Proactive Risk Assessment for Ebola-Infected Patients: A Systematic Approach to Identifying and Minimizing Risk to Healthcare Personnel

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Proactive Risk Assessment for Ebola-Infected Patients: A Systematic Approach to Identifying and Minimizing Risk to Healthcare Personnel

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Outbreaks of highly infectious diseases have significant implications for the safety of healthcare personnel (HCP). While there is extensive scientific rigor behind infectious disease epidemiology and clinical treatment, few mechanisms rapidly identify evidence-based care processes that optimize both HCP safety and patient outcomes.1 The recent outbreak of Ebola virus disease (EVD) within the United States highlights the importance of having well-defined clinical care protocols that employ risk-minimizing processes for HCPs providing care.2

Safety experts recommend using simulation to study systems, test protocols, and detect safety threats.3 When combined with risk analysis methods, healthcare simulations help identify unanticipated threats to safety.4 Failure mode and effects analysis (FMEA) is a proactive approach to risk analysis often used in highly reliable organizations. FMEA provides a systematic way to uncover latent threats to safety and to identify potential solutions to address high-risk work-related tasks.5 This research report describes the application of simulation and FMEA to the identification, quantification, and mitigation of risk associated with fecal management and hygienic care (patient cleaning and linen change) in EVD-infected patients. We analyzed hygienic care associated with fecal management because this is a major issue for providers caring for EVD patients and no clear evidence is available to support best practices.

METHODS

Care of an EVD patient was simulated using a standardized patient in an EVD care unit. A total of 4 teams of 2 HCPs wearing high-level personal protection equipment (PPE)1 completed a clinical scenario requiring provision of hygienic care and linen change to a patient with copious, continuous watery stool. Simulations were recorded via mounted cameras, and HCP wore video glasses to facilitate the identification of risks resulting from visual field restriction.

An FMEA was executed using the video recordings and existing EVD patient care protocols.5 A multidisciplinary team, including occupational health microbiologists, industrial hygienists, clinical experts, and human factors psychologists performed the FMEA. The analysis was designed to perform the following tasks: (1) identify discreet process steps for fecal management, (2) identify associated risks of failure, or failure modes, for each step, and (3) assign values based on the likelihood of failure occurrence (range, 1–10), severity if the failure mode had occurred (range, 1–10), and detectability if the failure mode had occurred (range, 1–10). The risk priority number (RPN) was calculated by multiplying these 3 values together. For example, when placing a peripheral intravenous line, withdrawing the needle has a moderate likelihood of failure (ie, needlestick; assigned value, 5) that can be easily detected (assigned value, 1) with a mild severity impact (assigned value, 2), resulting in an RPN of 10.

RESULTS

The FMEA identified 30 discrete steps and 16 unique failure modes associated with hygienic care and linen change for an EVD patient with copious watery stools (Table 1). The same failure mode was often associated with multiple steps (eg, provider contamination, Table 1). Failure modes ranged in RPN from 6 to 400 and were grouped by RPN into 4 relative risk categories (Figure 1). The solutions for each failure mode were identified and grouped into 4 categories: (1) implementation of a pre- or post-procedure checklist and brief, (2) scheduled pauses to allow patient and team reassessment (ie, time-outs), (3) development of new protocols or approaches, and (4) equipment modifications. Checklists, scheduled time-outs, and pre- or post-procedure briefs addressed 76.5% (62 of 81) of the overall failure modes, particularly those with lower RPNs.

