

Use of failure mode and effects analysis for proactive identification of communication and handoff failures from organ procurement to transplantation

A multidisciplinary team from the University of Wisconsin Hospital and Clinics transplant program used failure mode and effects analysis to proactively examine opportunities for communication and handoff failures across the continuum of care from organ procurement to transplantation. The team performed a modified failure mode and effects analysis that isolated the multiple linked, serial, and complex information exchanges occurring during the transplantation of one solid organ. Failure mode and effects analysis proved effective for engaging a diverse group of persons who had an investment in the outcome in analysis and discussion of opportunities to improve the system's resilience for avoiding errors during a time-pressured and complex process. (*Progress in Transplantation*. 2009;19:208-215)

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Notice to CE enrollees:

A closed-book, multiple-choice examination after this article tests your ability to accomplish the following objectives:

1. Discuss the complexity of system errors and the role of hidden or "latent" conditions that produce errors
2. Articulate the purpose of proactive risk assessment
3. Describe the process of performing a structured analysis using the Failure Mode and Effects Analysis (FMEA) method
4. Determine 3 ways that FMEA can be an effective and flexible tool for analyzing and improving transplant processes across the continuum of care

A conservative estimate is that at least 48 handoffs of significant information involving a minimum of 20 clinicians, staff, and family members occur in the continuum from organ procurement to transplantation care during the placement of 1 solid organ. Despite a multitude of safety checks and verification mechanisms,

errors do occur and the associated costs are significant. At a minimum, delays ensue and expensive resources (personnel time, operating room services) are wasted. More serious outcomes include donor organs compromised as a result of prolonged cold ischemia time or life-threatening donor-recipient mismatches. Communication and handoff problems are not uncommon in health care. The Joint Commission reports, "Inadequate communication between care providers or between care providers and patients/families is consistently the main root cause of sentinel events." Furthermore, they report that 75% of these communication-based events lead to death.¹

The prevalence of communication failures in health care results not only from the sheer volume of information exchanged but also from the many ways that communication channels can be disrupted and information mishandled. Although a lack of information may result in errors from uninformed actions, the problem in today's data-rich, technological environments becomes one of having too much information. The burden then becomes sifting through the less-critical,

irrelevant, or bloated information to find—and then interpret—relevant information, generally while within a time-pressured context. The resulting “cognitive overload” adversely affects decision making and distorts situational awareness.²

One study of decision support and information systems cites examples of adverse outcomes associated with information mismanagement.³ In one case, it was shown that adverse events increase significantly during periods of physician cross-coverage. Another example cites critical laboratory values that, although promptly reported in an information system, are overlooked because of the large volume of normal and less critical values.

Leonard et al⁴ suggest that the training and communication styles of nurses and physicians are fundamentally different, and the differences contribute to miscommunication. It is common for nurses, for example, to provide broad, narrative descriptions when consulting physicians. Conversely, physicians, looking for diagnostic cues, want them to “get to the point”; that is, provide only factual highlights concerning what they view to be the situation at hand. By definition, communication involves multiple participants, and it is rare for 1 person or factor to lead to a communication breakdown. Typically a series of hidden, or “latent,” flaws in the system interact to produce a failure.⁵ Unfortunately, the recipient of the failure may be a well-intentioned clinician or patient.

After experiencing 2 unrelated adverse events within a year, the Quality Resources Department at the University of Wisconsin Hospital and Clinics determined that the logistical complexities and time pressures associated with organ transplantation created a high-risk work flow and was worthy of additional analysis. Consequently, we launched a prospective risk analysis that used the Failure Mode and Effects Analysis (FMEA) method. Root cause analyses were conducted after each patient event to identify the contributing factors, to isolate primary causes, and to act to reduce future risk.⁶

Both root cause analysis and FMEA are useful tools in efforts to better understand complex systems and to cultivate high reliability within organizations. FMEA is a process historically used in manufacturing settings and is often employed in high-risk industries such as aerospace and the military. The FMEA framework was developed by the military in 1949 and is described as follows:

Military Procedure MIL-P-1629, titled Procedures for Performing a Failure Mode, Effects and Criticality Analysis, was used as a reliability evaluation technique to determine the effect of system and equipment failures. Failures were classified according to

their impact on mission success and personnel/equipment safety.⁷

Clinicians, however, have voiced concern over the use of FMEA in clinical situations. “Our patients are not machines!” is the mantra. Although it is true that the complexity of health care is unlike that of any other industry, FMEA has been successfully applied to clinical situations before the introduction of new clinical devices.⁸

