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EVALUATION OF RISK ANALYSIS IN BLOOD DONATION PROCESSES AT A TERTIARY CARE HOSPITAL

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ABSTRACT Integrating risk management into the quality management framework of blood banks is essential for maintaining process reliability and ensuring the safety of blood products. A structured assessment of potential process failures enables organizations to recognize, evaluate, and prioritize risks before they result in adverse events. This study highlights the application of Failure Mode and Effects Analysis (FMEA) as a systematic tool for identifying potential failures across blood bank operations. Risk evaluation was performed by assigning numerical ratings for severity, occurrence, and detectability of each potential failure. These ratings were combined to calculate the Risk Priority Number (RPN), which served as the basis for ranking process risks and determining the urgency of corrective or preventive interventions. The findings demonstrate that evaluating RPN values during the planning stage allows blood bank personnel to identify critical control points, allocate resources more efficiently, and implement preventive measures before process failures occur. The incorporation of risk-based thinking into routine quality management strengthens patient safety, improves operational performance, and supports continuous quality improvement within transfusion services.

KEYWORDS : Risk Management, Failure Mode and Effects Analysis, Risk Priority Number, Blood Bank, Quality Management, Preventive Action

INTRODUCTION

Quality management has become a fundamental component of modern transfusion services, ensuring that blood products are collected, processed, tested, stored, and distributed according to established standards. While the concept of risk is frequently discussed in transfusion medicine, it has traditionally been associated with occupational safety, infrastructure, biosafety, disaster preparedness, and environmental hazards. Comparatively less emphasis has been placed on the systematic evaluation of operational risks that may compromise the effectiveness of blood bank processes or the quality of blood components.

The International Organization for Standardization (ISO) defines risk in ISO 31000 as the effect of uncertainty on the achievement of objectives.(1) Consequently, process-related risks in a blood bank include any circumstance, activity, operational weakness, or human error that may prevent a process from fulfilling its intended purpose or reduce its overall effectiveness. Such risks may involve regulatory non-compliance, deviations from quality standards, equipment failures, staff-related errors, or hazards affecting both personnel and recipients of blood products.

ISO 9001:2015 further emphasizes the importance of risk-based thinking by requiring organizations to identify and address risks and opportunities during quality management planning. (2) The standard recommends that preventive actions should be proportional to the potential impact of identified risks, thereby minimizing undesirable outcomes and promoting continual improvement.

Failure Mode and Effects Analysis (FMEA) is a proactive risk assessment methodology that supports this objective by systematically identifying possible failure modes, investigating their underlying causes, and evaluating their potential consequences. (3,4) Each identified failure is assigned a Risk Priority Number (RPN), allowing organizations to classify risks according to their significance and determine appropriate preventive or corrective measures. Depending on the magnitude of the calculated RPN, interventions may range from additional verification procedures and enhanced process monitoring to comprehensive redesign of the affected process.

Early identification of process vulnerabilities enables blood bank managers and quality professionals to prioritize critical areas, optimize resource allocation, and implement effective control strategies before failures affect product quality or patient safety. Consequently, integrating structured risk assessment into routine quality management contributes significantly to the reliability and sustainability of transfusion services.

The primary objective of this study was to identify and evaluate potential risks associated with blood bank processes in order to establish an effective risk control strategy that enhances the quality and safety of blood products.

The specific objectives were to:

1. Identify and quantify the potential risks associated with each process activity.
2. Determine the underlying causes contributing to the identified risks.
3. Develop appropriate preventive and corrective action plans based on the level of risk associated with each activity.

MATERIALS AND METHODS

Study Design

The study was designed to establish a structured framework for risk assessment in blood bank operations using the principles of Failure Mode and Effects Analysis (FMEA). Prior to initiating the analysis, the concepts of risk and potential failure were clearly defined to ensure uniform interpretation throughout the evaluation process. Standardized scoring systems for severity, occurrence, and detectability were adopted from the QS 9000/ISO TS 16949 guidelines. (5) Although these standards were originally developed for the automotive industry, their systematic approach to process risk evaluation makes them applicable to healthcare and laboratory environments, including transfusion services.

The assessment focused on the principal operational activities routinely performed within a blood bank. These included donor admission and registration, donor interview, clinical assessment, blood collection, donor self-exclusion, blood component preparation, biological qualification of

blood components, and distribution of blood products. Each process was first represented using a detailed flowchart to identify every operational step and its sequence. Based on these flowcharts, an FMEA matrix was developed in which every activity was assigned a unique numerical identifier in consecutive order. This systematic representation facilitated the identification and evaluation of potential failure modes associated with each process.

