Prospective Risk Assessment and Intervention to Reduce Blood Transfusion Errors

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Abstract

- **Objective:** To describe a failure modes and effects analysis (FMEA) and subsequent process changes to reduce risk of clerical errors of blood transfusion and to reduce same-day surgery delays due to absence of adequate data or lack of product.

- **Methods:** A multidisciplinary team mapped the steps involved in ordering and administering blood products for surgical procedures. A risk priority index score was calculated for each failure mode. For the top 10 failure modes, corrective actions were initiated and reviewed.

- **Results:** There was an overall reduction of 53% in the risk priority index score for the 10 modes addressed. Hazard risk values decreased by 37% in the preoperative phase, 88% in the operative phase, 76% in the postanesthesia care unit phase, and 17% in the unit/floor phase.

- **Conclusion:** An FMEA can be applied to blood banking to identify and address weaknesses within the blood banking system.

Surgical volume and complexity of cases has resulted in increased blood transfusion requirements. Significant risks are associated with blood transfusions, including transmission of infectious agents or adverse events due to transfusion of incorrect blood products. Vigilant donor pool regulations and strict testing of donor units for infectious agents has decreased the transfusion-related infection rate [1]. The risk of ABO incompatible blood transfusion, however, is between 2.5 and 253 per 100,000 transfusion units, roughly a 100- to 1000-fold higher risk than the average viral risk [2]. Transfusion of ABO incompatible blood represents the most frequent cause of severe transfusion error [3,4]. Identification and prevention of these errors have become an increasingly important issue in transfusion safety.

Lack of suitable blood products for patients undergoing same-day surgery has been a significant problem when lack of current typing and screening results in delayed surgery and inefficient use of operating room (OR) time [5]. The increase in surgical procedures adds to the number of “emergent orders” a blood bank receives, as samples for these procedures are drawn within an hour or 2 of surgery. The process design must be adjusted so that the quality of blood bank service and the delivery of blood products remain optimal even when the volume of requests is high. If blood bank can not adjust to times of high volume, delays or cancellations of surgeries may result which will impact negatively on the reputation of the hospital.

In this article, we describe the use of a failure modes and effects analysis (FMEA) to reduce the risk of clerical errors of blood transfusions and to reduce surgery delays due to absence of adequate blood type data and lack of available blood products. FMEA is a method used to proactively identify possible failures in new, redesigned, or existing processes [6]. Failures are prioritized according to how serious their consequences are, how frequently they occur, and how easily they can be detected. The purpose is to take actions to eliminate or reduce failure, starting with the highest priority concerns.

**Setting**

Penn Presbyterian Medical Center is a tertiary care hospital with more than 300 beds and with a busy orthopedic surgery service specializing in revisions of large joint prostheses. The hospital has a high acuity rating with active thoracic and cardiac surgery departments. On average, we transfuse approximately 600 units of red blood cells, 200 units of fresh frozen plasma, 60 units of platelets, and 10 doses of cryoprecipitate per month.

**Assembly of Team**

A team was assembled comprising 2 surgeons, 2 nurses from the office practices, 2 blood bank staff members, one with a specific interest in quality assurance (JES), and nursing staff from the preoperative and operating suites, the postanesthesia care unit (PACU), and the floor/unit. The group met twice per month for 3 months to perform the
Failure Modes and Effects Analysis

Preoperative
1. Preadmission testing ordered
   • Correct ordering
   • Correct patient transfusion/pregnancy history
   • Correct documentation
   • Obtain consent for transfusion
   • Procured specimen adequately labeled

2. Specimen & request sent to blood bank
   • Review labeling and transfusion/pregnancy history
   • Perform historical review of previous patient testing
   • Accession and relatable with blood bank accession labels

3. Type & screen (& crossmatch) performed
   • Set up test
   • Perform test (ABO/Rh and antibody screen)
   • Re-perform ABO/Rh testing as necessary
   • Perform crossmatch testing

4. Blood bank test result entry
   • Select/barcode correct patient
   • Enter correct results
   • Verify against previous records

5. Blood bank storage
   • Select the correct blood product
   • Compare against crossmatch results in computer
   • Label blood for patient
   • Store in appropriate holding unit

6. Blood labeling, delivery & transport to operating room (OR) refrigerator
   • Identify patient requiring blood (patient ID check)
   • Check patient chart for consent
   • Complete blood request form
   • Deliver request to blood bank
   • Blood bank performs check of request against laboratory records
   • Blood bank issues blood to OR staff
   • OR staff delivers to OR blood storage unit

