

SHIP Project: Simulation and FMEA Results

Care of an EVD patient was simulated using a standardized patient in an EVD care unit. Teams (n=4) of two healthcare workers wearing high-level personal protection equipment (PPE) 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 as well as HCP-worn video glasses to allow identification of risk from visual field restriction.

A Failure Mode Effects Analysis (FMEA) was executed using the video recordings and existing EVD patient care protocols. A multidisciplinary team, including occupational health microbiologists, industrial hygienists, clinical experts, and human factors psychologists performed the FMEA. The analysis: (a) identified discreet process steps for fecal management, (b) identified associated risks of failure, or failure modes, for each step, and (c) assigned 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 three values together. For example, when placing a peripheral intravenous line, withdrawing the needle has a moderate (5) rate of failure (needlestick) that can be easily detected (1) with a mild (2) severity impact, resulting in an RPN of 10.

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

Figure 1.

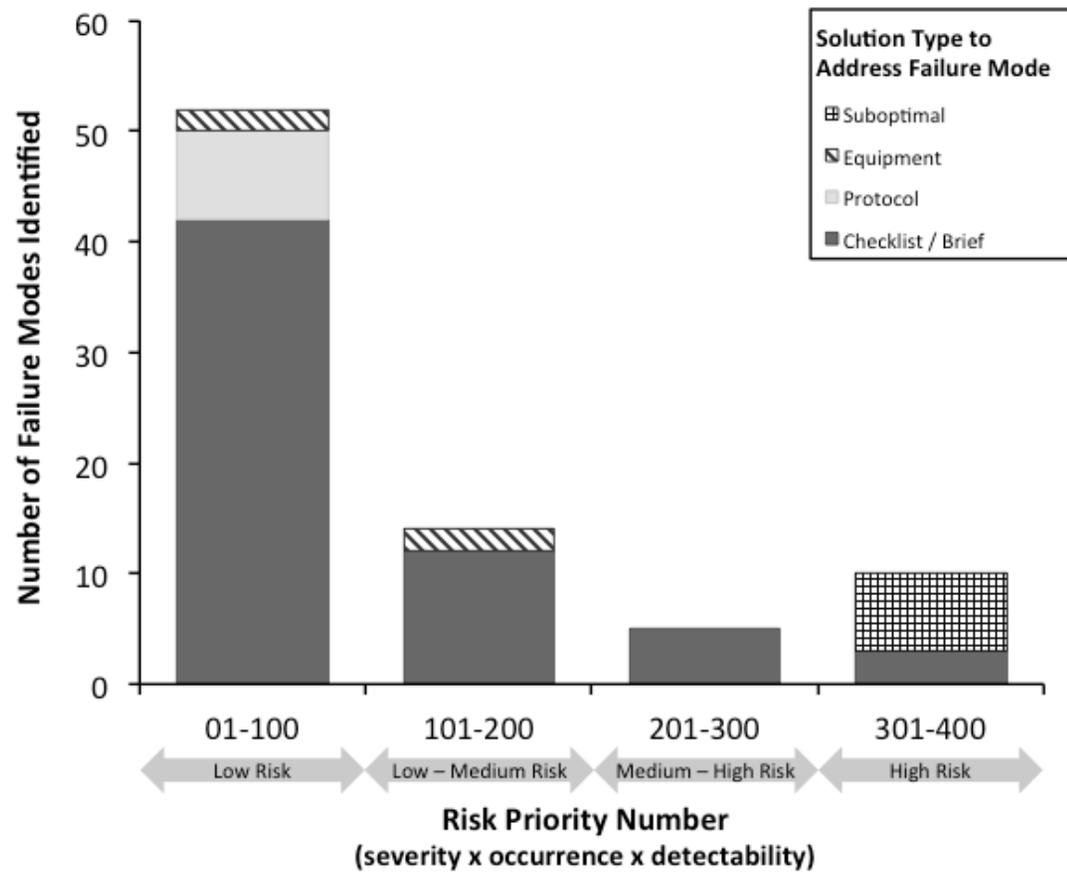


Table. Failure modes identified during risk analysis of hygienic care provision for an EVD patient with copious watery stool.