Study Setting

The investigation was conducted within the framework of the Quality Manager at Blood Centre of a Tertiary Care Centre.

Risk Assessment Procedure

Separate FMEA matrices were prepared for each blood bank process identified in the study. Activities were recorded in the same sequence as represented in the corresponding flowcharts to ensure consistency throughout the analysis. Every activity was evaluated individually to identify possible sources of failure and their potential effects on process performance and product quality.

The evaluation consisted of three sequential stages.

Severity Assessment

Initially, each potential failure mode was examined to determine the seriousness of its possible consequences. Severity ratings ranged from 1 to 10, where higher scores represented greater impact on patient safety, product quality, regulatory compliance, or operational performance. The assigned score reflected the extent to which a failure could compromise the objectives of the process.

Occurrence Assessment

Following severity evaluation, the underlying causes responsible for each potential failure were investigated. Based on the estimated likelihood of occurrence, each failure mode received an occurrence score ranging from 1 to 10. Higher values indicated a greater probability that the failure would occur under normal operating conditions.

Detection Assessment

Existing control measures designed to identify failures before they affected the final outcome were subsequently reviewed. The effectiveness of these controls was evaluated by assigning a detectability score between 1 and 10. Lower scores indicated highly reliable detection methods capable of identifying failures promptly, whereas higher scores represented failures that were difficult or nearly impossible to detect before causing adverse consequences.

Calculation of Risk Priority Number

After assigning values for severity (S), occurrence (O), and detectability (D), the Risk Priority Number (RPN) was calculated for every identified failure mode using the standard FMEA equation:

RPN = Severity × Occurrence × Detectability

The calculated RPN served as a quantitative indicator of the relative importance of each risk. Higher RPN values represented greater overall risk and therefore required more urgent management attention.

Risk Classification and Corrective Action Planning

To facilitate prioritization of improvement activities, RPN values were categorized according to predetermined thresholds established by consensus during the implementation phase.

- RPN greater than 100: Immediate corrective action required.
- RPN between 70 and 100: Corrective measures recommended within the short term.
- RPN below 70: Medium-term improvements considered sufficient unless additional circumstances justified earlier intervention.

This classification system enabled quality managers to distinguish critical risks from those already under acceptable control. Based on the assigned priority level, preventive and corrective actions were proposed for each identified failure mode.

RESULTS

Every identified failure mode was assessed according to its severity, probability of occurrence, and likelihood of detection. The calculated Risk Priority Number (RPN) provided an objective basis for ranking process risks and determining the level of intervention required.

For clarity, the findings are presented by comparing the activities with the highest RPN values to those with the lowest scores, thereby distinguishing processes requiring immediate corrective measures from those considered to be under satisfactory operational control.

Sr. No.	Quality Concern/Risk	Severity (S)	Occurrence (O)	Detection (D)	RPN (S × O × D)
1	Inappropriate donation interval	7	3	2	42
2	Inadequate antisepsis of the venipuncture site	8	3	5	120
3	Failure of self-exclusion	9	4	7	252
4	Insufficient under-standing (donor questionnaire /instructions)	7	5	6	210
5	Wrong blood grouping	10	2	3	60
6	Wrong labeling on blood bag	10	3	8	240
7	Incorrect venepuncture	6	5	4	120
8	Blood mixing not appropriate	8	4	5	160
9	Centrifuge malfunction	8	2	3	48
10	Needlestick injuries	7	2	3	42
11	Improper tube sealing	7	3	5	105
12	Adverse donor reactions	7	2	4	56

High-Priority Risks (RPN >100)

Several activities produced RPN values exceeding 100, indicating that these processes required immediate attention and implementation of corrective actions.

Among pre donation processes, inadequate donor comprehension of self-exclusion generated the highest RPN, reflecting the combination of significant clinical consequences and poor detectability.

In blood collection processes failures related to improperly sealed tubing resulting in an open collection system and centrifuge malfunction also produced elevated RPN values. These failures have the potential to compromise product sterility, processing efficiency, and overall component quality.

Similarly, in the biological qualification of blood components, operational problems involving incorrect functioning of label printers, poor adhesive quality of labels, and equipment malfunction were identified as critical risks. These failures increase the possibility of identification errors and may adversely affect traceability throughout the transfusion chain.

