Using a Patient Safety Analysis to Guide Infusion Therapy for Patients With COVID-19

Mary Hagle, PhD, RN, NPD-BC, FAAN • Kate Snyder, PharmD, BCPS • Karen Janicek, BSN, RN • Kimberly Bell, PharmD • Beth Dietz, MSN, RN, CCNS, CCRN-K • Nathan Gundacker, MD • Angelina Kinter, MSN, RN, CCRN-K • Annette Severson, EdD, RN

ABSTRACT

In the United States, during the Coronavirus Disease 2019 (COVID-19) pandemic, patients with COVID-19 overwhelmed available intensive care beds, staffing levels were unpredictable, and personal protective equipment was limited. The safety of situating electronic infusion pumps outside patient rooms was evaluated using an internal risk assessment. Based on a low level of risk, a procedure was developed to direct clinicians as to when this process is appropriate during a national crisis. A standardized analysis, Healthcare Failure Mode and Effects Analysis, was conducted to identify all potential risks and implement actions that would eliminate or control the risk. No adverse events were reported. Safe systems and preparation can protect patients.

Key words: COVID-19, HFMEA, ICU, infusion, patient safety, personal protective equipment, PPE, pump

Authors' Affiliation: *Clement J. Zablocki Veterans Affairs Medical Center, Milwaukee, Wisconsin.*

Mary Hagle, PhD, RN, NPD-BC, FAAN, *is a nurse scientist and codirector of the Interprofessional Fellowship Program in Patient Safety at the Zablocki Veterans Affairs (VA) Medical Center. She has extensive experience as a researcher and as an oncology clinical nurse specialist in academic and community medical centers. She works with nurses and their infusion therapy practice in acute, ambulatory, community, and long-term care settings. Dr Hagle served as a committee member for the 2011, 2016, and 2021 revisions of the* Infusion Therapy Standards of Practice. *She is a mentor for research and quality improvement teams and a leader for translating evidence into practice.* **Kate Snyder, PharmD, BCPS,** *was the postgraduate year 2 medication use safety and policy pharmacy resident and a patient safety fellow in the Interprofessional Advanced Fellowship in Patient Safety at the Zablocki VA Medical Center at the time of this project. She graduated from the University of Rhode Island College of Pharmacy and completed her year 1 pharmacy residency at Cape Regional Medical Center in Cape May Court House, New Jersey. Currently, she is a medication safety pharmacist–smart pumps at Cleveland Clinic in Cleveland, Ohio, and is a Board Certified Pharmacotherapy Specialist.* **Karen Janicek, BSN, RN,** *was the infection preventionist at the time of this project and led the taskforce. She was instrumental facility-wide in infection prevention management for the COVID-19 pandemic. She has 35 years of nursing experience and worked in infection prevention for 20 years. Ms Janicek is currently working as lead care coordinator for the Home Telehealth Program at the Zablocki VA Medical Center.* **Kimberly Bell, PharmD,** *is the division manager of pharmacy at the Zablocki VA Medical Center. She is also a clinical instructor at the University of Wisconsin School of Pharmacy in Madison, Wisconsin. Dr Bell has more than 15 years of pharmacy experience in several medical centers and is an expert in quality improvement processes. Her passion for patient safety is demonstrated through her initial faculty role in the Interprofessional Patient Safety Fellowship Program and oversight of the pharmacy resident program.* **Beth Dietz, MSN, RN, CCNS, CCRN-K,** *is a critical care clinical nurse specialist. She has worked within critical care for more than 35 years and has served as a clinical nurse specialist in both a community medical center and at the Zablocki VA Medical Center. Ms Dietz has led numerous initiatives that focused on improving patient care for the critical care population. Topics have included decreasing infection rates, reducing clinical alarms, ensuring evidence-based practice, and decreasing hospital-acquired pressure injuries. She also provides education on a variety of topics for clinicians working with critically ill patients.* **Nathan Gundacker, MD,** *is an infectious disease staff physician and COVID-19 lead physician at the Zablocki VA Medical Center. He is also an assistant professor at the Medical College of Wisconsin Division of Infectious Diseases in Milwaukee, Wisconsin.* **Angelina Kinter, MSN, RN, CCRN-K,** *was the intensive care unit (ICU) nurse manager of the COVID-19 unit at the Zablocki VA Medical Center at the time of this project. Her roles within critical care have included staff nurse, charge nurse, preceptor, and assistant nurse manager. Ms Kinter provided strong nursing leadership as the medical center established a new and separate COVID-19 ICU while continuing to manage the existing medical–surgical ICU. She supported the interdisciplinary team around the clock with the challenges that arose during the COVID-19 surge and remained committed to providing quality patient care and promoting professional development of all staff.* **Annette Severson, EdD, RN,** *is currently the nurse executive/associate director of patient care services for the academic medical center and community-based outpatient clinics at the Zablocki VA Medical Center. More than 250 000 veterans are served for primary, secondary, and tertiary care including all-encompassing inpatient and outpatient mental health and spinal cord injury/disorder services. Dr Severson has oversight for all nursing practice, as well as several other clinical departments. Her experience in academic medical centers is broad, including the roles of clinical nurse specialist, manager, and administrator. She was also associate vice president/chief academic officer for the Wisconsin Technical College System.*

