Safety and Health Investment Projects
FINAL REPORT REQUIREMENTS

The purpose of the final report of your SHIP project is to:

1. Evaluate and document the achievements, challenges, and shortcomings of the project for the constructive benefit of others interested in learning from SHIP projects; and
2. Provide the Division of Occupational Safety and Health with information that shows:
   a. The outcomes specified in the project application were met; and
   b. The grant was used for the purpose(s) for which it was approved and in accordance with relevant WAC rules and any special conditions or requirements; and
   c. The outputs of the project have been disseminated as specified in the application.

The report format has four sections:

1. Cover Sheet
2. Narrative Report (part I)
3. Financial Information (part II)
4. Attachments (part III)

Please provide complete and detailed information in the final report. If you have questions, please call your SHIP grant manager.

REMINDER!!: All products produced, whether by the grantee or a subcontractor to the grantee, as a result of a SHIP grant are in the public domain and can not be copyrighted, patented, claimed as trade secrets, or otherwise restricted in any way.

SAFETY AND HEALTH INVESTMENT PROJECTS
FINAL REPORT

Personal Protective Equipment Training for Health Care Workers Treating Patients with Highly Contagious Infectious Diseases

2014XH00293

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Ross Ehrmantraut, RN
rherma@u.washington.edu

Rosemarie Fernandez, MD
fernanre@uw.edu

University of Washington / UW Medicine / Virginia Tech Carilion Research Institute / MedStar Health

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R. Fernandez

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PART I
Narrative Report

Abstract

Background

Providing care to patients with highly lethal infectious diseases such as Ebola virus disease (EVD) presents a major, immediate challenge to healthcare institutions. High-level personal protective equipment (PPE) requirements for healthcare workers (HCWs) treating Ebola virus patients include equipment that can limit peripheral vision, gross and fine motor skills, and spatial awareness and result in injuries from needlesticks and falls. Currently available training on high-level PPE for US healthcare workers is inadequate and does not consider the physical limitations and additional safety risks posed by PPE.

Objective

To design and deliver a short course that addresses the unique health and safety needs of HCWs treating highly contagious, emergent infectious diseases.

Methods

Risk Assessment: We conducted 20 separate simulations to identify high-risk occupational hazards associated with high level PPE use during the routine care of patients with highly infectious disease. Simulations were video recorded and reviewed by a multidisciplinary panel to identify potential risks to HCWs as well as possible solutions.

Just-in Time Training App: The results from the risk assessment informed the development of a just-in-time training application for use on smartphones or tablets that could be used for either training purposes or to guide care at the bedside. The "app" specifically targeted high risk components of care and incorporated recommended solutions.

Train-the-trainer Course: We developed and implemented a full day train the trainer course that (1) described hospital response processes for high risk infectious disease outbreaks, (2) incorporated lessons learned from national and international response to EVD, (3) demonstrated how simulation could be used to train critical skills and assess individual and system proficiency, (4) taught participants a low cost method for teamwork training in high-risk environments, and (5) provided hands-on experience performing basic patient care while wearing full PPE. As part of the training, we developed a manual that outlined an evidence-based approach to risk assessment, provided a simulation guide including performance assessment, and contained all material presented during the course. Participant knowledge and comfort with procedures was assessed.

Results

Attendees rated the course as beneficial, with pertinent content and informative speakers. Pre- / post measures of attendee confidence demonstrated increased self-efficacy in all ten areas.

Abbreviations Used in Report

- **PPE** = personal protective equipment
- **EVD** = ebola virus disease
- **HCW** = healthcare worker
- **JIT** = just-in-time

Purpose of Project:

The purpose of our project was to provide training that ensures the occupational safety of HCWs engaged in the care of patients with highly contagious diseases by providing (1) information focused on high-risk activities, (2) opportunity for guided practice, and a (3) handheld JIT training app that can be deployed to any setting. Specifically, we planned to:

- Identify HCW high-risk occupational activities associated with high level PPE use during the care of patients with highly infectious, lethal diseases
- Decrease injuries and exposures associated with caring for patients with highly infectious, lethal diseases
- Improve HCW competency and comfort with wearing high level PPE during clinical care

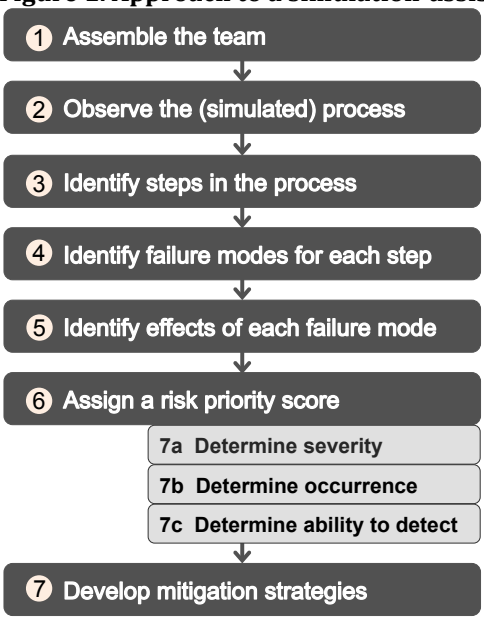
- Decrease anxiety associated with caring for patients with highly infectious, lethal diseases

Statement and Evidence of the Results:

Objective 1: Identify activities associated with significant risk for HCWs using high level PPE.

For **Objective 1**, the Project Team executed multiple simulations of routine care activities while wearing high-level PPE. They then performed a failure mode and effects analysis (FMEA), a proactive approach to risk analysis often used in high reliability organizations. FMEA provides a systematic way to uncover latent threats to safety and identify potential solutions to address high-risk work-related tasks.[5] Figure 1 outlines the steps in the FMEA.

Figure 1. Approach to a simulation-assisted FMEA.



We formed a total of 7 nurse/physician teams. Team composition was similar to what would exist in an Ebola unit. Each team performed multiple simulations, including:

1. Video-assisted intubation
2. Ultrasound-guided central venous catheter placement
3. Peripheral IV placement
4. Indwelling urinary catheter placement + urine receptacle change
5. Rectal tube placement (fecal management system) + stool receptacle change
6. Linen change and patient hygiene

Each simulation was video recorded from 4 views:

1. "Foot of the bed" view
   This view provided a holistic recording of all events, including HCW-HCW interaction, HCW-patient interaction, and HCW-equipment interaction.
2. Task view
   This view targeted the provider and patient as procedures were performed. The focus was on the part of the provider most at risk for exposure during the procedure.
3. Observer view
   This view reflected what the HCW team member charged with "observing" actually saw. Using "camera glasses" (Figure 2) we were better able to understand the role of the observer, the inherent limitations of the role, and ways to train the observer to make their role more effective
4. Provider view
   This view reflected with the HCW team member performing the procedure could see. This view also made use of camera glasses (Figure 2), this time worn by the HCW executing the

procedure. In this case, we were able to understand how high level PPE limited field of vision and overall visual awareness. Because the glasses also captured audio, we were able to detect challenges associated with hearing while in PAPRs (Figure 3).

Figure 2. Camera glasses

Once videos were recorded, the content from each camera view was synchronized to allow a comprehensive review of each procedure. An interdisciplinary team of nurses, physicians, industrial hygienists, and safety experts watched all videos and performed a risk analysis to identify components of care that were of particular threat to HCW safety. Several themes were identified as risks across all procedures. Below we list risk categories and identified solutions.

1. **Fatigue:** After only 30 minutes in full PPE, HCWs reported significant levels of fatigue. This correlated with increased inattention noted in the HCW observer. By using views from the HCW observer camera glasses, we were able to gauge when the observer seemed to have drifts in their attention. These became more frequent the longer HCWs spent in the high level PPE.

   Solution: Frequent use of time-outs and huddles to re-orient HCW attention and assess for need to rest. We noted that the solutions to fatigue were not without their own risks, and fatigue became the number one threat to HCW safety that could not be easily mitigated.

2. **Equipment preparedness:** Routine equipment set-up was found to be inadequate for executing procedures while wearing high-level PPE. Duplication of supplies provided a decrease in exposure risk and a decrease in spread of infectious agent. Additionally, routine supplies such as bed linens, towels, and disinfectant wipes were used at a much higher rate. Since these supplies were all disposed of after a single use, the amount of trash and need for multiple trash receptacles was considerably higher than initially suspected. Without easily accessed, foot-operated trash receptacles, HCWs often contaminated themselves attempting to dispose of trash.

   Solution: Use simulations to understand where supplies should be placed, including trash receptacles. To ensure adequate supplies, use a checklist-approach to each procedure to ensure adequate resources available. The checklist should be performed at the start of each procedure.

3. **Fall hazards:** Due to bulky clothing and decreased peripheral vision, HCWs had difficulty maneuvering within the clinical space. This was especially challenging when it was necessary to remove contaminated body fluids or materials from the floor. We noted significant fall risks and contamination risks. These were not easily remedied, and while we offered several solutions, all were considered suboptimal.

   Solution: Proper positioning of the HCW observer could help mitigate fall risks; however, keeping soiled material and body fluids off the floor (thus preventing spreading of agent) remained a constant challenge.

The investigators performed a full failure mode effects analysis (FMEA) on the changing of bed linens and provision of hygienic care. We chose this procedure for an in-depth analysis as there had been no reported evaluation of this procedure, yet managing copious stool production was recognized as a significant challenge in the care of Ebola-infected patients.

DELIVERABLE: Manuscript

Fernandez R, Mitchell SH, Ehrmantraut R, Simcox, NJ, Wolz, S, Meschke, JS, Parker SH. Proactive risk assessment for Ebola infected patients: A systematic approach to identify and minimize risk for healthcare personnel. *Infect Control Hosp Epidemiol* (in press, see Attachment 1).

Objective 2: Develop a training course for HCWs that specifically targets high-risk activities associated with high level PPE use.

The Project Team utilized the results of the risk assessment conducted in Objective 1 to create the framework for the training course. They then conducted an extensive literature review to ensure all content was up-to-date and relevant. Finally, they presented the content of their training to the project Advisory Board for feedback and recommendations. The training, ***Treating Patients with Highly Contagious Infectious Diseases: Using Technology to Advance Safety,*** included four components described briefly below.

DIDACTICS

The didactic component of training was designed to illustrate work-related activities that place HCWs using high-level PPE at risk for infectious agent exposure or other work-related injury. Our comprehensive approach involved descriptions of individual, team, and system approaches to dealing with emerging infectious diseases. First, this session brought experts in hospital preparedness to the audience to discuss a rapid, effective mechanism for preparing healthcare systems to safely and effectively address emerging infectious disease threats. Second, we focused on providing attendees with an evidence-based approach to risk assessment and mitigation using high-fidelity simulation and failure mode effects analysis (FMEA). We provided a step-by-step guideline for simulation design for both training and assessment. Finally, we introduced attendees to the importance of teamwork and team skills for HCWs functioning in high-risk environments such as specialized communicable disease units.

JUST-IN-TIME (JIT) TRAINING

Just-in-Time training provides targeted instruction when and where it is needed, thus eliminating loss of skills due to a lag between training and use. We used the information elicited through the FMEA (Objective 1) to design a JIT application targeting EVD patient hygiene and fecal management. To maximize usability, the JIT app is compatible with Android or iOS devices. The content of the training is flexible while ensuring adequate coverage of critical material. Specifically, the JIT training included (1) checklists to ensure adequate materials and resources for the procedure, (2) built in "time outs" to refocus HCW attention and perform fatigue checks, and (3) post-procedure debrief to review the procedure and prompt any recommendations for system changes. The HCW could revisit sections and seek further detailed information at any time, thus providing a flexible, tailored training experience. The resulting JIT training is easily disseminated, portable, and targeted to the learner.

SIMULATIONS

Figure 3. Simulated EVD airway management.

The simulations developed for the risk assessments in Objective 1 were adapted for use during the training course to provide a hands-on, immersive learning environment that replicates risks present in the actual clinical environment. We designed the simulations for both training and assessment purposes. To facilitate replication of simulations at other institutions, we developed an in-depth instructor guidebook for conducting simulations. We also created a workbook that includes a step-by-step approach to simulation design. This will facilitate the use of simulation for other high-risk activities presenting occupational hazards.

MEASURES
We developed specific measures to assess learner self-efficacy (confidence), knowledge of EVD care and infectious disease response, and skill performance during simulated EVD care scenarios. **Self-efficacy measures** were adapted from the literature and modified to reflect EVD patient care. These measures were piloted amongst a group of subject matter experts to ensure the material is relevant and appropriate and the wording of items is clear. Ambiguous or irrelevant items were further modified or discarded. A **basic knowledge multiple-choice exam** was developed to reflect understanding of the didactic material. Items underwent similar subject matter expert review to establish relevance and clarity of items. Finally, we developed existing **procedural skill checklists** that could be used to assess competency during simulated patient care experiences. These checklists were modified from existing validated assessment tools. Modified checklists were piloted and evaluated for evidence of reliability and content validity.

