CT Healthcare Failure Mode Effect Analysis (HFMEA®): The Misadministration of IV Contrast in Outpatients

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What Is an HFMEA®?
An HFMEA® is a proactive risk assessment of a high-risk or high-vulnerability area and has been widely used in the healthcare environment (HFMEA® is a registered trademark of Medical Risk Management Associates, LLC). It identifies and improves steps in a process, thereby reasonably ensuring a safe and clinically desirable outcome. An HFMEA® is a tool used to identify the effects or consequences of a potential product or process failure. It generates a living document that can be used to anticipate and prevent a potential failure from occurring. An HFMEA® process is most effective before a design is released or a new process begun; however, the process is relevant and beneficial when applied to current operations. The focus is on failure prevention, not detection.
This is a valuable tool in strengthening quality of care. It can improve workflow processes and performance management. The HFMEA® can also increase education and communication among department team members and minimize late changes and associated costs. It can create a preventative problem solving culture and facilitate continuous quality management.

**Keys to a Successful HFMEA®**

- Ensure the HFMEA® team represents all levels of operational staff (ie, front line, technical, and radiologist).
- Be sure to establish team member roles and responsibilities.
- Set realistic timelines and expectations.
- Be open to all brainstorming ideas.
- Be careful not to turn to quick solutions before identifying the root causes.
- Test the “before” and “after” process flows.

**Steps for an HFMEA®**

- Define the topic
- Define the process flow
- Define the failure modes
- Conduct the hazard analysis
- Determine failure causes
- Define actions and measures
- Process improvement recommendations
- Refine process flow to include actions
- Produce final product

**Background**

The MGH CT department, which includes the Main Campus (inpatients, outpatients, and emergency room patients) and the Yawkey Center (outpatients only) performs a high volume of CT exams daily. On average, 330 exams are completed each day. Of those, approximately 60% are outpatient exams. Approximately 40% of the outpatient population is injected with IV contrast for their CT exams. Because of the high volume, it is often difficult to obtain outside patient laboratory results and previous patient information. The possibility exists, therefore, that IV contrast is injected into the wrong patient or a patient who is allergic. The system that was in place before the HFMEA® was one where a breakdown in communication could occur and the patient could have been potentially injected with IV contrast when they should not have been. The goal of the HFMEA® was to prevent the misadministration of IV contrast in outpatients in the CT department. To achieve 100% compliance in quality patient care, we needed the right patient, right exam, and right drug for the outpatients in the CT department. All CT departments require lab results for the injection of IV contrast. The difficulty is always obtaining the results. For MGH, in particular, the volume of patients seen makes this process difficult and most of the patients are referred so it is very time consuming to call out of state to obtain lab results.

The CT HFMEA® team discussed operational occurrences that would disrupt the quality of care for MGH outpatients and errors which had the potential for causing significant damage. The misadministration of IV contrast in patients could lead to severe consequences. There are several reasons not to inject a patient with IV contrast, which include, but are not limited to: restriction of iodine intake, renal insufficiency, and prior allergies to IV contrast.

**Failure Points**

The following failure points related to the potential of major and minor medical healthcare errors impacting patient safety. They often caused patient delays, cancellation of exams, and could also result in inadequate exams performed. The team identified 7 categories of potential failure points.

1. **Ordering the Scan (Referring Practices)**
   - Incorrect data input by referring physician, secretary, or nurse practitioner.
   - Referring physician does not specify if IV contrast needed.
   - No recent bloodwork input on Radiology Order Entry (ROE). (There is a line on the order entry screen to enter the lab information, but it is not a mandatory field.)

2. **Reviewing Scheduled Appointments and Assigning Protocols (Radiologists)**
   - Previous patient history and pertinent information (eg, contrast allergy) not always available, not checked, or not immediately visible.
   - Radiologist assigning protocol is not same radiologist reading the exam.
3. Reviewing Contrast Questionnaire (Non-English Speaking Patients)

- Patient does not speak English and no interpreter is available.
- Patient and/or interpreter are not informed about the procedure and, thus, do not understand the questionnaire.

4. Contacting the Radiologist

- Designated radiologist may not be available. The radiologist who protocols the exam is not the radiologist who reads the exam and may not be available the day the exam is done.

5. Scheduler Error

- Lack of information from the referring physician’s office.
- ROE indications are checked off for both contrast and non contrast administration.
- Radiology Service Representative (RSR) error (ie, RSR inadvertently schedules an abdominal/pelvis as a chest).