This material was supported in part by the VA Office of Academic Affiliations Interprofessional Fellowship Program in Patient Safety, directed by the National Center for Patient

During national and world health crises, such as the coronavirus disease 2019 (COVID-19) pandemic, emergency measures in health care processes are often necessary. In the United States in 2020, COVID-19 patients overwhelmed available intensive care unit (ICU) beds; staffing levels were unpredictable; and personal protective equipment (PPE), critical medications, and supplies were limited. The situation was so dire that there was a national call for ideas to conserve PPE from the editors of the *Journal of the American Medical Association* on March 20, 2020.[1] Additionally, industry documents, anecdotal descriptions on social media, and professional websites provided resources and novel practices to care for patients with COVID-19. The national COVID-19 bed capacity, clinical staff shortage, and medication/supply shortage were echoed at the authors' Midwestern academic medical center.

Because the SARS-CoV-2 virus, which causes the COVID-19 disease, can be airborne, critically ill patients with COVID-19 were placed in negative pressure rooms, formally known as *airborne infection isolation rooms*. These rooms contain contaminated air from the patient that is filtered before it is blown outside. The door must be kept closed to maintain the negative air pressure. With all existing negative pressure rooms in use, additional rooms were converted to negative air pressure using free-standing improvised air filtration and fan systems. However, several challenges were noted. First, the fan systems were often noisy. Second, with room doors constantly closed, alarms were difficult to hear outside of the room.

Strict isolation protocols were in place for staff safety. Clinicians working in COVID-19 ICU rooms were observed while they donned appropriate PPE to ensure that they were protected when they entered a patient room and again while they doffed PPE after coming out of the room. This process took time but was critical in protecting staff. Often, nurses remained in the ICU rooms for 4 or more hours at a time because of the PPE shortage and time to don and doff. Other issues arose while working in these rooms. Clinicians became very warm while they worked, face masks or shields chafed their skin, and the powered air-purifying respirators dried their eyes. Frequent medication and/or rate changes also kept nurses in the room for extended periods of time.

Several clinicians saw journal comments and posts on social media about nursing staff situating electronic infusion pumps for intravenous (IV) therapies outside COVID-19 ICU patient rooms. In the interest of conserving PPE supplies and increasing staff efficiency, questions were raised as to whether this strategy could safely be adopted at the authors' medical center. Although the immediate benefits appeared to be clear, a taskforce was formed to validate the feasibility and safety of this new practice and then develop a procedure if indicated. An internal health and safety risk assessment was compiled with related risk control measures. A formal risk analysis, known as a Healthcare Failure Mode and Effects Analysis (HFMEA), was also conducted. Electronic infusion pumps were approved to be situated outside the COVID-19 ICU patient rooms, and a procedure was developed for use during the national crisis. The purpose of this article is to describe the procedure, report the findings of an HFMEA, and share outcomes of this procedural change.

SITUATING INFUSION PUMPS OUTSIDE COVID-19 ICU PATIENT ROOMS

In response to questions about situating electronic infusion pumps outside COVID-19 ICU patient rooms, an interdisciplinary taskforce was convened to examine risks and processes of this procedure. The taskforce was led by a nurse infection preventionist and consisted of an ICU clinical nurse specialist, managers, nurse scientist, pharmacists, an infectious disease physician, and other ancillary staff. The 10 taskforce members represented the following departments: biomedical engineering, facility management, industrial hygiene, infectious disease, nursing, pharmacy, and quality management (which includes infection control, medication management, and patient safety).

Several virtual and face-to-face meetings were held over the course of 3 weeks to identify known or foreseeable hazards and to describe these risks using an internal health and safety risk assessment tool. Global questions included: "What could happen?"; "How could it happen?"; and "Are there any particular factors or issues that contribute to the risk(s)?" During the meetings and via email, taskforce members considered possible adverse outcomes that could occur from situating infusion pumps outside COVID-19 ICU patient rooms. Potential adverse outcomes involved events related to, for example, trip hazard, tubing disconnection, infection, delay of medication administration, inaccurate infusion rates, medication waste, and depletion of IV extension tubing. It was noted by some taskforce members that the practice of running IV extension tubing under a door had been used infrequently but safely for patient care during magnetic resonance imaging services.

Discussion with facilities management staff helped the taskforce decide that having IV extension tubing run under the door would have no impact on negative air pressure.

Safety, Department of Veterans Affairs (K. Snyder), and with resources and the use of facilities at Clement J. Zablocki VA Medical Center, Milwaukee, WI.

The contents do not represent the views of the US Department of Veterans Affairs or the United States Government.

The authors of this article have no conflicts of interest to disclose.

