification model provides decision-makers with more effective information, crucial for quality improvement and development, as it also considers the impact of the failure mode on the system. As the system is improved and developed, the risk class of critical failure modes will decrease, ensuring continuous improvement within the system context.

These results demonstrate that the developed multidimensional classification model is well-designed and closely aligns with the judgements of experienced NICU process practitioners (i.e., nurses who routinely perform the assessed tasks and have substantial NICU experience), as evaluated in the practitioner-based agreement analysis (weighted agreement 93.7% agreement across 63 comparisons). Furthermore, they demonstrate that the model can serve as an effective decision-support tool in complex, multidimensional risk prioritization processes.

CONCLUSIONS

This study critiques the limitations of the classical FMEA fixed-threshold classification approach for assessing the system's contextual dynamics and proposes an alternative classification approach. Throughout this manuscript, the term "classical FMEA" refers to the conventional implementation that includes defining the O/S/D parameters and their anchored rating scales, calculating the RPN, and assigning risk classes based on fixed RPN cut-off thresholds. The results show that the fixed-threshold classification approach often underestimates the risk levels of specific failure modes compared to their actual impact on the system. In contrast, the dynamic model has been shown to provide a more accurate and comprehensive risk assessment by accounting for the distribution of failure modes and their impact on system workload.

Overall, the study highlights the following key points:

- While the classical FMEA method is helpful for regulatory compliance and basic risk classification, it often overlooks internal system priorities and contextual factors. Several studies in the literature emphasize that the classical FMEA approach's reliance on fixed thresholds does not adequately reflect contextual priorities and can mislead decision-makers [12].
- The dynamic classification model offers a more effective framework for reflecting the absolute and relative importance of failure modes within the system, utilizing both contribution percentage and percentile approaches.
- Therefore, the dynamic model supports sustainable and continuous improvement strategies by identifying current risks and monitoring systematic risk trends. While the classical model ensures cross-sector comparability and compliance with legal standards, the dynamic model provides a flexible and context-specific framework for managing risks. The dynamic model system provides a framework conducive to continuous improvement strategies by conducting self-assessments based on its own internal dynamics. When integrated with continuous improvement methods such as Plan-Do-Check-Act and Kaizen, this framework provides a strategic advantage in quality management.

In conclusion, while the dynamic model provides a sustainable foundation for ongoing improvement strategies, fixed threshold classification offers advantages in terms of legal requirements and cross-sector comparability. Therefore, combining fixed and dynamic models creates a balanced risk management framework that meets legal compliance, sectoral comparability, and contextual needs.

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AI USE

ChatGPT (GPT-5) was used only as a tool for text writing; all responsibility lies with the author.

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