

## **HHS Public Access**

Author manuscript *Am J Infect Control*. Author manuscript; available in PMC 2017 July 01.

Published in final edited form as:

Am J Infect Control. 2016 July 1; 44(7): 758–760. doi:10.1016/j.ajic.2016.01.010.

# Learning from the patient: Human factors engineering in outpatient parenteral antimicrobial therapy

Sara C. Keller, MD, MPH, MSHP<sup>a,\*</sup>, Ayse P. Gurses, PhD, MS, MPH<sup>b</sup>, Alicia I. Arbaje, MD, MPH<sup>c</sup>, and Sara E. Cosgrove, MD, MPH<sup>a</sup>

<sup>a</sup>Division of Infectious Disease, Department of Medicine, Johns Hopkins University School of Medicine, Baltimore, MD

<sup>b</sup>Armstrong Institute for Patient Safety and Quality, Johns Hopkins University School of Medicine, Baltimore, MD

<sup>c</sup>Division of Geriatric Medicine, Department of Medicine, Johns Hopkins University School of Medicine, Baltimore, MD

During the past several decades, increasingly complex health care technologies, such as dialysis, monitoring devices, home ventilators, ventricular assist devices, enteral tube feedings, and wound vacuums, have moved to the home. One commonly used technology in the home, outpatient parenteral antimicrobial therapy (OPAT), provides a way for patients needing long-term antimicrobial therapy to leave the hospital (or avoid the hospital altogether) and receive antibiotic agents through central venous catheters (CVCs).<sup>1</sup> OPAT reduces hospital stays, increases patient satisfaction, and decreases costs.<sup>1,2</sup> When used in hospital settings, many of the complex devices adapted for use in OPAT—the CVCs, infusion bags, and infusion pumps—can lead to errors that may lead to patient harm. We work to eliminate central line-associated bloodstream infections (CLABSI) and other catheter-related complications in hospitals. However, we do not fully understand how to reduce CLABSI and other complications from OPAT in the home, such as catheter-associated venous thromboembolism, adverse drug events, or other side effects of OPAT. To reduce these complications, we need to understand how OPAT is performed by patients and their caregivers.

Human factors (HF) is "the scientific discipline concerned with the understanding of interactions among humans and other elements of a system, and the profession that applies theory, principles, data and methods to design in order to optimize human well-being and overall system performance."<sup>3</sup> An HF approach to understanding how patients and caregivers manage OPAT may show us how to reduce OPAT complications.

In recent years, HF engineers have focused on interactions between health care workers and the systems and environments where they work to reduce errors and increase patient safety.<sup>4</sup> HF engineering offers robust methods to understanding health work systems<sup>5</sup> by

<sup>&</sup>lt;sup>\*</sup>Address correspondence to Sara C. Keller, MD, MPH, MSHP, Division of Infectious Disease, Department of Medicine, Johns Hopkins University School of Medicine, 10751 Falls Rd, Suite 412, Lutherville, MD20793. skeller9@jhmi.edu (S.C. Keller). Conflicts of Interest: None to report.

emphasizing data, theory, and design principles to optimize interactions between people and the systems in which they operate.<sup>6</sup> However, even in hospitals where health care workers have specific training and expertise to manage medical devices, medical devices contribute to 1 million errors yearly.<sup>7</sup> With HF, we can understand how to build systems and environments around people, instead of the other way around, with a goal of maximizing patient safety.

## HF ENGINEERING IN PATIENT SAFETY

When HF has been applied to assisting health care workers working with medical devices in inpatient settings, impressive improvements in patient safety have resulted,<sup>4,5</sup> particularly in infection prevention. For example, HF principles and methods have been used to dramatically reduce CLABSI in intensive care units<sup>8</sup> through informing the development of checklists<sup>9</sup> and of carts containing needed supplies.<sup>10</sup> More recently, HF approaches have led to new ways of understanding transmission of health care-associated *Clostridium difficile* infection.<sup>11</sup> HF approaches can help us understand how to prevent CLABSI and other complications of OPAT in the home, as well.