6. Bloodwork Results

- Current records are unclear or unreadable when faxed or written and may not have the date of labs drawn.
- Differing standards on acceptable bloodwork by division.
- Difficulty obtaining previous results from outside labs.
- Change in patient history does not trigger request for new bloodwork. No new results available.

7. Technologists/Nurse Error

- Floor tech (the tech that is responsible for all the information being available on the tracking form before the patient can go into the scan room) and nurse do not properly review the tracking form for lab results, history, and correct protocol.
- Floor tech and nurse do not properly verify patient information on the contrast questionnaire form.
- Scanning tech does not properly review the tracking form for the following information: lab results, correct protocol, and contrast questionnaire form.

A hazard analysis rating was performed for each failure point and potential causes and solutions were identified. A hazard analysis is a multi-step evaluation of each potential failure point. The team rated the failure points as to the severity and probability of the occurrence. The severity was based on how harmful the failure point would be to the patient or how harmful it would be to the process. The severity rating is listed on a scale from 1–4, with 1 being no harm to the patient or the process and 4 being severely harmful to the patient or the process. Probability is how frequently the failure point occurs. This is given the same rating of 1–4, with 1 being that it rarely happens and 4 being that it happens up to 2 or more times a day. The higher hazard scores would indicate which failure point was in need of immediate attention and where the resources should first be directed. See Tables 1 and 2.
After the hazard score was determined for each failure point, a decision tree analysis was performed to determine which failure points to address. A decision tree analysis indicates whether or not action should be taken on a failure point. The decision tree analysis consisted of 2 parts: single point weakness and detectability. The single point weakness refers to a failure point that has only 1 point of contact or observation and there is no other back up system in place to counter the failure point. The detectability refers to the fact that the failure point is obvious and readily observed.

The team discussions throughout the outpatient flow chart process (see Figure 1), hazard scoring analysis, and process improvement recommendations uncovered 2 common denominators linking all the failure points: lack of education and lack of effective communication. The CT HFMEA® team decided to focus on a systems management approach to solving these problem areas and recommended potential solutions. The recommendations required the collaboration of different hospital departments, managerial leadership, clinical leadership, and interdependent systems. A methodology was initiated that examined both process and people improvements.

The next section briefly describes the lack of education and the lack of effective communication in some of the failure points we chose.

### Lack of Education

**Referring Physician’s Offices.** Secretaries are not trained or educated in the difference between oral contrast and IV contrast. And referring physicians are not knowledgeable regarding the policy for BUN/creatinine results needed for patients who require IV contrast.

**Interpreter Services.** Often an interpreter does not understand the procedure the patient is undergoing and the use of IV contrast. Secondly, the interpreter may not understand the reaction and the potential severity of a misadministration.

**Radiology Service Representatives (RSR).** The RSR is responsible for the scheduling of CT exams and working in the different modalities to greet patients, get them into the Radiology Information System (RIS), and have them fill out appropriate forms. An initial competency assessment was currently in place for RSRs; however, there was a need to continuously assess their competency. Maintain RSR training initiatives and expand training opportunities due to new hires and job rotations.

### Lack of Effective Communication

**CT Department Staff.** The lack of communication and inability to trust staff involved in the hand-off of patient information could lead to the misadministration of IV contrast. The high volume and fast pace in CT could also lead to the misadministration of IV contrast, as staff could inadvertently miss patient information critical to the reason for not injecting IV contrast.

**Referring Physicians.** Ineffective communication between referring physicians and the radiologists who assign the exam protocol. The referring physicians use an order entry computer system to schedule their exams, so they do not send a written order with the patient. The radiologist protocols the CT exam the night before the patient’s exam and the requesting physicians are not available to speak with at this time which could lead to potential problems in determining whether or not to inject IV contrast.

**Documentation and Data Transmittal.** Incomplete and inaccurate information due to gaps in the computer order entry system that the requesting physicians use to order radiology exams and the conversion of this data into our RIS. This information is toggled over by a process that could leave out vital information in the patient’s history.

### Process Improvement Recommendations

The next step in the HFMEA® was to recommend process improvements for the failure points. The team developed short and long term solutions to address the most vulnerable
Figure 1. The outpatient process flow. This shows the complexity of the decision process that is followed each time a patient is ordered for a CT exam with IV contrast.

areas of weakness in the problem identification process. Several recommended solutions were even piloted within the CT department in order to validate that they were, indeed, workable solutions. Below are recommendations for some, not all, of the failure points previously listed.