FMEA methods were imported to health care from other industries by leaders in patient safety, including the National Center for Patient Safety of the Veterans’ Affairs.⁹ Their modification of the tool for health care accommodated scoring to better differentiate risk of patient injury when a health care process fails. By incorporating a requirement in the leadership standards of the 2002 edition of the Comprehensive Accreditation Manual for Hospitals, the Joint Commission provided a catalyst for the spread of this tool, challenging health care providers to identify vulnerabilities in their core processes for health care delivery. The Joint Commission requires that health care organizations apply this method to at least 1 process annually.¹⁰

The organ procurement and transplant programs had many reasons to engage in this self-analysis. As previously mentioned, the process from organ procurement to transplantation was known to be a complex, time-pressured activity; however, the full process had not previously been mapped in detail. Furthermore, the program had experienced various occurrences and breakdowns in process in recent years. The most serious event resulted in a donor not being properly identified as an extended-criteria donor (ECD) and subsequently an ECD kidney was transplanted into a non-ECD consenting recipient. Communication failures were a key component of this incident. Analysis of this process was endorsed by leaders at the University of Wisconsin Hospital and Clinics, which had recently redesigned its quality and safety structure in an effort to improve accountability, foster a culture of safety, and use more data-driven improvement methods to become a more transparent and adaptive learning organization.

Objective

The FMEA process is a prospective risk analysis method that capitalizes on the knowledge and experience of front-line clinicians to identify ways in which processes may potentially fail and enact plans to make processes more resilient. The traditional FMEA method can be very time-consuming and resource intensive. The scope is usually limited and focused on a narrow part of a complex process.

Because this initiative focused on the entire continuum of the organ donation and transplant process, the scope was narrowed by examining a common feature

across the entire process, specifically, communications and handoffs among clinicians. The success of the organ donation process is dependent upon these interactions, which occur under severe time constraints. This analysis identified the processes that were at highest risk for miscommunication or misidentification of critical information.

Methods/Participants

Professionals representing the key groups of the organ procurement organization and transplant center who had a stake in the process participated in this project. The team included the director of the transplant service line, the senior vice president of quality and information, managers of the abdominal and cardiothoracic transplant programs, operating room staff, the organ procurement clinical manager, the recovery specialist, quality improvement analysts, and staff from risk management. Both managers of the abdominal and cardiothoracic programs were practicing transplant coordinators who regularly took clinical call and were very familiar with the organ placement process. Transplant physicians were invited to participate but were unable to attend because of scheduling conflicts.

The FMEA was completed in 4 meetings over the course of 4 months. Before the first meeting, individuals from each key area constructed a high-level process map representing the core steps in the organ procurement and transplantation process. This map begins at the time a designated requestor identifies a potential organ donor and initiates a call to the donor referral answering service. A mapping tool known as a swim-lane diagram allowed the team to visually represent not only the sequence when key constituents became engaged in the process (organ procurement coordinator, procurement team, transplant surgeon, transplant coordinator, tissue typing laboratory, potential recipient, etc) but also illustrates which information was critical to completion of that step in the process (ABO, donor characteristics, recipient status, etc). Subsequent iterations of this mapping process yielded more detail and provided a valuable opportunity for team members to learn more about each other's roles and responsibilities during the entire process. The final process map offered enough detail to facilitate discussion yet did not devolve into such fine granularity as to become unwieldy (Figure 1).

In the first face-to-face meeting, the team applied the FMEA framework to key points of handoff communication. This process took 4 hours to complete and was facilitated by the senior vice president of quality and information and members of the Quality Resources Department. The group facilitator led the team through a process to answer the questions: What could go wrong with each step? What would be the consequence? What are the potential causes of this failure?

What steps are already in place to mitigate and prevent the failure from occurring? Through iterative discussion, severity, occurrence, and detection scores were assigned to each failure mode and a risk priority number was then calculated by multiplying these scores for each item. All risk priority numbers were ranked at the completion of the exercise.

In the second in-person meeting, the team continued the scoring, validated the issues identified by the analysis, prioritized the issues, developed a work plan, and identified accountabilities for follow-up. In the final phase of this project, communication occurred via e-mail to ensure that results were being generated on the work plan.