DELIVERABLE: Curriculum components
We have created a website to host all components of the training on-line at the UW DEOHS CE website (https://osha.washington.edu/pages/infectious-ppe) so HCWs across the state will have access to the training. We will disseminate study results and training materials by collaborating with our partners and practitioners from our Washington healthcare professional organizations. Components include (Attachment 3 – 8):

1. Course agenda
2. JIT training app available for download
3. Simulation flow sheets and procedural checklist
4. FMEA and simulation workbook
5. Self-efficacy measures (Likert scale)
6. Website link with all course materials

Objective 3: Training course delivery

The train-the-trainer course developed in Objective 2 was delivered to 44 learners on April 6, 2016 at the University of Washington WWAMI Institute for Simulation in Healthcare (Attachment 3, Course Agenda). ***Treating Patients with Highly Contagious Infectious Diseases: Using Technology to Advance Safety*** was offered at a cost of $100 (trainees $50). Attendees traveled from Alaska, California, Oregon, British Columbia and Washington State and represented a wide variety of clinical and non-clinical expertise. For example, one small group contained laboratory scientists, an industrial hygienist, a critical care physician, and an administrator responsible for occupational health within the fishing industry. All four components of training were delivered. Course evaluations are presented in Figures 4 – 6. In general, attendees appeared to have enjoyed the content and method of instruction. The conflicting feedback (i.e., one attendee would like to "remain in entire PAPR (PPE) longer" versus one attendee stating they would prefer "not being suited in PPE for entire workshops") likely reflected the wide variability in attendee background. Below we present key areas of evaluation (Figures 4 – 6).

Figure 4. Cumulative Speaker Performance (reflects evaluations across all presenters)

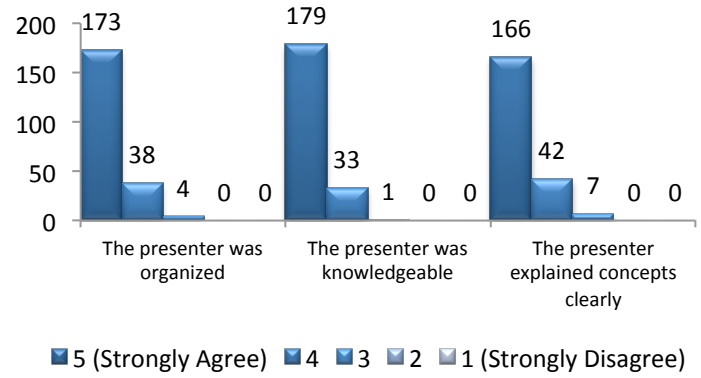


Figure 5. Presented Content

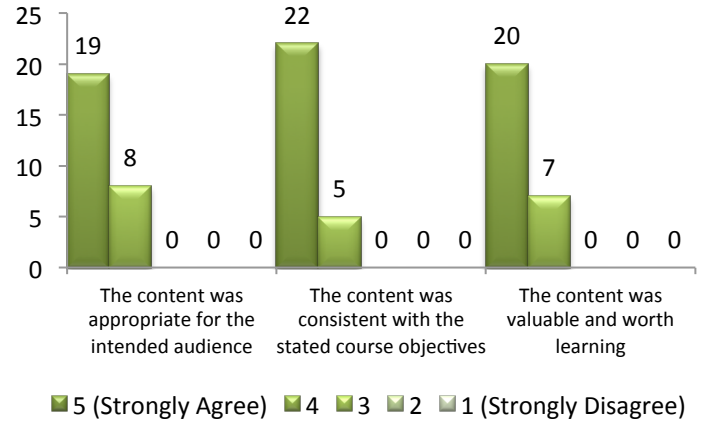
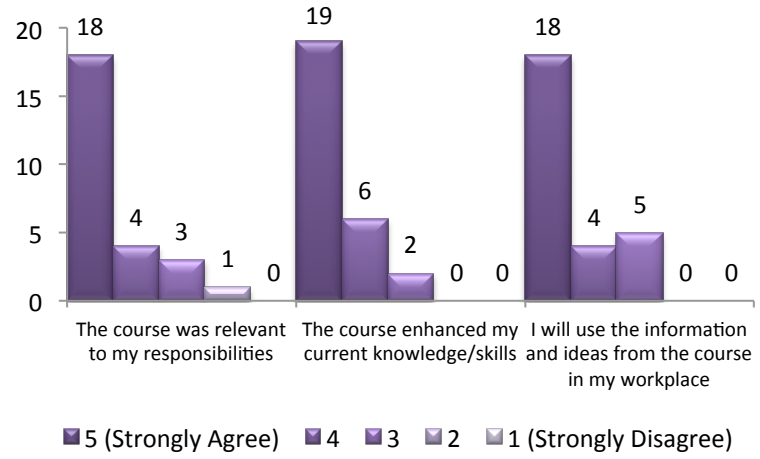


Figure 6. Participant benefits



DELIVERABLE: Video recordings of lecture material

Video recordings of the training are on-line at the UW DEOHS CE website:

(https://osha.washington.edu/pages/infectious-ppe).

Objective 4: Assessment of immediate outcomes

FULL COURSE – Treating Patients with Highly Contagious Infectious Diseases: Using Technology to Advance Safety (Seattle, WA)

Training outcomes were assessed using the measures developed in Objective 2.
Pre-/ post-training **self-efficacy outcomes** are shown in Table 1. We demonstrated significant improvement in self-efficacy in all 10 content areas.

Post-training knowledge improvement was assessed through the Centers for Disease Control ans Prevention continuing education website (www.cdc.gov/TCEOnline). Preliminary data demonstrate **mean posttest score of 90%.**

The Project Team intended to assess **procedural skill** competence during the simulation component of the course. However, a large number of attendees were not clinical providers (e.g., nurses or physicians); therefore, the clinical skill assessment did not make sense. We therefore shifted to focus of the simulations to provide all participants an opportunity to gain an appreciation of the challenges associated with providing clinical care while wearing high level PPE.

Table 1. Self-efficacy measurement pre- and post-training.

Self-efficacy Domains	Pre		Post		Mean Difference
	Mean	SD	Mean	SD	[95% CI]
Recognize the requirements of an institutional response to care of an EVD patient.	3.43	1.60	4.71	0.81	1.28 [0.59, 1.97]
Explain how institutions can develop healthcare worker EVD clinical expertise rapidly.	2.86	1.33	4.38	0.82	1.52 [0.91, 2.13]
Recognize the potential role of FMEA in the evaluation of EVD protocols.	2.12	0.95	4.38	0.82	2.26 [1.75, 2.77]
Identify specific risks associated with maintaining industrial hygiene and occupational safety during a "novel" infectious disease outbreak (e.g. EVD).	3.23	1.31	4.58	0.72	1.35 [0.76, 1.95]
Use FMEA data to inform protocol development.	1.93	1.00	4.38	1.06	2.45 [1.87, 3.03]
Identify appropriate applications for simulation-based training of HCWs on high-risk infectious disease-related activities.	2.64	1.31	4.46	0.83	1.82 [1.21, 2.42]
Execute a simulation-based technology based on training or assessment objectives.	2.19	1.18	4.21	0.93	2.02 [1.42, 2.63]
Understand key teamwork competencies germane to caring for a patient with EVD.	3.00	1.30	4.67	0.76	1.67 [1.07, 2.26]
Identify key teamwork behaviors that are critical to healthcare worker safety when performing high risk (e.g. EVD) patient care.	3.36	1.25	4.83	0.87	1.48 [0.88, 2.07]
Discuss the risks associated with wearing high-level PPE while performing routine patient care activities.	3.86	1.48	4.96	0.81	1.10 [0.45, 1.76]
Define three ways to mitigate occupational health risks to employees during the care of an EVD patient.	3.32	1.52	4.75	0.99	1.43 [0.72, 2.13]
Average Confidence	**2.92**	**1.04**	**4.57**	**0.71**	**1.65 [1.16, 2.14]**

FMEA AND SIMULATION CONDENSED CONTENT – Danger Will Robinson! Identify High Risk PPE-Related Occupational Activities

We presented a condensed 90 minute version of our full-day course at the *2016 International Meeting for Simulation in Healthcare, San Diego, CA.* This course focused on developing simulations to conduct FMEAs and identify healthcare risks (Attachment 2). **We targeted this conference as a way to develop shorter workshops for targeted audiences.** We felt that our methodology and

risk analysis approach was most applicable across a broad range of topics and therefore the best place to start. Through this course we trained an additional 13 indiviudals. Evaluations for this course are listed in Table 2.

Table 2. Course evaluation for the *2016 International Meeting for Simulation in Healthcare*

Item	Average Score*
Give an overall ranking for this course.	4.5
Degree to which learning objective #1 was addressed:	4.63
Degree to which learning objective #2 was addressed:	4.63
Degree to which learning objective #3 was addressed:	4.63
This course was applicable to my practice.	4.38
Degree to which this content matched my expertise on this topic:	4
Please evaluate the effectiveness of each faculty member for this course: Rosemarie Fernandez, MD	4.63
Please evaluate the effectiveness of each faculty member for this course: Ross Ehrmantraut, RN	4.63
Please evaluate the effectiveness of each faculty member for this course: Sarah Parker, PhD	4.63
Please evaluate the effectiveness of each faculty member for this course: Steven Harold Mitchell, MD	4.63

*Scored on a Likert scale (5= strongly agree, 4=agree, 3=neutral, 2=disagree, 1=strongly disagree)

Measures to Judge Success:

Objective 1. The FMEAs conducted for Objective 1 produced quantifiable risk assessment linked with safety solutions. Our process underwent peer review and was accepted for publication (Attachment 1).

Objective 2. Training development was closely monitored by our Advisory Board. Members of the Board were also recruited to help deliver key content during the course.

Objective 3. Training quality and delivery was assessed by course attendees.

- Treating Patients with Highly Contagious Infectious Diseases: Using Technology to Advance Safety (Figures 4 – 6)
- Danger Will Robinson! Identify High Risk PPE-Related Occupational Activities (Table 2)

Objective 4. Our data demonstrate improved self-efficacy and knowledge around EVD patient care, high-level PPE, risk assessment, and simulation (Table 1 and above). We wished to assess improvement in procedural skills; however, many of our conference attendees were non-clinical personnel. We therefore refocused our planned procedural stations to provide attendees with the materials and knowledge necessary to implement training at their facilities.

Relevant Processes and Lessons Learned:

Objective 1. We applied a structured risk analysis method (FMEA) to high-risk patient care activities. This approach can be adapted for a large number of clinical activities associated with risk for healthcare workers. We disseminated our efforts in a peer-reviewed manuscript and at the 2016 International Meeting for Simulation in Healthcare. This work provides an overview of how FMEAs can be used to proactively support healthcare worker safety related to emerging infectious threats. The workbook (Attachment 6) provides a step-by-step roadmap for this process. We feel it is important to stress that involving a truly interdisciplinary team in the FMEA was critical to both identifying safety risks and solutions.

Objective 2. We developed a Just-in-Time application that incorporates key error-prevention techniques (e.g., time-outs, checklists). This JIT approach goes beyond standard training to provide a bedside aid that supports healthcare worker safety. Others can use what we've created as a framework for applying similar technology and content to other high-risk activities.

Objective 3. Simulation-based training proved to be a powerful mechanism for both training and assessment of healthcare professionals. We found that video capable of capturing the healthcare workers' point of view was extremely valuable. These video recordings demonstrated the challenges associated with maintaining high levels of vigilance for long periods of time and underscored the importance of training observers and providing safety supports (e.g., JIT application).

Objective 4. Through our training, we attempted to advertise across a wide range of professions and clinical environments. The result was a very interprofessional audience. This resulted in several challenges, most notably difficulty meeting the specific needs of every attendee. Going forward, conducting two-day sessions might be useful. This would allow a single day of introductory material and administrative / training development details followed by a second day that focuses on hands-on clinical care. Several attendees also wished they had more time to network, which would have been something possible with more time.

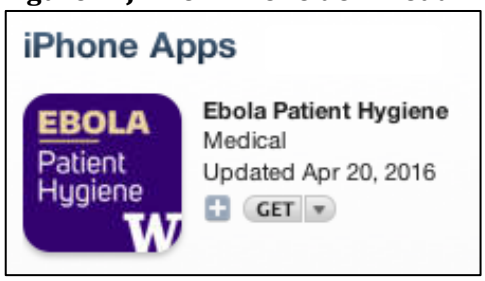
Product Dissemination:

Objective 1. The results from Objective 1 were disseminated in a peer-reviewed manuscript. Fernandez R, et al. Proactive risk assessment for Ebola infected patients: A systematic approach to identify and minimize risk for healthcare personnel. *Infect Control Hosp Epidemiol* (in press). (Attachment 1)

Our findings related to Objective 1 were also presented at the 2016 International Meeting for Simulation in Healthcare (Danger Will Robinson! Identify High Risk PPE-Related Occupational Activities) (Attachment 2)

Objective 2. The JIT application is available through the Google Play Store and the Apple App store (Attachment 4). We are also placing download instructions present on the UW DEOHS CE website (https://osha.washington.edu/pages/infectious-ppe).