Ordering the Scan and Reviewing Scheduled Appointments

The HFMEA® team identified several approaches to minimizing the effect of incorrect information on the front end of the ordering and scheduling process. An education
program was developed specific to each user group (ie, referring physician practices and internal RSRs).

**Referring Physician Practices.** The radiology marketing department had several meetings with the CT department leaders to improve the educational materials explaining the requirements for a CT exam. Updated information was created, reviewed, and presented to the referring physicians and their respective staff.

This renewed effort by the radiology marketing department, in partnership with the CT department leadership, has produced a more systemic, recurring education and training plan targeted to the referring practices. The increase of practices utilizing ROE for ordering the CT scans requires training specific to CT department needs, policies, and procedures.

**RSR Training.** The education program focused on training RSRs to interpret whether a CT scan does or does not require IV contrast. Again, the influx of new hires into the RSR role added to the challenge of consistent procedure adherence. In addition, not all RSRs who were schedulers were required to schedule CT exams and some RSRs may not routinely schedule the CT exams due to job rotations.

The CT HFMEA® team already piloted an educational focus group with RSRs at a staff meeting to learn more about the RSRs baseline knowledge in regards to the administration of IV contrast in CT exams. The purpose was to determine gaps in their knowledge and provide a context for implementing improved standard operating procedures for RSRs performing the scheduling task for CT exams.

A specific area of training highlighted during that pilot educational focus group was the information delivered to RSRs about the importance of "scheduling CT exams with the ampersand." The ampersand symbol (&) denotes whether the CT exam requested was to be performed with or without IV contrast. The default for ordering a CT exam is with and without IV contrast. The reason CT exams are ordered with IV contrast. The reason CT exams are ordered with IV contrast. The reason CT exams are ordered with IV contrast. Again, the influx of new hires into the RSR role has produced a more systemic, recurring education and training plan targeted to the referring practices. The increase of practices utilizing ROE for ordering the CT scans requires training specific to CT department needs, policies, and procedures.

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The CT HFMEA® team recommended:

1. **Setting aside a designated time for radiologists to review protocols during the day when it would be better to reach physicians (eg, 1–2 PM versus evening hours).**
2. **Securing a "Protocol Pager" whereby any radiologist who was responsible for protocols that day would be available on page.**

**Reviewing the Contrast Questionnaire**

Reviewing the contrast questionnaire form was the next failure point. This particular area launched a series of recommendations involving language barriers and interpretation services. The CT HFMEA® team recommended:

1. **IV contrast form to be translated into 4 different languages (Spanish, Chinese, Arabic, and Portuguese) and be readily on hand in the CT department.**
2. **Institute an information card designed to welcome patients, provide information, and answer frequently asked questions regarding the exam. The information card would be available in the languages mentioned above.**
3. **The interpreters at MGH are used throughout the whole hospital and not dedicated to radiology. They have no medical knowledge of radiology exams. Interpreters would be allowed to go directly into the exam room once the patient was ready to be scanned. The process would have the interpreter available when the patient arrived. The interpreter would then help the patient fill out any necessary forms and answer any questions the patient might have.**
out the contrast form, explain the exam, and then leave and come back when the patient was ready to be scanned. This could be over an hour later if the patient needed to drink oral contrast. The team thought it would be more advantageous and waste less time if the interpreter came when he or she was really needed, which was when the exam was being done, in case of a contrast reaction.

Another area for improvement was in the scheduling of these exams. The CT HFMEA® team recommended long term solutions around the potential of upgrades to ROE:

1. Require ROE computer scheduling system to ask the referring office if the patient can understand and converse in English. Use a mandatory checkbox in order to continue with the scheduling of the exam.
2. Enhance ROE computer scheduling system with the ability to print out “patient prep instructions” in any of the 4 designated languages.