## **OPAT AND POTENTIAL FAILURE MODES**

OPAT is a complicated task being performed not by health care workers but by patients and caregivers who may have just completed a long hospital stay, with significant potential consequences such as CLABSI and adverse drug events. With home-based OPAT, patients and caregivers manage the CVCs and infuse medications. OPAT requires patients to not only adhere to a complicated medication regimen, something that has recently been the focus of HF work,<sup>12</sup> but also maintain the integrity of catheter dressings, care for the catheter itself, appropriately flush the line, attach the antimicrobial agent, and manage either an infusion pump or boluses. An HF approach to understanding patient/caregiver work systems in OPAT can provide insights for this complicated set of tasks, similar to its role in reducing rates of inpatient CLABSI. We focus on failure modes: ways in which a defect in a system could harm a patient.<sup>13</sup> In taking an HF approach to the patient work system that is OPAT, we may identify and address these failure modes (Table 1).<sup>13</sup>

HF may show us how to ensure patients and caregivers use home infusion devices and care for CVCs in OPAT properly. In OPAT, medication delivery devices and CVCs may require troubleshooting. Because a trained professional may not be readily available to fix the CVC, patients and caregivers sometimes try to troubleshoot problems on their own in ways that may be harmful (failure mode).<sup>14</sup> For example, in hospital settings, nurses are skilled at disconnecting tubing from catheter hubs. In our clinical practice, we have seen patients use pliers from their toolsheds to disconnect tubing from peripherally inserted central catheters, damaging the integrity of the catheter hub.

HF may help us tailor instructions to patient and caregiver abilities. This is particularly important in OPAT. Users require time to get comfortable with using CVCs and performing infusions, but patients and caregivers are often expected to use them on their own within hours of hospital discharge (failure mode).<sup>14</sup> HF research has shown that older adults and

Am J Infect Control. Author manuscript; available in PMC 2017 July 01.

Keller et al.

younger adults may differ in preferences for training modalities,<sup>15</sup> and older adults may need more time to learn than younger adults.<sup>16</sup> HF approaches may help us improve the way by which patients and caregivers of different abilities are taught how to do OPAT. In addition to targeted teaching of patient and caregivers, performance of infusion and CVC management at home depends on a patient's ability to use devices like an infusion pump. Although the Food and Drug Administration requires medical devices like infusion pumps intended for home use to have lay usability testing, the people performing the testing may not have the same needs as an OPAT patient who just underwent major surgery and may be recovering from delirium and cognitive impairment.<sup>17</sup> HF studies have shown that patients struggle to use even common medical devices developed for patients, such as epinephrine autoinjectors.<sup>18</sup> HF may show us how to make these devices easier for patients and caregivers to use.

The technologies and devices used in OPAT, like infusion pumps and the CVCs themselves, are complicated and typically reserved for highly trained nurses. However, at baseline, many patients receiving OPAT may struggle with mobility, fine motor skills, vision, hearing, and cognitive functioning (failure mode). They are asked to take on these tasks after a hospital stay that may have left them overwhelmed, debilitated, or in need of other complicated home-based medical care (eg, wound care, physical and occupational therapy, and new oral medication regimens). They may be physically unable to perform some steps in caring for their catheter. An HF approach may help us understand how patient and caregiver abilities and disabilities affect the performance of OPAT.

The home environment may also affect OPAT performance. Ability to perform OPAT care may be influenced by poor lighting or distractions. Furthermore, the CVC dressing and CVC care may be influenced by dirt, crowding, poor lighting, humidity, pets, vermin, temperature variation, children, and clutter.<sup>19</sup> Even bathing with a CVC in OPAT may be a source of practice variation (failure mode). In the hospital, when a CVC dressing becomes soiled, nurses can take immediate action to change the dressing. In the home, a soiled dressing may not be noted until a weekly nursing visit, further increasing the risk of CLABSI (failure mode). HF methodology can help us better understand the influence of environment risk factors on patient safety.

