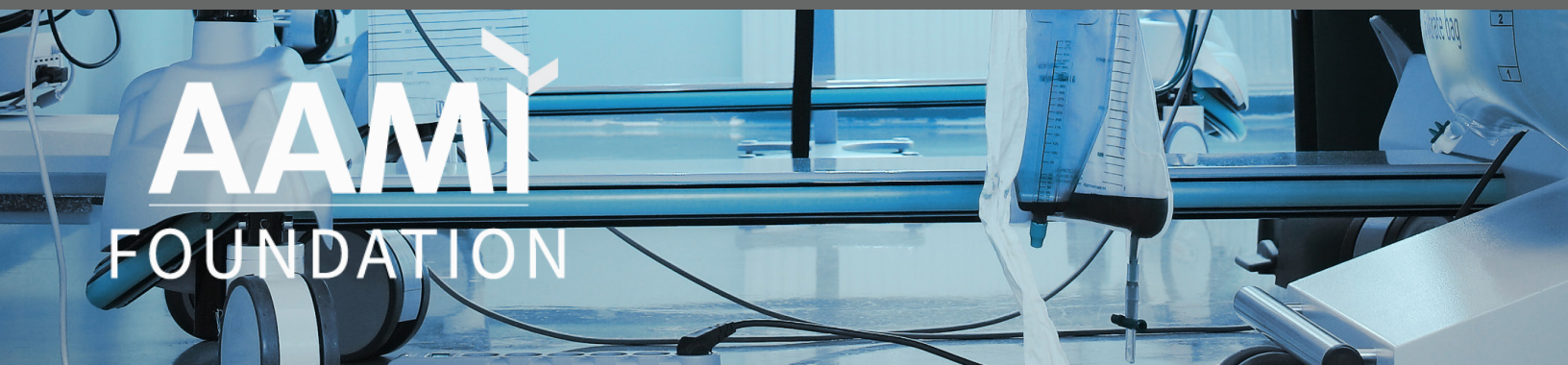
# ANTHOLOGY

## Complex Technology Solutions

## 2017–20



AAMI FOUNDATION

## About AAMI

The Association for the Advancement of Medical Instrumentation® (AAMI) is a nonprofit organization founded in 1967. It is a diverse community of 10,000 professionals united by one important mission—the development, management, and use of safe and effective health technology.

AAMI is the primary source of consensus standards, both national and international, for the medical device industry, as well as practical information, support, and guidance for healthcare technology and sterilization professionals. AAMI helps members:

- Contain costs
- Stay on top of new technology and policy developments
- Add value in healthcare organizations
- Improve professional skills
- Enhance patient care

AAMI provides a unique and critical forum for a variety of professionals, including clinical and biomedical engineers and technicians, physicians, nurses, hospital administrators, educators, scientists, manufacturers, distributors, government regulators, and others with an interest in healthcare technology. AAMI fulfills its mission through:

- Courses, conferences, and continuing education, including certification programs.
- Collaborative initiatives, working with the FDA.
- A rich array of resources, including peer-reviewed journals, technical documents, books, videos, podcasts, and other products.

## About the AAMI Foundation

Over its 55-year history, the Foundation has worked closely with its affiliate, the Association for the Advancement of Medical Instrumentation (AAMI), the world-renowned membership organization driving consensual standards in medical instrumentation.

The AAMI Foundation is committed to reducing preventable patient harm and to improving outcomes with complex healthcare technology. In addition to awarding scholarships, research grants and its national coalition work, the Foundation works to support and promote the healthcare technology management and sterilization professions to help drive improvements in patient safety.

# Anthology

Complex Healthcare Technology Solutions 2017–20

## Contents

# Advancing the Safe Use of Complex Healthcare Technology

At its best, healthcare technology enhances the ability of clinicians to improve patient outcomes. Yet despite the best intentions of the medical device industry, healthcare delivery organizations, and patient care providers, adverse events and near-misses still occur—and technology can be a contributing factor to such undesirable occurrences.

The marvels of modern medicine have a downside: As ever-more-advanced technologies are introduced at an ever-more-rapid pace into patient care environments, healthcare systems and clinicians can't always keep up. It's increasingly difficult for them to manage or master the array of complex technology in their daily, hectic practice. This introduces risk that compromises patient safety.

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This National Coalition operated like a think tank, with a diverse group of stakeholders, including nurses, physicians, respiratory therapists, clinician educators, healthcare technology managers, human factors engineers, and industry representatives.

To address the challenges, the AAMI Foundation launched the National Coalition to Promote Safe Use of Complex Healthcare Technology. This initiative built on insights from the AAMI Foundation Industry Council, as well as on AAMI Foundation National Coalitions on infusion therapy safety, alarm management safety, and opioid safety through continuous electronic monitoring. In the AAMI Foundation Industry Council and in each of the more targeted National Coalitions, the complexity of technology emerged as a common thread.

Thus, the National Coalition to Promote Safe Use of Complex Healthcare Technology addressed key, overarching issues of particular relevance to complex healthcare technology: developing the business case for acquisition of equipment; properly integrating new technology; planning effective clinician education, training, and competency assessment; designing and developing products for safety and ease of use; and learning from device use issues.

This National Coalition operated like a think tank, with a diverse group of stakeholders, including nurses, physicians, respiratory therapists, clinician educators, healthcare technology managers, human factors engineers, and industry representatives. They mined best practices and adapted tools and models from high-performing organizations for application by healthcare systems and hospitals and by product developers and suppliers.

This Anthology captures their work in one document, which is freely and publicly available to ensure open access to this important information. We encourage you to share and use this valuable content with your colleagues in your organization.

We are proud to contribute to the knowledge base for improving patient safety.

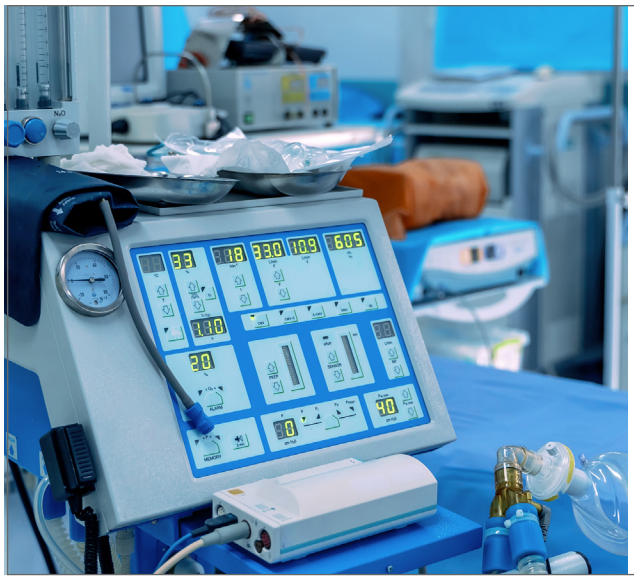
**Steve Campbell**

*Executive Director*
AAMI Foundation

*Acting President and CEO*
AAMI

# Answering the Call

2017–20



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"New and complex healthcare technologies require close collaboration of administrative, clinical, human factors, risk, and industry personnel for safe integration into the healthcare environment. This coalition report, developed with the assistance of a broad range of experts, provides guidance to facilitate such collaborative efforts."

—**Tandi M. Bagian,** chief engineer at the National Center for Patient Safety, U.S. Department of Veterans Affairs, and National Coalition team leader

## Defining Terms to Set an Agenda

"Complex healthcare technology" has become a buzz phrase in healthcare. But what does it really mean? A first order of business for the National Coalition to Promote Safe Use of Complex Healthcare Technology was to develop a shared definition of the ways in which technology can be complex, as shown in the sidebar on the right.

The National Coalition used these characteristics of complex healthcare technology to guide its ambitious scope of work. Launched in 2017, the AAMI Foundation charged this coalition with developing practical solutions to seemingly intractable challenges associated with complex technology for both healthcare delivery organizations and industry. Advancing patient safety is the overarching aim of the solutions this coalition created.

Coalition members focused on key pain points and opportunities that surfaced at its two-day kickoff event, which was informed by the AAMI Foundation Industry Council—companies that put competitive interests aside to collaborate with healthcare providers on their shared interest in improving patient safety. The Coalition's deliverables, which are included in this anthology, encompass:

### Characteristics of Complex Healthcare Technology

For the purposes of this National Coalition, complex healthcare technology is equipment that may:

1. Be computer-based.
2. Be difficult to learn.
3. Have a large number of controls for operation.
4. Have complicated, menu-driven controls.
5. Not easily communicate its operational status to users.
6. Make it hard to develop a "mental map" of how it works.
7. Make it hard to remember how to operate properly.
8. Promote use errors due to poor usability.
9. Be difficult to troubleshoot or recover from errors.
10. Have a high degree of operational variability across models.
11. Have a degree of multifunctionality.
12. Have high risk (including infrequent use).

1. Best practices, critical aspects, and a detailed template for building **the business case** for allocating financial resources to improve clinicians' preparation for safe use of complex technologies. The business case model explicitly connects patient safety to technology acquisition planning and decisions.
2. Guidance and templates for **proper integration of new medical technology.** These resources aim to reduce the burden of rolling out new technology, taking a systems approach through every phase of implementation and product use, and building in prompts for collaboration and planning activities for all stakeholders.
3. Guidance and best practices for **developing risk profiles of complex technology and using these risk profiles to plan clinician training.** This includes guidance on overcoming common barriers and challenges to safe and effective rollouts of new technology.
4. A **new, multi-professional definition of clinician competency and guidance, algorithms, and tools for conducting competency assessments.** These resources can inform plans for training and assessing clinicians' competency when onboarding or upgrading complex technology.
5. An **overview of human factors activities and associated standards** that support these activities. This overview maps human factors activities to every phase of product development, which supports safety, effectiveness, and efficiency.
6. An **adapted capability maturity model and guidance** for integrating human factors activities into product development. This model and guidance focus on how to institutionalize these activities to sustain a mature human factors program—making safety a top-of-mind goal at every stage of development.
7. A **strategy for learning from device issues** in the field. This includes fostering learning partnerships between product users and developers and taking a proactive approach to risk management—activities that can inform future design of safer products that improve the user experience.