Intraoperative
7. Intraoperative request for pick-up
   • Surgeon request unit for transfusion
   • Determine if blood available in OR
   • Alert OR nurse for blood delivery

8. Delivery to OR suite from OR storage
   • OR nurse selects blood from storage unit
   • Compares units selected against patient/product list
   • Documents blood removal from storage unit
   • OR nurse delivers blood from OR storage unit to OR suite

9. Confirmation of order, product, recipient
   • Obtain correct patient identification
   • 2 OR staff perform verification step of blood product labels against patient ID labels
   • Two (2) RN/MD verifications documented

10. Transfusion initiated
    • Vitals monitored by anesthesia staff
    • Vitals documented by anesthesia staff
    • Transfusion completed, documentation entered into patient medical records chart
    • Patient re-banded with ID bracelet

Postanesthesia Care Unit (PACU)
11. Order in PACU
    • Surgeon request unit for transfusion
    • Determine if blood available in OR storage unit
    • PACU nurse checks patient records for consent
    • PACU nurse dispatched for blood delivery

12. Blood retrieval to PACU
    • PACU nurse selects blood from storage unit
    • Compares units selected against patient/product list
    • Documents blood removal from storage unit
    • Complete blood request form
    • Deliver request to blood bank
    • Blood bank performs check of request against laboratory records
    • Blood bank issues blood to PACU staff
    • PACU nurse delivers blood to PACU

13. Confirmation of order, product, recipient
    • Obtain correct patient identification
    • 2 PACU nurses perform verification step of blood product labels against patient ID band
    • Two (2) RN verifications documented

14. Transfusion Initiated
    • Vitals monitored by PACU RN staff
    • Vitals documented by PACU RN staff
    • Transfusion completed, documentation entered into patient medical records chart

15. Additional transfusion requirements identified
    • Orders for additional transfusions reviewed
    • Availability and location of blood determined
    • Additional blood requirements reported to nursing staff receiving patient on unit/floor

Figure. Flowchart depicting the steps involved in the process of providing red blood cells for surgery starting with preoperative testing through postoperative care.
reports from the field

Patient safety

FMEA and develop the action plan. To address the problem of time away from assigned work areas over a period of a few months, 2 staff members from each service were appointed to the group so that at least 1 might be expected to attend every meeting. There was representation from all departments/units for all of the meetings scheduled.

Review of Processes

The team mapped all the steps involved in providing red blood cells for surgery. For each of the steps, subprocesses also were identified. A detailed flowchart was created; an abbreviated version of the complete flowchart is shown in the Figure.

Preoperative Processes

In our hospital, preadmission type and screen for patients with scheduled surgeries is highly recommended. This allows early awareness of unusual antibodies and timely preparation for adequate transfusion. At the time the sample is drawn, the patient confirms having no history of transfusion or pregnancy in the previous 3 months. With confirmation, the sample is stored and used for crossmatching purposes up to 30 days prior to surgery. If confirmation cannot be obtained, the sample can only be used for crossmatching purposes in the 72 hours prior to surgery. In preadmission type and screen and same-day samples, current ABO/Rh blood group results are compared with the blood bank history in the hospital laboratory information system.

The preoperative process also includes a request for type and crossmatch on the day of surgery, including the drawing in correctly labeled tubes as per blood bank policy and a reconfirmation that the patient has not been transfused or become pregnant since the original preadmission type and screen sample was drawn. In our hospital, requests for red blood cells without previous in-house ABO/Rh blood group history require that either a second technologist repeats the type and screen or, in absence of a second technologist, that a second patient sample is drawn for confirmation. The sequestering of red blood cell units after type and crossmatch, which is an electronic crossmatch in our institution (for those patients who currently or previously have not demonstrated blood groups antibodies), as well as adequate labeling and combination with paperwork and storage in the blood bank was reviewed. The set up and function of the transport and delivery to the OR refrigerators was also reviewed.

Intraoperative Processes

The intraoperative process includes the steps of requesting of red blood cells by the surgeon, delivery from the OR refrigerator to the OR suite, and confirmation of delivery of the correct product to the correct OR suite and the correct patient. Policy requires double verification of patient identification and product labeling prior to transfusion. Patient vital signs are monitored during the transfusion.