Ultimately, the FMEA process was applied to 48 elements of handoff communication (Table 1). Upon completion, the highest scoring items allowed the team to prioritize the failure modes into a work plan (Figure 2).

Before launching the work plan, team members presented their findings to hospital leaders, who endorsed the plan within the structure of the hospital's newly formed Safety, Satisfaction, and Performance Improvement Committee. The multidisciplinary nature of that committee offers a forum for discussion across departments and clinical service areas and serves to critically evaluate the investment of hospital resources necessary for improvement work.

Outcomes

Of the 48 points of handoff communication analyzed, the risk priority numbers ranged from 2 to 300. Five items had the highest risk priority numbers (range, 270-300) and 2 additional areas had scores of 150 and 180. These 7 items represented the initial work plan for the team. The group discussed the highest scoring items and validated them against known practice issues. The work plan (Table 2) lists some of the types of issues prioritized by the team.

To ensure that important and long lasting changes were instituted, the group determined that it was important to document and communicate the specific characteristics of this unique work process. Consequently, the team identified several important human factors and workload considerations: cognitive load, fatigue, and time demands/production pressure.

Cognitive Load

Up to 8 organs per donor may be in the allocation process at any one time. This process may involve multiple coordinators working with different recipients and their families. The coordinators may also be working on multiple donors at the same time, which leads to exponentially demanding coordination duties. On-call coordinators typically used their own systems for tracking the status of organ placement. This included a

