Healthcare FMEA in the Veterans Health Administration

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An interdisciplinary HFMEA team uses a five-step process to proactively evaluate a patient care process.

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Failure modes and effects analysis (FMEA) is a procedure that analyzes potential failure modes within a given system. Each failure mode is classified by severity to determine the effect of failures on the system. FMEA is widely used in manufacturing, such as during various phases of a product life cycle. It has become increasingly common to find FMEA used in the service industries.

A modified approach to FMEA for use in the healthcare environment – Healthcare Failure Mode Effect Analysis (HFMEA®) – has become an invaluable patient safety tool within at the Department of Veterans Affairs (VA). Since its implementation, literally hundreds of HFMEAs have been completed throughout the VA, which has led to improvements to the healthcare provided to veterans.

FMEA History Highlights

A U.S. military manual was published in 1949 entitled *Procedure for Performing a Failure Mode, Effects and Analysis.* It 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. It was adopted by NASA during tests on rocket technology for missions such as Apollo, and gained notoriety in the 1960s during America's push to put the first man on the moon. A decade later, following Ford Motor Company's release of the troubled Pinto, FMEA was introduced to the automobile manufacturing industry as a way to improve

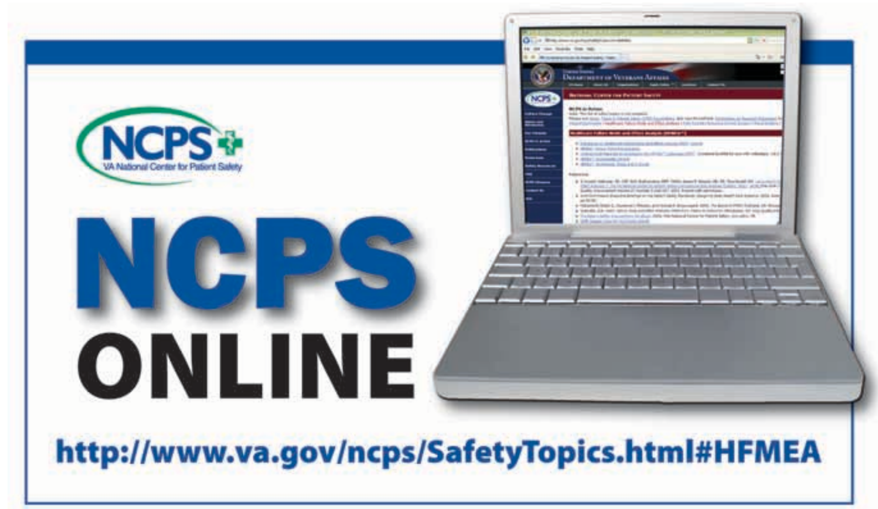
The acronym HFMEA is a registered trademark of CCD Health Systems

safety, production, and design. Adapting FMEA to the healthcare environment was one of the early initiatives of the VA National Center for Patient Safety (NCPS), established in 1999.

HFMEA and Patient Safety

Most patient safety reporting systems concentrate on analyzing adverse events *after* an injury has taken place. At VA, we also analyze close calls, which provide an exceptional opportunity for learning and afford the chance to develop preventative strategies and actions before a patient is harmed. Close calls have been shown to be anywhere from 3-to-300 times more common than actual adverse events.

HFMEA offers users analytical tools that can enable a team to *proactively* identify vulnerabilities in a care system and deal with them effectively. In essence, it is a systematic, engineering-based approach used to identify such system vulnerabilities and to correct them before they occur.



Learn more about HFMEA by clicking to this portion of VA NCPS Web site: http://www.patientsafety.gov/SafetyTopics.html#HFMEA

We offer a number of these HFMEA tools on our public Web site, www.patientsafety.gov. The material ranges from the "basics" to detailed guides, such as the "HFMEA Worksheet." We encourage readers to visit our site and learn more.

HFMEA in Action

A five-step process is used to evaluate a specific aspect of a healthcare system, such as reviewing the way laboratory specimens are drawn:

***Step 1:* Define the HFMEA topic.**

When selecting the topic, be specific about the process or product to be studied, thus narrowing the scope of the analysis.

***Step 2:* Assemble a multidisciplinary team.**

The team should include one or more subject-matter experts, as well as individuals who have no detailed knowledge of the process under review. When needed, others can be called in as consultants.

***Step 3:* Graphically describe the process.**

Team members develop and verify a flow-process diagram, not to be confused with a chronological diagram. Each step in the process under study is identified and numbered.

If a process is complex, a specific area is identified to keep the effort manageable. Appropriate sub-processes are also identified and flow-process diagrams developed.

***Step 4:* Conduct a hazard analysis.**

Focusing on the sub-processes, team members list all potential failure modes to determine their severity and probability. Cognitive aids developed by NCPS to support teams at this step include a Scoring Matrix and a Decision Tree.