Corresponding Author: *Mary Hagle, PhD, RN, Clement J. Zablocki VA Medical Center, Nursing Education & Research, 5000 W National Ave, Milwaukee, WI 53295 (mary.hagle@va.gov).*

DOI: 10.1097/NAN.0000000000000438

After deliberating, the taskforce agreed that the likelihood of an adverse event occurring was minimal and the consequences should an event occur would likely be minor. Furthermore, the taskforce brainstormed actions to eliminate or control other risks. Logistics ensured that a 2-month supply of extension tubing would be on hand, and pharmacy identified medications with critical shortages that would not be infused outside the room. Based on the summary of the risk assessment and the risk control measures, the procedure of situating infusion pumps outside COVID-19 ICU patient rooms was supported by clinical and administrative leadership.

Following leadership endorsement, a procedure was swiftly developed and promptly initiated. It outlined the process for implementation in patient rooms and identified risk control measures with available evidence, including alerts from the ECRI Institute, Infusion Nurses Society, and the Institute for Safe Medication Practices.[2-5] The procedure was indicated only for COVID-19 ICU patient rooms (Table 1).

Specifically, the procedure contained an initial checklist of applicable needs or conditions to situate the infusion pump outside the COVID-19 ICU patient room. If the decision was made to situate the infusion pump outside the room, the procedure stated that the patient must have a central venous catheter. The remaining procedure document was grouped into 3 topics: IV tubing considerations, infusion pump considerations, and medication directions. For example, regarding medication directions, infusing propofol outside the room generated much discussion because of safety concerns and a medication shortage at that time; it was decided not to infuse propofol outside the room.

The procedure was not a plan for total patient care: it did not address expected nursing practices such as appropriate and timely patient assessments, cautions when administering a medication the first time, and actions to take for patient responses to medications or procedures. The procedure was revised slightly after 1 month for readability and to acknowledge a new patient safety notice from the Department of Veterans Affairs to all patient safety managers.[6] This safety notice warned that situating infusion pumps outside of patient rooms should only be used as a last resort to conserve PPE. The conservation of PPE was already a condition of implementation; thus, no other changes were needed.

HFMEA FOR PATIENT SAFETY ANALYSIS

Soon after approval of the practice, nurses in the COVID-19 ICU successfully situated 1 pump outside a patient's room without any adverse events. To consider all potential vulnerabilities and gaps associated with situating infusion pumps outside COVID-19 ICU patient rooms, the patient safety managers recommended completing an HFMEA. Although this analysis is best performed before starting a new practice, the taskforce supported conducting this standardized patient safety analysis even after implementation of the procedure because there was minimal evidence to support this practice and benefits seemed to outweigh the risk.

Description of an HFMEA

An *HFMEA* is a tool and an approach that is often utilized to proactively assess vulnerabilities and identify potential problems in health care, particularly those relating to patient safety, before they occur and reach the patient.[9,10] The Failure Mode and Effects Analysis (FMEA) model has been used within the engineering community for >30 years.[11] Within the Department of Veterans Affairs, the National Center for Patient Safety adapted the FMEA model specifically for health care, resulting in the HFMEA acronym.

An HFMEA for a new process is composed of a series of activities that are systematically conducted to arrive at actions for mitigating risks. Although different numbers of actions have been reported, from 5 steps to 9 phases, the activities of HFMEA are similar.[10,12] Irrespective of how many steps or phases, all HFMEA activities are needed to complete the hazard or risk analysis and identify appropriate actions to be taken.

Steps of an HFMEA

In brief, the following 5 steps represent the HFMEA that was conducted by the authors:

1. Define the HFMEA topic
2. Assemble the team
3. Graphically describe the process
4. Conduct the hazard analysis
5. Determine actions and outcome measures.

One of the authors (K.S.) was a patient safety fellow at the time and initiated the HFMEA on this procedure change for taskforce review. First, the topic was defined as situating electronic infusion pumps outside of COVID-19 ICU patient rooms with long IV extension sets and/or multiple IV extension sets. This procedure was done in an effort to conserve PPE during the COVID-19 pandemic by minimizing entry into the patient room and to decrease caregiver exposure by reducing the amount of time in patient rooms.

Second, the HFMEA pump team was composed of the original taskforce members with additional experts from the medical center. In step 3, starting with the written procedure, a detailed description of the process was outlined. The procedure within the HFMEA was separated into 5 sections, starting with a decision to situate the infusion pump outside the room and ending with preparation to infuse medications and follow-up actions (Table 2).

