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

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CONCISE COMMUNICATION

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

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Performing patient care while wearing high-level personal protective equipment presents risks to healthcare providers. Our failure mode effects analysis identified 81 overall risks associated with providing hygienic care and linen change to a patient with continuous watery stool. Implementation of checklists and scheduled pauses could potentially mitigate 76.5% of all risks.

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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 floor[4] 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 1. Failure Modes Identified During Risk Analysis of Hygienic Care Provision for an Ebola Virus Disease (EVD) Patient with Copious Watery Stool

Failure Mode[a]	Process Steps Impacted[b]	Overview of Failure Mode[c]	Potential Solution	RPN Range[d]
Item not available or not enough of item available	• Containing fecal material spill on floor • Sanitizing gloves	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.	• Pre-brief checklist • Scheduled time-out	20–60
Item not in close proximity	• Placing fitted sheet onto mattress • Sanitizing gloves • Containing fecal material spill on floor	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.	• Pre-brief checklist • Scheduled time-out	20–168
Provider contamination (feet)	• Containing fecal material spill on floor	When providing hygienic care to patients with copious watery diarrhea, there is increased risk of having stool leak onto the floor.	• No optimal solution identified[e] • Identify patients appropriate for early rectal tube placement	10
Provider contamination, body	• Rolling patient onto side • Removing dirty linens • Cleaning patient • Placing contaminated linens into bin • Cleaning floor to remove contaminated linens	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.	• Ensure gowns are proper length • Scheduled time-out • Larger-sized cleansing wipes • Tongs or device to remove items from floor • No optimal solution identified[e]	175–400[f]
Spreading agent to other areas of the room	• Towel barrier on floor • Placing incontinence pad under patient • Removing fitted sheet • Cleaning mattress	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.	• Larger sized cleansing wipes • Scheduled time-out • No optimal solution identified[e]	30–192
Recontamination of clean linens	• Unrolling clean linens	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.	• Protocol for implementation of fecal management system	40
Tripping over materials on the floor	• Towel barrier on floor	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.	• No optimal solution identified[e] • Protocol for initiation of fecal management system	50
Accidentally dislodging medical devices[g]	• Roll patient onto side • Removing dirty linens	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.	• Time-out • Checklist item to identify all patient tubes and devices • Protocol to guide step	16–400[f]

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	80
Biohazard/linen container moves	• Removing dirty linens	Large volumes of linens need to be placed in a biohazard containers that are often on wheels, which can move when large bundles are placed in them, making it easy to drop contaminated waste on the floor or onto the provider.	• Consider other equipment solutions	20
Failing to use appropriate linens or moisture barriers	• 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	20
Forgetting a step	• Sanitizing gloves • Cleaning tongs • Cleaning i.v. tubing • Post-procedure steps	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	16–280
Dropping linens	• Removing dirty linens from bed • Removing dirty linens from 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	6–9
Failure to recognize gross contamination	• Cleaning bed frame and nearby equipment • Cleaning IV tubing • Disinfecting 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[e]	56–168
Cannot reach contaminated area	• Cleaning floor	May be difficult to reach an area on the floor under the bed, and it may be difficult to move the bed.	• Flashlight	50
No place to put contaminated equipment while in use	• Cleaning tongs	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	45

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]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.
[b]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.
[c]The overview provides a further explanation of why this particular failure mode was identified.
[d]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.
[e]For certain process steps, there were no potentially effective solutions identified to mitigate the failure mode or risk.
[f]The highest RPNs were associated with performing a task with a patient that could not assist with their care, i.e., an intubated patient.
[g]Examples of medical devices include i.v. tubing, indwelling urinary catheter, nasogastric tube, arterial lines, or endotracheal tube.