### Examples of Complex Healthcare Technology

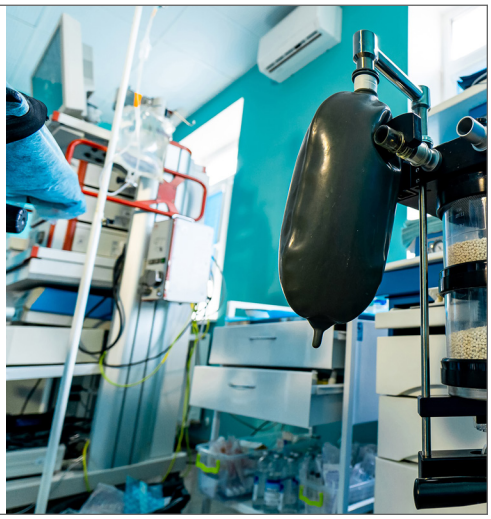
- Ventilators
- Cardiovascular support systems
- Infusion pumps
- Dialysis machines
- Patient monitoring systems
- Diagnostic imaging systems
- Information systems (e.g., electronic health records, medication dispensing systems, medication scanners), which support the physiologic processes that lead to improved health for patients

To accomplish this work, National Coalition teams reviewed research, best practices, and tools developed for healthcare and other industries, synthesizing and adapting this work to meet specific challenges with complex healthcare technology. Notably, the National Coalition took a holistic view of complex technology. Coalition members considered:

- The full life cycle of equipment, from acquisition to disposal, and everything that happens in between.
- The ecosystem of patient care, which includes many complex devices and systems that impact workflow, and the different environments in this ecosystem across the continuum of care.
- The range of organizations, people, professions, roles, and cultures that impact safe and effective use of complex technology.
- The myriad challenges of training and assessing clinicians to use complex healthcare technology. (See *Healthcare Technology Training for Nurses: Current State, Future State, and Barriers* on page 6.)
- The relatively new—but promising—role of human factors in the design, development, use, and monitoring the performance of complex healthcare technology.
- The increasing role that real-world data and evidence can play in informing purchasing decisions; patient care and device use in particular clinical environments; professional learning, competencies, and assessments for clinicians; and healthcare technology innovations and upgrades.

"Although all of our patient safety initiatives have been challenging, this particular initiative is even more so because it involves so many stakeholders inside and outside the walls of the hospital. It's important for all stakeholders to join this effort because, as devices become increasingly complex, the probability that clinicians will lack some vital knowledge of when, why, or how to use these products grows, and positive patient outcomes are at risk."

—**Marilyn Neder Flack,** executive director emeritus of the AAMI Foundation



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## Informed by the AAMI Foundation Industry Council

Prior to the launch of the National Coalition, the AAMI Foundation convened its first Industry Council meeting to discuss the current state of healthcare technology training for nurses, identify challenges to training, and describe what training should look like in the future.

Industry representatives hailed from BD, Connexall, Hospira, Masimo, and Medtronic; most of these companies became industry sponsors of the National Coalition. Nurses, patient safety advocates, and other healthcare professionals and experts joined this Industry Council meeting. The lists that follow summarizing their key points are sobering—and an indication of how much work is needed to better support the frontline clinicians who use healthcare technology. These lists informed the practical solutions and deliverables of the National Coalition.

## Healthcare Technology Training for Nurses: Current State, Future State, and Barriers

### Current State of Training

1. No requirements for demonstration of proficiency
2. Lack of consistency with educational materials
3. Lack of consistency among hospital systems
4. Cost of training not fully understood
5. More healthcare technology moving outside hospitals—what about training?
6. Demand by patients and families for newest technology
7. Growing number of devices; explosion of diverse technology
8. High turnover of nurses—continued training must be offered
9. Silos in hospitals between departments/people—training inconsistent
10. Industry has its own silos—some products easier to use than others of the same type
11. Device complexity increasing, number of devices increasing, usability is becoming a challenge
12. Inadequate requirements for manufacturers in designing highly intuitive and easy-to-use devices
13. Limited time to train and assess competency, and training is often inadequate
14. Increased demand on nurses, thus reducing their time to care for patients

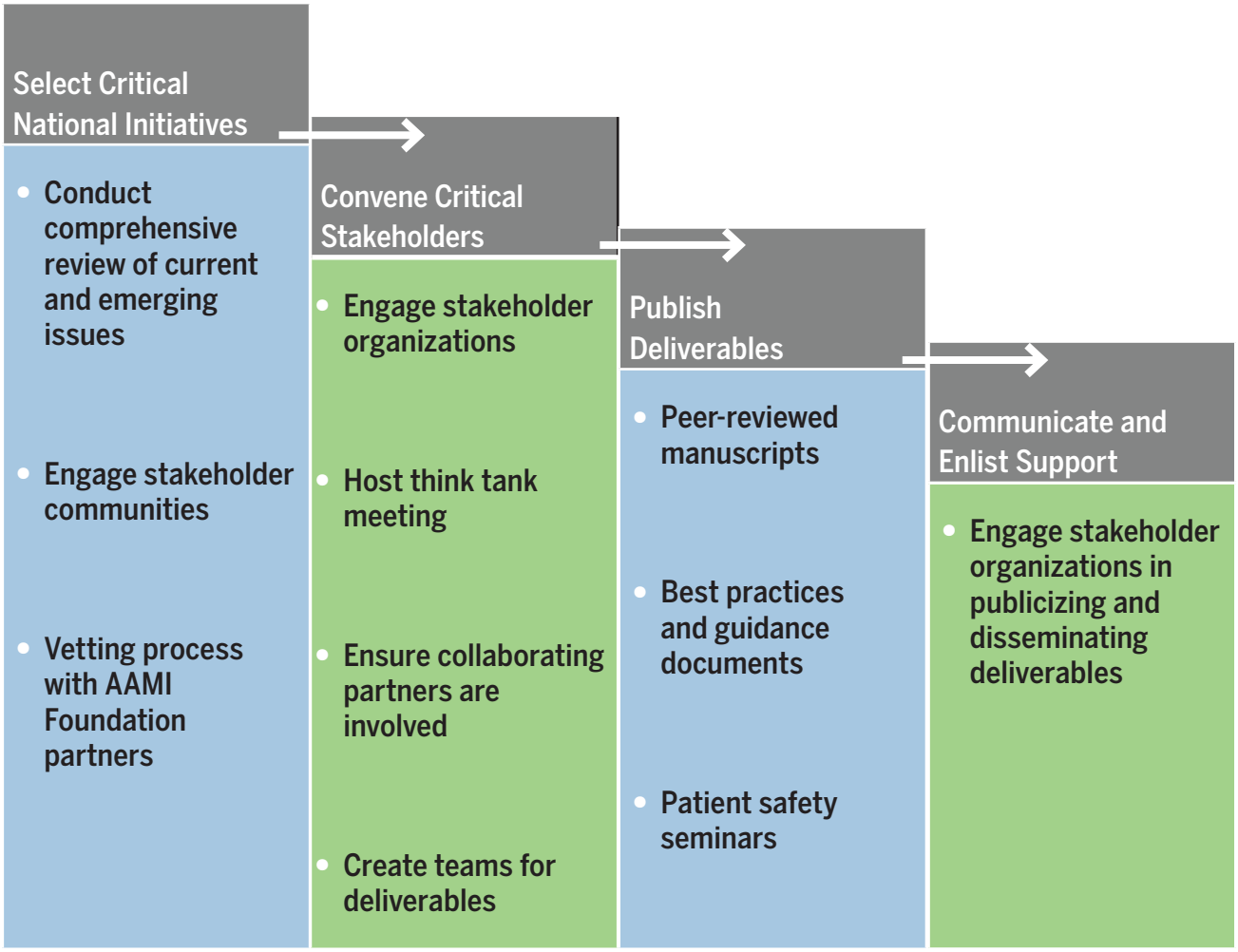
### Future State of Training

1. Simplicity
2. Education/training won't be the only answer
3. Clinicians/users work with manufacturers
4. Instructions available on the fly, electronically, "just in time"
5. Education is ongoing—not a one-time thing
6. Systems approach—not just one entity responsible—all work together to make excellent preparation on complex technology a reality
7. Identification and dissemination of best practices
8. Peer-to-peer training—community
9. Leadership-driven accountability
10. Tools to assess and maintain technology
11. Empowered staff to speak up when preparation is not adequate
12. At-the-elbow support available
13. Demonstration of verified competency
14. Superusers available and utilized
15. Elevated role of chief nursing officer, usability and human factors experts, and technology users in device acquisition and management
16. Visual and easy-to-use learning tools
17. Clinical nurse specialist on team

### Barriers to Training

1. Training takes nurses away from the bedside
2. Some hospital executives see training as "unproductive time" and won't support the level of preparation truly needed to ensure patient safety
3. One size does not fit all
4. Hospitals are overloaded with change
5. Regulatory- and standards-making bodies and accrediting bodies can be double-edged swords: Can have too many requirements for non-important things to be included in manuals; not strong enough with requirements for preparing clinicians on complex technology
6. Interoperability is a complicating factor
7. Business competition between manufacturers can encourage different bells and whistles on devices that make them difficult to use
8. Data overload on clinicians—impossible to learn all they need to know to use the devices safely—a significant issue
9. Liability/legal concerns to using "quick guides" on devices
10. Time and access to training
11. Training is evolving (cross-generational, technology, social media, less formal, "gamification")
12. Who will be trained? What will they be trained on?
13. Vendors won't work together
14. Mishmash of equipment in hospitals (age and manufacturers vary)
15. Knowledge sharing needs to happen, people keeping knowledge/power to themselves
16. Poor usability
17. Insufficient training resources/complex technological environment
18. Governance issues—appropriate governance must be in place to manage technology acquisition, training, use, and maintenance
19. Inadequate change management in hospitals not conducive to quick adoption of new models of learning
20. Insufficient feedback/knowledge sharing
21. Too many gatekeepers and unclear lines of responsibility
22. Changing learning habits

# How the AAMI Foundation Selects and Builds National Coalitions



# A Robust Collection of Knowledge

The National Coalition to Promote Safe Use of Complex Healthcare Technology developed guidance, models, templates, and practical solutions for managing many aspects of complex technology throughout its life cycle. We encourage you to put the resources in the pages that follow to use in your organization to improve the safety and effectiveness of medical devices and to spur innovation that leads to better care for patients.

Working in partnership, healthcare organizations and healthcare technology companies can address the many challenges associated with acquiring, integrating, using, designing, developing, and optimizing life-critical products.

**FOCUS: Healthcare Systems and Hospitals**
(pages 10–53)

**Overview**
**Best Practices for Acquisition, Integration, Training, and Competency Assessment**

**These resources are focused mainly on activities for healthcare delivery organizations, with industry support:**

1. **Developing a Business Case for Effective Acquisition**
2. **Guidance and Templates for Proper Integration of New Medical Technology**
3. **Using Risk Profiles to Plan Training and Introduce Complex Technology**
4. **Competency Assessment for Use of Complex Technology**

**FOCUS: Industry**
(pages 54–76)

**Overview**
**Best Practices for Design and Development**

**These resources are focused mainly on activities for industry, with support from healthcare organizations:**

5. **Human Factors Activities and Associated Standards**
6. **A Capability Maturing Model to Integrate Human Factors Activities: Guidance for Product Developers**
7. **Learning from Device Use Issues**

## Raising Awareness and Highlighting Best Practices

The AAMI Foundation and AAMI worked together on patient safety webinars and highlighted best practices that emerged from the National Coalition's work.

# FOCUS: Healthcare Delivery Organizations

## Overview: Best Practices for Acquisition, Integration, Training, and Competency Assessment

Challenges with complex healthcare technology, ranging from alarm burden and use errors to near misses and adverse events, are sometimes conflated as occurring only in clinical use and situated only in clinical settings. In reality, the stage for these and many other challenges may be set even before products are purchased and carry through to integration, training, and competency assessment.