Failure Modes ^a	Example(s) of Process Steps Impacted ^b	Overview of Failure Mode ^c	Potential Solution(s)	RPN Range ^d
Item not available / Not enough of item available	<ul style="list-style-type: none"> • 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.	<ul style="list-style-type: none"> • Pre-brief checklist • Scheduled time-out 	20 – 60
Item not in close proximity	<ul style="list-style-type: none"> • 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.	<ul style="list-style-type: none"> • Pre-brief checklist • Scheduled time-out 	20 – 168
Provider contamination (feet)	<ul style="list-style-type: none"> • 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.	<ul style="list-style-type: none"> • No optimal solution identified^e • Identify patients appropriate for early rectal tube placement 	10
Provider contamination (body)	<ul style="list-style-type: none"> • Rolling patient onto side • Removing dirty linens • Cleaning patient • Placing contaminated linens into bin • Cleaning floor to remove contaminated linens 	HCP is often in close contact with the patient. Multiple steps require the HCP to directly handle soiled materials or use tools (e.g.: tongs) or materials (e.g.: towels) that are not well designed for the task. Despite best efforts, observers were not able to notice all high-risk exposures due to positioning or decreased attentiveness.	<ul style="list-style-type: none"> • 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	<ul style="list-style-type: none"> • 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.	<ul style="list-style-type: none"> • Larger sized cleansing wipes • Scheduled time-out • No optimal solution identified^e 	30 – 192

Failure Modes^a	Example(s) of Process Steps Impacted^b	Overview of Failure Mode^c	Potential Solution(s)	RPN Range^d
Recontamination of clean linens	<ul style="list-style-type: none"> • 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 over.	<ul style="list-style-type: none"> • Protocol for implementation of fecal management system 	40
Tripping over materials on the floor	<ul style="list-style-type: none"> • 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.	<ul style="list-style-type: none"> • No optimal solution identified^e • Protocol for initiation of fecal management system 	50
Accidentally dislodging medical devices ^g	<ul style="list-style-type: none"> • Roll patient onto side • Removing dirty linens 	This risk is similar to risks encountered for all patients. What is unique for EVD patients is the relative few number of HCP in the room and difficulty in obtaining help. This was seen as a big problem for high-need intubated patients.	<ul style="list-style-type: none"> • Timeout • Checklist item to identify all patient tubes and devices • Protocol to guide step 	16 – 400 ^f
Biohazard / linen container too full	<ul style="list-style-type: none"> • Cleaning patient • Removing dirty linens 	Procedure creates a large amount of waste, including linens that are quite bulky.	<ul style="list-style-type: none"> • Pre-brief checklist • Scheduled time-out 	80
Biohazard / linen container moves	<ul style="list-style-type: none"> • Removing dirty linens 	There are large volumes of linens that need to be placed in a biohazard containers that are often on wheels, and can move when large bundles are placed in them, making it easy to drop contaminated waste on the floor or onto the provider.	<ul style="list-style-type: none"> • Consider other equipment solutions 	20
Failing to use appropriate linens / moisture barriers	<ul style="list-style-type: none"> • 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 two incontinence pads were needed to limit contamination. As this is a deviation from normal nursing care, it was often done incorrectly and represents a point for potential error.	<ul style="list-style-type: none"> • Checklist • Timeout for reminder 	20
Forgetting a step	<ul style="list-style-type: none"> • Sanitizing gloves • Cleaning tongs • Cleaning IV 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.	<ul style="list-style-type: none"> • Checklist • Timeout for reminder 	16 – 280

Failure Modes^a	Example(s) of Process Steps Impacted^b	Overview of Failure Mode^c	Potential Solution(s)	RPN Range^d
Dropping linens	<ul style="list-style-type: none"> • 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.	<ul style="list-style-type: none"> • Ensure close proximity of dirty linen container • Use a large-sized linen to wrap smaller linens 	6 – 9
Failure to recognize gross contamination	<ul style="list-style-type: none"> • Cleaning bedframe and nearby equipment • Cleaning IV tubing • Disinfecting floor 	Noticing all areas that become contaminated with stool is extremely challenging, especially if under the bed or other furniture. PPE limits visual fields and makes it difficult to see.	<ul style="list-style-type: none"> • Timeout • No optimal solution identified^e 	56 – 168
Cannot reach contaminated area	<ul style="list-style-type: none"> • Cleaning floor 	May be difficult to reach an area on the floor if under the bed and may be difficult to move bed.	<ul style="list-style-type: none"> • Flashlight 	50
No place to put contaminated equipment while in use	<ul style="list-style-type: none"> • Cleaning tongs 	Specialized equipment doesn't necessarily have a clearly designated place to rest while in use as they present a risk for spreading gross contamination.	<ul style="list-style-type: none"> • Create a place to set contaminated hardware during procedure 	45

^a 16 failure modes related to Ebola patient hygienic care were identified. While it is possible to consolidate failure modes, we did not do so, as 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 will 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 / risk

^f Highest RPN were associated with performing task with a patient that cannot assist with their care, i.e., intubated patient

^g Examples of medical devices include IV tubing, indwelling urinary catheter, nasogastric tube, arterial lines, endotracheal tube

FMEA = failure mode effects analysis; RPN = risk priority number; PPE = personal protective equipment; EVD = Ebola virus disease; HCP = healthcare personnel