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# Risk Evaluation in Blood Transfusion Using Failure Mode and Effects Analysis

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## Abstract

Risk Management in blood transfusion is a crucial process aimed at ensuring the safety and efficacy of transfusion services and processes. Failure Mode and Effects Analysis (FMEA) is a systematic approach used for identifying and mitigating the potential failures in the process of blood transfusion. In this paper, FMEA is used to rank risks and implement corrective actions to enhance patient safety. The aim of this work is to identify the risks and their management before they can cause harm, thus enhancing the patient's safety and effectiveness of blood transfusion process. Twenty failures mode were identified, and the risk priority number (RPNs) were calculated for each failure to identify the most critical failures that require immediate attention, so that appropriate corrective actions can be implemented to mitigate the risk. The analysis demonstrated five critical failure modes with the highest RPN in the blood transfusion process, and corrective actions have been identified.

## Subject Areas

Biomedical Engineering, Patient Safety

## Keywords

Risk Management, Blood Transfusion, Failure Mode and Effective Analysis, Risk Priority Number

## 1. Introduction

A blood transfusion is a common, safe medical procedure in which healthy donor blood is given through an intravenous, or IV line inserted into the blood vessels. Blood transfusions replace blood that is lost through surgery or injury. This treatment also provides blood if the body is not making blood properly on its own.

Four types of blood products may be given through blood transfusions:

- Whole blood.
- Red blood cells.
- Platelets, blood cell that help in blood clot.
- Plasma [1].

Red blood cells (RBC) contain hemoglobin and supply the cells of the body with oxygen. Historically, red blood cell transfusion was considered when the hemoglobin level fell below 100 g/L or hematocrit fell below 30% [2]. The blood is classified based on the presence and absence of antibodies and inherited antigenic substances on the surface of (RBCs). Some of these antigens are also present on the surface of other types of cells of various tissues [3]. To avoid a transfusion reaction, donated blood must be compatible with the blood of the patient who is receiving the transfusion. Before a blood transfusion, two blood tests must be done, known as a "type and cross match". Immune-mediated transfusion reactions occur when incompatible blood products are transfused into a patient's circulation [4].

Failure Mode and Effects Analysis (FMEA) is an effective risk management tool used to identify potential failures in the blood transfusion process. The primary goal is to eliminate the chance that an error will occur by systematically examining all ways in which a failure can occur [5].

## 2. Related Studies

In study [6], the author used FMEA throughout the whole process of blood transfusion and his result showed five failure mode with highest risk priority number RPN: insufficient preoperative assessment of the blood product requirement, reparation time before infusion of more than 30 minutes, blood transfusion reaction occurring during the transfusion process, blood plasma abuse and insufficient and/or incorrect clinical information on request form. Two stages of FMEA were used in the study [7], and there was a 56% improvement in the RPN in the second stage. The most important failure was: reporting of transfusion reactions, cross-matching ordered tests, patient identification, transmitting information about the transfusion request, completing and sending the transfusion control document, patient identification and sample identification. Four blood transfusion failures were identified with RPN over 75 in study [8], and these were: labelling, transfusion of blood or the component, patient identification and sampling. In this study, corrective actions were implemented and then re-evaluated after 6 months. In study [9], the failures during blood transfusion were identified and the solution (process redesign actions) was developed. This study measures outcome errors during the blood transfusion after the new process was accomplished and no outcome errors occurred. Various strategies aimed at improving blood product safety were examined in study [10], beginning with donor recruitment and continuing through stages such as collection, preparation, testing, labeling, distribution, and transfusion, concluding with hemovigilance and clinical quality improvement.

Key interventions include stringent donor screening, laboratory testing, adherence to transfusion guidelines. This comprehensive approach seeks to minimize the risks associated with blood transfusions, ultimately improving patient outcomes. The role of Failure Mode and Effect Analysis (FMEA), including its variants FMECA and HFMEA was highlighted in study [11], the study analyzed 18 papers focusing on processes such as drug prescribing and administration. A total of 220 high-risk priority numbers was identified. Improvement actions had not been systematically reported.