## HF AND PATIENT PERFORMANCE TO IMPROVE INFECTION PREVENTION

HF engineering increasingly is being used to inform infection prevention and control in hospital settings. Studies using HF models can help redesign health care work systems and processes,<sup>5</sup> develop effective training materials,<sup>20</sup> teach about cognitive processes preventing appropriate hand hygiene,<sup>21</sup> and provide insights into in hospital *Clostridium difficile* infection transmission.<sup>11</sup> However, these efforts have focused on clinical compliance with evidence-based guidelines. The emphasis of HF on improving patient performance in infection control and prevention in the home has been limited. Using HF to understand how patients perform OPAT can give us insights into how to prevent complications such as CLABSI in the home.

Am J Infect Control. Author manuscript; available in PMC 2017 July 01.

## Acknowledgments

SCK receives funding from the National Center for Advancing Translational Sciences/Johns Hopkins Institute for Clinical and Translational research (KL2 Award KL2TR001077). SEC and APG are employed by an institution that is part of the Centers for Disease Control and Prevention Prevention Epicenter Program and both receive funding from collaborative agreement U54 CK000447. AIA receives funding from the Agency for Healthcare Research and Quality (grant No. K08 HS22916).

## References

- Paladino JA, Poretz D. Outpatient parenteral antimicrobial therapy today. Clin Infect Dis. 2010; 51(Suppl 2):S198–208. [PubMed: 20731577]
- Dalovisio JR, Juneau J, Baumgarten K, Kateiva J. Financial impact of a home intravenous antibiotic program on a Medicare managed care program. Clin Infect Dis. 2000; 30:639–42. [PubMed: 10770722]
- 3. Human Factors and Ergonomics Society. What is human factors/ergonomics?. Available from: https://www.hfes.org//Web/AboutHFES/about.html. Accessed February 19, 2016
- Gurses AP, Ozok AA, Pronovost PJ. Time to accelerate integration of human factors and ergonomics in patient safety. BMJ Qual Saf. 2012; 21:347–51.
- 5. Holden RJ, Carayon P, Gurses AP, Hoonakker P, Hundt AS, Ozok AA, et al. SEIPS 2.0: a human factors framework for studying and improving the work of healthcare professionals and patients. Ergonomics. 2013; 56:1669–86. [PubMed: 24088063]
- Beer JM, McBride SE, Mitzner TL, Rogers WA. Understanding challenges in the front lines of home health care: a human-systems approach. Appl Ergon. 2014; 45:1687–99. [PubMed: 24958610]
- Bright, RA.; Brown, SL. Medical device epidemiology. In: Brown, SL.; Bright, RA.; Tavris, DR., editors. Medical device epidemiology and surveillance. England, UK: John Wiley & Sons Ltd; 2007. p. 27
- Pronovost P, Needham D, Berenholtz S, Sinopoli D, Chu H, Cosgrove S, et al. An intervention to decrease catheter-related bloodstream infections in the ICU. N Engl J Med. 2006; 355:2725e32. [PubMed: 17192537]
- Gurses AP, Seidl KL, Vaidya V, Bochicchio G, Harris AD, Hebden J, et al. Systems ambiguity and guideline compliance: a qualitative study of how intensive care units follow evidence-based guidelines to reduce healthcare-associated infections. Qual Saf Health Care. 2008; 17:351e9. [PubMed: 18842974]
- 10. Pronovost P, Berenholtz S, Dorman T, Lipsett PA, Simmonds T, Haraden C. Improving communication in the ICU using daily goals. J Crit Care. 2003; 18:71e5. [PubMed: 12800116]
- Yanke E, Zellmer C, Van Hoof S, Moriarty H, Carayon P, Safdar N. Understanding the current state of infection prevention to prevent *Clostridium difficile* infection: a human factors and systems engineering approach. Am J Infect Control. 2015; 43:241–7. [PubMed: 25728149]
- 12. Mickelson RS, Willis M, Holden RJ. Medication-related cognitive artifacts used by older adults with heart failure. Health Policy Tech. 2015; 4:387–98.
- DeRosier J, Stalhandske E, Bagian JP, Nudell T. Using health care failure mode and effect analysis<sup>™</sup>: the VA national center for patient safety's prospective risk analysis system. Jt Comm J Qual Patient Saf. 2002; 28:248–67.
- Henriksen K, Joseph A, Zayas-Caban T. The human factors of home health care: a conceptual model for examining safety and quality concerns. J Patient Saf. 2009; 5:229–36. [PubMed: 22130216]
- Mykityshyn AL, Fisk AD, Rogers WA. Learning to use a home medical device: mediating agerelated differences with training. Hum Factors. 2002; 44:354–64. [PubMed: 12502154]
- Charness, N. The people who receive and provide home health care. In: Olsen, S., editor. The role of human factors in home health care: workshop summary. Washington, DC: National Academies Press; 2010. p. 9-28.