In step 4 of the HFMEA, a hazard analysis was conducted; this consists of 2 parts. First, potential failure modes or hazards need to be identified; second, the failure mode is evaluated to determine the likelihood of its occurrence

TABLE 1

Procedure for Electronic Infusion Pumps Outside COVID-19 ICU Patient Rooms

This procedure is only for the COVID-19 ICU until further notice.[a]

Initial approval of procedure: 4/14/20; Revised: 5/19/20

I. Patient considerations for having an IV pump outside an ICU COVID-19 room:

- PUMP OUTSIDE ROOM:
  - Need to conserve PPE
  - Multiple medications with frequent changes
  - Patient requiring care from more than 1 nurse
  - Sufficient administration extension sets for all meds
- *NOTE: There is a Patient Safety Notice: this practice is not endorsed by Veterans Health Administration National Infectious Diseases Service. "Use of infusion pumps outside of patient rooms should only be used as a last resort, after all other efforts to conserve PPE have been exhausted, and in the very specific incidence of critical facility level PPE shortages."*[6]
- PUMP INSIDE ROOM:
  - Sufficient PPE or
  - Patient care and IV med/pump monitoring can be bundled

II. IV Pump outside an ICU COVID-19 room implementation:

A. Patient must have a CVC

B. IV tubing considerations
1. Use microbore tubing if possible,[2] although large bore can be used
   a. Using 20 feet of microbore tubing: accuracy was within specifications when infusion rates were between 5 and 300 mL/h[2]
      i. Less than 5 mL/h: infusion slow and occlusion alarm may be delayed
      ii. More than 300 mL/h: higher back pressure so more frequent alarms
2. Use triple port connector if needed
3. Include connector volume for priming volume of extension sets
4. Label tubing inside/outside room
5. Ports: use disinfection caps on all ports
6. Ports: do not use any y-sites or needle-free access ports that have been on floor.
7. Change IV administration sets and intermittent tubing every 7 days (along with the CVC dressing) to minimize handling.
8. Secure tubing to prevent disconnection or trip hazard:
   a. Cover tubing on floor with orange cord protector from operating room (trip cord protector, 8 × 24 inches)
   b. Post signage
9. Develop disinfection/cleaning schedule for floor around tubing/protector.
   a. Unknown: absorption from cleaning agents: ECRI recommends clean around tubing.[2]

C. IV pump considerations[5]
1. Occlusion pressure settings: follow manufacturer's recommendation to accommodate adjusting occlusion pressure rates based on resistance, low infusion rates, high infusion rates through CVC.
2. Patient identification (wristband) on patient and pump
3. Utilize designated pumps that are conducive for extension tubing; do not use syringe type pump set
4. No need to lock pump if visitors and patients are not walking around
5. Some hospitals keeping controlled substance infusions in room
6. Document in chart that IV pump is outside room

D. Medication directions
1. Prime long extension sets with medication before connecting to patient to minimize risk of delayed start
2. Flush rate to be the same as medication delivery rate so the medication infuses over ordered duration.
3. Medications that CANNOT be infused from the extended infusion set: propofol (because of shortage), blood, fat emollients, others as identified; insulin infusion[4]
4. Compatibilities:
   - Fentanyl is y-site compatible with dexmedetomidine and midazolam
   - Ketamine is y-site compatible with midazolam
   - Dexmedetomidine is y-site compatible with fentanyl and midazolam
   - Midazolam is y-site compatible with dexmedetomidine, fentanyl, and ketamine

III. Alternatives to IV pumps:

- If using gravity drip: must count drops, even with flow regulator device; rate may be slower because length of tubing: recalculate
- Hypodermoclysis for hydration

Abbreviations: CVC, central venous catheter; ICU, intensive care unit; IV, intravenous; PPE, personal protective equipment.

Resources and information from: ECRI,[2,7] Infusion Nurses Society,[3] Institute for Safe Medication Practices.[4,5,8]

[a]NOTE: Procedure developed by staff from the following departments: nursing, pharmacy, quality management and safety, infectious disease, biomedical engineering, facility management, and industrial hygiene. The contents do not represent the views of the US Department of Veterans Affairs or the US government.

and the severity of injury if an injury occurs. Thus, in part 1, potential failure modes were identified for each of the 5 sections of the procedure (Table 3). For example, in section 3, preparing and using the infusion pump, there were 3 potential failure modes: staff are unfamiliar with infusion pump manufacturer recommendations; wristbands are not attached to patient and/or not taped to pump; and staff are not familiar with different pump types.

TABLE 2

Example of Step 3 for Healthcare Failure Mode and Effects Analysis

Step 3. Describe the process in detail: based on the procedure for situating IV infusion pumps outside COVID-19 ICU patient rooms

