Applicability of Healthcare Failure Mode and Effects Analysis to Healthcare Epidemiology: Evaluation of the Sterilization and Use of Surgical Instruments

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Healthcare Failure Mode and Effects Analysis (HFMEA) is a methodology for correcting latent system errors before they lead to adverse events. We examined the utility of HFMEA in evaluating the sterilization and use of surgical instruments. First, a multidisciplinary team graphed the process in a flow diagram. A hazard analysis was then used to examine potential failure modes (i.e., ways in which a process can fail) and their causes and to score the severity and other factors for each failure mode cause. Actions were then planned to address the selected failure mode causes. Flow charts were created for 3 foci: sterilization process, reading of biologicals, and use of equipment. Information was gathered through interviews and a review of the literature. Multiple clinically significant system errors were identified, and actions to correct them were developed. The HFMEA methodology facilitated the detection of previously unrecognized system errors, demonstrating its potential utility in addressing healthcare epidemiology–related adverse events.

Adverse events in complex systems, such as health care delivery, are typically the result of multiple inherent errors (latent errors) in the system that predispose individuals in the system to, in turn, commit errors (acute errors) leading to adverse events [1, 2]. For example, lack of readily available hand hygiene alcohol rub dispensers or hand washing sinks near patient rooms (a latent error) may lead to inadequate hand hygiene by hospital staff (acute errors). Healthcare Failure Mode and Effects Analysis (HFMEA) is a qualitative methodology for detecting and correcting such latent system errors in the health care setting before they lead to adverse events.

The HFMEA methodology is an adaptation of the Failure Mode and Effects Analysis (FMEA) process for the health care setting by the Veterans Administration National Center for Patient Safety [3]. The HFMEA materials are set in the medical context. For instance, the severity grades of adverse outcomes refer to injuries to patients, staff, and visitors and damage to the facility (e.g., “most severe” includes patient death or permanent loss of function). In contrast to HFMEA and FMEA, root cause analysis (RCA) or standard quantitative methods (e.g., case-control study) may be used to investigate adverse events that have already occurred, although the latter may be problematic if there are a limited number of outcome events. HFMEA may be useful in prospectively evaluating the instrument sterilization process. Invasive procedures performed with insufficiently sterilized instruments have the potential to transmit infection with such pathogens as HIV and hepatitis B virus. The cleaning, sterilization, testing, and subsequent inspection and use of sterile surgical instruments comprise a complex process. Complete killing of spores in an enclosed tube—a “biological indicator”—is used to test the completeness of sterilization. However, it is not standard to quarantine non-implantable surgical instruments until a final, negative biological indicator reading is obtained at 48 h after sterilization [4, 5]. It is thus possible for a reading to have a positive result after the associated surgical instruments are used. Other immediately available tests of sterilization (e.g., visual color-change indicators) are also used. Alternatively, the results of a reading of biological indicators may be falsely negative. These
scenarios have the potential to lead to the transmission of infection or to cause psychological harm to patients who are recalled for the evaluation of such a potential transmission. In addition, the discovery of sterilization problems—especially as the time of surgery approaches—may lead to the delay of surgery as the questionable instruments are resterilized or replaced. This delay may cause the patient to experience adverse events if anesthesia is induced before the case is aborted or if the underlying illness progresses during the delay. Finally, the process of investigating a positive reading of biological indicators, including calling patients back for testing, requires significant expenditure of hospital staff time. Although there are other real-time means to double-check for sterilization adequacy (e.g., automated temperature, pressure, and time of sterilization monitoring by sterilizer machine and color change of paper indicators), biological monitoring is the accepted gold standard of sterilization completeness.

Hospital epidemiologists are familiar with the use of quantitative investigative techniques (i.e., using surveillance with benchmarking, then investigating with retrospective cohort or case-control studies). However, qualitative techniques, such as FMEA, are also useful and may be complementary [6]. Infection control is increasingly recognized as a critical component of patient safety [7, 8]. However, there are no healthcare epidemiology FMEAs in the medical literature to demonstrate the utility of this technique and to provide further guidance for its use in this field. With use of the HFMEA methodology, we undertook an investigation of the system of surgical instrument sterilization and use at our institution, primarily in response to the occurrence of positive biological indicators.