Figure 7. JIT for iPhone download link



Objective 3. Training materials, including powerpoint presentations, simulation instructions (flow
Objective 4. sheets), FMEA and simulation workbook, and assessments are all being placed on the UW DEOHS CE website (https://osha.washington.edu/pages/infectious-ppe) for easy accessibility. Additionally, we will have links to video recordings of presentations for viewing by any interested individual. Dr. Mitchell will be presenting the material to the Washington State Medical Association and will allow access to all training materials if desired.

Future Dissemination

We are planning an email blast advertising the **UW DEOHS CE website** (https://osha.washington.edu/pages/infectious-ppe) containing our materials. This will be sent to healthcare organizations including the Washington State Nurses Association (WSNA), Northwest Association of Occupational and Environmental Medicine (NAOEM), Washington State Association of Occupational Health Nurses (WAOHN), Association of Occupational Health Professionals in Healthcare (AOHP) and Washington State Healthcare Safety Council.

Our work will be presented at the **2016 Northwest Occupational Health Conference** (S. Wolz), a conference targeting 250 health and safety expertis in the Northwest.

We intend to submit our work for presentation at the **2017 WA Governor's Industrial Safety and Health Conference**.

Feedback:

1. Please see Figures 4 – 6 for direct feedback regarding our training course.

2. Please see Objective 4 (above) for training evaluation data.

3. We presented a condensed version of the course focusing on FMEA and simulation at the 2016 International Meeting for Simulation in Healthcare. Through this course we trained an additional 13 indiviudals. Evaluations for this course are listed in Table 2.

Project's Promotion of Prevention:

We produced training methods and materials that support healthcare worker training on best practices associated with EVD patient care. Our content reaches far beyond EVD care by providing a proactive approach to risk analysis and training for any high-risk patient care activity. The application of simulation-supported FMEA to patient care processes is somewhat novel and can be used across healthcare institutions. The simulations allow practical, hands on practice and assessment to ensure that healthcare workers can safely and effectively perform their tasks in a risk-free environment (simulation). Finally, the JIT app supports both an evidence-based, safety-focused approach to training AND implementation of best practices at the patient's bedside.

Of note, one of our course attendees, Christa Arguinchona, is presenting her work on the **Special Pathogens Unit at Providence Health Care (Spokane, WA)** to the 2016 Washington Governor's Industrial Safety and Health Conference. Our course helped us network with the community in Spokane and provided guidance and resources to this unit.

Uses:

Training

The didactic component of the EVD training curriculum could be used to provide foundational knowledge to all healthcare workers. The video recordings allow distributed, on-demand access and limits the training resources required. The simulations can be used with more targeted HCW learners, as they require more intensive resources. The simulations can easily be adapted to be more institutionally-specific, thus providing more realistic training experiences. This tiered approach to training is most cost-effective and delivers necessary information and skills to the correct individuals and teams.

JIT app

The JIT app can support both training as well as actual patient care. It is designed to be easily downloaded onto any portable device. Our recommended use is within the care environment, with a provider outside of the EVD "hot zone" guiding the actions of the bedside providers. As a training device, the JIT app can be used to assess performance to ensure safety-oriented approaches to activities.

Simulation-guided FMEA

The FMEA and associated workbook provides safety personnel, administrators, and HCWs with an approach to prospectively identify occupational risks. Our methodology involved combining simulation and FMEA. This was necessary, as no US institution has what one would consider substantial experience with EVD patients. In situations where one must assess risk associated with rarely performed activities, video-recorded simulations provide "experience" data to inform the FMEA. Our methodology can be applied to any number of clinical and non-clinical activities presenting high levels of risk to employees.

Organization Profile:

University of Washington (Managing Partner)

- The **University of Washington School of Medicine** is dedicated to improving the health and well being of the public. It acknowledges a special responsibility to the people in Washington, Wyoming, Alaska, Montana, and Idaho, who have joined with it in a unique regional partnership.
- The **UW School of Public Health DEOHS CEP** has as its primary goal to translate current occupational and environmental health research from UW faculty and others into usable information for practitioners and workplaces, and also improve pedagogical methods and use of technology in the delivery of training programs.

UW Medicine (Primary Industry Partner)

- **UW Medicine's** mission is to improve the health of the public by advancing medical knowledge, providing outstanding primary and specialty care to the people of the region, and preparing tomorrow's physicians, scientists and other health professionals. UW Medicine holds the core belief that it is a leader in healthcare, employee training, and occupational safety throughout Washington State and the WWAMI region.

Virginia Tech Carilion Research Institute (Subcontract)

- The **Virginia Tech Carilion Research Institute** seeks to improve human health and quality of life by providing leadership, innovation, and high-impact discoveries in biomedical research and by contributing to medical education. Research conducted by Institute scientists is aimed at understanding the molecular basis for health and disease and developing the diagnostic tools, treatments, and therapies that will contribute to the prevention and solution of existing and emerging problems in medicine. Institute investigators also contribute to solving these problems by participating in the research training of tomorrow's physicians enrolled in the Virginia Tech Carilion School of Medicine.

Medstar Health (Subcontract)

- MedStar Health combines the best aspects of academic medicine, research and innovation with a complete spectrum of clinical services to advance patient care. Our areas of clinical excellence include cardiology and cardiac surgery, orthopaedics, cancer, transplantation, rehabilitation, and emergency and trauma services.

Additional Information

Project Type

- ☐ Best Practice
- ☐ Technical Innovation
- ☒ Training and Education Development
- ☒ Event
- ☐ Intervention
- ☐ Research
- ☐ Return to Work
- ☒ Other (Explain): Risk analysis

Target Audience:

- Healthcare workers
- Occupational health and safety experts
- Industrial hygienists
- Travel health specialists
- Public health officials
- Hospital administration
- Healthcare educators

Languages:

English

Please provide the following information - - *(information may not apply to all projects)*

# classes/events:	2
# hours trained	12
# students under 18	0
# workers	57
# companies represented	>25
# reached (if awareness activities)	N/A*
Total reached	57*

*we will monitor access of our website; however we are unable to monitor manuscript access.

Have there been requests for project products from external sources?

No, but all of our material is or will be accessible to the public through our website: https://osha.washington.edu/pages/infectious-ppe

Industry Classification (check industry(s) this project reached directly)

- ☐ 11 Agriculture, Forestry, Fishing and Hunting
- ☐ 21 Mining
- ☐ 22 Utilities
- ☐ 23 Construction
- ☐ 31-33 Manufacturing
- ☐ 42 Wholesale Trade
- ☐ 44-45 Retail Trade
- ☐ 48-49 Transportation and Warehousing
- ☐ 51 Information
- ☐ 52 Finance and Insurance
- ☐ 53 Real Estate and Rental and Leasing
- ☒ 54 Professional, Scientific, and Technical Services
- ☐ 55 Management of Companies and Enterprises
- ☐ 56 Administrative and Support and Waste Management and Remediation Services
- ☒ 61 Educational Services
- ☒ 62 Health Care and Social Assistance
- ☐ 71 Arts, Entertainment, and Recreation
- ☐ 72 Accommodation and Food Services
- ☐ 81 Other Services (except Public Administration)
- ☐ 92 Public Administration

List, by number above, industries that project products could potentially be applied to.

92, 56, 81

Potential impact (in number of persons or companies) after life of project?

We created durable products that can be distributed throughout Washington State and beyond. Our train-the-trainer work allowed individuals to implement our material in their institutions and adapt it for other purposes as needed. Our JIT app will be available and "advertised" on our website: (https://osha.washington.edu/pages/infectious-ppe). We cannot project the number of persons impacted by our efforts; however, our materials will be directly offered to medical students, nursing students, and residents at the University of Washington. As such, we will reach a minimum of 1500 individuals throughout the WWAMI (Washington, Wyoming, Alaska, Montana, Idaho) region.

PART II

Financial Information
Budget Summary

Project Title:	Personal Protective equipment training for health care workers treating patients with highly contagious infectious diseases		
Project #:	2014XH000293	**Report Date:**	6/8/2016
Contact Person:		**Contact #:**	
Start Date:	02/01/2015	**Completion Date:**	05/31/2016

1.	**Total original budget for the project**	$ 199993
2.	**Total original SHIP Grant Award**	$ 199993
3.	**Total of SHIP Funds Used**	$ 199993
4.	**Budget Modifications (= or - if applicable)**	$ 0
5.	**Total In-kind contributions**	$ 39608
6.	**Total Expenditures (lines 3+4+5)**	$ 239601

Instructions:

- Complete the Supplemental Schedule (Budget) form first (on the next page).
- The final report must include all expenditures from date of completion of interim report through termination date of grant.
- Indicate period covered by report by specifying the inclusive dates.
- Report and itemize all expenditures during specified reporting period per the attached supplemental schedule.
- Forms must be signed by authorized person (see last page).
- Forward one copy of the report to **Arlene Hallom, SHIP Grant Manager** at **PO Box 44612, Olympia, WA 98504I-4612**

Project Title:	Personal Protective Equipment Training for Health Care Workers Treating Patients with Highly Contagious Infectious Diseases
Project #:	2014XH00293 **Report Date:** 6/8/16
Contact Person:	**Contact #:**
Total Awarded:	199,993

ITEMIZED BUDGET: How were SHIP award funds used to achieve the purpose of your project?

	Budgeted for Project	Amount Paid Out	Difference
A. PERSONNEL	143878	154154.4	-10276.4
Explanation for Difference and other relevant information: During the project period there was a mandatory salary & fringe rate increase for all key project personnel. We were able to offset this increase by having a substantial number of supply items donated by the primary institution, the University of Washington. The University of Washington WWAMI Institute for Simulation in Healthcare also donated the facility for the training course. As a result, the project stayed within budget despite salary increases.			

	Budgeted for Project	Amount Paid Out	Difference
B. SUBCONTRACTOR	23464	23464	0
Explanation for Difference and other relevant information: N/A			

	Budgeted for Project	Amount Paid Out	Difference
C. TRAVEL	3000	929.61	2070.39
Explanation for Difference and other relevant information: The initial budget reflected costs for two individuals to travel from out of state for the training course. We were fortunate that Dr. David Townes, an international expert on infectious disease response was present in Seattle during the conference. As a result, only support for Dr. Sarah Parker's travel was required. Of note, the PI Dr. Fernandez supported travel for Dr. Parker, Dr. Fernandez, and Dr. Mitchell to deliver the short course at the International Meeting on Simulation in Healthcare. This allowed us to use the difference in travel funds to support salary costs associated with mandatory rate increases.			

	Budgeted for Project	Amount Paid Out	Difference
D. SUPPLIES	8399	993.32	7405.68
Explanation for Difference and other relevant information: The project team was fortunate to have a large number of simulation supplies and PPE-related disposables donated for the training. This allowed us to use the difference in travel funds to support salary costs associated with mandatory rate increases.			

	Budgeted for Project	Amount Paid Out	Difference
E. PUBLICATIONS	1750	1100.41	649.59
Explanation for Difference and other relevant information: Costs for printing and memory sticks was less than anticipated. This allowed us to use the difference in travel funds to support salary costs associated with mandatory rate increases.			

	Budgeted for Project	Amount Paid Out	Difference
F. OTHER	1320	1169.24	150.76
Explanation for Difference and other relevant information: Costs were close to projected amounts. The small amount of remaining funds was used to support salary costs associated with mandatory rate increases.			