The FMEA identified several previously unrecognized equipment-related safety threats. For example, the biohazard waste containers were on wheels and were often moved as large volumes of linen were placed in the bin, presenting the risk that the soiled linens would be dropped. HCP often used their bodies to force the linens into the bin, thus increasing the likelihood of direct HCP contamination. Additionally, the use of linens or a solidifier to isolate the liquid stool on the floor4 created several threats, including a fall hazard and challenges associated with removing the soiled linens from the floor. Recommendations include the use of tongs to retrieve items...
<table>
<thead>
<tr>
<th>Failure Mode</th>
<th>Process Steps Impacted</th>
<th>Overview of Failure Mode</th>
<th>Potential Solution</th>
<th>RPN Range</th>
</tr>
</thead>
<tbody>
<tr>
<td>Item not available or not enough of item available</td>
<td>· Containing fecal material spill on floor</td>
<td>Hygienic care for EVD patients generally requires additional steps and supplies beyond what is routinely needed, especially if patient continues to contaminate clean materials. When HCPs forgot to gather required items, it resulted in repeatedly leaving the bedside with dirty gloves/gown to move across the room.</td>
<td>· Pre-brief checklist  · Scheduled time-out</td>
<td>20–60</td>
</tr>
<tr>
<td>Item not in close proximity</td>
<td>· Placing fitted sheet onto mattress  · Sanitizing gloves  · Containing fecal material spill on floor</td>
<td>Providing hygienic care requires the HCP to move from one side of the patient to the other. Having easily accessible supplies regardless of which side of the bed the HCP is working from is important. This includes sanitizing gel.</td>
<td>· Pre-brief checklist  · Scheduled time-out</td>
<td>20–168</td>
</tr>
<tr>
<td>Provider contamination (feet)</td>
<td>· Containing fecal material spill on floor</td>
<td>When providing hygienic care to patients with copious watery diarrhea, there is increased risk of having stool leak onto the floor.</td>
<td>· No optimal solution identified  · Identify patients appropriate for early rectal tube placement</td>
<td>10</td>
</tr>
<tr>
<td>Provider contamination, body</td>
<td>· Rolling patient onto side  · Removing dirty linens  · Cleaning patient  · Placing contaminated linens into bin  · Cleaning floor to remove contaminated linens</td>
<td>HCP are often in close contact with the patient. Multiple steps require HCP to directly handle soiled materials or use tools (eg, tongs) or materials (eg, towels) that are not well designed for the task. Despite their best efforts, observers did not notice all high-risk exposures due to positioning or decreased attentiveness.</td>
<td>· Ensure gowns are proper length  · Scheduled time-out  · Larger-sized cleansing wipes  · Tongs or device to remove items from floor  · No optimal solution identified</td>
<td>175–400</td>
</tr>
<tr>
<td>Spreading agent to other areas of the room</td>
<td>· Towel barrier on floor  · Placing incontinence pad under patient  · Removing fitted sheet  · Cleaning mattress  · Unrolling clean linens</td>
<td>Areas with no obvious gross contamination are at risk for direct exposure to infectious agent. Limited visibility resulting from the high-level PPE was a contributing factor.</td>
<td>· Larger sized cleansing wipes  · Scheduled time-out  · No optimal solution identified</td>
<td>30–192</td>
</tr>
<tr>
<td>Recontamination of clean linens</td>
<td>· Unrolling clean linens</td>
<td>This is a lengthy procedure. With patients having copious watery stools, there is a high risk of recontamination of clean linens before the procedure is complete.</td>
<td>· Protocol for implementation of fecal management system</td>
<td>40</td>
</tr>
<tr>
<td>Tripping over materials on the floor</td>
<td>· Towel barrier on floor</td>
<td>One recommended method to handle active stooling during this process is to create a dam of towels on the floor to limit spread of agent. This presents risk to the HCP, especially considering limited mobility and vision related to high-level PPE.</td>
<td>· No optimal solution identified  · Protocol for initiation of fecal management system</td>
<td>50</td>
</tr>
<tr>
<td>Accidentally dislodging medical devices</td>
<td>· Roll patient onto side  · Removing dirty linens</td>
<td>This risk is similar to risks encountered for all patients. EVD patients are unique in that relatively few HCP are in the room and it is difficult to obtain help, which was regarded as a significant problem when caring for intubated patients.</td>
<td>· Time-out  · Checklist item to identify all patient tubes and devices  · Protocol to guide step</td>
<td>16–400</td>
</tr>
</tbody>
</table>
| Biohazard/linen container too full | • Cleaning patient  
• Removing dirty linens | Procedure creates a large amount of waste, including linens that are quite bulky. | • Pre-brief checklist  
• Scheduled time-out  
• Consider other equipment solutions |
| Biohazard/linen container moves | • Placing clean linens under patient | Due to the volume of stool produced, the type and number of linens used on a patient’s bed is different than for routine patient care. For EVD patients, 2 incontinence pads were needed to limit contamination. As this is a deviation from normal nursing care, and it was often done incorrectly, which represents a point for potential error. | • Checklist  
• Time-out for reminder |
| Failing to use appropriate linens or moisture barriers | • Sanitizing gloves  
• Cleaning tongs  
• Cleaning i.v. tubing | Standard practice for HCP is to use gel sanitizer just before entering a room and upon leaving a room. The need to frequently sanitize gloves during EBV patient care is a departure from “normal” patient care. | • Checklist  
• Time-out for reminder |
| Forgetting a step | • Cleaning bed frame and nearby equipment  
• Cleaning IV tubing  
• Disinfecting floor | Linens can become saturated and may leak. HCP usually bundles dirty linens prior to moving them to the dirty linen bin. | • Ensure close proximity of dirty linen container  
• Use a large-sized linen to wrap smaller linens |
| Dropping linens | • Cleaning floor | Noticing all areas that become contaminated with stool is extremely challenging, especially if contamination is under the bed or other furniture. PPE limits visual fields and, thus, location of contamination. | • Time-out  
• No optimal solution identified* |
| Failure to recognize gross contamination | • Cleaning tongs | May be difficult to reach an area on the floor under the bed, and it may be difficult to move the bed. | • Flashlight |
| Cannot reach contaminated area | • Cleaning floor | Specialized equipment does not necessarily have a clearly designated place to rest while in use, which presents a risk for spreading gross contamination. | • Create a place to set contaminated hardware during procedure |
| No place to put contaminated equipment while in use | • Cleaning bed frame and nearby equipment  
• Cleaning IV tubing  
• Disinfecting floor | Proactive risk assessment for ebola 3