Accessing Bloodwork Results

A recent BUN/creatinine is needed in order to inject patients with IV contrast based on our BUN/creatinine policy. Updated bloodwork information accessible to technologists was vital. The CT department had a BUN/creatinine policy requiring that every patient over 60 years of age must have recent bloodwork drawn measuring their BUN/creatinine to determine their renal function. (Recent bloodwork is defined as any levels drawn within 3 months for patients that are diabetic or any renal issues and within 1 year for anyone over the age of 60.) Any patient with a creatinine level over 1.5 needed to have a radiologist approve the injection of IV contrast. The CT HFMEA® team recommended:

1. The evening RSR will review faxes that the CT department receives with BUN/creatinine results on patients scheduled for CT exams and input the BUN/creatinine results into the RIS.
2. The radiology marketing team will reeducate referring physicians’ offices on when to order IV contrast and what the BUN/creatinine policy is.
3. ROE would require a mandated checkbox for BUN/creatinine results for patients requiring IV contrast.
4. New product that would provide bloodwork results in real time. (This product is called EZ Chem from EZ-EM and is not available yet. This would utilize a creatinine stick and immediate results would be available.)

Reduction of Technologist/Nurse Error

This next failure point was somewhat controversial for the CT department at first. Both the technologists and the nurses were hesitant to acknowledge that they did not always trust new CT staff to be accountable or have the knowledge that seasoned technologists did to make correct decisions. In order to make all staff accountable, we instituted an “accountability card.” This accountability card included a line for everyone involved with the patient to initial their interactions. The first person the patient interacted with was the RSR. They have the patient fill out the contrast questionnaire form and when the patient completed this the RSR would look at it, decide if anything needed to be brought to the resource technologist’s attention, and would then initial the card. The resource technologist would then look at the contrast form, add the patients BUN/creatinine results with the date drawn, look at the exam protocol with the radiologist’s initials, and then initial the card. The nurse would then meet with the patient to go over all the information on the contrast form, place an IV, document what size IV was placed, and initial the card. The scanning technologist would then take the patient into the scan room and if the technologist had no questions and everything was in order and the patient was ready to be scanned, the technologist would initial the card. This was extremely helpful and dramatically reduced the stoppage in workflow. See Figure 2 for an example of the accountability card.

Measurement of Results

One of the keys to a successful HFMEA® is to implement and track the results of the short term solutions decided upon during the process. The HFMEA® team implemented 2 short term solutions and was able to track them.

The first short term solution measured was the incorrect, omission, or outdated patient history information on the ROE form as compared to the RIS patient history information. The CT HFMEA® team recommended that a review of the ROE and RIS patient history printouts be done to compare how often the patient history was omitted or
incomplete. Was there a significant mismatch or conflicting documentation presented between the ROE and the RIS? This was an area of particular challenge in the process—to ensure the accurate patient history was visible to the CT staff in order to reduce the need for rework in verifying the correct and updated patient history.

The team piloted data collection from 2 different weeks within each of the months of April, May, and June of 2005 of patient requests from both the ROE and the RIS systems. Each collection consisted of 210 ROE orders and 210 tracking form requests from the RIS:

- April 2005: 18 ROE requisitions did not match the history section on the tracking form requisitions from the RIS.
- May 2005: 11 out of the 210 requests from ROE did not match the history section on the tracking form requisitions from the RIS. There were 22 requests from the RIS that did not have an ROE requisition.
- June 2005: 20 out of the 210 ROE requisitions did not match the history section on the tracking form requisitions from the RIS. There were 14 requests that did not have an ROE requisition.

The second short term solution the team measured was the institution of the accountability card. The team logged the number of times that the scanning technologists had to stop the workflow to speak with the resource technologist or nurse to recheck certain information that was unavailable. The team collected this information for a period of 5 days during 2 different weeks to monitor how often the stoppage in the workflow occurred.

- April 22, 2005: 15 times during each of the 5 days, for an average of 8 minutes each time, that the scan technologist went to the resource technologist or nurse to ask questions regarding the laboratory information or exam protocol on the patient request form.
- June 15, 2005: 8 times during each of the 5 days, for an average of 10 minutes each time, the scan technologist went to the resource technologist or nurse to ask questions regarding the laboratory information or exam protocol on the patient request form.

**Conclusion**

The HFMEA® process produced an “after market” byproduct of a process improvement team (PIT). A PIT was formed to act as a steering committee that would monitor the process improvements suggested by the HFMEA® team. The PIT
members would identify and design training and interventions to lead continuous improvements within the CT department.

