Overcoming User-Centered Challenges with Complex Health Technology

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When an operator manual for a physiological monitor exceeds 800 pages and a manual for a hospital bed includes more than 100 distinct warnings and over 100 unique icons, it’s clear that medical equipment has become extraordinarily complex. The exponential growth in health technology brings wonderful innovations, many of which may be accompanied by challenges in device mastery for the people who are its prime users. Deploying an array of computers, video systems, digitally driven control systems, and other complex devices for patient care places new demands on clinical users to understand, set up, operate, and troubleshoot both stand-alone medical devices and integrated systems. These challenges are further complicated by the different makes, models, and software revisions produced by suppliers.

Clinicians’ effective use of complex technology depends on a wide range of factors, including information technology (IT) integration, technical support requirements from all stakeholders (e.g., IT, clinical engineering, vendors, users, patients), and ongoing system management (e.g., cybersecurity, software upgrades, costs of licensing, service contracts).

This article focuses on a narrower set of user-centered issues that also relate to effective use of complex technology: design for usability, training, competency assessment, and procurement activities. At its kickoff meeting in April 2017, the AAMI Foundation’s National Coalition to Promote the Safe Use of Complex Healthcare Technology identified these issues, among others, as priorities for patient safety. (For more on the coalition, see the sidebar on p. 29.)

The Rising Tide of Complex Technology Elevates Risk

In four years’ time, the types of nondisposable medical devices at The Johns Hopkins Hospital in Baltimore, MD, have increased by 23%. Many of these devices are complex technologies designed to improve patient care, ease caregiver workload, or improve workflows. Although it is hard to dispute their value and contributions to the medical mission, the demands of mastering the rising tide of incoming equipment, especially equipment used in procedures with greater risk, cannot be understated.

We can consider complex technology as that which cannot be fully mastered for safe and reliable use in a typical 15-minute in-service training. Complex technology often has one or more of the characteristics described in the sidebar (p. 27). Unfortunately, the inherent complexity of many devices and their apparent never-ending influx into the healthcare workplace introduce opportunities for risk. Risk factors include use errors based on poor design for usability and lack of proficiency of use.
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Usability Issues and Training Burden
“I thought all the problems I had with devices were due to me,” said an experienced nurse after learning about usability during a Hopkins human factors workshop. Now she realizes that usability issues often account for her vexations. Equipment that is not easy or satisfying to learn, use, or remember—and by inference, is not safe to use—invites harm and legal liability. In the United States, nearly one-quarter of operating room (OR) errors involve medical devices, contributing to $1.7 billion in annual costs. The point here is not to hold suppliers accountable for these issues; rather, it’s to collaborate better with them so that users can develop a good mental model of how a device functions, how to troubleshoot it, and how to use it safely.

If tools are not designed for safe use, we may strive to compensate for clinicians’ misgivings with training. However, in-service conditions often are less than ideal due to limited time, settings with poor visual or physical access to the product, limited participant availability, and sometimes low participation levels. Time constraints often preclude addressing all hazards and critical learning objectives, and the opportunity for hands-on skill development may be lacking. By delegating training responsibility to a supplier, an institution delegates control of training-related risks to the supplier while assuming associated liabilities.

By compensating for poor usability with training, we also must be cognizant of the burden medical device training imposes on organizations. The training list for all Hopkins OR nursing specialties includes 233 training activities for first-year comprehensive skills. That list is supplemented by 114 multimedia courses and a number of annual specialty courses (e.g., 38 for an obstetrics nurses). There are also 32 OR-specific policies to learn and 50 new orientees to train each year.

Adding to the training burden are vendor in-service training, internal device training, and ongoing refresher training. A case in point: Training for one Hopkins hospital bed involves in-services, online video courses, a quick reference guide, a tip sheet, and computer-based training embedded in the bed itself. Even so, these multimodal training and skill-building efforts do not include 20 significant warnings from the manual; therefore, Hopkins must provide supplemental fact sheets and further training.

A typical ICU nurse must complete 45 courses annually and comply with 248 interdisciplinary clinical practice policies, in addition to learning multiple standard-of-care policies. All of this is augmented by device training. Not only do nurses feel overdosed on training, but each nurse in training requires another to be on the job—an expense the institution must bear. Hopkins surgical techs also have training requirements. They must master the setup, operation, and troubleshooting for more than 70 types of devices. The hospital has more than 50 types of lasers alone.

Many hospitals now make use of integrated systems with digital controls to manage the relationships and behaviors of multiple hospital devices or systems in a dynamic manner. For example, a nurse call system and physiological monitoring system may be connected to clinicians’ wireless phones. As a result, technology developed to improve workflow and increase efficiency requires further nurse training. Medical device training thus places considerable burdens on clinicians, beyond the equally substantial institutional training that covers

Characteristics of Complex Technology
1. Difficult to learn
2. Hard to remember how to operate
3. Hard to develop a “mental map” of how it works
4. Has a large number of controls for operation
5. Has complicated menu-driven controls
6. Does not easily communicate its operational status
7. Promotes use errors due to poor usability
8. Difficult to troubleshoot or recover from errors
9. Is computer based
10. Has a high degree of operational variability across makes and models
organizational policies, practices, and standards of care. Given this reality, both healthcare delivery organizations (HDOs) and clinicians value and appreciate devices that are easy to learn, use, and troubleshoot.