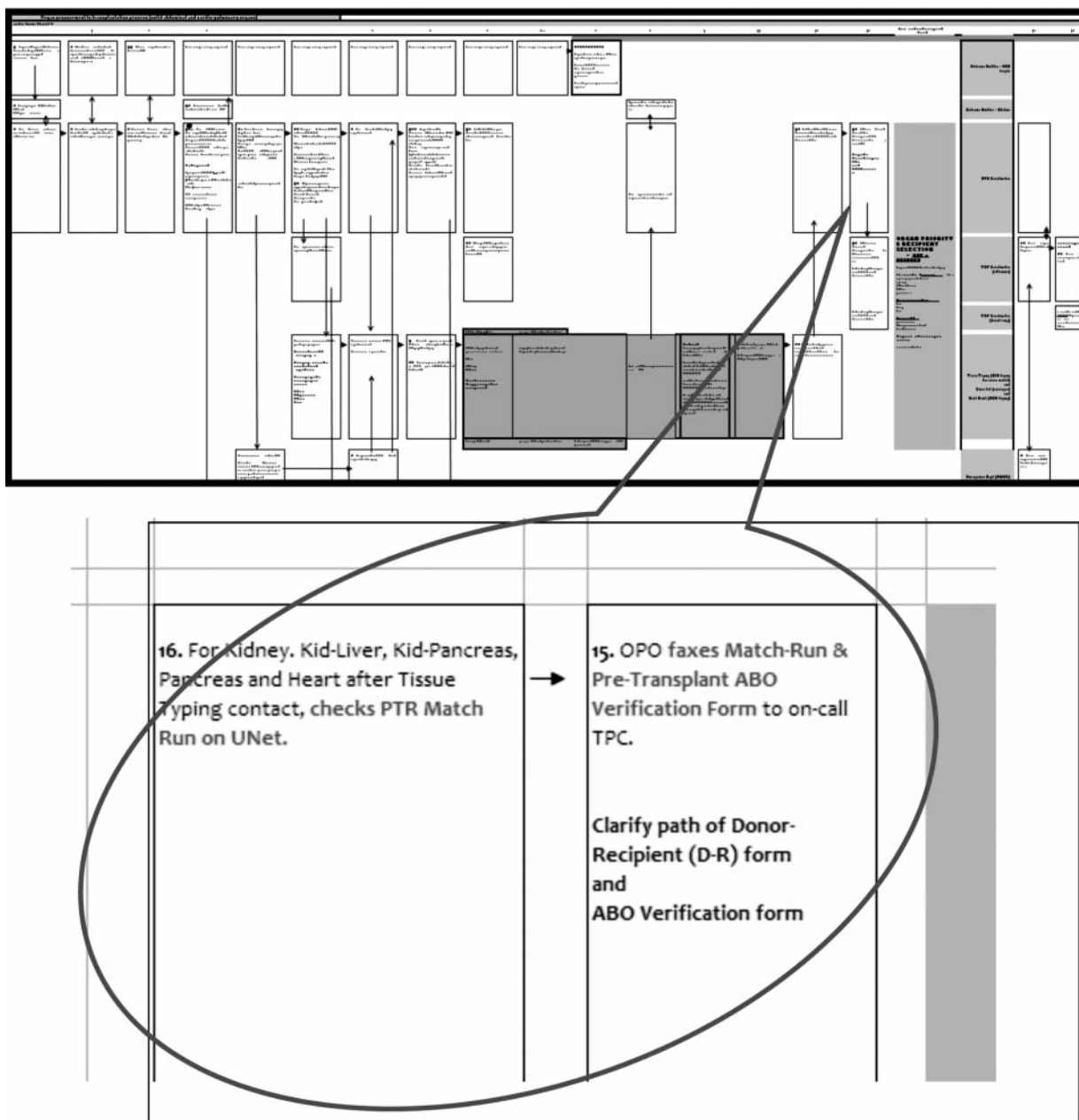


Figure 1 Excerpt of process map: organ procurement to transplantation.

variety of notes and flow sheets and a reliance on memory. One strategy to ease the mental burden and make the process more reliable involved instituting a structured “organ map” to serve as a standardized checklist for transplant coordinators to track the status of specific donor-recipient matches. A group of transplant coordinators evaluated the existing ad hoc tracking systems and designed a standard format and procedure.

Fatigue

Organ procurement and transplant coordinators commonly work during “off hours” when there are

fewer personnel and resources available. The work of organ placement does not stop until the organs are transplanted, which often leads to physical and mental fatigue. To address this problem, the organ procurement coordinators reevaluated their second-call policy and found that the team needed reeducation about the policy.

Time Demands/Production Pressure

Implicit and explicit time demands are involved in the entire process from procurement to transplantation. The unspoken rule of thumb is as follows: the

Table 1 Handoff communication elements identified in failure mode and effects analysis

Area	No. of items analyzed
Communication between organ procurement organization and referral agency about a potential donor	3
Obtaining donor blood sample for infectious disease testing and tissue typing	6
Registering the donor information	6
Obtaining the anatomical gift consent form	4
Establishing donor management orders and case coordination	5
Preparation of donor chart	2
Double verification of donor blood type	1
Verification of donor information by transplant coordinator	4
Recipient selection and preparation for transplant	8
Verification of recipient blood type	3
Verification of donor information by organ recovery team	1
Organ and specimen labeling	4
Organ and recipient verifications before transplant surgery (ie, operating room time-out procedure)	1
Total	48

quicker the turnaround time, the better the outcome of transplanted organs. An inherent risk of a high-velocity environment is that important details will be missed or shortcuts will be taken. Several documentation activities along the transplantation continuum were deemed to be vulnerable and were addressed in the action plan. These included an evaluation of the preoperative documentation by our surgical team and the donor-recipient form, which serves as a handoff tool between the procurement and transplant coordinators and the inpatient unit nurses.

In addition to generating the list of specific, actionable items for process improvement, the team recognized additional benefits as a result of participating in the FMEA process. First, this process analysis was one of the most comprehensive ones that the transplant team had undertaken in many years. It was also the first time that clinicians from all phases of the transplant continuum were sitting face to face in the same room. This process also served as a team-building function and enabled the staff to clarify others' roles and responsibilities, thus leading to a new shared understanding. The "busy-ness" and criticality of transplant work does not afford staff many opportunities to address cross-disciplinary issues and to build common ground.

Discussion

This FMEA tool offered a number of beneficial results that reinforced its utility and enhanced our organization's willingness to use it for other processes. The FMEA allowed the organization to critically evaluate procurement and transplant-related processes, eliminate redundancies in documentation, and streamline and enhance handoffs across settings and services. The outcome of the FMEA resulted in numerous changes to work processes and procedures, which we believe enhanced the reliability, efficiency, and safety of our services.

During the team debriefing, we asked participants to describe their perception of the FMEA activity. Participants commented that although they all work in segments of the transplant process together, the FMEA activity had been a rare event in which all "the players" were in one room at the same time, thoughtfully evaluating how they interact.