The primary benefit of the previous studies was the comprehensive identification of potential errors and their underlying causes. Additionally, these studies successfully reduced the risk evaluation threshold to 75, thereby enhancing the overall safety and reliability of the processes. Reducing the Risk Priority Number (RPN) threshold to 60 can enhance the overall safety and reliability of the processes by ensuring that even less critical risks are addressed and mitigated effectively.

## 3. Methode

This study aims to apply the Failure Mode and Effect Analysis (FMEA) methodology to identify, evaluate, and mitigate potential failures in the blood transfusion process. The data was collected through a multidisciplinary team approach, involving healthcare professionals from various departments and already they were worked in different healthcare facilities in Sudan. The FMEA process is a proactive risk management tool that helps in identifying potential failure modes, assessing their effects, and prioritizing corrective actions.

The study employed a mixed-methods approach, combining qualitative and quantitative data collection techniques to comprehensively analyze the blood transfusion process. The FMEA methodology was chosen for its systematic approach to risk assessment and mitigation. The data was collected in period from 2020 to 2023. According to the multidisciplinary team, this study covered seven hospitals within the state of Khartoum.

A multidisciplinary team was assembled, comprising:

- Hematologists: Specialists in blood disorders and transfusion medicine.
- Transfusion Medicine Specialists: Experts in the management of blood transfusions.
- Nurses: Frontline healthcare providers involved in administering blood transfusions.
- Laboratory Technicians: Professionals responsible for blood testing and cross-matching.
- Quality Management Personnel: Experts in healthcare quality and risk management.

The team members were selected based on their expertise and direct involvement in the blood transfusion process. The diversity of the team ensured a comprehensive understanding of the process from different perspectives.

An initial meeting was conducted to orient the team members about the FMEA process and the objectives of the study. The blood transfusion process was broken down into its constituent steps, from blood collection to post-transfusion monitoring. The steps included:

1) Ordering blood request: The physician determines the need for a blood transfusion based on the patient's condition, such as low hemoglobin levels, surgery, or trauma. The physician fills out a blood request form, specifying the type of blood components needed. The request form is submitted to the blood bank or transfusion service.

2) Patient identification: The patient's identity is verified using at least two unique identifiers, such as name, date of birth, or medical record number; however, in some hospitals only the full name is used.

3) Sampling (Collecting blood from patient): Sampling in the context of blood transfusion refers to the process of collecting and testing blood samples to ensure the safety and compatibility of the blood products being transfused. This process is crucial for preventing adverse reactions and ensuring that the recipient receives the appropriate type of blood. Proper labelling and handling samples are crucial to avoid errors.

4) Labelling (Attaching labels on tubes): Ensure the labels on the blood collection tubes include the patient's full name, medical record number, and the date and time of collection.

5) Analysis of blood samples: An analysis of Blood Samples is to end the labelled blood samples to the laboratory for analysis and to determine the patient's blood type (A, B, AB, or O) and Rh factors (positive or negative).

6) Compatibility testing: Perform a crossmatch test to ensure the donor blood is compatible with the patient's blood. This involves mixing the patient's serum with donor red blood cells and observing any reactions. Selection of blood components based on compatibility test results.