METHODS

The standard HFMEA methodology from the Veterans Association National Center for Patient Safety was used and is briefly summarized here [3, 9]. Of note, the spreadsheets, scoring instructions, and algorithms used in our HFMEA are all publicly available on the internet [3]. First, the topic and processes to be examined were defined. A multidisciplinary team that included methodological advisors was then assembled. Next, the process of surgical instrument sterilization was described in a flow diagram. The diagram included the process of sterilization as well as the testing and inspection of the sterilization process and instruments. A hazard analysis then iterated potential “failure modes” (i.e., ways that a process step can fail) for each step in the flow diagram, iterated causes for each failure mode that met preset criteria for the probability of the failure mode occurring and the severity of its consequences for patients, and similarly scored the failure mode causes. Finally, for each failure mode cause meeting preset criteria (defined in the referenced HFMEA instructions [3]), we determined actions to be taken to eliminate or control the failure mode cause, outcome measures to evaluate the actions, and the responsible person(s) for each action and outcome measure. Information gathering from other sources—interviews with subject matter experts and reviews of source documents or literature—were performed as needed. The results of the HFMEA analysis were then presented to the executive administrative group of our hospital (Veterans Administration Medical Center, Philadelphia, PA).

We calculated the number of person-hours spent on the HFMEA by multiplying the total number of hours the team met by the number of team members and then adding a conservative estimate of the unscheduled time spent outside of meetings. The institutional review board of the Veterans Administration Medical Center approved the study.

RESULTS

The specific topic of the HFMEA was determined through conversations between the Department of Infection Control, the Department of Surgery, and our hospital’s Quality Management group. The executive hospital administrative group then formally commissioned the HFMEA to be performed. The hospital epidemiologist directed the HFMEA team. The team also composed of 2 methodological experts from the Quality Management group; 2 infection-control practitioners; the chief of the Supply, Processing, and Distribution Division (SPD), which is the area where instrument sterilization is performed; a surgeon; and the operating room nursing supervisor.

During the course of the HFMEA, the team gathered information from interviews, meetings, and published materials. The HFMEA director conducted interviews with technical experts from the manufacturer of the biological indicators and the associated incubators (by telephone), the relevant national administrative leaders within the Veterans Health Administration (by telephone; to clarify areas of uncertainty in interpreting the Veterans Health Administration sterilization guidelines), and the surgery leadership at our institution (in person). A member of the surgery leadership also attended a meeting for further discussions with the HFMEA team. Reviewed materials included the manufacturer package insert for the biological monitors, the Centers for Disease Control and Prevention dental infection control recommendations (which address the monitoring of instrument sterilization) [5], the Veterans Health Administration guideline addressing instrument sterilization procedures [4], a healthcare epidemiology textbook [10], and other guidelines [11–13]. Information gathering occurred throughout the study period as areas of uncertainty arose.

The HFMEA director created a preliminary flow diagram after initial discussions by the HFMEA team. The team then expanded and edited the diagram into its final form using their knowledge of the various facets of the process. Given its complexity and length, the original flow diagram was divided into 5 foci. To limit the HFMEA to a more manageable scope, the...
Figure 1. Summary flowchart of subprocesses involved in the sterilization and use of surgical instruments.

The 8 HFMEA team members met for a total of 26.5 h in 19 meetings during February–August of 2004 (for a total of 212 person-hours). We estimate that the HFMEA director and other selected team members spent 140 h between meetings and after the final meeting editing materials generated by the team.