Am J Infect Control. Author manuscript; available in PMC 2017 July 01.

Keller et al.

- 17. Center for Devices and Radiologic Health. Applying human factors and usability engineering to optimize medical device design. Rockville, MD: Food and Drug Administration; 2016. Available from: http://www.fda.gov/downloads/MedicalDevices/deviceregulationandguidance/humanfactors/ ucm259760.htm Accessed February 19, 2016
- Edwards ES, Edwards ET, Simons FE, North R. Drug-device combination products in the twentyfirst century: epinephrine auto-injector development using human factors engineering. Expert Opin Drug Deliv. 2015; 12:751–62. [PubMed: 25435244]
- Story, MF. Medical devices in home health care. In: Olsen, S., editor. The role of human factors in home health care: workshop summary. Washington, DC: National Academies Press; 2010. p. 145-72.
- Pennathur PR, Thompson D, Abernathy JH, Martinez EA, Pronovost PJ, Kim GR, et al. Technologies in the wild (TiW): human factors implications for patient safety in the cardiovascular operating room. Ergonomics. 2013; 56:205–19. [PubMed: 23384283]
- Sax H, Clack L. Mental models: a basic concept for human factors design in infection prevention. J Hosp Infect. 2015; 89:335–9. [PubMed: 25676111]

### Table 1

#### Examples of failure modes in outpatient parenteral antimicrobial therapy

Potential failure mode: Patient/caregiver performs troubleshooting when a mechanical pump malfunctions instead of contacting a nurse.

Risk factor: Inadequate training about potential failures, cognitive decay in training about potential failures, role ambiguity between patient/ caregiver and nursing, hierarchical culture.

Potential intervention: Make reminders about who to contact in case of problems clearly visible on device, clear discussions about risk of interventions in absence of nursing support with patients.

Potential failure mode: Patient/caregiver does not receive clear instructions about flushing the central venous catheter.

Risk factor: Inadequate training about potential failures, lack of familiarity with device, conflicting instructions, organizational practices.

Potential intervention: Standardize training in flushing catheters, online video describing how to flush catheters, more nursing support during first few days at home.

Potential failure mode: Patient/caregiver has difficulty completing 1 or more of the steps in attaching infusate tubing to catheter hub due to arthritis in hands or cognitive difficulty.

**Risk factor:** Ambiguity in infusate tubing attachment step, certain strategies or instructions may increase contamination of hub, certain strategies or instructions may be difficult given patient/caregiver characteristics.

Potential intervention: Develop targeted strategies and instructions regarding how to clean the catheter hub before attaching tubing geared toward patient/caregiver abilities, design instructional materials that clearly convey these strategies and instructions.

Potential failure mode: Catheter dressing becomes soiled with water during bathing.

Risk factor: Lack of training about bathing with catheter, poor wrapping of site during bathing, lack of supplies to safely bathe with catheter.

Potential intervention: Development of pictorial descriptions about dangers of bathing with catheter, development of video describing methods of wrapping catheter, standardizing distribution of supplies to enable safe bathing with catheter.

Potential failure mode: Soiled catheter dressing not immediately changed by nurse.

**Risk factor:** Inadequate communication between patient/caregiver and nurse, hierarchical culture, organizational barriers preventing emergency nursing visits, patient distance from nursing staff.

**Potential intervention:** Standardized organizational protocol when home health staff learn about soiled catheter, expanding methods of communication with nurses or health staff (eg, telephone or text message), change ways of assigning staff members to patients to allow for rapid responses when patients have concerns.

Author Manuscript