1. Deciding if infusion pump can be outside patient room	2. Selecting and preparing correct tubing	3. Preparing and using infusion pump	4. Preparing for medications to be infused using extension sets	5. Other/further actions
A. Determine the following: i. Does PPE need to be conserved? ii. Does the patient have or is anticipated to have multiple IV medications that may require frequent changes? iii. Does the patient require care from more than 1 nurse? iv. Is there a sufficient amount of IV extension sets? B. May move forward with decision-making process for positioning infusion pump outside patient room.	A. Use microbore tubing if possible (although large bore can be used). • Using 20 feet of microbore tubing: accuracy was within specifications when infusion rates were between 5 mL and 300 mL according to ECRI.[2] B. Use triple port connector (if needed). C. Include connector volume for priming volume of extension sets. D. Label tubing inside/outside room. E. Use disinfection caps on all ports (do NOT use any y-sites or needle-free access ports that have been on floor). F. Cover tubing on floor with orange cord protector and post signage.	A. Follow manufacturer recommendations to adjust occlusion pressure rates based on resistance, low infusion rates, and high infusion rates through CVC. B. Ensure both patient and patient's pump have wristband or patient identification taped on infusion pump. C. Utilize designated infusion pump that is conducive for extension tubing; do not use syringe type pump set.	A. Determine if medication can be infused using extension set (those that cannot include blood, fat emollients, and insulin). • Consider propofol wastage if infusion outside the room. B. Prime long extension sets with medication before connecting to patient to minimize risk of delayed start. C. Flush rate should be the same as medication delivery rate, so medication infuses over ordered duration. D. Consider compatibilities (eg, ketamine is y-site compatible with midazolam).	A. Document in patient's chart that IV pump is outside patient's room. B. Change IV administration sets and intermittent tubing every 7 days. C. Develop disinfection/cleaning schedule for floor around tubing/protector.

Abbreviations: CVC, central venous catheter; ICU, intensive care unit; IV, intravenous; PPE, personal protective equipment.
Data from ECRI.[2]

TABLE 3

Example of Step 4, Part 1 for Healthcare Failure Mode and Effects Analysis

Step 4. part 1: identify potential failure modes–based on the detailed outline of the process for situating IV infusion pumps outside COVID-19 ICU patient rooms

1. Failure modes related to decision-making about the infusion pump outside patient room	2. Failure modes in selecting and preparing correct tubing	3. Failure modes in preparing and using the infusion pump	4. Failure modes in preparing medications to be infused using extra extension sets	5. Failure modes related to other actions
A. Nurse is unsure of current PPE and extension tubing inventory status. B. ICU team did not consider all of the following: PPE, patient, and tubing.	A. Nurse used infusion rate of <5 mL/h (which can result in slow infusion and delayed occlusion alarm) or >300 mL/h (which can result in higher back pressure further resulting in more frequent alarms). B. Nurse does not know where to find triple port connector. C. Tubing is not labeled inside and outside room. D. Disinfection caps are not used on all IV tubing ports. E. Tubing is not secured with orange cord protector.	A. Staff are unfamiliar with infusion pump manufacturer recommendations related to alarms. B. Wristbands not attached to patient and/or not taped to pump. C. Staff are not familiar with different pump types.	A. Staff infuses blood, fat emollients, or insulin using extension tubing. • ICU team does not consider propofol wastage before infusing using an extra extension set. B. Long extension set is not primed before connecting to patient. C. A different flush rate than ordered is used. D. Drug compatibility not confirmed.	A. Placement of IV infusion pump outside patient's room is not documented in patient's chart. B. IV administration set not changed per guideline.

Abbreviations: ICU, intensive care unit; IV: intravenous; PPE, personal protective equipment.

A recent article was reviewed outlining central vascular access device complications and preventive actions to determine whether any failure modes were missed in the procedure that was developed.[13] No changes were needed. Additionally, a team from China used FMEA to improve their catheter-related bloodstream infection rates in the ICU.[14] Their report of 25 failure modes and recommended actions were reviewed by the HFMEA pump team with no changes needed in the procedure or HFMEA. Last, 2 clinicians conducted an HFMEA to prevent harm from tubing misconnections.[15] They looked at all types of tubing: enteral feeding, oxygen, and vascular. No outcomes were reported. The HFMEA pump team reviewed the published failure modes and actions for possible changes in the procedure; as no changes were needed, work continued.

For step 4, part 2, these failure modes were then transferred to another table for the hazard analysis (Table 4). In the analysis, the HFMEA pump team evaluated the severity of patient injury if a failure occurred and the probability or likelihood of the failure occurring. In Table 4, the 3 potential failure modes from section 3 (Table 3) are listed with their severity, probability, and hazard scores. Definitions for each level of severity and probability are in Table 4. For example, a score of 2 (moderate) in severity means there could be an increased length of stay or increased level of care for the patient.[9] A probability score of 3 would mean it happens occasionally, that is, it could happen several times in 1 to 2 years.[9]

For step 5, each potential failure mode, such as a problem, hazard, or vulnerability, has a protective or preventive action and an identified individual who will use that action to control or eliminate the problem. Many HFMEAs have a threshold at which a hazard score requires an action to control the potential problem, for example, a hazard score of ⩾8. At the conclusion of an HFMEA, administrators or other decision-makers choose whether to implement the proposed process or project. The authors' completed HFMEA did not identify any other preventive actions than what was in the procedure, such as ensuring a 2-month supply of IV extension tubing.

The HFMEA for situating electronic infusion pumps outside COVID-19 ICU patient rooms was completed after implementation of the procedure; however, no new information or vulnerabilities were identified. The HFMEA was valuable from this aspect, and the patient safety managers accepted the analysis as completed.