The hazard analysis was then performed (figure 3). Although the overall process is the same, the precise algorithm used for scoring and determining what score necessitates action may differ among FMEA methodologies. Thirty-one failure modes were iterated during the hazard analysis for the 17 subprocesses listed in figure 1. Seventeen of these failure modes met criteria to continue with the hazard analysis, which led to the iteration of 39 potential causes of the failure modes. Twenty-eight of the potential causes met criteria for action to be taken. The following are selected, abridged examples from the hazard analysis.

- False-negative visual biological indicator readings (failure mode) as a result of incorrect reading (cause) can be prevented by a double-check of final readings by supervisor (action).
- False-positive rapid (fluorescence) biological indicator reading (failure mode) as a result of contamination via handling (cause) can be prevented by conversion to a newer incubator that automates early readings and decreases the need for handling of biological indicators (action).
- The surgical instrument tray not passing inspection by the operating room circulator, leading to delay in surgery and/or potential abortion of operation after the induction of anesthesia (failure mode), as a result of an alternative tray not being immediately available (cause) can be prevented by increasing surgical equipment available on-site and evaluating the possibility of a protocol for starting induction of anesthesia after initial inspection of surgical equipment.

The figure is available in its entirety in the online edition of Clinical Infectious Diseases.
<table>
<thead>
<tr>
<th>Failure Mode: First Evaluate failure mode before determining potential causes</th>
<th>HFMEA Steps 2.1 and 2.2 - ETO and Steam Sterilization Processes (see flowchart for subprocess step titles and numbers)</th>
</tr>
</thead>
<tbody>
<tr>
<td>Potential Causes</td>
<td>Scoring</td>
</tr>
<tr>
<td>2.1A(1) and 2.2A(1)</td>
<td>Inadequate or incorrect identification of item(s) in log, e.g., &quot;Operating Room Peel Pack&quot; (inadequate) instead of &quot;ENT Endoscopic Light Source&quot; (adequate)</td>
</tr>
<tr>
<td>2.1A(1)a &amp; 2.2A(1)a</td>
<td>SPD staff use general terms to log both items with long names and to bundle multiple items to save time</td>
</tr>
<tr>
<td>2.1A(1)b &amp; 2.2A(1)b</td>
<td>SPD staff miss items during the logging process</td>
</tr>
<tr>
<td>2.1A(1)c &amp; 2.2A(1)c</td>
<td>SPD staff do not know name of item, and use a general term instead of asking for assistance in identifying an item</td>
</tr>
</tbody>
</table>

**Figure 3.** The first panel of the Healthcare Failure Mode and Effects Analysis (HFMEA) hazard analysis of the sterilization and use of surgical instruments, detailing 1 of the 3 failure modes for the subprocess of performing visual evaluations of incubating biological indicators after the sterilization run. The complete HFMEA hazard analysis is available in the online edition.
team (i.e., the flow chart and hazard analysis). In addition, all
team members worked outside of meetings reviewing sup-
porting documents and critically reviewing drafts of the flow
diagram and hazard analysis. The final draft of the HFMEA
was submitted to the hospital administration in January of
2005. The Quality Management group at our facility maintains
a list of proposed actions for all HFMEAs (and RCAs); they
will provide follow-up with the person responsible for each
action to ensure completion. We estimate that >250 person-
hours were spent on the HFMEA.

**DISCUSSION**

We used the HFMEA methodology to address an issue not
amenable to quantitative techniques: the evaluation of system
efforts in the process of instrument sterilization and use. We
found the methods from the Veterans Health Administration
National Center for Patient Safety to be applicable to our issue.
Our investigation uncovered multiple causes of the potential
ways in which the system could fail (failure modes), as well as
determining actions to correct these latent system errors. How-
ever, our investigation required a large amount of personnel
resources.

Transmission of infection through inadequately sterilized
surgical instruments has not been described in the modern
sterilization era. However, after multiple positive biological indi-
cators, there was sufficient interest in verifying the reliability
of our system to warrant an investigation. There were no pa-
ients with documented transmission of infection, few instances
of positive biological indicators, and many of the system errors
that we found were not known before the study. Therefore, it
was not possible to conduct a quantitative study (e.g., a case-
control study evaluating risk factors for either transmission of
infection or positive biological indicators). However, qualitative
methods, such as FMEA and RCA (if there are any adverse
events), are appropriate tools for this setting [6].