These resources are intended to help healthcare systems and hospitals take disciplined approaches to complex technology at critical junctures—and improve patient safety along the way:

1. **Developing a Business Case for Effective Acquisition**—Complex technology can be a major capital investment—and most healthcare systems and hospitals have limited capital funds. To make the best of these funds, it is wise to consider business, financial, clinical, training, technical, and patient safety issues during the acquisition process. The guidance and template provided here will help you create a strategic and comprehensive business plan.

2. **Guidance and Templates for Proper Integration of New Medical Technology**—When a purchasing decision is made, it is important to carefully plan not just the technical and logistical requirements for integrating new hardware and software. Taking into account people, processes, and the environment—and preparing them to support a safe and successful technology rollout—can reduce risks to patients and staff.

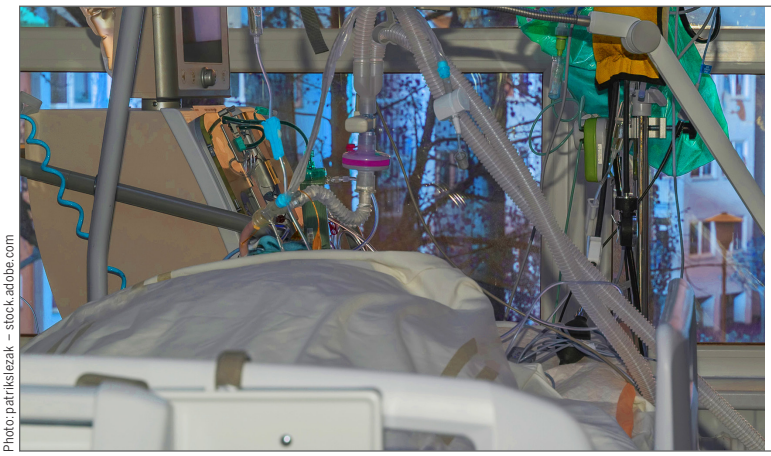
3. **Using Risk Profiles to Plan Training and Introduce Complex Technology**—The plethora of medical equipment in healthcare, and the competing priorities and time constraints on a diverse array of clinicians, make it increasingly essential to triage training efforts for new healthcare technology. The guidance and best practices provided here can help you allocate training resources based on the risk profiles of specific equipment.

**4. Competency Assessment for Use of Complex Technology**—The output of training should be competency to use complex technology safely and effectively. But there is no consensus on what competency means. This section introduces a new definition of competency, critical elements for competency assessment, and ways to measure that assessment, along with decision tools for competency assessment processes.

As a reminder, the National Coalition developed the resources in this Focus section to reflect this definition of complex technology:

| Characteristics of Complex Healthcare Technology | |
|---|---|
| **For the purposes of this National Coalition, complex healthcare technology is equipment that may:** | |
| 1. | **Be computer-based.** |
| 2. | **Be difficult to learn.** |
| 3. | **Have a large number of controls for operation.** |
| 4. | **Have complicated, menu-driven controls.** |
| 5. | **Not easily communicate its operational status to users.** |
| 6. | **Make it hard to develop a "mental map" of how it works.** |
| 7. | **Make it hard to remember how to operate properly.** |
| 8. | **Promote use errors due to poor usability.** |
| 9. | **Be difficult to troubleshoot or recover from errors.** |
| 10. | **Have a high degree of operational variability across models.** |
| 11. | **Have a degree of multifunctionality.** |
| 12. | **Have high risk (including infrequent use).** |

# 1. Developing a Business Case for Effective Acquisition



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A business case is a justification for a proposed project or acquisition, considering the benefits, costs, and risks of potential solutions and providing a rationale for the preferred solution.

Capital investments in medical technology have become increasingly expensive and complex as technology has evolved and dependence on technology has increased. With limited capital funds, healthcare organizations are refining the acquisition process to maximize their investments.

To ensure that scarce funds are allocated appropriately, organizations should leverage best practices related to the request for information (RFI) and request for proposal (RFP) processes. In addition, they should create a way to measure the effectiveness and appropriateness of acquisitions with an internal business case process. As technology now encompasses new capabilities, such as interoperability, wireless networking, mobile, and artificial intelligence solutions, it is essential to understand relevant information about the business and operational impact.

## Context and Challenges

An effective acquisition process is collaborative, which means all stakeholders are part of the process—from defining the need through implementation and into the point of care. Specialists in a number of clinical, technical, and financial disciplines must contribute to specific acquisition activities to ensure that the process moves smoothly and that acceptance and use of the technology are effective.

Clinical stakeholders may include requesting department leaders (e.g., medical imaging, lab, in-patient units). Technical stakeholders may include healthcare technology management, information technology services, facilities management, design and construction, and environmental services. Financial and business services stakeholders may include executive or C-suite management; supply chain management (e.g., sourcing, contracting, and procurement); finance, risk management, and compliance specialists; group purchasing organizations; and manufacturers marketing and sales specialists, according to AAMI's *Acquisition Guide for Clinical Technology Equipment*.[1]

Challenges of effective acquisition include:

- Lack of a standard acquisition process throughout the healthcare industry.
- Variability in terms of who is involved and how decisions on capital investments are made.
- Making many decisions with input from many who will use, support, operate, and integrate technology—without making the process so onerous that the outcome is undesirable.

## Barriers to an Effective Process

There can be many operational barriers to an effective acquisition process, such as departmental silos that have their own funding sources and the lack of a proper business plan.

When departments have their own funding sources, investments often are not properly evaluated in view of the impact they will have on the organization. Involving stakeholders from the whole organization can help to ensure standardization of technology within the institution and contract terms and conditions that can lead to related savings, such as reduced costs for training development and delivery and for support and repairs under warranty.

Creating a business case is one of the best ways to determine the need and potential impact of technology acquisitions. A business case is a justification for a proposed project or acquisition, considering the benefits, costs, and risks of potential solutions and providing a rationale for the preferred solution. A business case is especially valuable for acquiring complex healthcare technology.

Without a business case, it's possible to overlook some of the many decision points that should be identified and calibrated along the way. A business case considers the needs of many, if not all, stakeholders of the technology—and it will prompt discussion and input to help frame the justification for purchase as well as the potential risks, revenue streams, operational costs, and growth of programs.

## Actionable Information: Best Practices, a Business Case Model, and a Template

The guidance provided here can assist healthcare institutions in developing a business case that will supplement RFI and RFP for determining the proper supplier and specific deliverables required to meet the needs of the organization.

Organizations would derive significant benefits from following specific processes that help drive efficiencies into the acquisition process. AAMI's *Acquisition Guide for Clinical Technology Equipment*[1] presents a disciplined approach to managing the acquisition process. The guide identifies and describes:

- Clinical, technical, and financial stakeholders who may be impacted by technology acquisitions and whose perspectives and expertise can contribute to wise purchases, well-planned implementation, and effective use and management throughout the life cycle of the equipment.
- Seven phases of the acquisition process.
- Leading practices, definitions of key terms, and additional resources.

The guidance in this section provided by the National Coalition complements AAMI's acquisition guide and extends it with:

- Critical aspects of a business case model for complex healthcare technology, which are outlined in the sidebar on *page 15.*
- A template that can be adapted for particular acquisitions of complex healthcare technology in your organization, which begins on *page 16.*

With scarce funding for capital acquisitions and competing priorities in organizations, the business case is an important adjunct to the acquisition process to help frame decisions about investments and the impact they will have on the organization. The template in Table 1.1 provides a framework for developing a business case for particular equipment in your organization.


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The National Coalition to Promote Safe Use of Complex Healthcare Technology developed this template for building a business case for complex healthcare technology to help healthcare delivery organizations leverage a full range of criteria as part of a needs assessment and acquisition process.

## Critical Aspects of the Business Case Model for Complex Healthcare Technology

1. Focuses on defining all costs for all resources and staff requirements [e.g., capital, preparation, installation, integration, training, implementation, operational (including supplies), servicing, and life-cycle sustainability]
   - Clear expectations for resources, with remediation options
2. Builds the clinical case
3. Quantifies anticipated return on investment (ROI)
   - Will there be a staff reduction if approved?
   - Is additional staff required to operate the technology? If so, is certification required? (e.g., for computed tomography or magnetic resonance imaging technicians)
4. Considers factors beyond ROI:
   - Litigation risk
   - Regulatory issues
   - Safety (clinician and patient safety)
   - Literature review
   - Internal data
   - Community best practices (e.g., survey hospitals in the region)
   - New case mix
   - New patients
   - Workflow impact
   - Network/information technology systems impact
   - Infrastructure impact (installation, interoperability)
5. Develops timeline and project plan to implement, train, and go live
6. Compares #1 (costs for resources and staff requirements) with number #2 (the clinical case)
   - Identifies codependencies between #1 and #2
   - Differentiates quantitative vs. qualitative costs
7. Performs post-implementation analysis to assess whether benefits expected have been realized

**Table 1.1.** Template for developing a business case for complex health technology.

| Template for Developing a Business Case for Complex Health Technology | |
|---|---|
| **[Title of Project or Initiative]** | |
| **Project Abstract** | Give a brief summary of the project, including the overall goal of the initiative, how it ties to the organization's mission or strategic plan, and its relevance to patient safety. |
| **Team Members** | List team members, emphasizing the partnership among clinical, safety, risk management, and financial leaders, and others. |
| **Project Dates** | List the expected start date and the anticipated timeframe for measurement, analysis, and reporting of prepurchase and trial data results. |
| **Executive Summary** | Include all of the key points of the business plan. Will the reader have all of the important information needed to make a decision based only on this section?<br>• Describe the project and the "problem."<br>• Be sure to illustrate the relevance to the strategic priorities of the organization as well as the intended impact on organizational financial priorities.<br>• Include key known (baseline) measurement details. This can include any vital specifics from within the organization and national data for comparison.<br>• Conclude with a summary of key financials. |
| **Introduction** | Provide a detailed description of the project and be sure to:<br>• State your patient safety goal or objective. How is it connected to the organization's strategy?<br>• State a hypothesis or predict the outcomes of the project.<br>• Include key known (baseline) measures. Examples: clinician satisfaction, cost associated with length of stay, number of patient falls, number of lost workdays due to a safety outcome, known risks with existing tools or technology.<br>• List key stakeholders for whom this project will meet specific needs. |
| **Clinical Case** | Incorporate clinician input, datasets, and how you will collect and interpret the data. Be as specific as possible. Examples include:<br>• Clinical recommendation from stakeholders<br>• Review of the patient population<br>• Analysis of patient population (including number of candidate patients)<br>• Systematic review of the literature to include the Food and Drug Administration's Manufacturer and User Facility Device Experience (MAUDE) data, ECRI institute data if available, and pertinent research<br>• Input from other clinical institutions |