	Budgeted for Project	Amount Paid Out	Difference
TOTAL DIRECT COSTS	181811	181811	0
	Budgeted for Project	Amount Paid Out	Difference
TOTAL INDIRECT COSTS	18182	18182	0
	Budgeted for Project	Amount Paid Out	Difference
TOTAL SHIP BUDGET	199993	199993	0

	Budgeted for Project	Amount Paid Out	Difference
G. IN-KIND	39608	39608	0
Explanation for Difference and other relevant information:			

I hereby certify that the expenditures listed on this report were made with my approval:

June 9, 2016
Date

Signature of Project Manager

PART III
Attachments:

PUBLISHED WORK

Attachment 1. Manuscript describing FMEA methodology and results
Attachment 2. Workshop Abstract, *2016 International Meeting on Simulation in Healthcare*

CURRICULAR COMPONENTS

Attachment 3. Course agenda
Attachment 4. Just-in-Time download instructions
Attachment 5. Simulation flow sheets and procedural checklist
Attachment 6. FMEA and simulation workbook
Attachment 7. Self-efficacy measures
Attachment 8. Website link with all course materials

COURSE ADVERTISEMENT

Attachment 9. Save-the-date announcement
Attachment 10. Course advertisement / Flyer
Attachment 11. Press release

*all materials are available on the course website: https://osha.washington.edu/pages/infectious-ppe

Published Work

Attachment 1. Manuscript describing FMEA methodology and results

Attachment 2. Workshop Abstract, *2016 International Meeting on Simulation in Healthcare*

Manuscript describing FMEA methodology and results (Attachment 1)

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

Rosemarie Fernandez, Steven Mitchell, Ross Ehrmantraut, John Scott Meschke, Nancy J. Simcox, Sarah A. Wolz and Sarah Henrickson Parker

Infection Control & Hospital Epidemiology / *FirstView* Article / May 2016, pp 1 - 5
DOI: 10.1017/ice.2016.78, Published online: 26 May 2016

CONCISE COMMUNICATION

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

Rosemarie Fernandez, MD;[1] Steven Mitchell, MD;[1] Ross Ehrmantraut, RN;[2] John Scott Meschke, PhD, JD;[3] Nancy J. Simcox, MS;[3] Sarah A. Wolz, MS;[3] Sarah Henrickson Parker, PhD[4]

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.

Infect Control Hosp Epidemiol 2016;1–5

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.

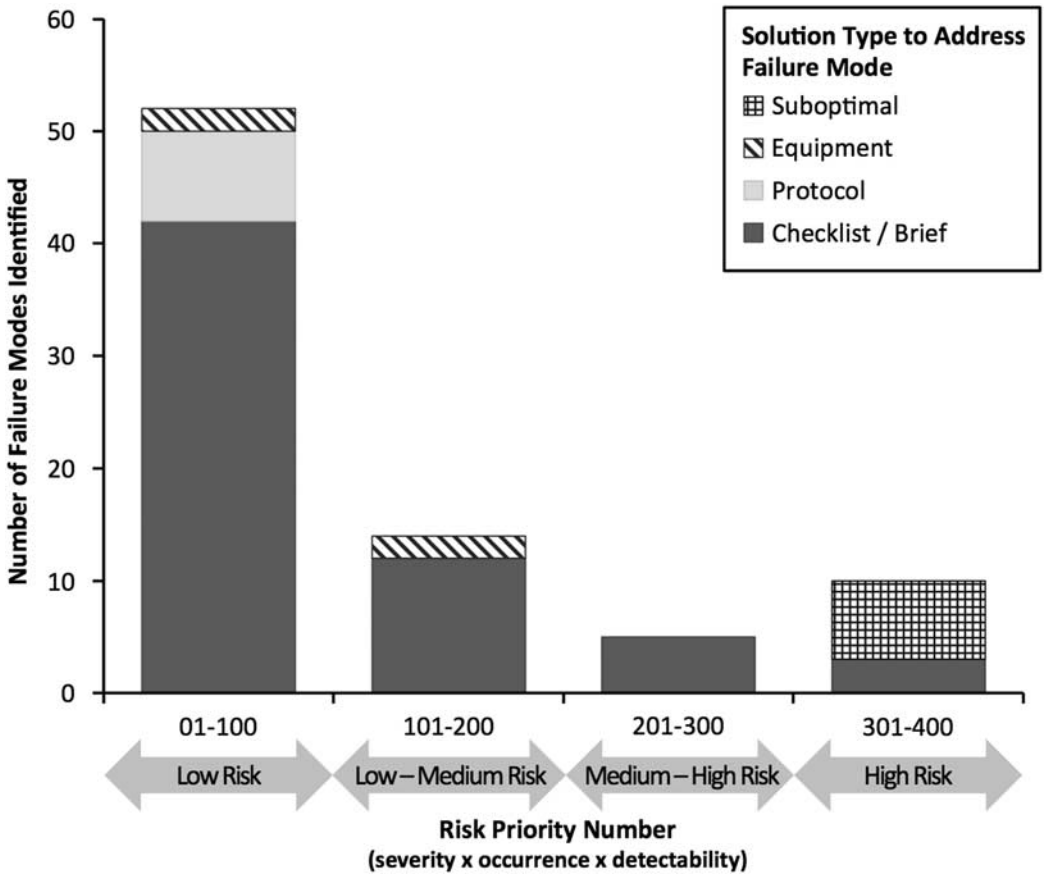


FIGURE 1. Results of failure mode effects analysis organized to demonstrate failure modes and potential solutions to mitigate risk grouped by risk priority number.

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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Potential conflicts of interest: All authors report no conflicts of interest relevant to this article.

Affiliations: 1. Division of Emergency Medicine, University of Washington, Seattle, Washington; 2. Department of Surgery and Institute for Simulation and Interprofessional Studies, University of Washington, Seattle, Washington; 3. Department of Environmental and Occupational Health Sciences, University of Washington School of Public Health, Seattle, Washington; 4. Virginia Tech Carilion Research Institute, Department of Psychology, and Department of Biological Science, Virginia Tech, Roanoke, Virginia.

Address correspondence to Rosemarie Fernandez, MD, Associate Professor, Department of Medicine, University of Washington, Box 359702, 325 Ninth St, Seattle, WA 98104 (fernanre@uw.edu).

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Workshop Abstract, 2016 International Meeting on Simulation in Healthcare
(Attachment 2)

Course Overview
This session will demonstrate how simulations can be combined with Failure Modes and Effects Analysis (FMEA) to identify high-risk activities for healthcare workers. The faculty will use a case study of provider performance while wearing high-level personal protective equipment. While the topic is highly relevant to the development and implementation of Ebola patient care training, the methodology can be applied to any healthcare process.

Learning Objectives
1. **Knowledge:** Learners will understand the theory and process of event-based simulation design and FMEA.

2. **Skills:** Learners will be able to design and execute a simulated clinical event that can support the execution of a rigorous FMEA.

3. **Skills:** Learners will be able to execute and interpret an FMEA based on a simulated clinical event.

Background and Rationale
Failure mode and effects analysis is a systematic technique used frequently by high-risk industries to determine the potential causes of system and equipment failures. Recently, FMEA has been implemented in healthcare as a way to systematically analyze complex processes to identify specific areas of high risk and determine the likelihood and consequences of process failure. Executing FMEAs requires systematic observations of the process(es) of interest. Event-based simulations, when properly designed, can provide the necessary raw data to support FMEA.

The recent Ebola virus disease (EVD) epidemic provides an example of how FMEA can identify high-risk behaviors and threats to provider safety at the front lines of care. High-level PPE requirements for healthcare workers treating Ebola virus patients include equipment that can limit peripheral vision, gross and fine motor skills, and spatial awareness, potentially increasing the risk of occupational injuries such as needle sticks and falls. Without methodologically rigorous risk analyses, EVD-related protocol implementation required significant rework and rapid training amendments. Through risk analysis methods such as FMEA, training could be properly focused on high-risk components of patient care, and patient management protocols could take these high-risk behaviors into account.

Goal
The **goal** of this session is to provide attendees with the theoretical knowledge and methodological skills necessary to execute simulation-based FMEA.

Course Agenda
Introductions
The workshop faculty will introduce themselves and their area of expertise. They will then provide a brief overview of the workshop. Disclosures will be made here.

Foundational knowledge
The faculty will present a brief overview of the theory supporting FMEAs to ensure a foundation of knowledge for the learners. They will then present a stepwise approach to conducting an FMEA that will be used during the workshop. Finally, we will present an overview and approach to event-based simulation design that can support FMEAs.

Small Group Work

Introduction to Small Group Work
The faculty will present an example of a healthcare process related to the care of EVD patients. Small group facilitators will provide learners with a hypothetical situation and will define the scope (boundaries and detail) of an FMEA.

Step 1: Create FMEA Worksheet
Small group facilitators will assist learners with the design of an FMEA worksheet. This work will be based upon material provided during the didactic component of the workshop.

Step 2: Design Event-based Simulation for FMEA
Small group facilitators will assist learners with the development of an event-based simulation that can provide necessary observations to support the FMEA planned in Step 1.

Report out: Steps 1 and 2

Step 3: Identify Failure Modes
Using a video of an event-based simulation and pre-designed worksheet, participants will identify failure modes and begin to identify failure consequences (effects).

Step 4: Determine risk and consequences
Faculty will perform a brief demonstration of the next steps of the FMEA to allow participants to understand how they can calculate risk priority and criticality. Faculty will then facilitate small group work focused on using existing FMEA data to inform recommendations for process change, and how simulations can be used again to evaluate these recommendations.

Wrap up
At the end of the session, all participants will receive a guidebook containing detailed steps for both simulation design and FMEA execution.

Adult Learning Concepts
This workshop will be almost entirely interactive, with hands-on learning to promote skill-building and demonstration-based learning to provide in-depth understanding. All learners will be asked to consider how the techniques presented can be used within their institutions. Small group work will provide the opportunity for guided practice to ensure learners develop a working knowledge of key concepts. Overall, this workshop will use didactics, small group work, and demonstration-based learning to ensure all participants are effectively engaged.

Instructional Resources
As noted earlier, this simulation will use the following training techniques and resources:

1. Didactics
   Powerpoint based with handouts
2. Small group interaction
   Faculty will facilitate small group sessions and report-out to large group
3. Demonstration-based learning
   Faculty and participants will engage in an interactive discussion around how to turn their analyses into process change recommendations. Learners will be encouraged to consider how this process could be implemented in their institutions.
4. Workbook
   All participants will leave with the materials necessary to plan an event-based simulation capable of supporting an FMEA. Learners will also receive FMEA guidelines and a comprehensive reference list for further information and guidance.

Interactivity Component

This workshop is highly interactive and learner-centered. The following interactive training strategies are planned:

1. **Small group work**

   Learners will work in small groups to develop EVD patient care related event-based simulations that can support FMEAs. They will then execute the key steps involved in conducting an FMEA. Where necessary, the faculty will provide pre-existing data to facilitate small group work within the workshop time constraints.

2. **Facilitated group work**

   Faculty will use pre-existing EVD FMEA data to guide learners through risk and criticality calculations. An interactive discussion format will be employed to help learners see how FMEA results can inform process change recommendations.

3. **Reporting**

   Small groups will report out to the group and will elicit input on any issues that were challenging. Debriefing and group input will be encouraged.

References

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Attachments

Curricular Components

Attachment 3. Course agenda

Attachment 4. Just-in-Time App download and instructions

Attachment 5. Simulation flow sheets and procedural checklist

Attachment 6. FMEA and simulation workbook

Attachment 7. Self-efficacy measures

Attachment 8. Website link with all course materials

Course Agenda
(Attachment 3)

Treating Patients with Highly Contagious Infectious Diseases:
USING TECHNOLOGY TO ADVANCE SAFETY

Harborview Medical Center, University of Washington

Agenda April 6, 2016

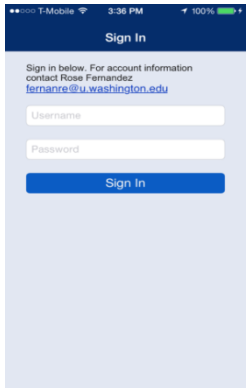
7:30 - 8:00 am	**Registration**
8:00 – 8:15	**Welcoming Remarks** (Course co-directors) Rosemarie Fernandez, MD John Scott Meschke, JD, MSES, PhD
8:15 – 9:15	**Responding to the Challenge: Understanding the Need to Mobilize Personnel to Respond to an Infectious Disease Emergency** John Lynch, MD, MPH Steven Mitchell, MD
9:15 – 10:15	**Worker Protection, Hazard Analysis and Risk of Infectious Agents** John Scott Meschke, JD, MSES, PhD
10:30 – 11:00	**Using Virtual Reality to Develop Hospital Protocols** Dmitri Bouianov
11:00 – 12:00	**Lessons Learned from the CDC:** **Adapting Highly Specialized Protocols for a Local, Frontline Response** David Townes, MD, MPH, DTMH
12:00 – 12:45	**Lunch**
12:45 – 1:15	**SHIP (Safety and Health Investment Project):** **Application of Failure Mode Effects Analysis to Occupational Health** Sarah Parker, PhD
1:15 – 1:45	**SHIP: Design of Event-based Simulations to Train High Risk Procedures** Rosemarie Fernandez, MD
1:45 – 2:00	**Leveraging the TeamSTEPPS Framework to Support Communication and Safety During High Risk Patient Care Activities** Ross Ehrmantraut, RN, HRET Senior Fellow
2:00- 2:15	**Introduction to Fecal Management and JIT Training App** Rosemarie Fernandez, MD
2:15-4:45	**Workshops: Hands-on Skills Practice for High-Risk Procedures Wearing High-Level PPE** *Attendees will divide into groups and rotate through the following stations, wearing high-level PPE through most of the workshop*:* ***1.*** *Donning High Level PPE* ***2.*** *Event-Based Simulations: Common Clinical Procedures Wearing High-Level PPE (i.e. Airway Management, IV Access, Rectal Tube Placement)* ***3.*** *Virtual Reality Participation Exercise* ***4.*** *TeamSTEPPS/communication Exercise* **Appropriate attire for wearing BSL3-type PPE is recommended*
4:45 – 5:00	**Wrap-up and Evaluation**