Qualitative investigations are required by the Joint Com-
mission on Accreditation of Healthcare Organizations for
health care–associated infection sentinel events [14, 15] and are
complementary to quantitative methods for addressing health-
care epidemiology problems [6]. However, there are few
publications providing guidance for performing qualitative in-
vestigations in the medical setting [3, 9, 16], particularly for
healthcare epidemiology [6, 8].

We found the Veterans Health Administration National Cen-
ter for Patient Safety HFMEA methodology [3] to be applicable
to our healthcare epidemiology investigation. The HFMEA in-
vestigation found multiple system errors that had not been
previously considered and acted upon. These errors have the
potential to cause patients to experience adverse events. By
taking action to correct these causes of failure modes, we may
avert future adverse events. Our flow diagram and hazard anal-
ysis will also provide a blueprint for solving future problems
at our institution, as well as assist other institutions in im-
proving their system for sterilizing and using surgical instru-
ments.

The HFMEA required 7 months of scheduled meetings in
addition to substantial time commitments between and after
the meetings to summarize and review the team’s findings. In
part, this is because of the scope of our investigation. We could
have chosen any 1 of our 3 foci for the entire HFMEA. Even
with only 3 foci, our HFMEA was one of the largest ever per-
formed at our facility. We agree with other authors that the
hazard analysis is tedious (albeit useful) and that, given the
significant human resources needed to complete them, these
investigations should be reserved for the most clinically sig-
nificant problems [17]. Conversely, positive biological indica-
tors, one of our outcomes of interest, necessitate a time-con-
suming investigation and raise the possibility of significant
physical and psychological harm to patients. We believed that
our investigation was worth the effort because of the multiple,
correctable system errors that were discovered in this critical
process and the creation of a valuable blueprint (i.e., the flow
diagram) to use when addressing future surgical instrument
issues. We also believe that subjecting the system to a rigorous
investigation by the involved parties was educational for the
HFMEA team members and will enhance communication and
cooperation among the different hospital areas.

Our case may be an example of when the HFMEA meth-
odology is useful: when there is concern or evidence that either
system errors are present and there have been or there is the
potential for serious adverse events. We believed that our case
was too multifocal for a single RCA. We were concerned with
positive biological indicators, but we didn’t want to limit the
investigation to that single end point. Likewise, a case-control
study would have been limited as a result of too few (or no)
adverse events, multiple potential outcomes of interest (e.g.,
positive biological indicators and transmission of disease), and
the suspicion that many potential risk factors were not known
before the study was completed.

Our study has several limitations. As in other qualitative
investigations, it is difficult to demonstrate a statistically or
clinically significant decrease in rare events (e.g., a decrease in
the occurrence of positive biological indicators), and it is im-
possible to demonstrate a decrease in events that have not
occurred (e.g., transmission of infection). Thus, we cannot
prove that the HFMEA will increase the safety of patients at
our institution nor can we perform a cost-benefit analysis. The
lack of quantitative outcome data may increase the difficulty
of obtaining administrative support for interventions, partic-
ularly if monetary investment is involved. However, our study
uncovered previously unacknowledged system errors that po-
tentially may have led to adverse events for patients. The face

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validity of such findings may be helpful in gaining administrative support for proposed changes.

We are reporting the use of the HFMEA methodology to address system errors in the sterilization and use of surgical instruments. This is, to the best of our knowledge, the first published use of HFMEA in the healthcare epidemiology literature. Our study provides an example of the use of the HFMEA methodology in healthcare epidemiology. The flow diagram and hazard analysis of an instrument sterilization and use system is also presented for others to use. Although it is difficult to verify the utility of these resource-intensive qualitative investigations, the HFMEA methodology is complementary to quantitative investigations and useful in identifying latent errors in complex medical systems.

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References