**Table 1.1.** *(continued on page 17)*

**Table 1.1.** Template for developing a business case for complex health technology *(continued)*.

| | |
|---|---|
| **Measurement Methods** | Outline how you will collect prepurchase and trial data, and how to interpret the data. Be as specific as possible. Examples include:<br>• Surveys<br>• Outcome measure data<br>• Interviews and stories<br>• Analytical or reporting tool data<br>• Literature review<br>• Metrics and key performance indicators<br>• In-hospital trials<br>Outline how you will use existing or planned purchases of measurement or benchmarking tools or technology. Has the organization already invested in the technology you plan to use?<br>It will be critical to reach out to the stakeholders who are intended to collect the data. Without their cooperation and commitment, you may find yourself up against a significant roadblock. |
| **Cost Estimations** | Summarize the estimated cost of the initiative. If any costs need explanation, include that here. Reference detailed costs in an appendix if necessary.<br>Note costs of implementing, maintaining, and sustaining the technology.<br>Outline potential costs if the initiative is not implemented. Other potential cost considerations:<br>• Raise awareness of financial penalties when patient safety is found to be at risk.<br>• Explain possible withholds, penalties, and liability.<br>• Differentiate between financial (hard dollars–cost savings) and nonfinancial (soft dollars–efficiency savings).<br>• Include cost of disposables in acquisition cost.<br>• Include training costs for operators and maintainers.<br>• Estimate costs and benefits of different service models: internal, external, or a hybrid model for maintenance and service? Possible need for increase in maintenance staff?<br>• Estimate conversion costs, including commodity/supply costs.<br>• Estimate cost aversion.<br>• Estimate current litigation cost.<br>• Consider lease vs. purchase cost tradeoff, if applicable. |

**Table 1.1.** *(continued on page 18)*

**Table 1.1.** Template for developing a business case for complex health technology *(continued)*

| | |
|---|---|
| **Impact** | Explain the impact this project will have on the organization with respect to:<br>• Specific space (office, unit, system, community)<br>• Strategic goals/mission<br>• Care that is delivered<br>• Improved operational performance<br>• Costs<br>• Workforce safety/quality<br>• Impact on reimbursement (This must be determined with a clear understanding of your organization's payment process.)<br>• Additional impacts |
| **Timeline and Results Projection** | Outline the anticipated start date, data collection and analysis period, and expected date when a report will be provided.<br>Be sure to schedule regular progress reports throughout the project's cycle. This will demonstrate the team's willingness for transparency and accountability.<br>• Describe potential immediate or short-term returns as well as long-term payback potential.<br>• Estimate when you expect to see improvement or changes within the organization. |
| **Business Analysis** | Highlight project assumptions. Consider the following components to demonstrate the value of the program with respect to your organization's strategic goals and mission:<br>• Calculation of risk avoidance/cost avoidance<br>• Validation of national claims/vendor claims with internal data<br>• Financial calculations ("hard" or "dark green" dollars)<br>• Impact to the organization ("soft" or "light green" dollars)<br>• Break-even point<br>• Variability<br>• Metrics and key performance indicators<br>• Regulatory requirement<br>• Review of the community and national standards<br>• Marketplace pressures/competition<br>• Benefits over existing technology<br>• A formal decision analysis of available devices (including any pilot data)<br>This section may touch on reputation and patient and staff satisfaction. Additional considerations may include:<br>• Branding/market share<br>• Turnover<br>• Stories<br>• Trust<br>Include a patient story/case study/success story. It is important that the story be clearly related to the project and fundamentally tied to the organization's mission or strategic plan. |

**Table 1.1.** *(continued on page 19)*

**Table 1.1.** Template for developing a business case for complex health technology *(continued)*

| | |
|---|---|
| **References** | Include a list of all references used in the business case.<br>List all sources used for measurement data, including internal sources of data collection. |
| **Appendices** | Include all additional and supporting documentation including data. |

**Source:** Institute for Healthcare Improvement / National Patient Safety Foundation.[3]

## Best Practices for Building a Business Case for Complex Technology Acquisition

### *BJC Healthcare*

A BJC Healthcare project exemplifies the successful application of a business case model, as recommended by the National Coalition to Promote Safe Use of Complex Healthcare Technology.

The St. Louis, MO-based healthcare system embarked on a capital project to invest in continuous capnography for high-risk patients receiving opioids. The process, outlined in a case study[2] in AAMI's peer-reviewed journal, *Biomedical Instrumentation and Technology (BI&T),* outlined the comprehensive approach taken to evaluate all aspects of the technology and acquisition. BJC Healthcare took steps to fully understand the impact of this acquisition, including clinical, operational, and business impacts as important adjuncts to the more common—and still very important—RFI and RFP practices that many healthcare systems follow.

Evaluating acquisition cost, anticipated operating costs, estimated cost aversion, and then current litigation costs helped embolden the case for a system-wide implementation of continuous capnography. The additional scope of work was a critical aspect of BJC Healthcare's project, which showcases the importance of researching all elements to help identify gaps as well as the impact of the investment. Moreover, creating a business case brings together the essential stakeholders to discuss and weigh the overall need and validity of a large-scale request.

## Resources and References

1. Davis-Smith C. *Acquisition Guide for Clinical Technology Equipment.* Arlington, VA: Association for the Advancement of Medical Instrumentation, 2019.
2. Milligan PE, Zhang Y, and Graver S. *Case study: Continuous bedside capnography monitoring of high-risk patients receiving opioids. Biomedical Instrumentation & Technology*. May/June 2018; 52(3), 208–217.
3. Institute for Healthcare Improvement / National Patient Safety Foundation. *Optimizing a Business Case for Safe Health Care: An Integrated Approach to Safety and Finance*

# 2. Guidance and Templates for Proper Integration of New Medical Technology

"The use of complex technology demands a full systems approach to avoid the many possible failure modes. Only through close coordination of industry and other healthcare professionals can we approximate ideal safety."

—**Peter Doyle**, senior human factors engineer and National Coalition team leader

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Adopting new medical devices and systems into hospitals is burdensome, requiring numerous departments to bring significant effort to bear to ensure safe technology use during all life-cycle phases. The increasing complexity of healthcare technology further increases the burden of implementation.

This guidance and the templates developed by the National Coalition to Promote Safe Use of Complex Healthcare Technology are intended to reduce the impact of integrating new medical technology. The guidance provides considerations for high-level project management. The templates help direct discussions and planning activities about technology implementation among manufacturers and healthcare procurement, acquisition, healthcare technology management, and clinical teams. Using these templates will help all parties recognize and anticipate system implementation needs to ensure safe and effective system performance in the care of patients.

The templates support the design and implementation of complex medical products and systems by:

- Identifying key considerations at each implementation phase.
- Providing an implementation template that can be applied (with modifications if needed) for any type of complex medical device technology.
- Recommending topics for discussion that will increase communication and cooperation between hospitals and medical device manufacturers.

Ultimately, use of these templates will facilitate knowledge transfer pertaining to technology implementation between healthcare systems and manufacturers—with the aim of increasing the safe and effective use of healthcare technology and decreasing the burden of implementation on the healthcare organization.

## A Systems Approach to Implementing Complex Technology

The integration of complex technology into hospitals requires more than unboxing or loading the product, plugging it in, and using it for patient benefit. For purposes of identifying complex technology as addressed here, it's useful to bear in mind the common characteristics of complex technology, introduced on *page 3.*

A systems approach that considers hardware, software, people, processes, and the environment is required to safely implement and use complex medical technology. Such a systems approach requires strong project management to successfully implement such technology.

Table 2.1 outlines project management considerations for onboarding complex technology. Many of these touch upon areas addressed in other guidance in this Anthology (e.g., purchasing and competency assessment). The topics in Table 2.1 require consideration in more detail in view of all technology use phases, from procurement to decommissioning and disposal. By thoroughly addressing these topics and planning accordingly before making purchase decisions, management can determine whether it has the right resources—time, funding, staff, space, and infrastructure—to successfully embark on the integration of the new technology.

**Table 2.1.** Project management phases and high-level project management considerations for complex technology implementation.

| Project Management Phases | High-Level Project Management Considerations |
|---|---|
| Initialize | **Executive Ownership**<br>• Sense of urgency<br>• Funding<br>• Resources (installation, operation and use, maintenance)<br>• Staff buy-in (all departments)<br>• Executive committee |
| Plan | **Technological Readiness**<br>• Valid need for the technology<br>• Infrastructure readiness<br>• Vendor knowledge sharing<br>• Other technology in place<br>• Integrated technology |
| | **Human Factors**<br>• Risk assessment<br>• Environment of use<br>• Staff aptitude and skill<br>• Required tools and tasks<br>• Quantity of users |
| | **Staff Education, Training, and Support**<br>• Installation, operation and maintenance training for all<br>• Training content development<br>• Role/workflow-based<br>~ Use a phased approach, which is typically better than big bang.<br>~ Identify and train super users.<br>~ Assess and track individual qualifications for use. |
| | **Policy Development** |

**Table 2.1.** *(continued on page 23)*

**Table 2.1.** Project management phases and high-level project management considerations *(continued)*.

| | |
|---|---|
| **Execute and Control** | **Rollout**<br>• 24x7 support for initial rollout<br>• Pharmacy, nursing, engineering, etc.<br>• Daily debriefs<br>• Vendor support<br>• Adjustments to training |
| | **Standardization of Tools and Processes** |
| | **Communication through Departments and Management Levels** |
| **Close** | **Assessment of Integration Success** |
| | **Goals** |
| | **Metrics** |
| | **Methods for Continued Monitoring** |


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A key benefit of the joint planning and implementation will be managing expectations on both sides. Also, joint planning and implementation will enforce a relationship-wide discipline to the planning, implementation, and follow-up processes.

## How This Guidance Was Developed

The National Coalition's review of medical device regulations and standards determined seven high-level phases of use:

1. Procurement
2. Installation and initialization
3. Operation
4. Cleaning/sterilization
5. Maintenance and repair
6. Transportation and storage
7. Decommissioning and disposal

## Guidance for Integration of Complex Technology

The National Coalition also reviewed articles and checklists pertaining to hospital implementation of medical devices and systems that met several of the criteria for complex technology. The team created a table for each use phase, outlining considerations and actions for each phase of implementation, along with suggestions for manufacturer support (Tables 2.2–2.7).

These tables can serve as templates for checklists for the design and onboarding of equipment. Such templates could be treated as active documents, being supplemented and scaled over time by both hospitals and vendors as they sequentially onboard advanced technology. Tailoring the templates will ensure that checklists developed are contextual and capable of uncovering interoperability challenges for the specific intended clinical use and environment.

A key benefit of the joint planning and implementation will be managing expectations on both sides. Also, joint planning and implementation will enforce a relationship-wide discipline to the planning, implementation, and follow-up processes.