Just-in-Time App Download and Instructions (Attachment 4)

iOS Device (iPhone or iPad)

1. Search "Ebola Patient Hygiene" in the App Store and download it.
2. If necessary, login with your Apple ID and password.
3. Open the app once downloading is complete.
4. You will be prompted with a login screen. Use the following login information:

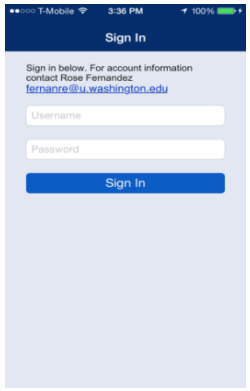
   Username: uwashington
   Password: uw2016



5. Login is only required when you first download the app.

Android Device

1. Open the "Google Play Store" App.
2. If necessary, login with your Gmail account and password.
3. Search "Ebola Patient Hygiene" and download it.
4. Open the app once downloading is complete.
5. You will be prompted with a login screen Use the following login information:



Username: uwashington
Password: uw2016

6. Login is only required when you first download the app.

Simulation Flow Sheets and Procedural Checklists (Attachment 5)

Fecal management system placement
Indwelling urinary catheter placement
Video-assisted intubation
Peripheral IV placement
Ultrasound guided central venous catheter (CVC) placement

Fecal Management System Placement

Initial Script: You are taking care of a patient who has tested positive for Ebola and you need to place a fecal management system (FMS). For the purpose of this simulation, please focus on the procedural aspect of the simulation.

Start
RN approaches simulator at patient bedside and explains he/she will place a fecal management system.

Preparation Actions:
1. Prepare his/her materials
   a. FMS kit
   b. Connect FMS to tubing to bag
   c. Securing device
2. Place second pair of gloves
3. Prep area - perineum

Fecal Management system Placement:
1. Insert FMS
2. Establish stool flow
3. Inflate balloon
4. Secure bag to bed

Clean up:
1. Disposal of kit
2. Appropriate disposal of towel/ chux

End
Sim ends after tubing is connected and materials are cleaned up

Logistics

Supplies
1. FMS kit
2. Securing kit
3. Towel/blue chux
4. Sterile gloves
5. Artificial feces

Simulator
1. Gown
2. Sheet
3. Rectum simulator

Length:
10 minutes/sim

Environment
1. Stepping Stool (if appropriate)
2. Bedside table
3. Trash receptacle

Set up: Patient on stretcher with gown. A bedside stand is next to the patient with all necessary materials. The simulator is ready.

Note: these supplies in addition to standard PPE for EVD care

Notes:
Artificial feces can be made with a mixture of water and chocolate pudding. Mix it well enough to dissolve the solid, but not too much that the mixture froths.

3/30/16

Indwelling Urinary Catheter Placement

Initial Script: You are taking care of a patient who has tested positive for Ebola and you need to place a urinary catheter. For the purpose of this simulation, please focus on the procedural aspect of the simulation.

Start
RN approaches simulator at patient bedside and explains he/she will place a catheter for urine collection

↓

Preparation Actions:
1. Prepare his/her materials
   a. Catheter kit
   b. Connect cath to tubing to bag
   c. Securing device
2. Place second pair of gloves
3. Prep area - perineum

↓

Indwelling urinary catheter Placement:
1. Insert Catheter
   1. Male and female
2. Establish urine flow
3. Inflate balloon
4. Tubing secured to leg
5. Secure bag to bed

↓

Clean up:
1. Disposal of kit
2. Appropriate disposal of towel/ chux

↓

End
After line is connected and materials are cleaned up sim ends

Logistics

Supplies
1. Foley cath kit
2. Securing kit
3. Towel/blue chux
4. Sterile gloves
5. Fluid to fill simulator bladder

Simulator
1. Gown
2. Sheet
3. Simulator- female and male perineum

Length:
10 minutes/sim
20 minutes total to demonstrate female and male

Environment
1. Stool (if appropriate)
2. Bedside table
3. Trash receptacle

Set up: Patient on stretcher with gown. A bedside stand is next to the patient with all necessary materials. The simulator is ready with male and then female perineum.

Note: these supplies in addition to standard PPE for EVD care

Notes:

3/30/16

Video-assisted Intubation

Initial Script: You are taking care of an Ebola patient who requires intubation. For the purpose of this simulation, medications have been drawn, and once pushed the patient will immediately be ready for intubation.

Start
MD is led to patient bedside and confederate greets him/her
"Are you here to intubate the patient?"

↓

Preparation Actions:
1. Prepare materials
   a. Glidescope
   b. ETT/stylet
   c. Syringe
   d. CO_2 detector
   e. ETT securing device
   f. Patient is on non-rebreather mask
2. Place second pair of gloves
3. Ambu-bag with oxygen tubing

↓

Intubation:
1. Pre-oxygenation
2. Position properly
3. Blade enters mouth
4. ETT placed
5. Balloon inflated
6. Stylet removed
7. CO_2 checked while bagging
8. Tube secured

↓

End
After tube is secured, bagging begins, and CO_2 detector used, the case is ended.

Logistics

Supplies
1. Glidescope
2. ETT/stylet
3. 10cc syringes
4. CO_2 detector
5. ETT secure device
6. Ambu-bag

Patient (SimMan 3G)
1. Gown
2. Sheet
3. IV in place

Environment
1. Oxygen headwall
2. Bedside table
3. Airway cart

Length:
10 minutes/sim

Set up: Mannequin in stretcher, glidescope is at bedside. Table with supplies at bedside (decide if in cart or table).
Note: supply list in addition to standard PPE for EVD care

Notes:

3/30/16

Peripheral IV Placement

Initial Script: You are taking care of a patient who has tested positive for Ebola and you need to place a peripheral IV. For the purpose of this simulation, please focus on the procedural aspect of the simulation.

Start
RN is led to patient bedside and patient greets him/her
"Are you here to place my IV?"

↓

Preparation Actions:
1. Prepare his/her materials
   a. Line
   b. Tegaderm or similar
   c. Gauze
2. Place second pair of gloves
3. Place tourniquet
4. Prep area

↓

IV Placement:
1. Vein cannulated
2. Needle retracted
3. Luer lock connected
4. Line secured

↓

Clean up:
1. Sharps placed in sharps container
2. Appropriate disposal of waste

↓

End
After line is connected and materials are cleaned up, SP states "Thank you for doing that, it didn't hurt a bit."

Logistics

IV supplies
1. IV catheters
2. Gauze
3. Connector
4. Tegaderm
5. Alcohol preps
6. Basin
7. Bag
8. IV tubing

Patient (with IV simulator)
1. Gown
2. Sheet
3. Stool
4. IV simulator

Environment
1. Stool
2. Bedside table
3. Cart
4. Sharps container

Length:
10 minutes/sim

Set up: Patient in stretcher with gown. A bedside stand is next to the patient with all necessary materials. The patient is prepped with IV simulator. He/she will follow any instructions given by the practitioner.

Note: these supplies in addition to standard PPE for EVD care

Notes:

3/30/16

US-Guided CVC Placement

Initial Script: You are taking care of an Ebola patient who is critically ill and needs a R IJ CVC. For the purpose of this simulation, the patient is intubated, no local anesthesia is indicated. An ultrasound is available.

Start
MD is led to "patient" bedside and confederate greets him/her
"Are you here to place a central line?"

Preparation

1. Prepare US
   a. US gel
   b. Sterile cover
2. Prep patient
   a. Sterile drape
   b. Chloroprep
3. Prep line
   a. Place Luer lock
   b. Flush line
4. Prep self
   a. Sterile gown
   b. 2nd layer gloves

CVC Placement:

1. Consent confirm
2. Time out completed
3. IJ site confirmed with US
4. Needle inserted into IJ using US guidance method
5. Wire placed and confirmed in place with US
6. Needle removed and stored appropriately
7. Dilator deployed
8. Catheter advanced over wire
9. Wire removed and stored appropriately
10. Catheter checked for blood return
11. Catheter line flushed
12. Catheter secured
13. Sharps safely disposed

End: All sharps are safely disposed of and materials are cleaned up

Logistics

Supplies

1. Central line kit
2. Central line cart
3. US machine
4. Sterile gown
5. Sterile gloves
6. Saline Flush

Patient (SimMan 3G)

1. Gown
2. Sheet
3. IV in place

Environment

1. Central line cart
2. Oxygen headwall
3. Bedside table
4. Airway cart

Length:
10 minutes/sim

Set up: Mannequin in stretcher, central line trainer next to mannequin

Notes:

3/30/16

FMEA and Simulation Workbook
(Attachment 6)

Simulation – Assisted FMEA to Identify and Mitigate High-Risk Tasks for Healthcare Workers

Acknowledgements

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Ross Ehrmantraut, RN, HRET Senior Fellow, TeamCORE Clinical Manager, WWAMI Institute for Simulation in Healthcare (WISH)

Rosemarie Fernandez, MD, Associate Professor, Emergency Medicine, UW School of Medicine, Harborview Medical Center (HMC)

John Lynch, MD, MPH, Associate Professor of Medicine, Medical Director of Infection Prevention and Employee Health, UW Medicine HMC

Scott Meschke, JD, MSES, PhD, Professor, Environmental and Occupational Health Sciences, UW School of Public Health

Steve Mitchell, MD, Assistant Professor, Emergency Medicine, Acting Medical Director, Emergency Department, UW Medicine, HMC

Sarah Parker, PhD, Carilion Research Institute, Virginia Tech University

Nancy J. Simcox, MS, Environmental and Occupational Health Sciences, UW School of Public Health

David Townes, MD, MPH, DTM&H, Associate Professor, Emergency Medicine, UW School of Medicine, Harborview Medical Center (HMC)

Sarah Wolz, MS, Environmental and Occupational Health Sciences, UW School of Public Health

Table of Contents

Fundamental Knowledge

Background

Failure mode and effects analysis (FMEA) is an analysis technique for defining, identifying and eliminating known and/or potential failures, problems, and errors from system, design, process and/or service before they cause harm to the patient or provider (Stamatis, 1995). The main objective of FMEA is to identify potential failure modes, evaluate the causes and effects of different component failure modes, and determine what could eliminate or reduce the chance of failure. The results of the FMEA can help analysts identify and correct 'failure modes' that are potentially harmful to healthcare workers and patients. FMEA has been extensively used in a wide range of industries, including aerospace, automotive, nuclear, electronics, chemical, mechanical and medical technologies industries.

The purpose of FMEA is to prioritize the likelihood, frequency and/or severity of the failure modes of the product or system in order to assign the limited resources to the most serious risk items. In general, the prioritization of failure modes for corrective actions is determined by following a protocol to calculate a **risk priority number** (RPN). In order to analyze a specific product or system, a cross-functional team should be established for carrying out FMEA.

1. The first step in FMEA is to identify all possible steps in a process.

2. Systematic brainstorming and critical analysis is performed on each step to identify possible failure modes.

3. The failure modes are then assigned a numerical estimation of risk by the likelihood of occurrence (O), severity if the failure mode occurs (S) and likelihood of detection, if the failure mode occurs (D).

4. A RPN is then obtained by finding the multiplication of the O, S and D of a failure mode. The higher the RPN of a failure mode, the greater the risk is for product/ system reliability.

5. With respect to the scores of RPNs, the failure modes can be ranked and then proper actions will be preferentially taken on the high-risk failure modes.

6. RPNs should be recalculated after the corrections to see whether the risks have gone down, and to check the efficiency of the corrective action for each failure mode.

Background (cont.)

Simulation can re-create the process being analyzed. By allowing FMEA team members to observe the steps in the process, simulation can allow a more in-depth understanding of potential failure modes. Simulating the clinical process allows the team to gauge communication, performance, and whether the steps in the process are being executed as intended. It is important here to reinforce with simulation participants that they should behave as they normally would in a real occupational situation. In other words, they should perform work-arounds and shortcuts if that is part of their daily routine. Otherwise, system-related safety threats will not come to light. Using a theoretically sound methodological approach to simulation design will help support an objective, rigorous risk analysis.

Liu HC, Liu L, Liu N: **Risk evaluation approaches in failure mode and effects analysis: A literature review.** *Expert Systems with Applications* 2013, 40(2):828-838.