Postanesthesia Care Unit

In our institution, red blood cells previously delivered to the OR can be administered in the PACU. Blood retrieval to the PACU can be obtained either directly from the OR refrigerator from already delivered blood products or via the blood bank. There is a double verification policy of patient identification and product labeling prior to transfusion, and patient vital signs are monitored during transfusion.

Unit/floor

When a patient is admitted to the intensive care unit or the

Figure. continued
Failure modes and effects analysis

Floors after PACU, unused units are returned to the blood bank for product inspection and do not travel with the patient. If needed in the intensive care unit on the floor, units can be redistributed or redelivered to there from the blood bank.

Failure mode identification

Once all steps in the processes and subprocesses were identified, the group identified failure modes, or what could go wrong and how, using brainstorming and nominal group technique. Each of these failure modes was listed with its consequence/effects of failure and then consecutively numbered. Numeric values and rating scales were created and assigned to each category: severity of failure, likelihood of failure (occurrence rate), and detection rate. These scales were developed using the nominal group technique and based on either industry standard, internal benchmarks, or an estimate based on expertise and knowledge of the members of the group. For severity of failure, a rating from 1 to 5 was assigned indicating a situation categorized from a near miss (1) to a catastrophic event (5). Similarly, the occurrence rate was scaled from 1 to 5 according to the estimated frequency of failure ranging from less than 1 in 500,000 (1) to 1 in 5 (5). The detection scale was established similarly ranging from almost certain detection (1) to absolute uncertainty of detection (5). A risk priority index (RPI) was then calculated as the product of the severity, occurrence, and detection scores for each failure mode identified. The failure modes with the highest RPI were selected for action based on the Pareto principle (80% of the consequences stem from 20% of the causes). The top 10 failure modes according to RPI are listed in Table 1.

Actions Taken

Corrective actions were discussed and implemented for the top 10 failure modes.

Preoperative Failure Modes

Among the preoperative failure modes, incorrect labeling of specimens was considered a system failure. In addition, the absence of appropriately processed specimens for type and screen and type and crossmatch represented another system failure, resulting in delay of scheduled surgeries. Historically, delinquent laboratory test results were added to the queue of STAT labs on a given morning. This problem was compounded when antibodies were detected, which further prolonged processing. Provider education and a change in handling of preoperative blood specimens were proposed to facilitate change. Provider education included communicating a recent policy modification for preadmission type and screen testing, which included extending the 72-hour period for which specimens were held to 30 days, with the provision that the patient had not received blood products or been pregnant 3 months prior to sample procurement and up to the 30-day period for which the samples are stored [7]. New easy to read labels were designed and staff were reeducated on the use of preadmission forms, including details of recent pregnancy and transfusion. Review of blood orders 24 hours before surgery by nurses was introduced to avoid lack of product at the time of surgery.

Operative Failure Modes

Human error in correct identification of blood product and positive identification of the correct patient was considered to have the highest hazard probability. Double verification by 2 staff (either nurse or physician) confirming correct patient identity and product labeling was reinforced, including documenting that it had been performed. A new patient labeling system was implemented that replaced the card reader stickers, which were often inadequately printed. The stickers are attached to blank patient identification bands and used as part of the patient identification process.

PACU Failure Modes

Patient identification may be impaired in patients in whom identification bands were removed during surgery and not reattached before leaving the OR. Additionally, transfusion-related information may not be accurately transmitted when patients are moved from the OR to the recovery area.

Table 1. Top 10 Failure Modes by Risk Priority Index

<table>
<thead>
<tr>
<th>Failure Mode</th>
<th>Risk Priority Index</th>
</tr>
</thead>
<tbody>
<tr>
<td>Preoperative</td>
<td></td>
</tr>
<tr>
<td>Inaccurate screen: received blood or developed antibodies</td>
<td>24</td>
</tr>
<tr>
<td>Incorrect label on specimen: rejection</td>
<td>18</td>
</tr>
<tr>
<td>Type and crossmatch not ordered</td>
<td>12</td>
</tr>
<tr>
<td>Operative</td>
<td></td>
</tr>
<tr>
<td>One person verifies blood to patient</td>
<td>50</td>
</tr>
<tr>
<td>Patient ID not verified upon receipt of blood</td>
<td>25</td>
</tr>
<tr>
<td>PACU</td>
<td></td>
</tr>
<tr>
<td>No vital signs monitored during transfusion</td>
<td>25</td>
</tr>
<tr>
<td>Patient transfer during, immediately after transfusion</td>
<td>20</td>
</tr>
<tr>
<td>Patient ID not rebanded in OR</td>
<td>15</td>
</tr>
<tr>
<td>Unit/floor</td>
<td></td>
</tr>
<tr>
<td>New order is not recognized, delay in transfusion</td>
<td>60</td>
</tr>
<tr>
<td>EMR display unable to “flash” unexecuted “blood” order</td>
<td>32</td>
</tr>
</tbody>
</table>