**Table 2.2.** Procurement tasks, considerations, and actions.

| Procurement Phase | | | |
|---|---|---|---|
| **Tasks** | **Considerations and Questions** | **Actions** | **Desired Manufacturer Support** |
| **Identify need** | • Is technology needed to replace and/or supplement current means of task performance? | • Assess best practices.<br>• Complete full needs assessment in view of user and support personnel tasks.<br>• Evaluate the true need for technology to fill gaps identified. | • Explain product features, functions, and benefits. |
| **Compare products** | • What are the key performance elements?<br>• Assess risks for safe use.<br>• Which risks are most likely to impact patient safety?<br>• What is the ease of integration at your facility?<br>• Determine the life-cycle costs. | • Compare features and functions.<br>• Review external data (performance at other institutions and independent labs, FDA reports, trends of misuse).<br>• Conduct usability/safety testing.<br>• Compare and assess risks and means to control or eliminate them.<br>• Weigh safety and usability as heavily as functionality and price.<br>• Assess compatibility with your infrastructure and existing technologies.<br>• Compare life-cycle costs, including integration costs. | • Provide data to support comparisons. |
| **Perform product trade-offs and determine preferred product** | • Analyze performance and safety in view of cost. | • Assign quantitative or qualitative values to performance, safety, and cost to determine if product is preferred in terms of performance and risks.<br>• Compare across products. | • Provide data on performance, safety and cost. |

**Table 2.3.** Installation and initialization tasks, considerations, and actions.

| Installation and Initialization Phase | | | |
|---|---|---|---|
| **Tasks** | **Considerations and Questions** | **Actions** | **Desired Manufacturer Support** |
| **Integrate technology with other technology, processes, and procedures** | • What does the technology have to integrate with, apart from electronic health record (EHR)?<br>• What accessories, disposables, personal protective equipment (PPE), or other items are needed to install the device?<br>• Are there interoperability concerns with other devices/equipment to be used with this technology? | • Create a list of other technology, databases, procedures, workflows, and so on that the technology must integrate with during installation, initialization, storing, transporting, operating, cleaning, maintaining, repairing, and disposal.<br>• Update procedures, workflows, and databases with new technology. | • Guidance on preparation steps<br>• Best practices<br>• Interface specs<br>• Integration tips |
| **Installation** | • Who is qualified to install technology?<br>• Are special tools needed for installation?<br>• Are there environmental concerns or adjustments needed for the installation location?<br>• What infrastructure changes (e.g., power/data cabling) are required? | • Assess and implement infrastructure changes.<br>• Identify personnel for installation.<br>• Identify equipment for installation. | • Installation manual or instructions<br>• On-site support |

**Table 2.3.** *(continued on page 27)*

**Table 2.3.** Installation and initialization tasks, considerations, and actions *(continued)*.

| Tasks | Considerations and Questions | Actions | Desired Manufacturer Support |
|---|---|---|---|
| Initialization (perform initial setup) | • Who is qualified to initialize the technology?<br>• Who will be users?<br>• What level of access does each user group require? | • Identify personnel to initialize setup.<br>• Identify users.<br>• Provide appropriate access (training access as well as use), passwords, and so on to end users. | • Installation manual or instructions<br>• Training<br>• Setup support and guidance |
| Validation of use environment | • What are the clinical applications and use environments?<br>• Do the workflows in the software match your processes? | • Identify all use cases and environments.<br>• Identify all user types.<br>• Identify interoperability concerns for specific clinical applications and use environments. | • Validation criteria |
| | • Is it configurable or does it require customization? | • Can a non-programmer/technician create a list of users (e.g., in a text file or similar) or must a programmer manage the lists using code? | • Instructions and on-site guidance for customization |

**Table 2.4.** Operation tasks, considerations, and actions.

| Operations Phase | | | |
|---|---|---|---|
| **Tasks** | **Considerations and Questions** | **Actions** | **Desired Manufacturer Support** |
| **Initial training** | • What are the risks for safe use and operator maintenance?<br>• What does the manufacturer recommend?<br>• What does the manufacturer have available?<br>• What different groups need training?<br>• How will the training be different?<br>• How much time is needed for training? When does it need to be completed?<br>• How is the new equipment different than what is currently used? | • Identify risks from manuals and those in the use environment.<br>• Identify risks from external sources such as Food and Drug Administration's *Manufacturer and User Facility Device Experience (MAUDE)* database and *ECRI Institute*.<br>• Complete a full educational needs assessment.<br>• Create an "institution-wide" training initiative.<br>• Schedule training.<br>• Implement a learning management system (attendance tracking tool).<br>• Review and adapt the National Coalition's best practices training model, *Using Risk Profiles to Plan Training and Introduce Complex Technology*<br>**Resource:** *How to Successfully Train Your Staff on New Medical Devices* | • Patient safety advocates<br>• Training, user manual, e-learning, certification, help line, release notes |
| **Competency assessment** | • What are the key performance elements?<br>• Which are most likely to impact patient safety? | • Create a performance-based competency checklist.<br>• Review and adapt the National Coalition's *Competency Assessment for Use of Complex Technology*. | • Certification processes |

**Table 2.4.** *(continued on page 29)*

**Table 2.4.** Operation tasks, considerations, and actions *(continued)*.

| Tasks | Considerations and Questions | Actions | Desired Manufacturer Support |
|---|---|---|---|
| Quick guides | • What does the manufacturer have?<br>• What does the institution need?<br>• How close does it need to be to the device?<br>• Where can it be stored so that all users have access to the most current information? | • Investigate options.<br>• Use the National Coalition's *Guidance and Templates for Proper Integration of New Medical Technology*. | • Quick reference guides, tips guides |
| Continued competency | | • Conduct annual evaluation. Consider Donna Wright's competency assessment approach and tools.[1,2] | • Certification, training |
| Monitoring for safe use | • Any indications of patient harm?<br>• Any *close calls*?<br>• Any reports to the FDA?<br>• Any trends in misuse (local, general, global)? | • Create a *surveillance tool* for iterative feedback, with data collection points from end users on patient care units and, e.g., clinical/biomedical engineering and risk management:<br>~ Passive surveillance<br>~ Clinical studies<br>~ Active, *registry* surveillance<br>~ *Postmarket Surveillance of Use Error Management*<br>• Follow the National Coalition's recommendations for capturing end-user feedback in *Learning from Device Use Issues*<br>• Set up a place to report identified issues to manufacturers. | • Updates to training and user manual, customer communication and support |

**Table 2.4.** *(continued on page 30)*

**Table 2.4.** Operation tasks, considerations, and actions *(continued).*

| Tasks | Considerations and Questions | Actions | Desired Manufacturer Support |
|---|---|---|---|
| **Monitoring for safe use** *(continued)* | • Any recalls or adjustments from the manufacturer? | • Monitor commercial and/or FDA recall databases. | • Communication and support |
| **Distribution of updates** | • Does manufacturer have updates to the technology?<br>• Does it affect the user experience? | • Provide a central location for new and updated information about the technology.<br>• Continue providing updates in multiple formats (written, shared drive, verbal, enduring materials) to maximize safe use of technology. | • Communication and support |

**Table 2.5.** Maintenance and repair tasks, considerations, and actions.

| Maintenance and Repair Phase | | | |
|---|---|---|---|
| **Tasks** | **Considerations and Questions** | **Actions** | **Desired Manufacturer Support** |
| **Assess service life and disposal** | Prior to purchase, consider:<br>• Does the device or system have a defined service life?<br>• How will uses be tracked?<br>• How will the technology be decommissioned?<br>• Are there environmental concerns for disposal? | • Enter equipment into maintenance database.<br>• Establish a mechanism for tracking uses.<br>• Update service life and disposal procedures, workflows, and databases with new technology. | • Defined and updated service life<br>• A method for tracking uses/operation time<br>• Decommissioning and disposal instructions |
| **Determine preventive maintenance needs** | Frequency of preventive maintenance (PM) requirements:<br>• Who is qualified to maintain technology?<br>• Are special tools needed for PM?<br>• Are there environmental concerns or adjustments needed for PM?<br>• What type of power/data cabling is required?<br>• Is training required for service personnel? | • Ensure adequate access for maintenance is included in design.<br>• Assess trade-off for vendor vs. hospital staff vs. hybrid model to service equipment.<br>If hospital staff performs PM:<br>• Enter required PM into hospital PM database.<br>• Verify required PM tools are in the hospital or purchased.<br>• Schedule PM training for healthcare technology management (HTM) staff. | • PM manual or logistics/instructions to return device to manufacturer for PM<br>• Required tools for PM<br>• A means for data entry into the hospital PM database if a vendor performs PM |

**Table 2.5.** *(continued on page 32)*

**Table 2.5.** Maintenance and repair tasks, considerations, and actions *(continued)*.

| Tasks | Considerations and Questions | Actions | Desired Manufacturer Support |
|---|---|---|---|
| **Determine servicing and repair needs** | Assess maintenance costs:<br>• Will servicing/repair be performed by hospital staff or a third-party service provider?<br>• Who is qualified to repair technology?<br>• Are special tools needed for repair?<br>• Are there environmental concerns or adjustments needed for servicing/repair?<br>• Is training required for service personnel? | If hospital staff will perform repairs:<br>• Verify required tools are in the hospital or purchase them.<br>• Schedule training for HTM staff.<br>• Enter service manual, troubleshooting, and/or malfunction instructions in database or store user manual with other maintenance manuals. | • Troubleshooting information, repair manual and/or logistics to return device to manufacturer for malfunctions and repair work |
| **Determine cleaning/ sterilization needs** | • Will cleaning/sterilization be performed by hospital staff?<br>• Who is qualified to perform cleaning/ sterilization?<br>• Are special tools or materials needed?<br>• Are product materials compliant with cleaning products used?<br>• Are there environmental concerns or adjustments needed for cleaning/ sterilization?<br>• Is training required? | If hospital staff is to perform cleaning and/or sterilization:<br>• Verify required equipment and supplies are in the hospital or purchase them.<br>• Schedule training for clinical and central processing personnel as applicable.<br>• Enter cleaning/sterilization instructions in nursing and/or central processing database or store this user manual with other cleaning/sterilization manuals.<br>• Determine the number of device uses (e.g., surgical device uses) allowed prior to replacement. | • Cleaning instructions<br>• Sterilization instructions<br>• Assembly and disassembly instructions<br>• Labeling for single-use and reusable components |

**Table 2.6.** Storage and transportation tasks, considerations, and actions

| Storage and Transportation Phase | | | |
|---|---|---|---|
| **Tasks** | **Considerations and Questions** | **Actions** | **Desired Manufacturer Support** |
| Assess environmental conditions | • What are the temperature, altitude, relative humidity, atmospheric pressure, and sound pressure ranges to store and transport the technology?<br>• Is the device or system qualified for air transport?<br>• What fire/high pressure or other safety considerations apply? | • Review product and component safety data sheets for storage requirements.<br>• Enter actual values into maintenance log. | • Specifications and warnings in user manual for storage and transport |
| Transport: Assess equipment orientation | • Does the device or system require upright orientation during in-use transport?<br>• Can the device function in transport in vertical, horizontal, and upside-down positions? | • Include in end-user curriculum. | • Specify orientation for transport in user manual. |
| Storage: Assess battery charge | • Should the device or system be plugged in during storage to ensure full battery charge?<br>• What is the useful life of the battery?<br>• What is the battery runtime?<br>• How often should batteries be charged during storage? | • Establish a policy to require devices remain plugged into external AC unless in transport (if required).<br>• Include in end-user curriculum. | • Battery charge requirements |