**NOTE.** FMEA, failure mode effects analysis; RPN, risk priority number; PPE, personal protective equipment; EVD, Ebola virus disease; HCP, healthcare personnel; i.v., intravenous.

*A total of 16 failure modes related to EVD patient hygienic care were identified. While it is possible to consolidate failure modes, we did not do so because we did not want to lose important details or nuances captured during the FMEA.*

*The same failure mode was often identified for multiple process steps. We list examples of process steps identified. A total of 30 discrete process steps were evaluated.*

*The overview provides a further explanation of why this particular failure mode was identified.*

*The RPN range reflects that the same failure mode at a different process step may have a different risk priority, given that the occurrence, detectability, or severity vary based on the nature of the given process.*

*For certain process steps, there were no potentially effective solutions identified to mitigate the failure mode or risk.*

*The highest RPNs were associated with performing a task with a patient that could not assist with their care, i.e., an intubated patient.*

*Examples of medical devices include i.v. tubing, indwelling urinary catheter, nasogastric tube, arterial lines, or endotracheal tube.*
from the floor; however, the tongs were unwieldy and presented additional safety threats.

Of the failure modes with RPNs >300, 70% (7 of 10) were associated with failure modes attributed to observer inattention resulting in provider contamination or spread of the infectious agent. Most solutions suggested for these failure modes were deemed suboptimal because they were based on improving observer vigilance, an ineffective approach that is susceptible to fatigue. In fact, the FMEA found provider fatigue to be a threat to almost every step, especially during the clean-up phase of the procedure. Scheduled time-outs and checklists were identified as possible ways to help identify fatigue and mitigate its impact on performance.

**DISCUSSION**

HCP safety is a major concern when caring for patients with highly infectious diseases. Preemptively assessing risk is critical in rapidly evolving situations, such as the EVD crisis. An FMEA can reduce redundancy, reduce inefficiency, and facilitate training that is ready to be integrated into practice. Using FMEA reduces non-systematic protocol and process building that can introduce practices that are unsafe for HCPs. This proactive approach identifies potential risks associated with human limitation, provides unique insight into other high-risk safety threats, and helps identify potentially effective solutions. We found that adherence to a checklist would address a significant number of risks associated with fecal management in EVD patients.

Our analysis revealed that combining checklists with effective team-based interventions such as team briefs and time-outs for reassessment enforce a systematic approach and encourages the development of shared situational awareness between providers. Situational awareness supports highly effective teamwork and patient safety in highly dynamic, high-risk patient care settings. These teamwork concepts also promote adaptability, allowing HCPs to efficiently incorporate changes in protocols and procedures.

Placement of an effective fecal management system could mitigate risk associated with several failure modes by limiting continued HCP exposure to gross contamination. Currently, no clear guidelines exist regarding the factors that should trigger placement of a rectal tube or other fecal management system. This information would be helpful and could be incorporated into an existing checklist to guide decision making.
The FMEA results highlighted significant risks associated with HCP fatigue. Fatigue was a notable safety threat at almost every step; physical and mental exhaustion of both team members factored into the performances during the simulated cases. Observer inattention resulted in increased contamination of HCP PPE during the procedure; likewise, the HCP performing the procedure was less vigilant about appropriately positioning supplies to minimize potential spread of fecal waste. An omnipresent risk such as fatigue can be treated as a multiplier of existing risk during the FMEA, thus further increasing the RPNS associated with these tasks.10 We noted that building in scheduled time-outs could also provide an opportunity for HCP to assess their level of fatigue and decrease the risk attributed to observer inattention.

HCP safety is of paramount importance yet is difficult to ensure during the emergence of healthcare crises. FMEA provides an objective, quantifiable approach to risk identification and prevention that can be rapidly deployed. Solutions such as checklists and time-outs consider human capabilities and limitations and offer possible solutions to address safety threats encountered when providing care to patients with highly infectious diseases.

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