OUTCOMES

The procedure was in practice for several months until the emergency ended with availability of PPE, other supplies, and staff. Monitoring relevant COVID-19 literature, process implementation in the COVID-19 ICU, and adverse events continued until the practice ended in spring 2021. Less

TABLE 4

Example of Step 4, Part 2 for Healthcare Failure Mode and Effects Analysis

Step 4. Part 2: Identify severity and probability for each potential failure mode and calculate a hazard score—related to preparing and using the infusion pump

Potential failure modes in preparing and using the infusion pump	Severity[a]	Probability[b]	Hazard score[c]
A. Staff are unfamiliar with infusion pump manufacturer recommendations.	2	3	6
B. Wristbands not attached to patient or not taped to pump.	2	3	6
C. Staff are not familiar with different pump types.	2	2	4

[a]Severity score for a patient outcome:
1-Minor: no injury, increased length of stay, or increased level of care
2-Moderate: increased length of stay or increased level of care for 1 or 2 patients
3-Major: permanent lessening of bodily function, disfigurement, surgical intervention, increased length of stay or level of care for 3 or more patients
4-Catastrophic: death, major permanent loss of function

[b]Probability of occurring:
1-Remote: unlikely to occur (may happen sometime in 5–30 years)
2-Uncommon: possible to occur (may happen sometime in 2–5 years)
3-Occasional: probably will occur (may happen several times in 1–2 years)
4-Frequent: likely to occur immediately or within a short period (may happen several times in 1 year)

[c]Hazard score: severity score multiplied by probability; preventive action must be identified if score ≥8

[a,b,c]Data from US Department of Veterans Affairs.[9]

than 20 patients in COVID-19 ICU patient rooms have had infusion pumps situated outside their rooms. Although this is a low frequency compared with some hospitals, patients were often hospitalized in the COVID-19 ICU for up to 4 weeks.

Nurses reported that it was easier to implement this process before the patient was admitted to the room. There were mixed perceptions by nurses on whether this procedure decreased PPE usage or the number of times nurses went into the room. One nurse noted that there was no delay in titrating medication infusion rates because the nurses did not have to wait until there were several patient cares or actions needed before going into the room. This was attributed to grouping care in order to reduce PPE usage. Additionally, nurses were not in 1 room for hours at a time, reducing exposure and physical strain. Nurses' concerns included drug waste due to the extension tubing and securement of connection sites and tubing. No reports were received about infusion pump function issues if the rate was <5 mL/h or >300 mL/h.

Several failure mode themes were identified in the authors' HFMEA. These included needing an interdisciplinary decision, implementation of protective or preventive actions, increased risk of infection, and increased risk of human error attributed to multiple steps. The final procedure addressed these themes. The issue of drug wastage versus scarcity was important. Propofol is a high-alert medication, and tubing needs to be changed every 12 hours. This results in 34.4 mL of additional medication waste every 24 hours, based on the standard setup. For certain patients, this may be appropriate to balance PPE conservation and worker exhaustion. However, because of the national propofol shortage at the time, propofol was administered inside the ICU patient room.

There were no reported clinician or patient falls related to IV extension tubing, no identified central line-associated bloodstream infections (CLABSI), and no reported medication events related to the use of IV extension tubing. There was 1 occurrence of a propofol infusion outside the COVID-19 ICU patient room; no adverse events occurred. Last, no policies were changed for this specific procedure; it was for 1 patient care unit only and was kept with other COVID-19 special practices.

DISCUSSION

During a health crisis or national emergency, electronic infusion pumps may be safely situated outside ICU patient rooms to conserve resources, such as PPE or other supplies. Before implementing this procedure, stakeholders conducted an internal health and safety risk assessment, developed an approved internal procedure, completed an HFMEA, and staff instituted the practice without any adverse events reported.

The COVID-19 pandemic forced health care organizations to balance PPE preservation, health care worker exposure and absence, drug shortages, and optimal patient care simultaneously. These stressors forced the creation of strategies to conserve PPE and work with limited numbers of clinicians in ICUs and other units. Several organizations cautioned against the placement of IV pumps outside patient rooms, stating that this should be a last resort when there are critical shortages of PPE.[2-6]

Recent Reports About Infusion Pumps Outside COVID-19 ICU Patient Rooms

As of June 14, 2021, 5 reports related to this topic were found. The Society of Critical Care Medicine published a summary of experiences about managing patients with COVID-19 in ICUs.[16] Situating infusion pumps outside ICU rooms was addressed extensively with recommendations for nurses and pharmacists. Almost all of the recommendations were listed in the authors' COVID-19 ICU procedure, including securing tubing to the floor to eliminate a trip hazard. At the authors' institution, 2 of the operating room nurses deployed to the COVID-19 ICU recommended use of a cord protector floor mat routinely utilized in the operating room, which was put into place.