7) Transfusing blood components: Transfusing blood components is a critical and detailed process that requires careful attention to ensure patient safety and the effectiveness of the transfusion. The blood component bag is visually inspected for any signs of damage, discoloration, or clots. It is ensured that the bag is intact, and the blood component appears normal. The expiration date on the blood component bag is checked to ensure it has not expired. It is verified that the blood component has been stored under appropriate conditions (e.g., refrigerated for red blood cells, room temperature for platelets). A dedicated blood administration set with a filter (170 - 260 micron) is used to remove any clots or debris from the blood component. The blood component bag is carefully spiked with the administration set, ensuring a tight seal to prevent air entry. The transfusion begins at a slow rate (e.g., 2 mL/min for the first 15 minutes) to monitor for any immediate adverse reactions. The patient is stayed with during the initial phase of the transfusion to observe for signs of transfusion reactions, such as fever, chills, hives, shortness of breath, or changes in vital signs. The patient's vital signs (tempera-

ture, pulse, blood pressure, respiratory rate) are recorded before starting the transfusion and at regular intervals (e.g., every 15 minutes for the first hour, then every hour until completion). As the transfusion nears completion, the patient is closely monitored for any delayed reactions.

### 3.1. Identification of Potential Failure Modes

Team members were asked to identify potential failure modes and its effect at each step of the blood transfusion process. Brainstorming sessions and group discussions were facilitated to ensure a comprehensive list of failure modes. Each team member contributed based on their expertise and experience. Failure modes were documented in detail, including descriptions of the potential failures and their causes and the effects of each failure on the patient and transfusion process as shown in Table 1.

### 3.2. Risk Assessment

For each identified failure mode, the team assessed the following parameters:

Severity (S): The potential impact of failure on patient safety and outcomes. Severity was scored on a scale of 1 to 10, with 1 being the least severe and 10 being the most severe.

Occurrence (O): The likelihood of failure occurring. Occurrence was scored on a scale of 1 to 10, with 1 being the least likely and 10 being the most likely.

Detection (D): The ability to detect failure before it affects the patient. Detection was scored on a scale of 1 to 10, with 1 being the easiest to detect and 10 being the hardest to detect. A scoring system (1 - 10) was used for each parameter, with higher scores indicating greater risk.

This assessment was based on the team's expertise, historical data and understanding of the potential consequences of each failure mode, more over the assessment considered the existing control measures and their effectiveness in identifying failures before they impact the patient. The rate assigned to each score is determined by calculating the average from all raters.

### 3.3. Calculation of Risk Priority Number (RPN)

The RPN was calculated for each failure mode using the formula:

$$\text{RPN} = S \times O \times D \tag{1}$$

Failure modes with higher RPN values were prioritized for further analysis and mitigation. The RPN values provided a quantitative measure of risk, allowing for objective prioritization.

In this paper, the Risk Priority Number (RPN) threshold was ≥60 and that helps prioritize the most critical failure modes that require immediate attention. By focusing on failure modes with higher RPNs, resources can be allocated more effectively to address the most significant risks first. A lower threshold would include more failure modes, potentially capturing less critical risks that could spread resources thinly, potentially reducing the effectiveness of interventions at the highest risks, on the other hand the higher threshold would focus efforts on only the most critical risks, potentially missing some significant but slightly lower risk issues and there is a risk of overlooking failure modes that, while not the highest risk, still pose significant threats to safety and efficiency.

**Table 1.** Potential failure mode for each step of blood transfusion including the severity, probability of occurrence and probability of detection score.