Lower-Priority Risks (RPN <70)

Several identified failure modes generated comparatively low RPN values despite some being associated with potentially serious clinical consequences. These lower scores resulted primarily from the presence of effective preventive controls, reduced probability of occurrence, or highly reliable detection methods.

Examples within the blood donation process included blood splashing during collection, needlestick injuries, adverse donor reactions, and plasma thawing-related events. Although certain failures possessed relatively high severity scores, their overall RPN remained low because they occurred infrequently and were generally detected promptly through existing quality control procedures.

Within the biological qualification process, events such as accidental exchange of labels between blood components, inappropriate disposal of blood units, and failure to discard all affected components also demonstrated relatively low RPN values. Existing verification procedures substantially reduced the probability that these errors would progress unnoticed through the system.

Overall, these findings suggest that the current control mechanisms implemented for these activities are functioning effectively and contribute to maintaining acceptable levels of operational risk.

DISCUSSION

The results revealed that activities involving donor selection, donor self-exclusion, blood collection, equipment performance, and labeling generated the highest RPN values. These processes require immediate management attention because failures occurring at these stages may directly affect blood safety, product traceability, regulatory compliance, and ultimately patient outcomes. Similar observations were reported by Najafpour et al., who applied FMEA to the hospital blood transfusion process and identified patient identification, blood sample labeling, specimen collection, and transfusion ordering as the highest-risk activities. (6) The authors concluded that communication failures, inadequate staff training, and weaknesses in standard operating procedures were the principal contributors to elevated RPN values, findings that closely parallel those observed in the present study.

An important finding of the present investigation is that most high-priority failures were related to human factors rather than technical limitations. Errors involving donor assessment, incomplete implementation of self-exclusion procedures, incorrect venipuncture-site preparation, and improper equipment operation primarily reflected procedural non-compliance, communication gaps, or insufficient competency rather than deficiencies in laboratory technology. These observations are consistent with the broader literature in transfusion medicine, which recognizes human error as one of the leading causes of preventable transfusion-related adverse events across the entire transfusion chain.(7,8)

Equipment-related failures also contributed substantially to elevated RPN scores. Malfunction of centrifuges, labeling systems, and blood component processing equipment may compromise component quality, increase turnaround time, and create opportunities for identification errors. Comparable findings were reported by Han et al., who demonstrated that automation of blood bank procedures significantly reduced RPN values compared with manual workflows.(9) Their multicenter evaluation showed that automated blood grouping systems minimized human intervention, reduced variability, and improved overall process reliability. These results support the present study by suggesting that investment in automation and technological upgrades can substantially decrease operational risk within blood bank services.

Another noteworthy observation concerns donor education and communication. Failure of donors to correctly understand or disclose self-exclusion decisions generated one of the highest RPN values in this study. This finding indicates that improving donor counseling, simplifying educational materials, and confirming donor understanding before blood collection may significantly reduce operational risk.

The present study also highlights the importance of procurement and equipment maintenance within an integrated quality management system. Poor label adhesion, equipment malfunction, and deficiencies in purchased materials contributed to increased RPN values.. Preventive maintenance schedules, routine calibration, equipment validation, and performance verification should also be incorporated into risk reduction strategies to minimize equipment-related failures.

Despite its advantages, FMEA has certain limitations. The assignment of severity, occurrence, and detectability scores inevitably involves expert judgment, introducing a degree of subjectivity into the calculation of RPN values. Furthermore, risk profiles may differ among institutions depending on workflow design, staffing patterns, technological infrastructure, and local regulatory requirements. Consequently, periodic reassessment of risks is recommended, particularly following process modifications, implementation of new technologies, or revisions to standard operating procedures.

CONCLUSION

The findings revealed that activities related to donor selection, blood collection, component processing, equipment performance, and labelling represent critical control points requiring focused preventive and corrective actions. In contrast, processes with lower RPN values reflected the effectiveness of existing control measures and highlighted the importance of maintaining established quality assurance practices. Early identification of high-risk activities allows blood bank managers to allocate resources efficiently, strengthen operational controls, and implement targeted interventions before failures compromise product quality or patient safety.

Overall, integrating FMEA into blood bank operations enhances process reliability, improves patient and staff safety, optimizes resource utilization, and promotes a culture of continuous quality improvement. Future studies should evaluate the long-term effectiveness of risk reduction strategies and investigate the integration of complementary quality management tools, such as Root Cause Analysis and Statistical Process Control, to further strengthen transfusion service performance.

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