This recommendation was presented at a CT staff meeting and several staff members volunteered to serve. The PIT goal was to lead and monitor the process improvements generated by the HFMEA® in regards to the misadministration of IV contrast in CT outpatients. The PIT team discussed developing a training program for the process improvements centering on 2 key areas:

1. Steps to reviewing a protocol
2. How and what to look for in a tracking form

The HFMEA® is a valuable patient safety tool. It is easy to come up with solutions while documenting the failure points, but try not to fix the problem before finishing the HFMEA®. It is important to find all failure points, score them, and work on long term solutions. Implement a project timeline, stay focused, and meet regularly with your team.

The HFMEA® is an important JCAHO patient safety goal for healthcare institutions to implement. However, it is much more important to do an HFMEA® because of the quality and safety of your patients that your department prides itself on, not just because it is a JCAHO patient safety goal. To be proactive and reduce the chance of a medical error is a win for everyone.

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Questions

Instructions: Choose the answer that is most correct.

1. What does HFMEA® stand for?
   a. Hospital failure method and effect analysis
   b. Healthcare failure mode and effect analysis
   c. Healthcare family method and external analysis
   d. None of the above

2. What is the purpose of this article?
   a. To learn what a HFMEA® is
   b. How to pick an appropriate topic
   c. Steps to follow for implementation
   d. All of the above

3. What is an HFMEA®?
   a. A patient safety goal identified by JCAHO
   b. A proactive risk assessment of a high-risk area
   c. A known medical error
   d. None of the above

4. What is the primary focus of a HFMEA®?
   a. Detection
   b. Problem solving
   c. Failure prevention
   d. Decision making

5. Keys to a successful HFMEA® include:
   a. Representation from all levels of operational staff
   b. Openness to all brainstorming ideas
   c. Established team member roles and responsibilities
   d. All of the above

6. What would be the first step in conducting an HFMEA®?
   a. Determine failure causes
   b. Define actions and measure
   c. Conduct the hazard analysis
   d. Define the topic

7. What was the goal of the HFMEA® in this article?
   a. To identify problems with outside patient laboratory results
   b. To prevent problems associated with obtaining previous patient information
   c. To prevent the misadministration of IV contrast in outpatients in the CT department
   d. None of the above
8. What would be a reason why you would not inject a patient with IV contrast?
   a. Prior allergies to IV contrast
   b. Restriction of iodine intake
   c. Renal insufficiency
   d. All of the above

9. Which of the following were identified as potential failure points in this particular study?
   a. Ordering the scan
   b. Contacting the radiologist
   c. Technologist/nurse error
   d. All of the above

10. What is the multi-step evaluation of each potential failure point?
    a. A hazard analysis
    b. A potential problem
    c. A potential cause
    d. None of the above

11. In this study, the decision tree analysis consisted of what two parts?
    a. Single point weakness and detectability
    b. Failure point and hazard score
    c. Patient dose and administration method
    d. All of the above

12. What were the two common denominators linking all the failure points in this study?
    a. Lack of managerial leadership and lack of knowledge
    b. Lack of education and lack of effective communication
    c. Lack of employee involvement and improvements
    d. Different hospital departments and a lack of communication

13. One problem identified with the referring physician’s office in this study was the lack of knowledge by the referring physicians regarding the policy for BUN/creatinine results needed for patients who require IV contrast.
    a. True
    b. False

14. Interpreter services may pose a problem when the interpreter does not understand:
    a. The procedure the patient is undergoing
    b. The use of IV contrast
    c. The potential severity of a misadministration
    d. All of the above

15. In this study, where was the lack of effective communication most notable?
    a. CT department staff
    b. Referring physicians
    c. Both a and b
    d. None of the above

16. The HFMEA® in this study resulted in process improvement recommendations that focused on which of the following?
    a. Ordering the scan
    b. Reviewing scheduled appointments
    c. Referring physician practices
    d. All of the above

17. The CT HFMEA® team focused on training the radiology service representatives.
    a. True
    b. False

18. After reviewing the contrast questionnaire form, the HFMEA® team recommended:
    a. The form be translated into 4 different languages
    b. The patient information card be available in four different languages
    c. Both a and b
    d. None of the above

19. An “accountability card” was instituted in order to:
    a. Reduce technologist/nurse error
    b. Identify the referring physician
    c. Assess blood work results
    d. None of the above

20. What was the purpose of the PIT?
    a. To identify and design training for continuous improvements within the CT department
    b. To act as a steering committee to monitor the process improvements suggested by the HFMEA® team
    c. Both a and b
    d. None of the above
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**Questions?**

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