**Table 2.6.** *(continued on page 34)*

**Table 2.6.** Storage and transportation tasks, considerations, and actions (*continued)*

| Tasks | Considerations and Questions | Actions | Desired Manufacturer Support |
|---|---|---|---|
| Storage: Assess battery environmental conditions | • Should the battery be replaced or maintenance performed if it is stored in excess temperatures? | • Include and document requirements in maintenance plan. | • Battery maintenance requirements in user manual<br>• Battery disposal instructions |

**Table 2.7.** Decommissioning and disposal tasks, considerations, and actions.

| Decommissioning and Disposal Phase | | | |
|---|---|---|---|
| **Tasks** | **Considerations and Questions** | **Actions** | **Desired Manufacturer Support** |
| Assess end-of- life cycle and explore alternative technologies | • Product reliability<br>• Availability of alternative technologies<br>• Cost of alternative technologies | • Review metrics of successful product integration.<br>• Research alternative technologies using the methods in Tables 2.2–2.7. | • Education and documentation for alternative technologies |
| Identify replacement technology | • Product features vs. needs<br>• Product cost and other procurement issues in Table 2.2 | • Identify product features, including safety in view of clinical and engineering requirements.<br>• Perform cost analyses and analyze trade-offs.<br>• Address other procurement issues in Table 2.2. | • Specify product features and costs and compare to alternatives.<br>• Identify risks of alternative technology. |
| Plan new technology integration | • See considerations in Tables 2.2–2.7. | • See actions in Tables 2–7. | • See manufacturer support requirements in Tables 2.2–2.7. |
| Determine disposition of the technology | • Safety for decommissioning, removal, and disposal | • Determine how to maintain clinical support during decommissioning.<br>• Determine safe removal and storage.<br>• Determine if vendor support is needed for removal.<br>• Assure safe disposal from environmental perspective, including local regulations. | • Assess trade-in value and accept product as trade.<br>• Provide removal assistance if needed.<br>• Provide guidance and instructions on safe disposal. |

## Anticipated Benefits and Limitations

Using the National Coalition's technology integration templates in Tables 2.1 to 2.7 allows both healthcare systems and product manufacturers to develop a plan for complex technology implementation that proactively anticipates challenges. Optimal usefulness of the templates depends on their dissemination to and use by both parties. Healthcare systems can use the templates to develop project plans—from high-level project management through all seven phases of use. Manufacturers can use these templates to develop systems that are designed for interoperability, excellent training, and good implementation support.

One limitation of these templates is the extent to which they are tailored for the specific technology, healthcare system, and use environment. Tailoring the templates will ensure that they are contextual and capable of uncovering interoperability and other challenges for the specific intended clinical use and environment. Tailoring for specific medical technology should be done by the manufacturer. Tailoring for specific facilities and clinical use should be done by the healthcare system.

Keep in mind that technology implementation spans many hospital departments, processes, procedures, and personnel and therefore requires good project management to assure a good fit. The lack of a system-wide project manager to oversee and ensure the successful implementation of new technologies within a healthcare system will render these templates less effective. The templates alone cannot provide the detailed project management needed for safe and effective implementation.

## Conclusion

The templates provided can serve to develop checklists to be used as a design approach for both manufacturers and hospital systems to conduct the seven phases of complex technology integration, from procurement to disposal. Use of these templates can help ensure a comprehensive and sequential approach to technology adoption and implementation, circumventing the many costly pitfalls.

### References

1. Wright D. (2005). *The ultimate guide to competency assessment in healthcare.* Third Edition. Minneapolis, MN: Creative Health Care Management, Inc.
2. Wright D. (2015). *Competency assessment field guide: A real world guide for implementation and application*. Minneapolis, MN: Creative Health Care Management, Inc.

# 3. Using Risk Profiles to Plan Training and Introduce Complex Technology

Identifying use and other risks prior to onboarding technology will help shape training requirements and better prepare providers for safe and effective use of complex healthcare technologies.

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Given all the competing priorities of patient care, it is unreasonable to expect clinicians to learn all the intricacies of complex healthcare technology using typical approaches to training. A paradigm change is needed to assure clinicians can learn the critical aspects of technology use, thereby helping to ensure that patients and staff are safe.

The guidance provided here by the National Coalition to Promote Safe Use of Complex Healthcare Technology presents a model for such a paradigm. It also provides resources for implementing this model and addresses related barriers and challenges.

It is well understood that a lack of mastery in the use of complex medical technology has the potential for harm. Improvements in mastery are, of course, dependent on the quality of training afforded those who use the equipment. The proliferation and complexity of medical devices make it very difficult for clinicians to even attend training for each new device—let alone develop all the needed skills. This is further complicated by the increasing demands on providers' time, which make it impossible to provide idealized training for the many medical devices in use. Consider too that there is a deeply rooted culture in nursing to focus on the patient, not the technology. All these issues set the stage for challenges in mastering equipment for safe use.

Addressing these challenges requires the available training resources to be properly allocated to those devices and use activities that invite the highest risk. To accomplish this, it is essential to first ascertain the risk profiles of equipment in use—preferably doing so before the procurement process lands a hazardous device in the fleet.

## Developing Technology Risk Profiles

Profiling risk for classes of equipment can be accomplished by using accepted risk assessment practices or by relying on known sources for equipment evaluation and reporting. Table 3.1 provides web resources, recommended internal informational sources, and other references to identify equipment that has known risks.

Table 3.2 provides resources and methods to carry out risk assessment of known risks and other risks identified internally through both proactive and reactive means. Once equipment risks are assessed for severity and frequency, the results can be used to formulate a comprehensive set of risk profiles for classifying different equipment. An important element of success in establishing the profiles is to ensure that a multidisciplinary team reviews, collects, and discusses available materials so that the risk profiles are comprehensive, covering the necessary clinical, technical, and quality concerns.

Once equipment is profiled for risk, criteria can be developed to allocate training resources accordingly. Ideally, organizations would leverage a variety of data to determine which equipment to focus on first in training programs—that is, those which would likely be involved in the most adverse events. Tables 3.1 and 3.2 provide resources for leveraging such data. See *page 41* for a best practice example of how one organization uses risk profiles to allocate training resources.

**Table 3.1.** External resources for identifying known technology risk

## External Resources for Identifying Known Technology Risk

| Food and Drug Administration | |
|---|---|
| *Medical Device Recalls* | Device recalls are an important source of information for managing risk. Creating a process to track assets, identify required steps to correct issues, and support communications between care areas and vendors are important components of managing risk. Healthcare technology management (HTM) professionals are well suited to address and lead the process of working through how recalls will be managed. |
| *MAUDE* (Manufacturer and User Device Experience) | This searchable database uses medical device reports to monitor device performance, detect potential device-related safety issues, and contributes to benefit-risk assessments of products. |
| *Medical Device Safety Communications* | The FDA posts Medical Device Safety Communications to describe the FDA's analysis of current issues and provides specific regulatory approaches and clinical recommendations for patient management. |
| *MedSun* (Medical Product Safety Network) | The primary goal of the *MedSun* adverse reporting system is to work collaboratively with the clinical community to identify, understand, and solve problems with the use of medical devices. |
| *MedWatch* | This site allows professionals, consumers, and patients to voluntarily report observed or suspected adverse events related to medical devices using the online Form 3500. The National Coalition to Promote Safe Use of Complex Healthcare Technology advises working closely with quality and risk departments when evaluating and submitting information. |
| *Medical Device Safety Action Plan* | A 2018 report, *Medical Device Safety Action Plan: Protecting Patients, Promoting Public Health*, describes key actions the FDA is taking in these areas:<br>• Establishing a robust medical device patient safety net in the U.S.<br>• Exploring regulatory options to streamline and modernize timely implementation of postmarket mitigations<br>• Spurring innovation to safer medical devices<br>• Advancing medical device cybersecurity<br>• Integrating CDRH's premarket and postmarket offices and activities to advance the use of a total product life cycle approach to device safety |
| **ECRI Institute** | |
| *Top 10 Technology Health Hazards* | Every year, ECRI Institute releases its top 10 hazards for healthcare organizations. A good tip is to review previous years and look for trends in device categories. |

**Table 3.2.** Resources for assessing and managing risk internally.

## Resources for Assessing and Managing Technology Risk Internally

| | |
|---|---|
| **American National Standards** | |
| ANSI/AAMI/ISO 14971, *Application of risk management to medical devices* | Provides well-accepted methodology for assessing risk and developing risk profiles for medical devices |
| **Food and Drug Administration** | |
| *National Evaluation System for health Technology* (NEST) | Through a cooperative agreement with the Medical Device Innovation Consortium, the FDA is collaborating with medical device stakeholders to build NEST, which is generating evidence across the total product life cycle by strategically and systematically leveraging real-world evidence and applying advanced analytics to data tailored to the unique data needs and innovation cycles of medical devices. |
| **The Joint Commission** | |
| *Survey Analysis for Evaluating Risk® (SAFER™) Matrix* | This tool for identifying risks associated with Requirements for Improvement, also can be useful to healthcare organizations for evaluating technologies, determining risks, and using the data to establish training criteria. |
| Environment of Care® (EC) \| Medical Equipment Management Plan (MEMP) | An MEMP is required for organizations accredited by The Joint Commission. Joint Commission standards EC.02.04.01 and EC.02.04.03 provide elements of performance for hospitals to manage medical equipment risks. |
| *Standards: FAQs* | This is a good resource for identifying common issues involving the environment of care. |
| *Patient Safety* | This web portal provides quick links to information on high reliability in healthcare, National Patient Safety Goals, sentinel event reporting, and current patient safety topics. |
| **Other Resources for Internal Management of Risk** | |
| *DNV* | DNV (formerly DNV GL) offers accreditation, standards, and certification that follow the International Organization for Standardization (ISO) 9001 quality framework. |
| HTM and Risk Management Specialists | HTM, clinical, and biomedical engineering departments can track performance data, including repairs, operator errors, product recalls. These data are a useful adjunct to user experience information. These departments can identify and address issues, provide remediation strategies, and collaborate with clinicians and vendors on solutions as an essential component of managing risk. |
| Regulatory Compliance Office | This office can provide management plans, identify changes in pertinent standards, and share requirements to inform others of changes and the requirements to ensure compliance. |

## Memorial Herman Health System

### Best Practice for Training for Introducing Complex Technology

The best way to manage barriers and challenges to safe and effective use of complex technology is a systems approach to training, which entails all stakeholders working together to prepare for its proper introduction and use. The model presented here exemplifies a systems approach in that it includes multiple disciplines to address training issues for technology.

Memorial Herman Health System in Houston exemplifies this approach. Following a patient incident, Memorial Hermann established an interdisciplinary Fail Safe Program fully supported at the organizational level. The program had a team that spanned quality and safety, risk management, education management and specialists, clinicians, and the supply chain. The group created a process that would ensure that new, critical life safety and monitoring devices would not be placed into service until nurses and other caregivers who would use those devices received formal, in-service training, and the training was documented. The team published their work in *Advanced Critical Care*, a journal of the Association of Critical-Care Nurses:

> "Memorial Hermann Fail Safe Process Medical devices are classified by level of risk to patients if caregivers are not reliably educated. Educational rigor, with tracking and accountability management, is then scaled to that risk assessment. The objective is to decrease safety events related to use of medical devices by ensuring failure-free medical device use. An interdisciplinary team was created to design a "fail-safe" process to analyze and scale training for use of medical devices, with a risk assessment tool predicting the potential severity and frequency of harm to patients. The fail-safe process became an approved procedure and practice standard at the institution."[1]

According to the policy, devices categorized as "critical high risk" by the Fail Safe Steering Committee must have 100% documented compliance with individual caregiver education prior to being rolled out onto the unit. Those categorized as "complex medium risk" require 80% documented compliance.

