EDUCATIONAL COMMENTARY – USING QUALITY IMPROVEMENT TOOLS TO IMPROVE PATIENT SAFETY

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**Florida licensees, please note: This exercise is NOT intended to fulfill your state education requirement for Medical Errors. It will fulfill requirements for Supervision/Administration.**

Learning Objectives

On completion of this exercise, the participant should be able to
- differentiate the three phases of the total testing process;
- list several quality tools used in laboratory medicine; and
- understand the strengths and limitations of the quality improvement tools for proper application in patient safety events.

Case History

A 60-year-old woman, Mrs. CM, underwent a kidney transplant. On postoperative day 2, she developed hypotension (blood pressure, 90/40 mmHg) in the intensive care unit. Routine laboratory tests showed that she was anemic and had elevated serum creatinine. Her hemoglobin concentration was 6.5 g/dL (reference range, 12.0-16.0 g/dL) and serum creatinine was 3.5 mg/dL (reference range, 0.5-1.5 mg/dL). A surgical bleed was suspected, and the patient was scheduled to return to the operating room (OR) for an emergency exploratory surgery. An order for three units of packed red blood cells (pRBCs) for the patient “CM” was placed in the computerized ordering system.

At the time of Mrs. CM’s pending return to the OR, another patient, Mrs. RM, was undergoing a kidney transplant in the OR. An order for six units of pRBCs had been placed in the computerized system for patient RM. Mrs. RM’s transplant surgery was uneventful, and she was transported to the postsurgical waiting area to be monitored. Mrs. CM was then wheeled into the OR for the exploratory surgery, and her surgeon requested that the three units of blood be brought up from the blood bank. The OR nurse handed the blood bank transfusion requisition to a courier, who went to the blood bank and picked up the blood. During transfusion of the third unit, the anesthesiologist noticed that the name on the transfusion record was not the same as the name on the OR computer and stopped the transfusion.

A quick review in the OR revealed that the paper requisition form sent to the blood bank was labeled with Mrs. RM’s demographic information rather than Mrs. CM’s. Mrs. RM’s blood type was group O, RhD-positive. Mrs. CM’s blood type was group B, RhD-positive. The antibody screen was negative in both patients. The pRBCs were type O, RhD-positive, and thus were compatible for Mrs. CM. Fortunately, no
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adverse event occurred secondary to the blood transfusion; however, a formal review of the patient safety error was initiated.

Patient Safety Tools in Laboratory Medicine

This case illustrates a labeling error. The blood bank issued pRBCs to the wrong patient based on incorrect patient labeling. Labeling errors are common, affecting the preanalytic phase of the testing continuum known as the total testing process (TTP). The Centers for Disease Control and Prevention (CDC) developed this process to analyze the quality of laboratory testing and practices.1 TTP is a cyclical process with three phases: preanalytic, analytic, and postanalytic. The process starts with the preanalytic phase, involving steps that occur before the patient's sample arrives at the laboratory. A few examples of preanalytic steps are test ordering, patient identification, specimen collection, specimen transportation, and specimen preparation. The analytic phase involves the manual or automated testing of the patient sample. The postanalytic phase includes test interpretation and reporting.

Medical errors are not uncommon: they affect approximately 10% of all hospitalized patients and result in significant morbidity and mortality. Because medicine is not practiced in a vacuum, medical errors that occur can affect all phases of the TTP. A 2009 analysis of medical errors showed that the analytic phase had the lowest frequency of errors, 13.3% to 15%.2 In comparison, the frequency of errors was 61.9% to 68.2% in the preanalytic phase and 19.8% to 23.1% in the postanalytic phase.2 As demonstrated by the frequency of errors in the analytic phase, errors originating in the laboratory are relatively uncommon.

Laboratory medicine has a long-standing history of commitment to the reduction of medical errors and the improvement of patient safety, beginning with the institution of proficiency testing by the American Society of Clinical Pathologists (ASCP) in 1946.3 To ensure patient safety, many quality tools are currently used in medical laboratories nationally. Quality tools are varied and must be chosen appropriately.

Quality Tools

Quality improvement (QI) in health care organizations begins with analyzing the breakdown in the process that resulted in a patient safety issue. A QI process sets the foundation for understanding the gaps in the system and helps to ensure a successful process change. The steps undertaken in a QI process include identifying the customer, understanding the current state of the system, identifying gaps in the system, proposing new solutions to address the gaps, changing the process, and analyzing and learning from the process.4 The QI review involves quality tools such as root cause analysis (RCA) and failure mode and effects analysis (FMEA).
Root Cause Analysis

Root cause analysis was adapted from the manufacturing industry for the health care industry. An RCA retrospectively reviews the process that resulted in a patient safety event to identify contributory factors or gaps that led to the event. The focus of an RCA is on the system and not the individuals who may have caused the errors.