| Step | Potential Failure Mode | Potential Cause(s) of Failure | Severity | Potential Effect(s) of Failure | Occurrence | Detection |
|---|---|---|---|---|---|---|
| Ordering blood request | Incorrect patient information on request form | Request form filled out incorrectly or partially completed | 2 | Normal process is interrupted | 3 | 5 |
| | Inadequate evaluation of the blood product requirement | Incorrect assessment of the condition or anticipated blood loss | 6 | Blood cannot be ready in time following an emergency cross-matching procedure | 2 | 2 |
| Patient identification | Incorrect patient identification | Patients with same name | 9 | Patient receives mismatched blood | 6 | 3 |
| | Not Checking ID Bracelet | Nonadherence to guidelines or assumptions during the admission process | 9 | | 3 | 2 |
| | Patients use fake identity | Insurance Fraud | 9 | | 3 | 5 |
| Sampling (Collecting blood from patient) | Sample incorrectly labeled | Patient's information not checked carefully | 10 | Severe transfusion reaction may occur | 3 | 2 |
| | Insufficient or unclear information on the sample label | Importance of providing complete clinical data not recognized or illegible labelling | 4 | Cross-matching halted until complete clinical data obtained | 6 | 1 |
| Labelling (Attaching labels on tubes) | Delivery of blood sample/request form delayed | High volume of simultaneous distributions process | 2 | Delay in providing blood products or test results | 3 | 7 |
| | Mismatch between the labels and the request form | Design issues or non-compliance with labeling protocols | 8 | Acute hemolytic transfusion reactions are potentially fatal | 3 | 4 |
| Analysis of blood samples | Blood sample /request form delayed | High volume of simultaneous distributions | 2 | Delay in providing blood products or test results | 1 | 8 |
| Compatibility testing | Inaccurate cross-matching | Sample information not verified; equipment malfunction; improper sample handling; insufficient training | 9 | A blood transfusion reaction may occur | 2 | 3 |

**Continued**

| | | | | | | |
|---|---|---|---|---|---|---|
| Issue of blood components | Incorrect blood components issued | Information or blood product not verified accurately | 3 | Blood products cannot be transfused within the appropriate time frame | 2 | 4 |
| | Quality checks not performed on blood products | Insufficient or inaccurate quality checks | 8 | Poor quality blood components may cause transfusion reaction | 2 | 1 |
| | Blood components for different patients issued simultaneously | Heavy workload at the blood releasing window | 7 | Wrong blood products delivered to patients | 3 | 2 |
| | Blood product delivered to the wrong department | Multiple patient samples in one delivery box | 8 | Transfusion delay or adverse reaction | 2 | 2 |
| | Delivered blood bag to the wrong unit/hospital | Human error, heavy workload, or simultaneous high-volume deliveries | 8 | Patient receives mismatched blood | 3 | 2 |
| Transfusing blood components | Not verifying blood type, quality or quantity | Knowledge deficit or lack of standard procedure | 2 | Lack of standard procedure | 1 | 4 |
| | Failure to perform pretransfusion checks | Final identification checks not performed at bedside | 10 | Life threatening transfusion reaction | 2 | 2 |
| | Transfusion not completed in time | Delays in transfusion start after delivery | 6 | Transfusion delayed or uncertain quality blood product | 4 | 2 |
| | Transfusion reaction during process | Patient not monitored | 9 | Delayed emergency treatment | 4 | 5 |

The FMEA data in Table 1 presented is a structured approach to identifying and mitigating potential failures in the blood transfusion process. It outlines various steps in the transfusion workflow, from ordering blood requests to transfusing blood components, and systematically lists twenty potential failure modes, their causes, and effects. Each failure mode is evaluated based on its severity, occurrence, and detection ratings, which are then used to calculate a risk priority number (RPN). This RPN helps prioritize areas that require attention to reduce risks and improve the reliability of the transfusion process.

The table highlights critical issues such as incorrect patient identification, inadequate evaluation of blood product requirements, and inaccurate cross-matching, which can lead to severe transfusion reactions or delays in treatment. It also addresses operational challenges like high workload and human errors that could result in mismatched blood products being delivered or transfused.

## 4. Result

Blood transfusion is a critical medical procedure that plays a pivotal role in saving lives and supporting various medical treatments. By using FMEA method, twenty failure modes were enlisted in FMEA form during the whole blood transfusion steps. The risk associated with each failure mode was quantified using the RPN, calculated by using formula (1) as shown in Table 2.