Designing Simulation to Support FMEA

Event-based Simulation Design

Event-based design systematically identifies and introduces events within the simulation that provides known opportunities to observe behaviors of interest. Event-based simulations provide a highly replicable, predictable representation of clinical and occupational safety events that can support high level risk analyses.

Event: Substantive task with a clear beginning and ending

Trigger: Standardized, scenario-specific indicators embedded in the scenario, designed to force a transition between events

Order: The design and sequencing of events and triggers should depend upon the objectives and realistic progression of the scenario

Example: Simulation to identify risks associated with hygienic care in an EVD patient

Process Steps:

- Gather linens
- Arrange waste receptacles
- Ensure adequate disinfectant
- Execute pre-brief

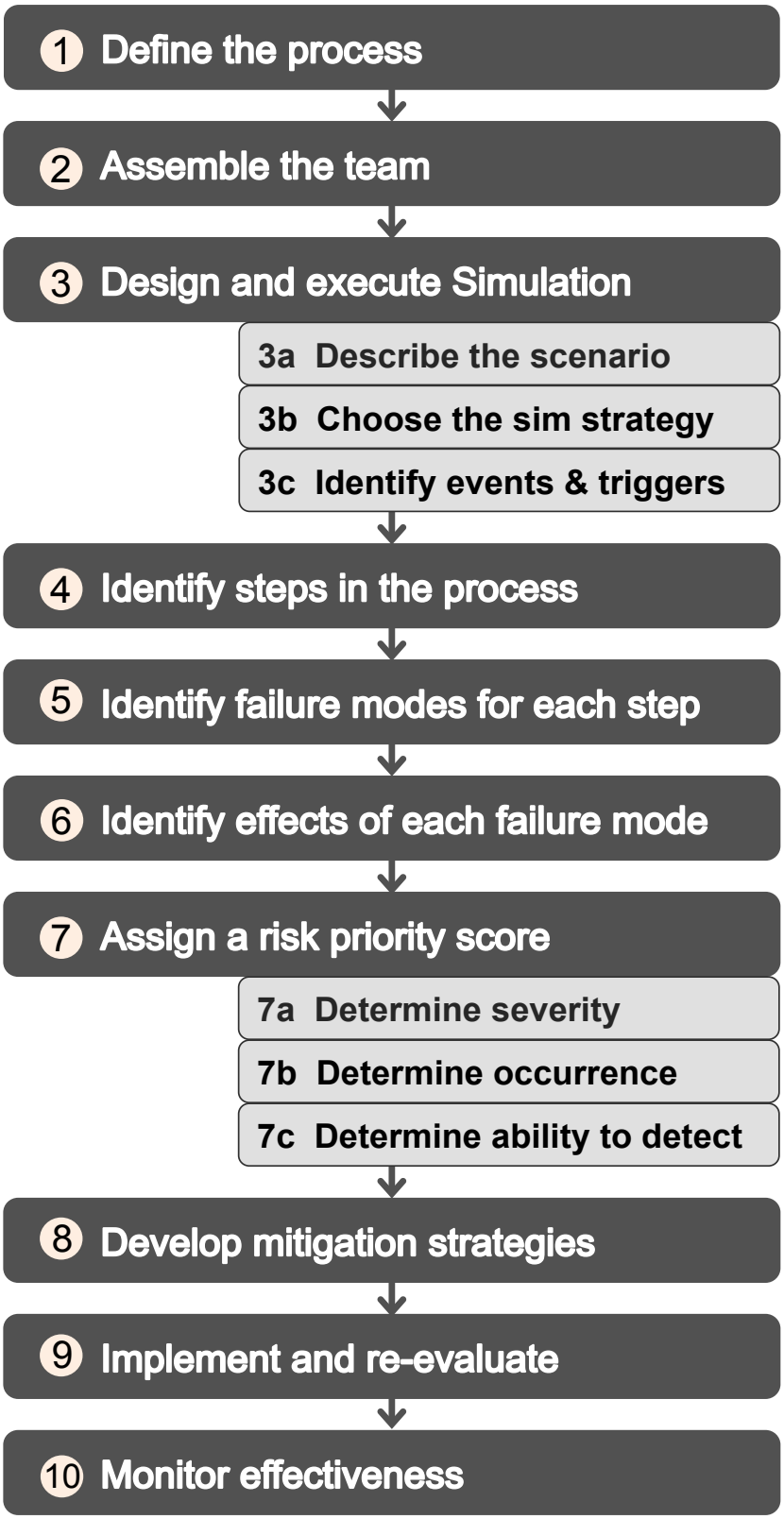
- Roll patient
- Position devices/ tubes
- Remove head/foot
- Release fitted sheet
- Prepare new linens

- Create barrier on floor
- Discuss fecal management system
- Revisit Event 2

- Ensure supplies duplicated on other side
- Gross contamination check
- Repeat Event 2

- Remove all materials from floor
- Bleach floor
- Clean tubing/ equipment

FMEA Overview



Step 1: Define the process

It is critical that you are as specific as possible when defining the process you wish to evaluate. Starting with a clear description of the process ensures that everyone on the team understands what is being analyzed. For instance, when we approached Ebola Virus Disease (EVD) patient care, we considered processes that were under-researched and presented high risk. We therefore focused on patient hygiene in an EVD patient with copious diarrhea. While describing the process, team members found that there was additional variation present based upon the stability of the patient. We chose to concentrate our analysis on an awake, cooperative patient because it seemed to be the most frequently encountered situation. We agreed that follow-up FMEAs would be needed to address intubated, unresponsive patients.

Consider the questions below during this step. Not all may be relevant in every situation.

What clinical situation or occupational safety event do you want to evaluate?
What are the characteristics of the patient(s) involved? Clinical stability, age, presence of invasive monitoring, ability to communicate, etc.
What are the characteristic(s) of the environment? Time of day, census, staffing, resources available, etc.
What are the characteristic(s) of the worker(s) involved? Time of day, census, staffing, resources available, etc.
What pieces of the unit or system are part of the process? Paging system, security, other units, etc.
Does the process vary markedly based on worker, environmental, or patient characteristics?

Helpful Tips

1. Be sure an identifiable process is chosen for FMEA. A process is a series of actions or steps taken to achieve an end.

2. Narrow the scope of focus of FMEA as much as possible. For instance, do FMEA on administration of a particular task under certain situations rather than on the task in general.

3. To get employees to support FMEA, senior management should engage frontline staff early in the process and ensure they are involved in all components of the analysis.

4. Consider using FMEA to evaluate new processes. It is a good technique for anticipating what could happen so processes can be made safer before full implementation.

Step 2: Assemble the team

Consider who will comprise your simulation development team and who will participate in the FMEA process.

Type of Team Member	Simulation development team	FMEA Team
Healthcare worker (represent all disciplines and ancillary staff if appropriate)		
Leadership / Management		
Occupational safety expertise (if appropriate)		
Simulation expertise		
Human factors expertise		
Safety/quality science expertise		
Project manager		
Recorder/note-taker		

Helpful Tips

1. Minimize the number of management or supervisory level individuals on the team. Staff members may be inhibited from speaking up during critical discussions about process problems if their direct supervisor is in the room.

2. Involve frontline employees and those who have specific experience with the process being analyzed. It is important to understand the process as it is actually performed, including why staff make mistakes and develop work-a-rounds.

3. Include people from all shifts on the team, when possible. The experiences of staff working during the day may be much different than what happens during the evening and night shift. A successful FMEA is highly dependent on the ability of the team members to understand how a process functions at varying times and what occasionally goes wrong.

4. Meet formally as a team. It can sometimes be tempting to complete FMEA by interviewing those involved in the process, without any formal meetings of the team. While this might move the analyses along quicker, the frank discussions that occur during team meetings are more likely to lead to a successful FMEA – one that actually improves the safety of a high-risk resident care process.

Step 3: Design and execute simulation

3a: Describe the scenario

Describe in a few sentences the overall scenario you wish to create. Use the process information obtained in Step 1 to determine the scenario characteristics, healthcare workers involved, and environmental cues present. Define a clear start and stop for the simulation.

3b: Choose the simulation strategy

Determine the modality of simulation that best fits your scenario and objectives. Consider what components need to be most "realistic" to allow a meaningful examination of risks. Make sure you are able to replicate the components of your simulation in a way that elicits meaningful behaviors from the participants.

3c: Event-based Simulation Design

Event-based design systematically identifies and introduces events within the simulation that provides known opportunities to observe behaviors of interest. Event-based simulations provide a highly replicable, predictable representation of clinical events that can support high level risk analyses.

Event: Substantive task with a clear beginning and ending
Trigger: Standardized, scenario-specific indicators embedded in the scenario, designed to force a transition between events
Order: The design and sequencing of events and triggers should depend upon the objectives and realistic progression of the scenario

Example: Simulation to identify risks associated with hygienic care in an EVD patient

Behaviors

• Gather linens • Arrange waste receptacles • Ensure adequate disinfectant • Execute pre-brief	• Roll patient • Position devices/tubes • Remove head/foot • Release fitted sheet • Prepare new linens	• Create barrier on floor • Discuss fecal management system • Revisit Event 2	• Ensure supplies duplicated on other side • Gross contamination check • Repeat Event 2	• Remove materials from floor • Clean/disinfect floor • Clean tubing/ equipment

Step 3 Worksheet

Events		Triggers	
Sample	**Intubation** Patient becomes progressively more hypoxic, requiring intubation. It is expected that the team will recognize this need early; however, the hypoxia will continue to progress until this is accomplished.	**Ta**	Increased RR to 30 with a pulse ox reading 85.
		Tb	Patient no longer speaking, pulse ox reads 65
		Tc	Nurse (confederate) states "I think we need to intubate now."
1	**Nurse cleans and disinfects dirty areas.** Cleaning and decontamination of contaminated surfaces is a multistep process involving containment, pre-disinfection, cleaning and removal of gross soil, and thorough disinfection.	**1**	
		2	
		3	
2		**4**	
		5	
		6	
3		**7**	
		8	
		9	
4		**10**	
		11	
		12	
5		**13**	
		14	
		15	

Step 4: Identify steps in the process

The team should clearly define the process to be analyzed. Watching the simulation can help get everyone on the same page. There are several ways to approach this step. One way is to construct a flowchart of the steps. Write down the first step in the process and each subsequent step. Each event will likely contain multiple steps. If there is confusion about the process steps it may be necessary to refine the scope of the FMEA.

Example: Event 2 in EVD Hygienic Care

Steps:

- Remove patient gown / clothing
- Position devices/tubes
- Remove header/footer of bed
- Prepare area on floor to ensure spills are absorbed
- Roll patient on side
- Place clean incontinence pad under patient on top of dirty bottom sheet
- Release fitted sheet and roll under patient (under incontinence pad)
- Clean patient
- Clean mattress and dry
- Prepare new linens
- Place clean fitted sheet on mattress with 2 clean incontinence pads

Once you've determined the steps in the process, enter them into Column 1 of the FMEA worksheet.

Helpful Tips

1. Be sure to involve frontline staff.
2. Start with the overall events of the simulation.
3. Watch video recordings (preferred) or live simulations to break each event into discrete steps.
4. Be specific. The more specific and discreet the steps, the more concise your risk analysis will be.
5. If team members cannot agree on how the process currently works in their area and the process scope cannot be narrowed to obtain agreement, it usually is a signal of a very unreliable process. An unreliable process is one that is not performed consistently – people pretty much do whatever works best for them.
6. Include each repetition of a step. Risks can vary based on when in the overall process a step occurs.
7. For a complex process with many steps, it may be better to do several FMEAs by breaking-up the process into manageable pieces.

Step 5: Identify failure modes for each step in the process.

Failure mode = something that can go wrong

Here is where the knowledge and experience of team members combined with a robust simulation can ensure a rigorous FMEA. For each process step identified in Step 4, the team determines what can go wrong or what can fail (failure modes). The team members who do the work every day are in the best position to know what can (and does) go wrong. By observing the simulation, you ensure that aspects of the process are not forgotten. You also have the ability to have frontline providers observe the process, thus offering them a different perspective. After the possible failures are identified for one step, the team moves on to identifying failures that might occur in the next step. Step 5 is complete when the team is satisfied all possible failures have been identified for each step.

Example: Failure modes related to one step in EVD hygienic care

Step	Failure mode
Positions devices / tubes	Provider forgets step
	Positioning is suboptimal
	Optimal positioning risks contamination with stool

Step 6: Identify effects of each failure modes

Starting with the first step in the process, the team considers each failure that was identified in Step 5 – answering the question, “What would happen if this failure occurs?” The team methodically goes through each failure identified during Step 5.