The Scoring Matrix is used to determine the probability of an event's reoccurrence and its severity; the Decision Tree is used to determine if corrective actions should be taken.

***Step 5:* Actions and outcome measures.**

The team determines what the best course of action is to take. Outcome measures are identified to analyze and test redesigned processes.

HFMEA Examples

The following examples were conducted at VA medical centers.

Blood Glucose Monitoring

Providers used blood glucose monitoring to determine dosage, frequency, and insulin effectiveness; however, the HFMEA team discovered a number of potential vulnerabilities with the facility's monitoring system.

As a result of the HFMEA, new actions were recommended when critically high glucose values were identified during bedside glucose monitoring, such as regularly recording a patient's glucose levels while administering additional care for those found with higher than normal levels. In addition, it was discovered that the bedside system relied on a computer upload process that could potentially lead to a failed capture of the results in the laboratory computer system.

Patient Flow

Another facility's team reviewed the flow of patients through the emergency department in an effort to prevent overcrowding. The team's actions included recommending "navigators" be used in the emergency room to direct patient flow. Improving the patient flow process in the emergency room not only promotes the efficient use of limited resources, but can reduce delay in the delivery of care, treatment, and services.

Since its inception, the HFMEA process has been implemented at all 153 VA medical centers.

MRI Safety

A number of HFMEAs assessed facility MRI safety in response to patient safety alerts. Developed by NCPS, patient safety alerts and advisories discuss specific issues relating to equipment, medications, and procedures that might cause harm to patients. The alerts and advisories are shared nationally and worldwide on VA Intranet and Internet sites (http://www.patientsafety.gov/alerts.html); more than 175 have been published since 2000.

One of the issues involved users being unaware that the MRI machine was turned on, which led to unauthorized equipment being left in the MRI suite. Because of this, equipment could potentially fly into an MRI machine, harming a patient and causing millions of dollars in damage.

Improvements at VA facilities included posting signage in more than one language, due to the diverse VA patient population and work force, and installing controlled access monitors to restrict access to MRI suites.

Evacuation of all Patients from a VA Medical Facility

A VA medical center experienced a complete power loss during normal operating hours, resulting from an electrical fire in the emergency generator room on the basement level of the hospital. Though the fire department quickly put out the blaze, lighting, air conditioning, and other systems remained shut down in certain areas of the building; all patient care areas were affected, including several surgeries in process.

An HFMEA team was formed to review the facility's ability to implement a complete patient evacuation during an emergency. Evacuation plans must meet and adhere to Joint Commission standards, VA directives, and National Fire Protection Association standards. In addition, each VA medical facility is tasked to address how to continue operations without external support for up to 96 hours.

The team revised the facility's evacuation plan, to include various scenarios that could be tested for effectiveness in specific care areas, and revised as required.

Reprocessing Reusable Medical Devices

In 2007, each VA medical facility completed a mandated HFMEA on one of 20 supply, processing, and distribution (SPD) department processes, including those used for scopes, orthopedic devices, or sterilization methods. A summary document of lessons learned was developed by VA NCPS following completion of this work and is posted on the NCPS Intranet site, for use by VA medical professionals. (VA employees can access the site: http://vaww.ncps.med.va.gov/Initiatives.html#SPD)

A complete list of facility assignments is also provided on this web site to enable VA patient safety managers (or others) to request additional in-depth information on these proactive risk assessments.

Conclusion

HFMEA is an important aspect of VA's patient safety effort, which is based on taking a systems approach to problem solving. Regardless of the caregiver involved, a poorly designed process can repeatedly generate an unfortunate sequence of events and can result in a patient being harmed.

The goal is to break that link in a chain of events that can cause a recurring problem: find the underlying systems-based problem that has been ignored or unaddressed—and focus on prevention, not punishment.

Since its inception, the HFMEA process has been implemented at all 153 VA medical centers. In addition, NCPS staff members have conducted numerous day-long, hands-on training sessions to provide VA staff members with core concepts of the HFMEA process.

If readers have specific questions on HFMEA, email us at ncps@va.gov.

About NCPS

Headquartered in Ann Arbor, Michigan, the National Center for Patient Safety (NCPS) was established in 1999 to develop and nurture a culture of safety throughout the Veterans Health Administration. Our goal is the nationwide reduction and prevention of inadvertent harm to patients as a result of their care. Patient safety managers at 153 VA medical centers and patient safety officers at 21 VA regional headquarters participate in the program. PSQH

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__Ryan Wilson__ is a program analyst for NCPS. He is responsible for providing operational, analytical, and evaluative support to program managers and other key staff. Wilson conducts training and support for VA patient safety managers to improve the root cause analysis process. He gained a background in aircraft safety while serving with the U.S. Navy, while participating in numerous helicopter cargo transport operations, anti-mine countermeasures, and search and rescue operations. He has an MS in organizational and business leadership from Concordia University, Ann Arbor, Michigan, as well as significant background in health care economics/finance and computer science.

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