Some structural considerations contributed to the effectiveness of our collective work. For example, during the meetings we used a paper checklist that served both to guide work steps and to document completion. By visually flowing out the process, we more easily uncovered issues and branches of the work flow that were problematic or inefficient. The use of a multidisciplinary group was an effective way to identify the vulnerable points in the work flow and gain reasonable confidence that we had made the scope of the project broad enough to fully identify the inherent risks. The group members shared the assignment of hazard, prevention, and detection scores and were involved in developing the action plan. The process facilitators worked very hard outside of the group meetings to ensure that documents and agenda were well organized in order to make the best use of the collective group time. The hazard analysis, when followed meticulously step by step, is necessarily tedious and time-consuming. An interested and invested group membership ultimately makes the process more thoughtful and effective. Previous teams that comprised only some of the process owners have been met with skepticism and resistance.

Subsequent to and in no small part because of the perceived benefit, University of Wisconsin Hospital and Clinics has used the FMEA in other important processes, including most recently the implementation of new electronic health record modules for medication management, integrated emergency department documentation, clinical documentation of patient care, and computerized entry of physicians' orders. The organization continues to find value in the deployment of the FMEA tool for improving important patient care and operational processes and enhancing patient safety.

Because the organ procurement organization at University of Wisconsin Hospital and Clinics is

Item/Function [refer to flowchart - each step is numbered]	Potential Failure Modes "How can this step go wrong?"	Potential Effects / Consequences of Failure "What happens when it fails in this way?"	Potential Causes/Mechanisms of Failure	Detection	SEVERITY	OCCURRENCE	DETECTION	RPN
12b donor form	data entry problems	wrong - organ	human error					
	may upload wrong info to UNOS	wrong match	fatigue	downstream	8	5	7	280
		wrong match run/donor size	incorrect interpretation of available info	catch	8	5	7	280
39a labeling of spleen, lymph, blood	mislabelled sample - blood inappropriate label	reject, not recoverable; can not	human error, fatigue,	lab or Blood bank examines specimen	2	2	1	4
	wrong tissue		hard to find tissue technical		2	2	1	4
	auto-generated labels (from UW systems) come from un-verified db fields		system lacks verification.forcing function		10	10	3	300

Figure 2 Excerpt of scoring grid used in failure mode and effects analysis.

Table 2 FMEA action items

Process step	Item	Issue	Action
12b	Organ donor form in chart	Accuracy of data entry	Identify key elements and frequency of quality audits and devise a plan for random audits of charts as well as how the plan will be implemented.
17	Donor/recipient form (s)	Concern about confusion when coordinators are working on multiple donors, assigning organs to multiple recipients	Develop a CHECKLIST and ORGAN MAP to be used by abdominal transplant coordinators. Previously, a similar method was used that allowed the coordinators to track which recipient was assigned each organ. The program manager will bring these documents to the larger coordinator group for input and validation. Ongoing evaluation of the design and utility of these tools. Report after 1 year of use.
23	Kidney/pancreas pre-selection of recipients before match run completed—clarify what data is available for transplant coordinators	Time gap between when transplant coordinator is asked by transplant surgeon to identify a potential recipient and when the match run is ready for review	Tissue typing department has reported the match-run list is available for coordinators to use approximately 2 hours in advance of the full cross-match list. Manager to educate on-call transplant coordinators about the availability of the list to facilitate recipient selection.
23	Kidney/pancreas pre-selection of recipients before match run completed—create decision support tools	Use of computer queries in transplant database may make preselection of organ recipients more reliable	Currently a “hot list” is pulled for liver and pancreas recipients, which makes it easier for coordinators to address surgeon’s questions (previous surgeries, body mass index, etc) Preselecting kidney recipients is more difficult because the list is much longer. A database query tool can help coordinators start selecting recipients. Program manager will design an in-service training session for on-call coordinators to learn about using this tool.
39a	Specimen labeling—organ procurement organization	Known, ongoing issue	Plan-Do-Study-Act in progress with organ procurement organization and University of Wisconsin Laboratory, with 2 changes being tested: (1) at hospitals in donor service area—improved guidance (verbal and written) given to staff about elements of obtaining and labeling specimens; (2) Information technology programming change to require double-verification of key identifiers by staff from organ procurement organization.
36	Operating room check of 3 signatures on organ verification form	Missing signatures or documentation of organ verification	Per group discussion, to be handled on a case-by-case basis. Operating room staff should promptly report these occurrences to the administrative program director. Consider use of Patient Safety Net to report these. Relates to surgeons’ requirement to lead a preoperative time-out.

hospital-based and part of the university, its staff members have access to the expertise of staff members in the Quality Resources Department who are trained in conducting FMEAs and root-cause analyses. As the vast majority of organ procurement organizations are independent organizations, they would benefit from training a quality manager or other staff members in FMEA methods. By identifying and mitigating potential risks, the hospital supports the delivery of safe, quality care to donors and recipients and increases the efficiency and effectiveness of the team members involved in the complex cycle from procurement to transplant.