Helpful Tips

1. Create an atmosphere where team members feel safe talking about process mistakes, unplanned events, or work-arounds that occur.
2. To decrease “protectionism” where staff are reluctant to talk about safety threats, make it clear from the beginning that everyone makes occasional mistakes, and most mistakes are the result of a poorly designed process.
3. Sometimes the team identifies failure modes that are extremely rare - don’t exclude those things!!! Be creative in your risks.
4. Video recordings of one or more simulations can help inform risks. Individuals often have such ingrained work patterns that they do not recognize risks.
5. Staff may identify places where the actual work flow deviates from the simulation, which may depict what theoretically is supposed to happen as compared with what actually does.

Example: Failure mode effects related to one step in EVD hygienic care

Step	Failure Mode	Effect
Positions devices / tubes	Provider forgets step	Tube accidentally dislodged
	Positioning is suboptimal	Tube accidentally dislodged
	Optimal positioning risks contamination with stool	Tube becomes contaminated

Helpful Tips

1. When defining outcomes that will occur following a failure, identify likely outcomes and worst-case scenarios. Do not forget that outcomes for some failures may not directly harm patients or healthcare workers and may go unnoticed, such as delays in treatment or services.
2. This may be informed by recent events in the hospital.
3. Keep in mind that failure mode effects can present a safety threat to patients, healthcare workers, and the public. For example, some failure modes could increase healthcare worker exposure to highly infectious agents during patient care.
4. You can consider “system” failures into your simulation to see the downstream effects.

Step 7: Assign a risk priority score

7a: Determine severity of failure mode

The team must assign a score to rate the severity of the consequences of each failure mode. Severity is usually rated on a scale from 1 to 10, where 1 is insignificant and 10 is catastrophic. If a failure mode has more than one effect, write on the FMEA table only the highest severity rating for that failure mode. This decision can be made by the team while they are identifying the outcomes or the seriousness can be determined after all outcomes have been determined. For each outcome, the team must decide how "bad" the particular outcome would be for the patient, provider, unit, or system. This is a subjective judgment made by team members based on their knowledge and experience. Using a decision-making process such as nominal group technique or multi-voting, the team methodically agrees to a severity ranking for each outcome.

On the FMEA table, list the severity rating for each failure mode.

Sample severity rating scale as applied to occupational safety risks to healthcare workers.

Rating	Outcome Category	Description
9 – 10	Catastrophic	HCW experiences death or major permanent loss of function (sensory, motor, physiologic, or intellectual). (e.g., death due to exposure to highly infectious agent).
7 – 8	Major	HCW experiences permanent lessening of bodily function (sensory, motor, physiologic, or intellectual), disfigurement, surgical intervention required, or increased level of care for 3 or more days (e.g., transmission and illness related to exposure to highly infectious agent).
5 – 6	Moderate	HCW experiences an event, occurrence, or situation (e.g., exposure to highly infectious agent requiring quarantine until clinically clear) which can cause harm but will not cause permanent injury or lessening of bodily function or require the delivery of additional healthcare services
3 – 4	Minor	HCW may experience a minor injury be exposed to a risk-related situation (e.g., exposure to highly infectious agent while wearing appropriate PPE), but most likely would not be affected by the failure and it would not cause any permanent injury or need for further care.
1 – 2	Near miss	HCW would not experience any injury, changes in job task, or be exposed to any physical risk (e.g., highly infectious agent).

HCW = healthcare worker; PPE = personal protective equipment

7b: Determine occurrence of failure mode

The team now judges how often each failure is likely to occur. Occurrence is usually rated on a scale from 1 to 10, where 1 is extremely unlikely and 10 is inevitable. It can sometimes be problematic for team members to judge how often a failure might occur. Sometimes there is a tendency to seek the "right" answer when, without any prevalence data, a correct answer is not possible. In the absence of data, ask the team members to estimate based on their experience and a sense of what happens in their unit/institution. Ask the frontline providers on the team to estimate how often they think this failure occurs. A more accurate estimate of failure probability might be obtained if management level personnel are not in the room.

On the FMEA table, list the occurrence rating for each failure mode.

Sample Occurrence Scale

Rating	Description
9 – 10	Very high probability: failure is most inevitable
7 – 8	High: repeated failures
5 – 6	Moderate: occasional failures
3 – 4	Low: relatively few failures
1 – 2	Remote: failure is unlikely

7c: Determine the likelihood of detecting the failure mode

The team now must determine how likely it is that the failure mode can be detected. For each failure mode, determine the detection rating, or D. This rating estimates how well you can detect either the cause or its failure mode after they have happened but before the patient/provider/system is affected. Detection is usually rated on a scale from 1 to 10, where 1 means you are absolutely certain to detect the problem and 10 means the you are certain not to detect the problem (or no control exists).

On the FMEA table, list the detection rating for each cause.

Sample Detection Scale

Rating	Description
9 – 10	Controls will not or cannot detect the existence of a failure. No known controls available to detect failure mode.
7 – 8	Controls have a poor chance of detecting the existence of failure mode.
5 – 6	Controls may detect the existence of a failure mode.
3 – 4	Controls have a good chance of detecting failure mode, process automatically detects failure mode.
1 – 2	Current controls almost certain to detect the failure mode. Reliable detection controls are known with similar processes. Process automatically prevents further processing.

Calculate Risk Priority Number (RPN)

Severity X Occurrence X Detectability = RPN

*see Liu, et al for limitations and cautions associated with prioritization based on RPN

Liu HC, Liu L, Liu N: **Risk evaluation approaches in failure mode and effects analysis: A literature review**. *Expert Systems with Applications* 2013, **40**(2):828-838.

Step 8: Develop mitigation strategies

Identify recommended actions. These actions may be design or process changes to lower severity or occurrence. They may be additional controls to improve detection. Also note who is responsible for the actions and target completion dates

To determine how the process should be changed the root cause of each failure chosen for action must be identified. The team may need to gather additional input from other staff members to help in determining the root causes of failures.

Once the cause of each failure is clear, the team develops actions to reduce or eliminate the failure. When developing these actions consider questions such as:

1. What safeguards are needed to prevent this failure from happening?
2. What would have to go wrong to have a failure like this happen? How can we prevent this from going wrong?
3. How could we change the way we do things to make sure that this failure never happens?
4. If a failure like this happened, how could we quickly catch and correct the problem before the healthcare worker ended up being harmed?
5. If the healthcare worker were harmed by this failure, how could we minimize the effect of the failure on the healthcare worker condition?

FMEA Worksheet

Identify Steps	Potential Failure Mode	Potential Failure Effects	SEV	OCC	DET	RPN	Mitigation Strategy
What is the Process Step?	In what ways can the Process Step fail?	What is the impact if there is a failure?	How **Severe** is the effect to the customer?	How **often** does cause or FM **occur**?	How well can you **detect** the Cause or the Failure Mode?	**SEV x OCC x DET**	What are strategies for mitigating risk by reducing the occurrence of the cause, or improving detection?
Set up blankets on floor to dam liquids	*Provider trips over towels*	*Immediate physical injury*	*10*	*5*	*1*	*50*	*Position observer* *Use colored towels*

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1. Fowlkes J, Dwyer DJ, Oser RL, Salas E: **Event-based approach to training (EBAT)**. *Int J Aviat Psychol* 1998, **8**(3):209-221.

2. Alinier G. **A typology of educationally focused medical simulation tools**. *Med. Teach.* 2007;29(8):e243-e250.

3. Liu HC, Liu L, Liu N: **Risk evaluation approaches in failure mode and effects analysis: A literature review**. *Expert Systems with Applications* 2013, **40**(2):828-838.

4. DeRosier J, Stalhandske E, Bagian JP, Nudell T: **Using Health Care Failure Mode and Effect Analysis™: The VA National Center for Patient Safety's Prospective Risk Analysis System**. *The Joint Commission Journal on Quality Improvement* 2002, **27**(5):248-267.

5. van Tilburg CM, Leistikow IP, Rademaker CMA, Bierings MB, van Dijk ATH: **Health care failure mode and effect analysis: a useful proactive risk analysis in a pediatric oncology ward**. *BMJ Qual Saf* 2006, **15**(1):58-63.

6. Whiteley GS, Derry C, Glasbey T. **Failure analysis in the identification of synergies between cleaning monitoring methods.** *Am. J. Infect. Control.* Feb 2015;43(2):147-153.

7. Herzer KR, Rodriguez-Paz JM, Doyle PA, et al. **A practical framework for patient care teams to prospectively identify and mitigate clinical hazards.** *The Joint Commission Journal on Quality and Patient Safety.* 2009;35(2):72-81.

8. Fernandez R, Mitchell SH, Ehrmantraut R, Meschke, JS, Parker SH. **Proactive risk assessment for Ebola infected patients: A systematic approach to identify and minimize risk for healthcare personnel.** *Infect Control Hosp Epidemiol* (in press).

9. Agency for Healthcare Research and Quality, **AHRQ Issue Brief: Health Care Simulation To Advance Safety: Responding to Ebola and Other Threats**, February 2015.

Self-efficacy Measures
(Attachment 7)

Pre / Post Confidence Measure

With regard to EVD Preparedness, how confident are you in your ability to:	Not at all confident					Very Confident
	1	2	3	4	5	6
Recognize the requirememements of an institutional response to care of an EVD patient						
Explain how institutions can develop healthcare worker EVD clinical expertise rapidly						
Recognize the potential role of FMEA in the evaluation of EVD protocols						
Identify specific risks associated with maintaining industrial hygiene and occupational safety during a “novel” infectious disease outbreak (e.g., EVD)						
Use FMEA data to inform protocol development						
Identify appropriate applications for simulation-based training of HCWs on high-risk infectious disease-related activities						
Execute a simulation-based technology based on training or assessment objectives						
Understand key teamwork competencies germane to caring for a patient with EVD						
Identify key teamwork behaviors that are critical to healthcare worker safety when performing high risk (e.g., EVD) patient care						
Discuss the risks associated with wearing high-level personal protective equipment while performing routine patient care activities						
Define three ways to mitigate occupational health risks to employees during the care of an EVD patient						

EVD = Ebola virus disease
FMEA = Failure mode effects analysis

Website link with all course materials (Attachment 8)

Treating Patients with Highly Contagious Infectious Diseases: Using Technology to Advance Safety
Resource Page

April 6, 2016

WISH Institute, Harboriview Medical Center

Seattle, WA

Responding to the Challenge: Understanding the Need to Mobilize Personnel to Respond to an Infectious Disease Emergency

John Lynch, MD, MPH

Associate Professor of Medicine

Medical Director Infection Prevention and Employee Health

University of Washington Medicine, Harborview Medical Center

Steven Mitchell, MD

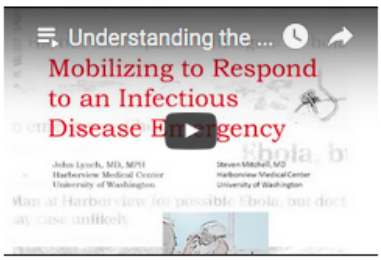
Assistant Professor, Emergency Medicine

Acting Medical Director, Emergency Department

University of Washington Medicine, Harborview Medical Center

View the presentation PDF

Watch Presentation Recording:



https://osha.washington.edu/pages/infectious-ppe

Attachments

Course Advertisement

Attachment 9. Save-the-date announcement

Attachment 10. Course advertisement / Flyer

Attachment 11. Press release

Save-the-Date Announcement
(Attachment 9)

SAVE THE DATE

Treating Patients with Highly Contagious Infectious Diseases: Using Technology to Advance Safety

APRIL 6, 2016

DATE & LOCATION

April 6, 2016

Institute for Simulation & Interprofessional Studies at Harborview Medical Center

Ninth & Jefferson Bldg.
Room 3NJB365
908 Jefferson Street
Seattle, WA 98104

Phone: 206-685-4747
http://isis.washington.edu/

REGISTRATION

Register online at **osha.washington.edu** or by calling the Northwest Center at **206-543-1069**.

Standard Registration: $100

Students: $50

INFORMATION

206-543-1069 or
800-326-7568
ce@uw.edu
osha.washington.edu

Photo: Nixxphotography/iStock/Thinkstock

Healthcare workers and public health officials—particularly those in direct contact with patients extremely ill from a highly contagious agent such as the Ebola virus—must be well-prepared and thoroughly trained for the next outbreak of emerging infectious diseases. This CE course will provide attendees with an overall background on the biology and epidemiology of Ebola and other highly infectious agents, and present best practices for infection control procedures and work safety when treating such patients. At the culmination of a rigorous risk assessment protocol, certain high risk medical procedures—while wearing maximum personal protective equipment—in the ED and ICU will be discussed and practiced by participants to minimize health care worker exposure.