Table 2. Failure mode and RPNs score.

| No. | FAILURE MODE | S | O | D | RPN |
|---|---|---|---|---|---|
| 1 | Incorrect patient information on request form | 2 | 3 | 5 | **30** |
| 2 | Inadequate evaluation of the Blood product requirement | 6 | 2 | 2 | **24** |
| 3 | Incorrect patient identification | 9 | 6 | 3 | **162** |
| 4 | Not Checking ID Bracelet | 9 | 3 | 2 | **54** |
| 5 | Patients use fake identity | 9 | 3 | 5 | **135** |
| 6 | Sample incorrectly labelled | 8 | 4 | 2 | **64** |
| 7 | Insufficient or unclear information on the sample label | 4 | 6 | 1 | **24** |
| 8 | Delivery of blood sample and/or request form delayed | 2 | 3 | 7 | **42** |
| 9 | Mismatch between the labels on the tubes and the request form | 8 | 3 | 4 | **96** |
| 10 | Blood sample or request form are delayed | 2 | 1 | 8 | **16** |
| 11 | Inaccurate cross-matching | 9 | 2 | 3 | **54** |
| 12 | Incorrect blood components issued | 3 | 2 | 4 | **24** |
| 13 | Quality checks not performed on blood products | 8 | 2 | 1 | **16** |
| 14 | Blood components for different patients issued at the same time | 7 | 3 | 2 | **42** |
| 15 | Blood product delivered to the wrong department | 8 | 2 | 2 | **32** |
| 16 | Delivered blood bag to the wrong unit/hospital | 8 | 3 | 2 | **48** |
| 17 | Not verifying the type, quality, amount, and kind of blood taken from the blood bank ward | 2 | 1 | 4 | **8** |
| 18 | Failure to perform pretransfusion checks | 10 | 2 | 2 | **40** |
| 19 | Transfusion cannot be completed within the appropriate time | 6 | 4 | 2 | **48** |
| 20 | Blood transfusion reaction occurs during the transfusion process | 9 | 4 | 5 | **180** |

Failure modes with an RPN greater than 60 were prioritized for further analysis and corrective action. The failure with highest RPN were: Incorrect patient identification (RPN: 162), Patients use fake identity (RPN: 135), Sample incorrectly labelled (RPN: 64), Mismatch between the labels on the tubes and the request form (RPN: 96) and Blood transfusion reaction occurred during the transfusion process. (RPN: 180) as shown in Table 2.

### Descriptive Data Analysis

Descriptive data analysis plays a crucial role in understanding and interpreting

(FMEA) data. By using descriptive data analysis, we can summarize and make sense of the large amounts of data that come out of an FMEA. This helps us see the bigger picture of the risks involved in a process or system.

The IBM SPSS statistic 23 (Statistical Package for the Social Sciences software) was used in this paper to conduct the analysis, see Table 3.

**Table 3.** Descriptive variables are severity occurrence detectability and RPN.

| | N | Minimum | Maximum | Mean | Std. Deviation |
|---|---|---|---|---|---|
| Severity | 20 | 2.0 | 10.0 | 6.45 | 2.856 |
| Occurrence | 20 | 1.0 | 6.0 | 2.95 | 1.56 |
| Detectability | 20 | 1.0 | 8.0 | 3.30 | 1.922 |
| RPN | 20 | 8.0 | 180.0 | 56.95 | 48.726 |
| Valid N (listwise) | 20 | | | | |

This table provides a snapshot of the central tendency (mean) and variability (standard deviation) of the severity, occurrence, detectability, and RPN scores for 20 different failure modes. Severity scores range from 2 to 10, with a mean of about 6.5 and a standard deviation of about 2.9, indicating a wide variability in the seriousness of failure effects. Occurrence scores range from 1 to 6, averaging about 3 with a standard deviation of about 1.6, showing less variability in the frequency of failures. Detectability scores vary from 1 to 8, with a mean of about 3 and a standard deviation of 1.9, reflecting moderate variability in the ability to detect failures. RPN scores, which combine the previous three metrics, range widely from 8 to 180, with a mean of 57 and a high standard deviation of about 50, indicating significant differences in the perceived risk levels of the failure modes. All 20 observations are complete, with no missing data.