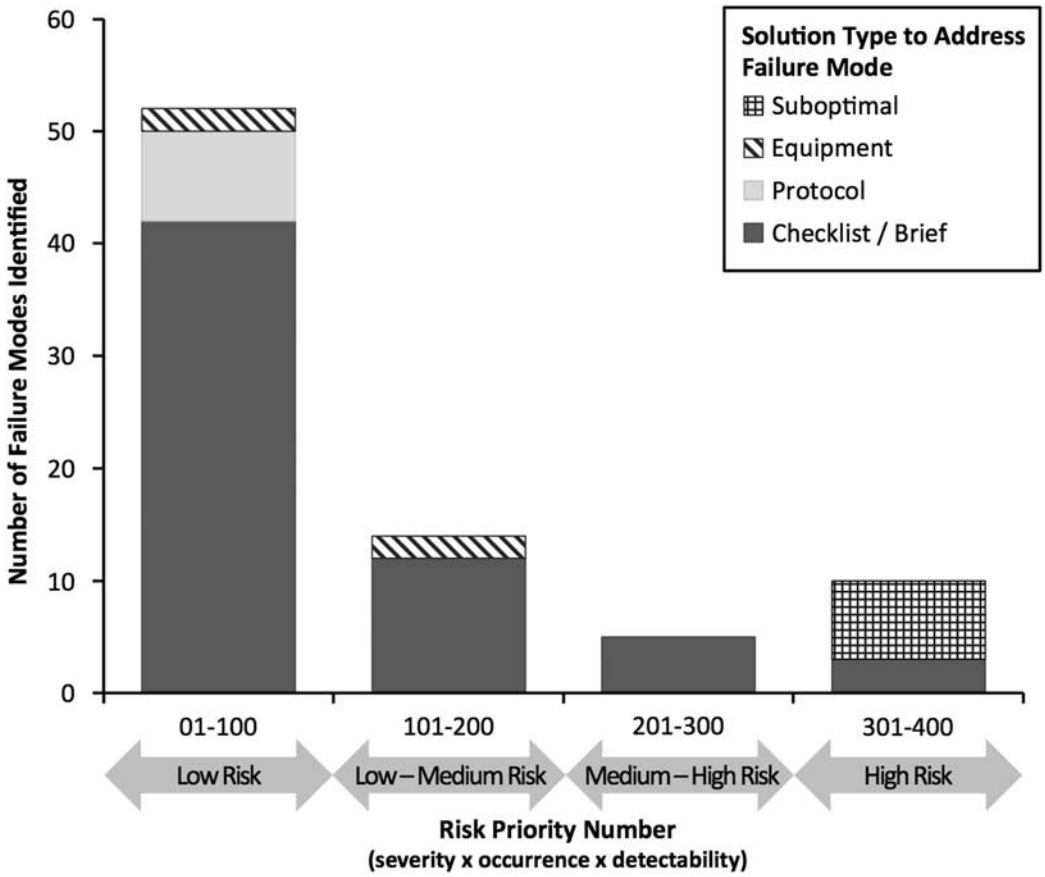

FIGURE 1. Results of failure mode effects analysis organized to demonstrate failure modes and potential solutions to mitigate risk grouped by risk priority number.

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.[6] 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.[7] 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 enforces a systematic approach and encourages the development of shared situational awareness between providers.[8] Situational awareness supports highly effective teamwork and patient safety in highly dynamic, high-risk patient care settings.[9] 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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REFERENCES

1. Ringen K, Landrigan PJ, O Stull J, Duffy R, Melius J, McDiarmid MA. Occupational safety and health protections against Ebola virus disease. *Am J Ind Med* 2015;58:703–714.
2. De Carli G, Fusco FM, Puro V, Ippolito G, Euro NWG. Adopting a global safety standard for the prevention of ebola needle-stick exposures. *Infect Control Hosp Epidemiol* 2015;36:745–746.
3. Agency for Healthcare Research and Quality. AHRQ Issue Brief: Health Care Simulation To Advance Safety: Responding to Ebola and Other Threats. Rockville, MD. February 2015.
4. Occupational Safety and Health Administration. Cleaning and decontamination of Ebola on surfaces: guidance for workers and employers in non-healthcare/non-laboratory settings. *OSHA Fact Sheet*. https://www.osha.gov/Publications/OSHA_FS-3756.pdf. November 2014.
5. Krouwer JS. An improved failure mode effects analysis for hospitals. *Arch Pathol Lab Med* 2004;128:663–667.
6. Donaldson MS. An overview of to err is human: re-emphasizing the message of patient safety. In: Hughes RG, ed. *Patient Safety and Quality: An Evidence-based Handbook for Nurses*. Rockville, MD: Agency for Healthcare Research and Quality. http://www.ncbi.nlm.nih.gov/books/NBK2673/. 2008.
7. Lipol LS, Haq J. Risk analysis method: FMEA/FMECA in the organizations. *IJBAS-IJENS* 2011;11:74–82.
8. Tschan F, Semmer NK, Gurtner A, et al. Explicit reasoning, confirmation bias, and illusory transactive memory a simulation study of group medical decision making. *Small Gr Res* 2009;40:271–300.
9. Burke CS, Salas E, Wilson-Donnelly K, Priest H. How to turn a team of experts into an expert medical team: guidance from the aviation and military communities. *Qual Saf Health Care* 2004;13:I96–I104.
10. Preventing worker fatigue among ebola healthcare workers and responders. Centers for Disease Control and Prevention website. http://www.cdc.gov/niosh/topics/ebola/pdfs/preventingworkerfatigueamongebolahcw122914.pdf. Accessed October 06, 2015.