Acknowledgments

Additional members of the FMEA team were Dave Lorentzen, Sara O'Loughlin, Linda Coughlin, Matt Bock, Jan Haedt, Jeff Fenne, Tracey Kaltenberg, Mike Armbrust, Mary Francois, and Linda Sauer.

Financial Disclosures

None reported.

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CE Test Test ID 4000.125: Use of failure mode and effects analysis for proactive identification of communication and handoff failures from organ procurement to transplantation. Learning objectives: 1. Discuss the complexity of system errors and the role of hidden or "latent" conditions that produce errors 2. Articulate the purpose of proactive risk assessment 3. Describe the process of performing a structured analysis using the Failure Mode and Effects Analysis (FMEA) method 4. Determine 3 ways that FMEA can be an effective and flexible tool for analyzing and improving transplant processes across the continuum of care

1. Which of the following is the method used during Failure Mode and Effects Analysis (FMEA) to analyze and rank threats associated with potential problems?

- a. Ranking priority numeral
- b. Risk assessment tool
- c. Risk priority number
- d. Ranking assessment tool

2. Which of the following statements reflects the correct definition of FMEA?

- a. A technique that focuses on retrospective analysis of historical events
- b. A technique that prospectively attempts to predict areas of vulnerability and risk within a process
- c. A technique that assesses data outcomes to determine quality of a program
- d. A system for evaluating a causal relationship between an identified problem and all possible causes of the problem

3. Which organization requires hospitals to proactively analyze at least one process every year?

- a. Centers for Medicare and Medicaid
- b. National Center for Patient Safety
- c. United Network for Organ Sharing
- d. The Joint Commission

4. This article describes one organization's application of FMEA to what process?

- a. Communication across the transplant continuum of care
- b. ABO verification and documentation
- c. Recipient selection for kidney transplant
- d. Coordination of the procurement team

5. Which statement best describes the selection of the FMEA team members?

- a. The FMEA team should be limited to no more than 4 people to minimize disruption of processes.
- b. The FMEA team should include "front-line" representatives of each part of the processes under analysis.
- c. The process will last 1 year and consist of bi-weekly meetings.
- d. The FMEA team is more efficient when managers can attend and speak about their employees' processes.

6. Which of the following human factors was identified as a possible risk factor in the analysis presented in this article?

- a. Team communication and stress levels
- b. Fatigue and time demands
- c. Experience of coordinators and surgeons
- d. The number of organs being offered and communication with transplant centers receiving the organs

7. Which of the following has been identified by The Joint Commission as a consistent root cause of sentinel events occurring in hospitals?

- a. Lack of documentation of ABO on admission
- b. Poor hand washing techniques in the operating room
- c. Inadequate communication between health care providers
- d. Inexperienced clinicians caring for complex patient populations

8. During the organ procurement to transplant process how many communication handoffs were identified and analyzed during the placement of one organ?

- a. 8
- b. 22
- c. 270
- d. 48

9. The FMEA process identified which of the following beneficial outcomes?

- a. Roles and responsibilities were clarified.
- b. Redundancies were eliminated in the processes from procurement to transplant.
- c. Handoffs were streamlined across the clinical settings.
- d. All the above

10. A process map of the core steps in the handoffs during organ procurement to transplantation helped to identify which of the following?

- a. Sequence of handoffs
- b. Roles of various members of the multidisciplinary team
- c. Critical information required to complete each step
- d. All the above

Test answers: Mark only one box for your answer to each question. You may photocopy this form.

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Objective 4 was met	<input type="checkbox"/>	<input type="checkbox"/>
Content was relevant to my nursing practice	<input type="checkbox"/>	<input type="checkbox"/>
My expectations were met	<input type="checkbox"/>	<input type="checkbox"/>
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