In August 2020, an interprofessional team of ICU clinicians in the United States published their process of situating infusion pumps outside COVID-19 ICU patient rooms.[17] Their detailed explanations of equipment and procedures provide guidance for implementing this practice. There were several differences between the authors' procedure and what was done by Shah et al.[17] For example, they put an identification wristband on the patient and taped a wristband to the inside of the glass door for scanning, whereas the authors' procedure directed the nurse to put a wristband on the patient and a wristband on the infusion pump pole outside the room. With no reported adverse events using either identification method, future discussion of a preferred method with rationale may be helpful. The procedure by Shah et al[17] was implemented institution-wide among various ICUs, although no specific outcomes were reported. With a current pandemic and limited resources, "This practice should be given consideration,[17]" although cautions were also offered about this practice: it is not ideal and is not recommended under typical circumstances. Shah et al[18] then studied the impact of this practice on 18 patients with COVID-19 before and after pump location inside and outside COVID-19 ICU patient rooms. They found significantly fewer nurse entries into the COVID-19 ICU rooms after pumps were situated outside the rooms ($P < .0001$); this was cautiously extrapolated into a corresponding decrease in PPE use. Also, there were no reports of CLABSI or extravasation for these patients, mirroring the HFMEA pump team's experience of no reported CLABSIs.[18]

An interprofessional team from Italy shared their experiences in situating a variety of devices outside ICU rooms during the COVID-19 pandemic.[19] They addressed cross-contamination, technology, and regulatory issues. Information was provided for remote monitoring of a ventilator, continuous renal replacement therapy, vital signs, and drug and fluid administration. They noted that there is resistance to utilizing these remote practices in the clinical setting, but it is technologically possible. For example, when administering drugs or fluids via an electronic infusion pump, the ability to monitor pressures within the pump exists. Cautions about pump infusions were given, such as being aware of higher flow resistance attributed to longer IV tubing, knowing the internal diameter of IV tubing, and considering fluid viscosity, as well as tubing disconnection. The authors noted that it is essential to prevent transmission of infections, to keep patients safe, and to protect clinicians during a pandemic.[19] Last, implications for nurses, pharmacists, and providers when IV pumps are situated outside COVID-19 ICU patient rooms were summarized by an interprofessional team.[20] An important point was that nurses need more information and education when working with remotely situated IV pumps, although during a crisis time is at a premium.

Recent Reports About Related HFMEA Projects

HFMEA is a productive methodology to prevent harm to patients. However, not all reviewed HFMEA reports included outcomes. In a 2021 systematic review of 33 articles about medication safety, 31 had corrective actions recommended.[21] Anjalee et al[21] found that 6 articles reported a reduction in errors. In addition, the perceptions of FMEA participants about its advantages were reported; these included the ability to gather the collective knowledge of the team, analyze complex processes, increase clinicians' awareness of health care risks, and promote safety. Several drawbacks were listed as well, such as being a time-consuming process, subjective in nature, and having a single-institution focus.[21]

In a 2020 systematic review of 158 articles about HFMEA health care projects, Liu et al[22] made recommendations for conducting future HFMEA projects and identified gaps in research. One of their recommendations was to have more than the usual 5 team members as reported in the literature because the complexity of health care systems often requires more experts on the team. The HFMEA pump team wanted the representation of all stakeholders involved in situating infusion pumps outside a patient's room. This provided diverse perspectives and the ability to consider more risks. Thus, the HFMEA pump team included 10 members from 7 departments.

CONCLUSION

Situating electronic infusion pumps outside ICU patient rooms can be safe and successful but should be a practice reserved for emergencies. Proactively using a systematic method and a step by step analysis, such as an HFMEA, to analyze a new process and prevent adverse events was a productive use of time, talent, and energy in instituting a novel procedure. In addition, monitoring outcomes of high-risk process change is important to correct failures and maintain a safe system for patients. Despite many cautions, clinicians and administrators need to be prepared for future health emergencies and possible shortages. The implementation of infusion pumps outside COVID-19 ICU rooms allowed for PPE conservation, and the protocol will be in place at the authors' institution for future pandemics, if needed. As we navigate the current pandemic and prepare

for the future, a focus on system safety permits clinicians to focus on their patients.

Infusion therapy clinicians and managers need to be aware of issues addressed in this article, because they may be called on as stakeholders and experts for patient safety issues. Their familiarity with different patient populations, venues of care, and professional standards guiding practice make infusion therapy clinicians and managers essential to committees and councils that regularly develop and revise policies and procedures, let alone when a taskforce is needed during emergencies. Even when clinicians are not familiar with a venue of care, such as an ICU, principles of patient safety, infection prevention, use of best evidence, and methods for risk evaluation can be maintained with the necessary experts involved.

ACKNOWLEDGMENT

Grateful appreciation is extended to all departments for their interprofessional collaboration, as well as to medical center administrators and auxiliary staff who supported the expertise and needs of frontline clinicians.