AUDIENCE

Healthcare providers, infection control practitioners, occupational health professionals

FACULTY

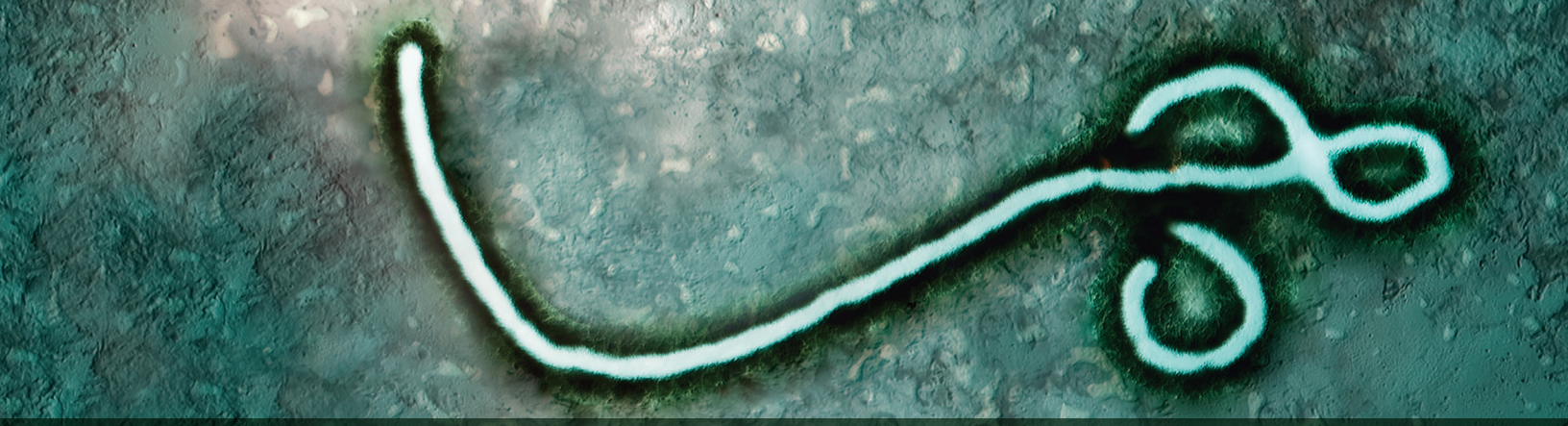
Ross Ehrmantraut, RN, CCRN, Institute for Simulation and Interprofessional Studies, UW School of Medicine
Rosemarie Fernandez, MD, UW Harborview Medical Center Emergency Department
John Lynch, MD, MPH, UW Harborview Medical Center Infection Control, Antibiotic Stewardship and Employee Health
Scott Meschke, JD, MS, PhD, Department of Environmental and Occupational Health Sciences, UW School of Public Health
Debra Metter, MN, RN, CCRN, CCNS, Trauma and Critical Care, UW Harborview Medical Center
Steve Mitchell, MD, UW Harborview Medical Center Emergency Department
Sarah Parker, PhD, Human Factors Research, Virginia Tech Carilion School of Medicine

ACCREDITATION

CME/CNE accreditation is pending for this activity

Funding for this course is provided by Washington State Department of Labor & Industries, Safety and Health Investment Project (2014XH00293-K-1901).

Course Advertisement / Flyer
(Attachment 10)



Treating Patients with Highly Contagious Infectious Diseases: Using Technology to Advance Safety

APRIL 6, 2016

DATE & LOCATION

April 6, 2016

WWAMI Institute for Simulation in Healthcare (WISH) at Harborview Medical Center
Ninth & Jefferson Bldg.
Room 3NJB365
908 Jefferson Street
Seattle, WA 98104

Phone: 206-685-4747
http://isis.washington.edu/

REGISTRATION

Register online at **osha.washington.edu** or by calling the Northwest Center at **206-543-1069**.

Standard Registration: $100

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INFORMATION

206-543-1069 or
800-326-7568
ce@uw.edu
osha.washington.edu

Photo: Nixxphotography/iStock/Thinkstock

In collaboration with the Institute for Simulation and Interprofessional Studies at Harborview Medical Center and the Carilion Research Institute at Virginia Tech University

Healthcare workers and public health officials—particularly those treating patients extremely ill from a highly contagious agent such as the Ebola virus—must be well-prepared and thoroughly trained for the next outbreak of an emerging infectious disease and have the tools to protect themselves while providing patient care.

This course will offer a basic hazard analysis of various infectious agents and present a framework for mobilizing a public health and hospital response with a focus on occupational safety. Attendees will be introduced to a risk assessment approach for developing work practices, share new communications and training tools, and be offered hands-on simulated practice opportunities. Certain high risk medical procedures performed while wearing maximum personal protective equipment will be discussed and practiced by participants to minimize healthcare worker exposure.

COURSE OBJECTIVES

Upon course completion participants will be able to:

- Describe 3 key factors involved in the development of infectious disease response systems
- Define the purpose of an infection prevention risk assessment
- Describe 5 challenges associated with healthcare worker safety in an emerging healthcare crisis
- Discuss 3 key steps of creating a Failure Mode Effects Analysis risk assessment approach and recognize its potential application to high risk healthcare processes
- Apply event-based simulation design technique when training high risk procedures during practices simulations
- Incorporate 3 TeamSTEPPS (Team Strategies and Tools to Enhance Performance and Patient Safety) principles into the care of patients with highly contagious infectious diseases during practice simulations
- Recognize 2 high risk patient care activities associated with patients diagnosed with highly contagious infectious diseases

Treating Patients with Highly Contagious Infectious Diseases: Using Technology to Advance Safety

AGENDA APRIL 6, 2016

7:30–8:00 am	**Registration**
8:00–8:15	**Welcoming remarks** (Course Co-Directors) Rosemarie Fernandez, MD John Scott Meschke, JD, MSES, PhD
8:15–9:15	***Responding to the Challenge: Understanding the Need to Mobilize Personnel to Respond to an Infectious Disease Emergency*** John Lynch, MD, MPH Steven Mitchell, MD
9:15–10:15	***Worker Protection, Hazard Analysis, and Risk of Infectious Agents*** John Scott Meschke, JD, MSES, PhD
10:30–11:00	***Using Virtual Reality to Develop Hospital Protocols*** Dmitri Bouianov
11:00–12:00	***Lessons Learned from the CDC: Adapting Highly Specialized Protocols for a Local, Frontline Response*** David Townes, MD, MPH, DTM&H
12:00–12:45	**Lunch**
1:00–1:30	***SHIP (Safety and Health Investment Project): Application of Failure Mode Effects Analysis to Occupational Health*** Sarah Parker, PhD
1:30–1:45	***SHIP: Design of Event-based Simulations to Train High Risk Procedures*** Rosemarie Fernandez, MD
1:45–2:15	***Leveraging the TeamSTEPPS Framework to Support Communication and Safety During High Risk Patient Care Activities*** Ross Ehrmantraut, RN, HRET Senior Fellow
2:15–4:45	***Workshops: Hands-on Skill Practice for High-risk Procedures*** *Attendees will divide into groups and rotate through the following stations, wearing high-level PPE through most of the workshop.** 1. Donning High Level PPE 2. Event-based Simulations: Common Clinical Procedures *Airway Management, IV Access, Rectal Tube Placement* 3. Virtual Reality Participation Exercise 4. TeamSTEPPS and Communication Exercise **Appropriate attire for wearing BSL3-type PPE is recommended*
4:45–5:00	**Wrap up and evaluation**

Funding for this course is provided by Washington State Department of labor & Industries, Safety and Health Investment Project (2014XH00293-K-1901).

APRIL 6, 2016

ACCREDITATION

CME and **CNE** are available for this activity. Please visit *osha.washington.edu* for full accreditation and disclosure details.

INTENDED AUDIENCE

Healthcare providers, infection control practitioners, occupational health professionals, public health professionals, hospital administrators and operations staff

COURSE FACULTY

David Townes, MD, MPH, DTM&H, Associate Professor- Emergency Medicine and Adjunct Associate Professor- Global Health, University of Washington
Medical Epidemiologist and Guest Researcher, International Emergency Response and Recovery Branch, Center for Global Health, Centers for Disease Control and Prevention
Public Health and Medical Technical Advisor, Office of Foreign Disaster Assistance, United States Agency for International Development

Dmitri Bouianov, CEO, Context VR

Ross Ehrmentraut, RN, HRET Senior Fellow, TeamCORE Clinical Manager, UW Medicine WWAMI Institute for Simulation in Healthcare

Rosemarie Fernandez, MD, Associate Professor- Emergency Medicine, UW School of Medicine, Harborview Medical Center (HMC)

John Lynch, MD, MPH, Associate Professor- Medicine, Medical Director of Infection Prevention and Employee Health, UW School of Medicine, HMC

John Scott Meschke, JD, MS, PhD, Assistant Professor- Environmental and Occupational Health Sciences, University of Washington School of Public Health

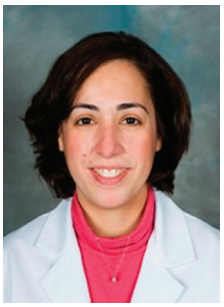
Steven Mitchell, MD, Assistant Professor- Emergency Medicine, Acting Medical Director- Emergency Department, UW School of Medicine, HMC

Sarah Parker, PhD, Research Assistant Professor, Carilion Research Institute, Virginia Tech University

COURSE DIRECTORS

John Scott Meschke, PhD, MS, JD
Professor, Department of Environmental and Occupational Health Sciences University of Washington School of Public Health

Dr. Meschke is an environmental and occupational health microbiologist, specializing in the fate, transport, detection, and control of pathogens in environmental media (Air, Water, Food, and Surfaces). Dr. Meschke's research focuses heavily on the transmission and movement of pathogens, and how risks can be reduced.



Rosemarie Fernandez, MD
Associate Professor, Emergency Medicine
Harborview Medical Center
University of Washington School of Medicine

Dr. Fernandez is the Associate Director for Education at the UW Medicine Center for Scholarship in Patient Care, Quality, and Safety. Dr. Fernandez completed a Patient Safety Leadership Fellowship at the AHA-National Patient Safety Foundation in 2011. She is an expert in creating care environments that are safe and effective for patients and care providers.

Treating Patients with Highly Contagious Infectious Diseases: Using Technology to Advance Safety

Notes:

CONTINUING EDUCATION PROGRAMS
NORTHWEST CENTER FOR OCCUPATIONAL HEALTH AND SAFETY
DEPARTMENT OF ENVIRONMENTAL AND OCCUPATIONAL HEALTH SCIENCES
University of Washington School of Public Health

Press Release
(Attachment 11)

Keeping hospital workers safe: A hands-on simulation

Doctors and nurses were among the first people infected during the 2014 Ebola outbreak in West Africa. Then, when an infected African patient entered a Texas hospital, he passed the virus to two nurses.

The World Health Organization reports [http://www.who.int/features/ebola/health-care-worker/en/] that health workers are between 21 and 32 times more likely to be infected with Ebola than people in the general population, but that well-defined clinical care protocols can prevent such infections.

A potentially life-saving rehearsal is coming up April 6, in a course titled "Treating Patients with Highly Contagious Infectious Diseases: Using Technology to Advance Safety. " [https://osha.washington.edu/professional-development/course/hcid-0416]

The course is sponsored by the University of Washington's Department of Environmental and Occupational Health Sciences [http://deohs.washington.edu], in collaboration with the WWAMI Institute for Simulation in Healthcare [http://isis.washington.edu/]at UW Medicine's Harborview Medical Center and the Carilion Research Institute at Virginia Tech University, with funding from the Washington State Department of Labor & Industries, Safety and Health Investment Project.

Simulation provides a safe way to study systems, test protocols, and detect safety threats, said course co-directors Rosemarie Fernandez, [http://depts.washington.edu/doemuw/home/faculty/fernandez-rosemarie] a UW associate professor in the Division of Emergency Medicine, and Scott Meschke, [http://deohs.washington.edu/faculty/meschke_john]a UW professor in the Department of Environmental and Occupational Health Sciences. When combined with risk analysis methods, these simulations can help identify unanticipated threats to safety.

Healthcare workers and their managers need to know "what to do if a sudden, horrible thing happens that is so different from what they do day to day,"

Fernandez said. Ebola was such a threat, turning one of the simplest hospital procedures – changing sheets – into one of the riskiest.

Ebola patients produce an almost unbelievable amount of watery stool, she explained. Heavy protective gear can make it awkward for healthcare workers to move patients or handle their linens. The simulation will let workers practice, using a runny mixture of root beer, yogurt, and chocolate pudding to represent Ebola symptoms.

The one-day course is designed for healthcare providers, infection control practitioners, occupational health professionals, public health professionals, hospital administrators, and operations staff.

To register and for more information, visit the department's Continuing Education Programs: https://osha.washington.edu/professional-development/course/hcid-0416

References

CDC guidance for US hospitals, http://www.cdc.gov/vhf/ebola/healthcare-us/hospitals/infection-control.html