The education plan is much bigger than a one-time lesson. It may include information from the vendor, other online training modules, and/or hands-on skills training, followed by skill and knowledge validation through written, online, or oral quizzes and/or return demonstrations. All devices also must have support and resources available during "go live." Critical high-risk devices require trained super users.

During the initial phase of the program (2012–15), the Fail Safe Steering Committee assessed 83 medical devices, of which 39 (47%) were deemed "critical high risk." In May 2016, the system began phasing in operating room (OR) and outpatient services. Since then, seven OR medical devices have been assessed as "critical."

To decide on the elements of education programs for particular technologies, the health system can supplement the risk assessments with existing data elements in the organization as well as several external resources.

## Barriers and Challenges

There are many organizational barriers that hinder robust training for individuals. Even if the technology is well designed, effective integration of the equipment is likely to fail if the training and implementation are not designed well. Challenges to proper training may include:

- **Regulations and credentialing requirements.** There are no professional regulatory or credentialing requirements for clinicians to receive training before using most devices. This influences the allocation of training resources to meet desired levels of proficiency. Implementing the recommendations in the best practice model described above will help to address this concern.
- **Governance issues.** Appropriate governance may not be in place to manage technology acquisition, training, use, and maintenance. There may be a lack of management commitment, responsibility, and accountability to establish a structured training program. Establishing an executive committee or representative to conduct proper governance should assure:
    - ~ Derivation of learning objectives and steps, to include assessment of risks and means for their mitigation.
    - ~ Determination of appropriate training media for training delivery (e.g., classroom, virtual, in-service, simulation).
    - ~ Representative end-user participation in pilot testing and subsequent training.
    - ~ Assessment and feedback/failure reporting.
    - ~ Collaboration with vendors.
- **Stakeholders.** All stakeholders are not necessarily included in planning the development and delivery of training activities. They may not be informed of the criticality of the need for training. Dependence on vendors to identity all risks and address them in training does not guarantee thorough and appropriate means for risk reduction. In-hospital clinical, education, risk, and biomedical staff all can offer insight into the development of training materials.
- **Workflow and interoperability issues.** Training may not focus on how to integrate the technology into the workflow, including its relationship and interactions with other equipment. Suppliers that provide training are not typically aware of specific workflow considerations, so their training may overlook workflow issues. Proactive collaboration among vendors, in-hospital clinical, operations, and biomedical staff will help to identify and address unforeseen complications that hinder clinical processes and invite harm. This should include examination of typical and rare use conditions.
- **Post-implementation training evaluation.** Training effectiveness may not be assessed or validated at different intervals. Equipment, user feedback, and patient outcome data are insufficient or not timely. Evaluating clinical performance and determining sources of risk or harm enable identification of critical learning objectives that may have been overlooked during training development. Revising training accordingly helps to assure thorough and standardized training content.

- **Upgrades and recalls.** Training for such changes may not be perceived to be as critical as training for regular implementations—but often, they should trigger additional training by the vendor.

## Conclusion

The National Coalition to Promote Safe Use of Complex Healthcare Technology recommends that complex medical devices be classified according to risk profiles and that education resources be scaled and applied in a manner that fits those profiles. The resulting education should be developed and delivered in formal, in-service training that has been validated. Training delivery should be documented so the institution can implement controls to assure that equipment is used only by those properly trained. Finally, leadership must provide accountability of the complete process.

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# 4. Competency Assessment for Use of Complex Technology

Photo: sudok1 – stock.adobe.com

Hospitals are better situated than vendors to define competency expectations around the use of healthcare technology within their own organizations.

Effective use of complex healthcare technology is critical to patient safety. Currently, however, there is no unified definition, process, or even philosophy to assess competencies for the multiple disciplinary specialists who use complex technology across the continuum of care.

Fundamental to the challenge of effective training and subsequent technology use is the strategy of defining and assessing competency. The National Coalition to Promote Safe Use of Complex Healthcare Technology identified critical elements for competency assessment and how that assessment could be measured.

## Context and Challenges

Education (knowledge) alone does not ensure that a user is competent in the use of complex healthcare technology. The National Coalition postulated that demonstration of skill in using technology—in real time with actual patient populations, with the opportunity to practice actions and respond to the technology—is the ideal way to onboard new equipment and systems.

Moreover, as part of this onboarding process, hospitals are better situated than vendors to define competency expectations around the use of healthcare technology within their own organizations. With that premise in mind, how can knowledge development, skills performance, and competency assessments—co-designed by product developers and hospital consumers—be reconciled for the most effective use of complex technology and devices?

The purpose of this section of this Anthology is twofold:

1. To introduce a competency definition that reflects a synthesis from multiple professions.
2. To present an algorithm for healthcare professionals to guide their competency assessment process when onboarding or upgrading complex healthcare technology in their institutions.

## Best Practices and Models

Use errors with complex healthcare technology can occur when the user's mental model or framework for how a device is supposed to work is inconsistent with how the device actually functions during patient care. Use errors are possible if the user is unable to adapt when the technology is used on a real patient. Technology errors also can occur when the user is not adequately prepared with the knowledge and skill to manage the technology. This can lead to curbside consultations with other staff members, workarounds that can compromise patient safety, or both.

Ideally, assessing competency of all users (e.g., nurses, anesthesiologists, respiratory therapists) on technology before use should occur in a real-life setting. This should include assessing risks, knowledge gaps, clinical reasoning, and skill performance rather than simply identifying primary functionalities (e.g., on/off buttons, alarm settings, tubing changes) in a classroom setting.

Assessing competency has historically been achieved through a variety of methods and in varied settings, including:

- Demonstration/return demonstration
- Direct observation
- Lectures or videos with tests of knowledge
- Documentation or other audits
- Case scenarios with discussion
- Simulation of equipment use in simulation labs or classroom settings
- Review of written or visual materials such as policies and procedures, brochures, and frequently asked questions (FAQs), followed by a repeat back or tests

An effective assessment program for complex healthcare technology competency consists of three primary steps:

1. Defining the competency to be measured
2. Developing the means for measuring the user's competency
3. Evaluating the outcomes of the competency—that is, does the user demonstrate competence at the completion of the assessment process?

To properly define, develop, and evaluate complex healthcare competencies, hospitals or healthcare organizations must consistently commit to an appropriate timeline and budget and integrate them into device deployment activities. To expedite hospital administrators' acceptance of this recommendation, a competency definition and a set of competency development algorithms are presented below for use in developing and evaluating complex healthcare technology deployment across the care continuum.

## Defining Competency

There is a wide variety of competency definitions across the clinical disciplines that use complex healthcare technology. Here is a sampling summarized by the National Coalition:

- The Association for Nursing Professional Development (ANPD) describes competency as the expected level of performance. It integrates knowledge, skills, ability, and judgment. Competency is more than just the technical skill of being able to use a piece of equipment.
- The American Nurses Association (ANA) describes competencies as a combination of knowledge, skills, abilities, and behaviors that contribute to individual and organizational performance.
- The American College of Clinical Pharmacy (ACCP) describes competency as the knowledge, skills, attitudes, and behavior to deliver comprehensive medication management.
- The American Association of Respiratory Therapy (AART) examines identifying barriers, generational learning, and maintenance of intervals of training (frequency, content, and type of training) as instrumental to competency.
- The American Society of Anesthesiology (ASA) focuses competency assessment on knowledge and practice and not necessarily on devices or technology.

The National Coalition incorporated these definitions and those of other professional organizations into a multi-professional competency definition, presented on *page 47.*

Photo: Jose Prieto – stock.adobe.com

## A Multi-Professional Definition of Competency

Competencies are a cluster of knowledge, skills, abilities, behaviors, and judgments associated with the safe use of healthcare technology. Critical elements for competency assessment to promote the safe use of healthcare technology shall be classified according to a technology stratification (simple, complex, or critical), and the application of tiered levels of user competency (basic, intermediate, and/or advanced). Best practices for competency assessment include feedback loops for periodic and ad hoc assessments to account for shifts in knowledge or degradation in knowledge over time and with technology changes/updates.

### Definition of Terms

**Knowledge:** Facts and information acquired by a person through experience or education; the theoretical or practical understanding of a subject.
Source: *https://en.oxforddictionaries.com/definition/knowledge*

**Skill:** An ability and capacity acquired through deliberate, systematic, and sustained effort to smoothly and adaptively carry out complex activities or job functions involving ideas (cognitive skills), things (technical skills), and/or people (interpersonal skills). Coming from one's knowledge, practice, and/or aptitude.
Source: *Business Dictionary*

**Ability:** An acquired or natural capacity or talent that enables an individual to perform a particular job or task successfully.
Source: *Business Dictionary*

**Behavior:** The actions or reactions of a person in response to external or internal stimuli. For example, incorrect use or avoided use of equipment/technology features.
Source: *https://www.thefreedictionary.com/behavior*

**Feedback Loops:** The operating principle of feedback loops is to share information with people about their actions in real time (or near-real time), and then provide an opportunity for action or change. In this context, feedback loops could include information-sharing activities—such as product recalls, incident or safety reports, observation of equipment use in practice, quality improvement activities and trends—to trigger reviews of how effectively and competently the equipment is being used in practice.

## Process Algorithm

To complement this new, multi-professional competency definition, the coalition developed three algorithms to support complex healthcare technology competency assessment in healthcare organizations.

The first algorithm, shown in Figure 4.1, is the starting point for decisions about assessing competencies when technology is being introduced into the healthcare setting. The second algorithm, shown in Figure 4.2, shows the decision-making process when completely new technology is coming onboard. The third algorithm, shown in Figure 4.3, shows the decision-making process for currently used technology that is being deployed to a new area of the organization or is being upgraded.

These algorithms identify the critical steps of the competency assessment process, including elements that help define the steps and provide required actions that the National Coalition believes will ensure a better deployment process for complex healthcare technology.