**Developing, Assessing, and Defining Competency**

Complex devices require quality training to encourage proficient and consistent use of tools across users. We need to be wary of the quick in-service and on-the-job training that does not standardize content, develop troubleshooting skills, or identify error recovery actions. Training should provide thorough attention to significant hazards and the means to mitigate them. That means using established methods to develop training, such as the instructional systems design method—a systematic approach to determine essential training content and to develop, deliver, evaluate, and validate the training.

Competency can be defined as the application of knowledge, skills, and behaviors, including interpersonal, technical, and critical-thinking behaviors. As such, competency is best assessed via a hands-on return demonstration—not as a test after an education session. A review of medical training and education literature focusing on education techniques, frequency, setting, and media found that passive instruction (reading or lecture) was not as effective as interactive approaches and had little or no beneficial effect. Interaction with the instructor and feedback on performance (both typical components of hands-on demonstrations) were shown to be important, supporting the view that achievement of competency depends on use, feedback, and practice.

Simulations, mock reviews, and case studies are helpful to assess device competency. However, bear in mind that credentialing addresses clinical procedures but not necessarily the skill levels needed for proper use of tools and technologies. The Joint Commission has highlighted the importance of training at a level that establishes competencies. Ultimately, however, hospitals must define their own training needs and provide training as they see fit.

**Improved Design for Usability, Better Approaches to Procurement**

A challenge lies before us. Considering the many complex devices “in play,” do our institutions have sufficient resources to define and assess all needed competencies given the demands of a high-production environment? Can we identify all critical learning objectives? Can we provide adequate time and opportunity to develop skills with hands-on demonstrations? Are resources sufficient to manage competency development and retention? The need to perform these functions is supported by evidence of the OR error rates and associated costs cited above. Hospitals bear other costs as well, including those associated with forensic analyses and disruptions to productivity, not to mention patient harm, death, and the suffering experienced by second victims.

These user-centered patient safety issues can be addressed in good part by improved design for usability and better approaches to procurement. Usable devices are not only safer, but they reduce the training burden because training is easier, quicker, and more effective as knowledge retention is improved. From a procurement stand-

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**Selecting and Purchasing Safe and Effective Health Technology**

1. Determine if the device has undergone adequate usability testing according to Food and Drug Administration guidance.
2. Evaluate the device in-house for user-centered design qualities, in addition to reviewing third-party evaluations.
3. Test equipment in the actual physical use environment.
5. Ask specific questions to determine whether the command input process and output sequences are well designed.

Does the device:
- a. Offer the actions I wish to initiate?
- b. Understand my instructions?
- c. Deny inappropriate inputs?
- d. Offer the opportunity to change inputs as needed?
- e. Provide easy access to appropriate status information given the actions performed?
- f. Provide proper cues for subsequent command options?
- g. Have adequate external or embedded instructions for use?
- h. Do all this in a manner that is safe and easy to use?

This sidebar content was adapted from *A Roundtable Discussion: Understanding Medical Devices and Users in Context.*
point, we at Hopkins and others have found value in performing human factors evaluations when purchasing infusion pumps and other medical equipment with a direct influence on patient safety.

HDOs can collaborate more closely with suppliers to develop designs that are easy to learn, use, and troubleshoot. Engaging the assistance of a human factors engineer in such activities can prove beneficial. Working with suppliers to identify needed hazard mitigations and procedures deemed important for training also is advisable. Then, HDOs can determine:

- What standards and controls are in place to ensure that instructor skills, course content, and competency assessments support proper skill development.
- Whether suppliers will provide training to ensure that they are assessing staff competency on key skills.

Finally, to minimize the training burden, support clinician mastery, and improve patient safety, consider the user-centered recommendations in the sidebar (p. 28) for selecting and purchasing medical devices.

**Conclusion**

The exponential growth of complex medical devices introduces risk related to challenges in developing and maintaining mastery of device use. Overcoming these challenges in a healthcare work environment that is already stressed by high-production pressures and a rapid pace of change requires greater attention to design for usability, careful attention to the quality of training and competency assessment, and thoughtful practices in the procurement of medical devices.

**References**


**Overcoming Challenges Surrounding the Purchase and Use of Complex Technology**

The AAMI Foundation’s National Coalition to Promote Safe Use of Complex Healthcare Technology is taking on the challenges of complex healthcare technology for clinicians, hospitals, and suppliers. Launched in spring 2017, the coalition consists of a diverse group of stakeholders, including nurses, physicians, human factors engineers, and industry representatives. During its first two years, the coalition is seeking to develop the following:

- Best practices for selecting and purchasing complex technology. Create a toolkit.
- Best practices for educating and training for the use of complex technology. 1) Provide guidance to healthcare facilities to help them determine which technologies to focus on first (i.e., those that cause the most adverse events in their facilities). 2) Identify models: manufacturer/hospital partnerships, content management, examples of high-performing organizations.

- Best practices for establishing minimal levels of proficiency and for assessing that proficiency. Identify critical elements for assessment and how proficiency can be measured.
- Business case. 1) Build the case for allocating financial resources to improve how clinicians are prepared for safe use of complex technologies, highlighting patient safety for financing the initiative. 2) Create a return-on-investment template and identify data sources to help frame discussion.
- Design and development considerations. 1) Develop ongoing discussions regarding what the design and development of products may look like and what the impact on end users may be. 2) Create information on proven tools to help address the concepts of design that should be included. 3) Provide tools for having discussions with manufacturer partners about existing fleet support, upgrades, and product development.

To learn more, visit [www.aami.org/complexechnology](http://www.aami.org/complexechnology).


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