## 5. Discussions

By using FEMA in whole blood transfusion process found that:

Blood transfusion reactions occur during the transfusion process is the most critical failure mode in this list, with the highest RPN = 180. These reactions can occur due to incompatible blood types, contaminated blood products, or patient sensitivities. To avoid this failure, strict protocols for monitoring patients should be implemented during transfusions, including vital sign checks and observation for signs of reactions, as well as maintain accurate and up-to-date records of patient blood types, transfusion history, and any adverse reactions.

Incorrect patient identification is the second highest RPN failures (RPN = 162). This failure can lead to severe consequences, including transfusion reactions, incorrect treatment, and potentially fatal outcomes. Errors in patient identification can occur due to human error, inadequate verification processes, or system failures. To avoid this failure, the facilities can utilize one of personal identification methods during the patient registration, such as barcode scanning, biometric identification or Radio Frequency Identification (RFIT) tag. in addition to Implement a robust patient identification protocol that includes the use of two unique patient identifiers, such as name and date of birth or medical record number.

Patients using fake identities are also the highest RPN failures RPN = 135. It can lead to incorrect medical records, inappropriate treatments, and transfusion errors. This failure mode can compromise patient safety and the integrity of healthcare delivery. The above personal identifier methods that previously mentioned can also be used as corrective action, as well enhance the verification process by requiring government-issued identification or other reliable forms of ID, beside train staff to recognize and respond to suspicious behaviour or discrepancies in patient information, finally introduce double-check systems where two healthcare professionals verify patient identity before any transfusion also can help to prevent causes of this failure.

The mismatches between sample labels and request forms can lead to errors in blood typing, cross-matching, and transfusion (RPN = 96). This failure mode can result in transfusion reactions and other adverse outcomes. To avoid this failure standardized process should be implemented for labelling and documenting blood samples and request forms; likewise, conduct regular audits and checks to verify the accuracy of labelling and documentation. In addition to using technology solutions, such as barcode systems, to ensure accurate matching of labels and forms.

Finally, Incorrect labeling of blood samples (RPN = 64) can result in misidentification, leading to incorrect blood typing and cross-matching. This can cause transfusion reactions and other adverse events. There are a lot of actions that can be taken to prevent this failure, such as: Standardize labelling procedures and use pre-printed labels with barcodes to minimize manual errors, ensure that labelling is done at the patient's bedside to verify identity and reduce the risk of sample mix-ups, moreover provide ongoing training and education for staff on the importance of accurate sample labelling.

Addressing these high-priority failure modes requires a combination of process improvements, technology solutions, and staff training. By implementing these corrective actions, healthcare providers can enhance the safety and reliability of the blood transfusion process, ultimately improve patient outcomes and reduce the risk of adverse events.

## 6. Conclusion

The application of FMEA in this study has highlighted its value in enhancing patient safety and improving process reliability; by implementing these corrective actions, healthcare providers can enhance the safety and reliability of the blood transfusion process, ultimately improve patient outcomes and reduce the risk of adverse events.

## 7. Limitation

This paper provides valuable insights into the application of FMEA in improving the safety and reliability of blood transfusion processes. Here are some limitations of the paper:

- The FMEA process relies heavily on the subjective judgment of the multidisciplinary team to assign Severity (S), Occurrence (O), and Detection (D) scores. This subjectivity can introduce bias and variability in the risk assessment process.
- The paper does not report any inter-rater agreement statistics, which are crucial for demonstrating the consistency and reliability of the scores assigned by different team members.
- Implementing FMEA and the recommended corrective actions can be resource-intensive, requiring significant time, effort, and expertise. Smaller healthcare facilities or those with limited resources may face challenges in adopting and sustaining these practices.
- The paper does not provide data on the long-term effectiveness of the corrective actions implemented. This is due to the situation in Sudan after the war and the destruction of most health facilities more over the deterioration of health services.

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## Conflicts of Interest

The authors declare no conflicts of interest.

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