An RCA is frequently presented as a narrative. However, a few diagrammatic tools such as the Ishikawa diagram and the scatter diagram are also used. An Ishikawa diagram, also known as a fishbone diagram, visually categorizes the root causes for a process error into groups. The diagram may be used during a brainstorming session to generate ideas for each category, depicted as a large branch. Each causative factor is listed as a smaller branch on the main one. An example of a standard fishbone diagram is seen in Figure 1. There are also several variations, such as 1) the time-delay fishbone, which enables more people to provide input by placing the diagram in a high-traffic area; 2) the process fishbone, which diagrams only main process errors; and 3) the reverse fishbone, where participants brainstorm a proposed solution to the problem rather than its possible causes.

![Ishikawa Diagram](image)

Figure 1. Ishikawa diagram.

A scatter diagram analyzes the relationship between numerical data pairs. If there is a relationship, the data points will fall along a curve or line, with a stronger relationship seen as points hugging the curve. A scatter diagram is constructed by gathering the paired data, drawing a graph with horizontal (x) and vertical (y) axes, placing one point for each data pair, and determining whether the data fall into a line or curve. If a line or curve exists, there is a relationship. However, one must be careful in analyzing, as the
relationship might not be a causal relationship but might be a result of an unrelated third factor. An example of a scatter diagram is seen in Figure 2.

![Figure 2. Scatter diagram.](image)

Using an RCA has the advantage of identifying the underlying causes, indirectly contributing risk factors, and human performance that led to a patient safety event. The disadvantage is that important details may be omitted because the narrative is subjective.

**Failure Mode and Effects Analysis**

Failure mode and effects analysis (FMEA), which was developed by the United States military, identifies failures in a system’s processes. The goal of an FMEA is to eliminate the identified failures by prioritizing their severity. It requires a multidisciplinary team and uses the following steps:

1. Use flowcharts to understand processes, identify functions and customers.
2. Identify potential failures in each step.
3. Determine each failure severity (S) on a scale from 1 (insignificant) to 10 (catastrophic).
4. Determine the occurrence (O) rating, the probability of each potential failure to occur, also rated on a scale from 1 to 10.
5. Determine the detection (D) rating, which identifies causes that might harm the patient. This rating is also scored on a scale from 1 to 10.
6. Calculate the risk priority number (RPN) by using the formula: RPN = S × O × D.
7. Address the potential failures in the order determined by the risk priority number.
Flowcharts, Pareto diagrams, and fault trees may be used to illustrate an FMEA. Flowcharts show the sequential steps of a process, which helps to determine potential failures in each step. A Pareto diagram highlights the significant step as the longest bar on the left of a bar graph. A fault tree analysis, depicted as a tree trunk, identifies changes that reduce the likelihood of failure. Examples of a flowchart, Pareto diagram, and fault tree analysis are seen in Figures 3, 4, and 5, respectively.

**Figure 3.** Flowchart.

**Figure 4.** Pareto diagram.
The advantage of an FMEA is identification of high-risk processes that need to be changed. The disadvantage is that conducting an FMEA is time-consuming.

Conclusion

The provision of safe patient care requires understanding the processes in a system where mistakes can occur. The OR labeling case was investigated using an RCA. The root cause leading to this error was preprinted labels left in the OR. The incorrect patient label was affixed to the blood bank transfusion requisition form leading to an incorrect crossmatch and selection of packed red blood cells. Because compatible red blood cells were chosen, no patient was harmed. However, the RCA led to removal of preprinted OR labels and re-education of all staff of the pretransfusion circle, ensuring that all processes from labeling of patient samples to the transfusion of blood products are done properly. Health care, including laboratory medicine, has borrowed and adapted QI tools from industries such as manufacturing, shipping, and aeronautics to reduce patient safety events. The laboratory has a long history of developing initiatives and processes to improve quality and patient safety, from the creation of proficiency testing by ASCP, to regulations such as the Clinical Laboratory Improvement Amendments (CLIA) of 1988, and beyond. By employing QI tools such as RCA and FMEA and the TTP to improve various steps
of the laboratory process, laboratory medicine continues to remain at the forefront of advancing patient safety.

References


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