REFERENCES

Note: All electronic references were accessed May 21, 2021

1. Bauchner H, Fontanarosa PB, Livingston EH. Conserving supply of personal protective equipment-a call for ideas. *JAMA*. 2020;323(19):1911. doi:10.1001/jama.2020.4770
2. ECRI Report. Large-volume infusion pumps: considerations when used with long extension sets outside patient rooms to help reduce staff PPE use. Published April 1, 2020. https://d84vr99712pyz.cloudfront.net/p/pdf/covid-19-resource-center/covid-19-clinical-care/covid-alert-large-vol-infusion-pumps-3.pdf
3. Infusion Nurses Society. Frequently asked questions related to covid-19 health care related challenges. Published April 1, 2020. https://www.ins1.org/wp-content/uploads/2020/04/Frequently-Asked-Questions-Related-to-COVID-19-Health-Care-Challenges-Amended-on-04.01.2020.pdf
4. Institute for Safe Medication Practices. Clinical experiences keeping infusion pumps outside the room for COVID-19 patients. Published April 3, 2020. https://ismp.org/resources/clinical-experiences-keeping-infusion-pumps-outside-room-covid-19-patients
5. Institute for Safe Medication Practices. Acute care ISMP medication safety alert: planning for anticipated shortage of smart infusion pumps and dedicated administration sets. Published April 9, 2020. https://ismp.org/sites/default/files/newsletter-issues/20200409.pdf
6. Department of Veterans Affairs Veterans Health Administration National Center for Patient Safety. Patient safety notice: patient safety aspects of using infusion pumps outside of patient rooms, N20-07. Internal communication. Published May 11, 2020.
7. ECRI. COVID-19 Resource Center. Published 2021. https://www.ecri.org/coronavirus-covid-19-outbreak-preparedness-center
8. Institute for Safe Medication Practices. COVID-19 resources. Published 2021. https://ismp.org/covid-19-resources
9. Department of Veterans Affairs Veterans Health Administration National Center for Patient Safety. Healthcare Failure Modes and Affects Analysis (HFMEA) Guidebook. Published January 2021. www.patientsafety.va.gov/docs/joe/HFMEA-Guidebook-January2021.pdf
10. Department of Veterans Affairs Veterans Health Administration National Center for Patient Safety. Healthcare Failure Modes and Affects Analysis (HFMEA): a simple step by step guide. Published January 2021. www.patientsafety.va.gov/docs/joe/Step-by-Step-Guidebook-HFMEA-January2021.pdf
11. 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. *Jt Comm J Qual Improv.* 2002;28(5):248-267, 209.
12. Polancich S, Rue L, Poe T, Miltner R. Proactive risk mitigation: using failure modes and effects analysis for evaluating vascular access. *J Healthc Qual*. 2018;40(1):58-65. doi:10.1097/JHQ.0000000000000125
13. Berndt D, Steinheiser M. Central vascular access device complications. *Amer Nurs Today*. 2019;14(10):6-13.
14. Li X, He M, Wang H. Application of failure mode and effect analysis in managing catheter-related blood stream infection in intensive care unit. *Medicine*. 2017;96(51):1-8. doi:10.1097/MD.0000000000009339
15. Kimehi-Woods J, Shultz JP. Using HFMEA to assess potential for patient harm from tubing misconnections. *Jt Comm J Qual Patient Saf*. 2006;32(7):373-381. doi:10.1016/s1553-7250(06)32049-1
16. Halpern NA, Kaplan LJ, Rausen M, Yang JJ. Configuring ICUs in the COVID-19 era. Published June 15, 2020. https://www.sccm.org/getattachment/03130f42-5350-4456-be9f-b9407194938d/Configuring-ICUs-in-the-COVID-19-Era-A-Collection
17. Shah AG, Taduran C, Friedman S, et al. Relocating IV pumps for critically ill isolated coronavirus disease 2019 patients from bedside to outside the patient room. *Crit Care Explors.* 2020;2(8):e0168. doi:10.1097/CCE.0000000000000168
18. Shah A, Xu J, Friedman S, Puskas JD, Bhatt HV, Yimen M. Comparative analysis of intravenous pumps relocation for critically ill isolated COVID-19 patients from bedside to outside the patient room. *J Intensive Care Med.* 2021;36(6):719-725. doi:10.1177/0885066621989920
19. Garzotto F, Comoretto RI, Ostermann M, et al. Preventing infectious diseases in intensive care unit by medical devices remote control: lessons from COVID-19. *J Crit Care.* 2021;61:119-124. doi:10.1016/j.jcrc.2020.10.014
20. Blake JWC, Giuliano KK, Butterfield RD, et al. Extending tubing to place intravenous smart pumps outside of patient rooms during COVID-19: an innovation that increases medication dead volume and risk to patients. *BMJ Innov.* 2021;7:379-386. doi:10.1136/bmjinnov-2020-000653
21. Anjalee JAL, Rutter V, Samaranayake NR. Application of Failure Mode and Effect Analysis (FMEA) to improve medication safety: a systematic review. *Postgrad Med J.* 2021;97(1145):168-174. doi:10.1136/postgradmedj-2019-137484
22. Liu HC, Zhang LJ, Ping YJ, Wang L. Failure mode and effects analysis for proactive healthcare risk evaluation: a systematic literature review. *J Eval Clin Pract*. 2020;26(4):1320-1337. doi:10.1111/jep.13317