EMR = electronic medical record; OR = operating room; PACU = postanesthesia care unit.
remedy these potential areas of error, a strict identification check before leaving the OR was implemented to ensure patient identity. In cases in which blood units were administered at the final stage of recovery room/PACU care, the monitoring of patients’ vital signs was not consistently performed or documented, which could potentially leave transfusion reactions undetected. The patient care flowsheet was revised and a policy developed to ensure the monitoring and documentation of patients’ vital signs prior, during, and after the transfer of patients to remote units.

Postoperative Floor Care Failure Modes

It was discovered that new transfusion orders were not always recognized in a timely manner after the patient had returned to the floor. A goal of 2 hours was set for the time from order to blood delivery on nonemergency transfusion requests. In addition, a notification alert on the patient computer chart data screen for unexecuted blood orders was also considered to help remedy delays in transfusion. A change in the information technology system was requested.

Three months after implementation of the recommended changes, the RPIs were recalculated. Table 2 shows the RPI calculations before and after implementation and monitoring, grouped by area. There was an overall reduction in risk of failure by 53%. The risk declined by 37% in the preoperative area and by 88% in the operative time frame. RPI values decreased by 76% and 17% in recovery room/PACU and postoperative/floor care frames, respectively.

**Discussion**

We conducted an FMEA for the ordering and administering of blood transfusions in the hospital setting. This included evaluating the accuracy of blood/patient identification and timeliness of transfusion orders. Such an analysis is best accomplished by a broadly multidisciplinary team in order to identify otherwise obscure risks.

After the implementation of changes to decrease failure risk and observation over a 3-month period, the factors were reassessed and the hazard analysis was repeated. The results indicate that the interventions resulted in a significant decrease of risk associated with human error in transfusion of blood.

We applied numerical values to the risks we identified. The numerical value attached to each risk is, naturally, subjective. If, however, group consensus is given and the relative values to given risks are adequately maintained, the resulting numerical values should represent valid data points.

The quality assurance department recognized that participation in intradepartmental group activities can be stifling and frustrating for health care professionals. To address this problem, the quality assurance department selected a quality tool known as the nominal group technique to collect information and process the data within the group. This tool is a structured method of brainstorming that encourages equal participation from everyone, provides a process for constructive dialogue, and includes unanimous decision making. Prior to the first meeting, an educational packet was distributed to all team members. The packet introduced members to the tool and provided a framework for how the meetings were going to be run and outlined rules for participation in the group. During the first meeting, further education was provided and the FMEA began once all members understood the process and agreed to the rules. The tool was extremely helpful to the group, leading to more times of open discussion and clarification rather than stalemates, conflicts, or tensions among group members.

Another challenge we encountered was that competing priorities among the health professionals in the group led to disagreements. This was addressed by the group by providing as much information about each individual priority and with the nominal group technique, prioritizing the needs, and coming to unanimous group decisions about them.

In summary, a FMEA can be applied to blood banking to identify and address possible weaknesses within the blood bank system. Implementation of changes and reassessment of risk after implementation of changes can provide numerical changes of value and can be used for quality assurance processes. In order to apply FMEA as benchmarking system, mandatory sets of comparable risk factors must be developed to avoid subjectivity and skewing of data.

<table>
<thead>
<tr>
<th>Table 2. Change in Risk Priority Index (RPI) by Area for Top 10 Failure Modes</th>
</tr>
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<tbody>
<tr>
<td>Failure Mode Area</td>
</tr>
<tr>
<td>Preoperative</td>
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<tr>
<td>Operative</td>
</tr>
<tr>
<td>PACU</td>
</tr>
<tr>
<td>Unit/floor</td>
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<tr>
<td>Prioritized RPI</td>
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</tbody>
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FMEA = failure modes and effects analysis; PACU = postanesthesia care unit.

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**References**

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