**Figure 4.1.** Competency assessment process for complex technology.

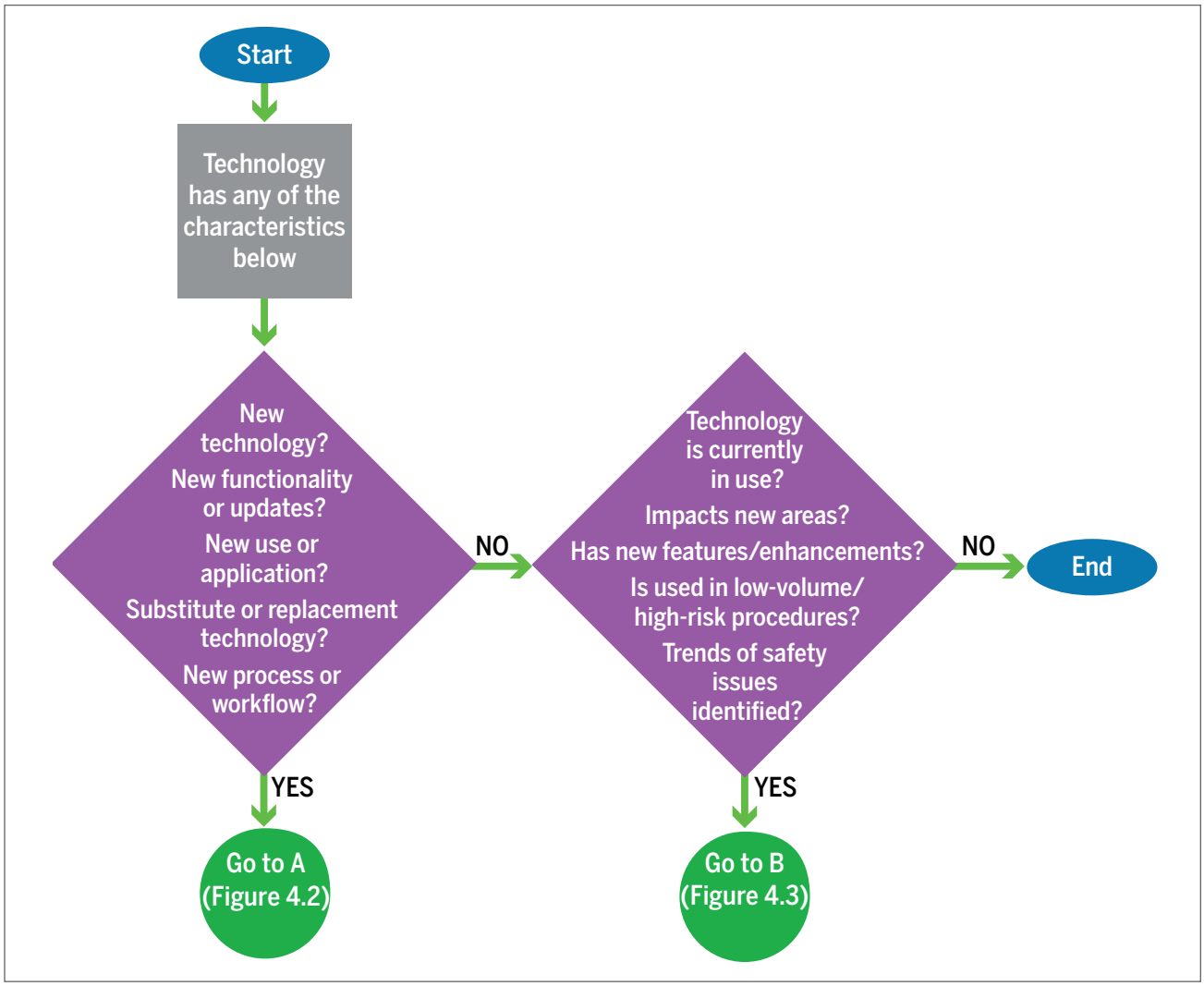


**Figure 4.2.** Competency assessment process for new technology.

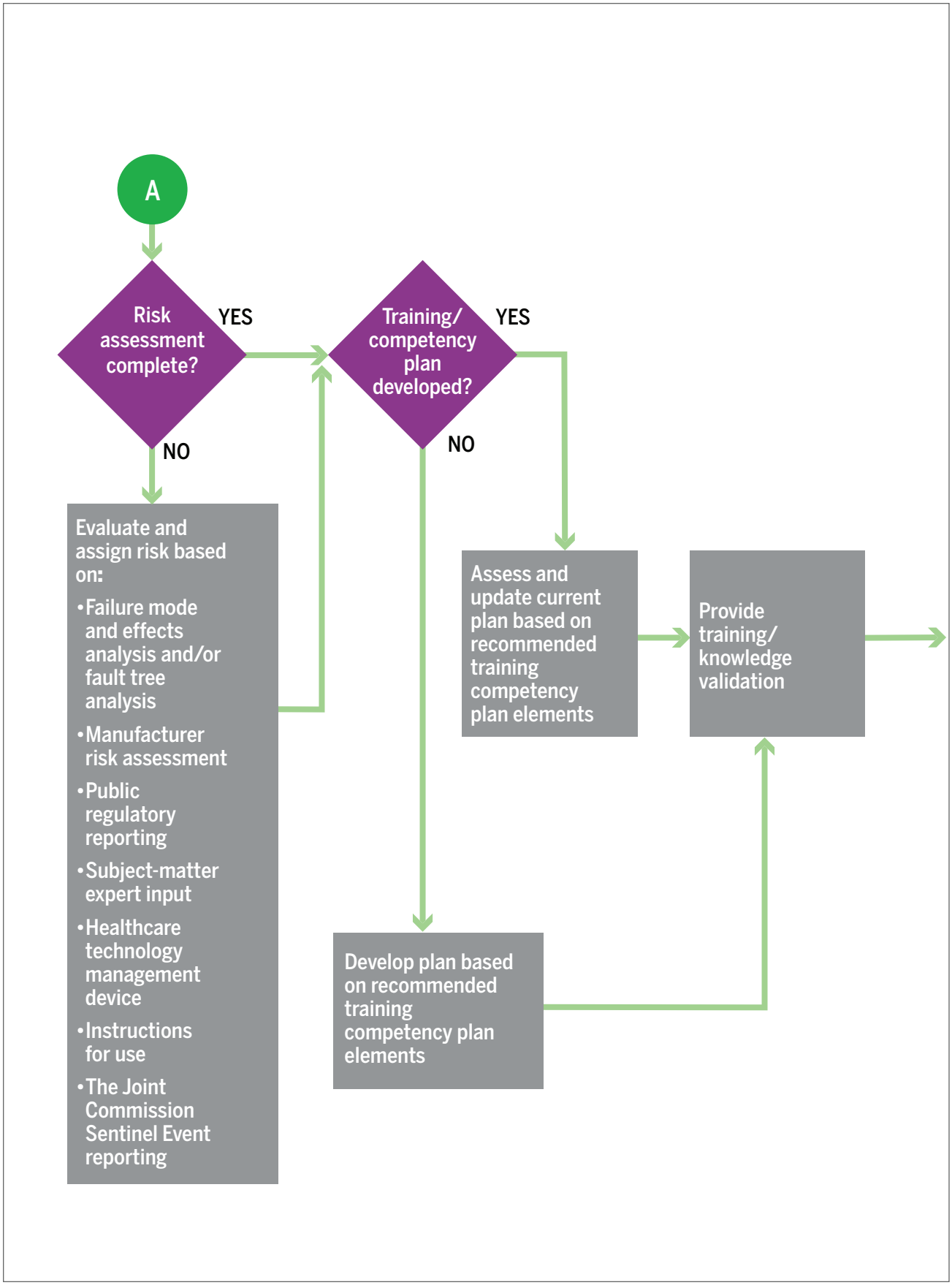



**Figure 4.2.** *(continued on page 50)*

**Figure 4.2.** Competency assessment process for new technology *(continued)*.

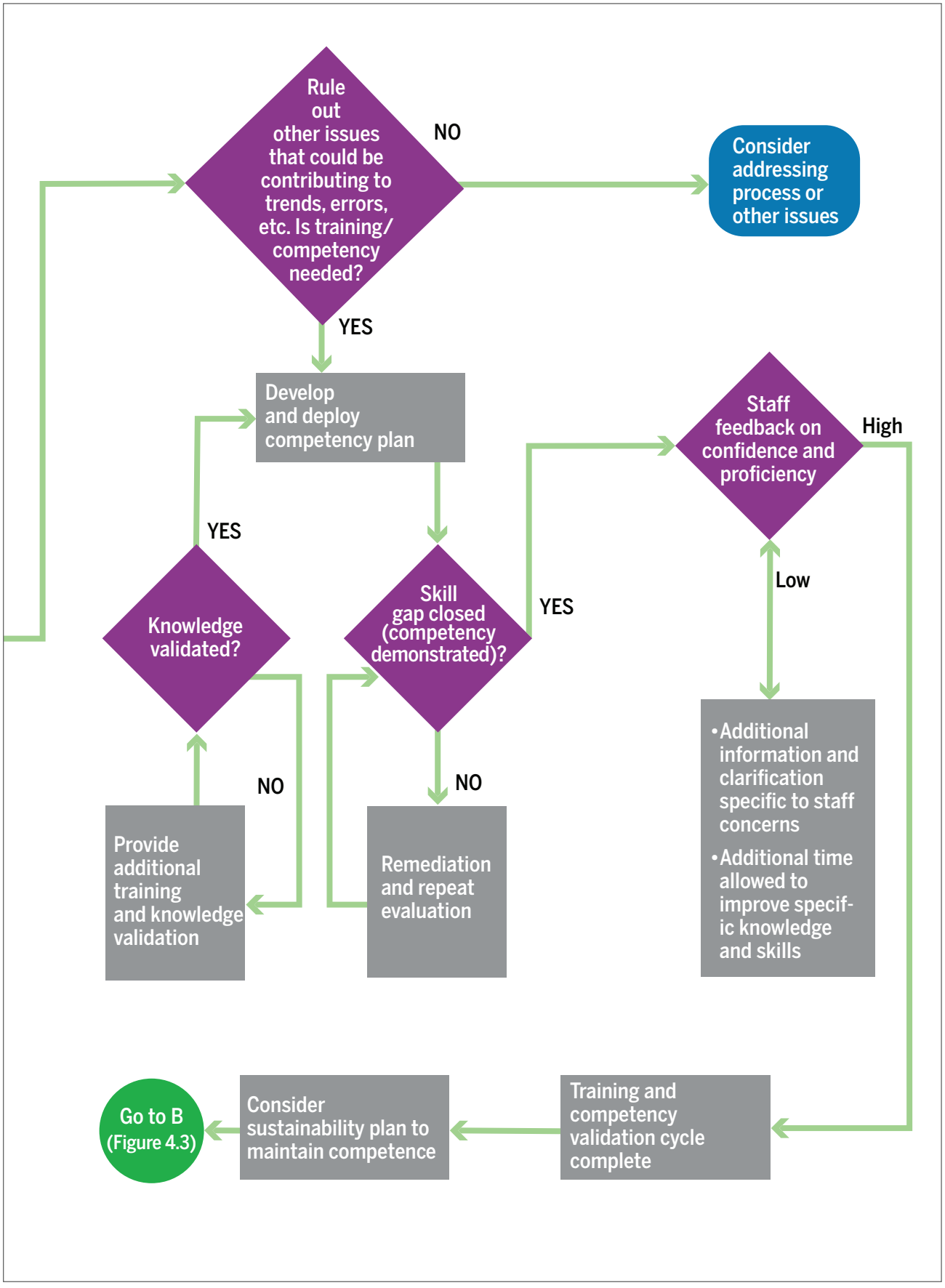
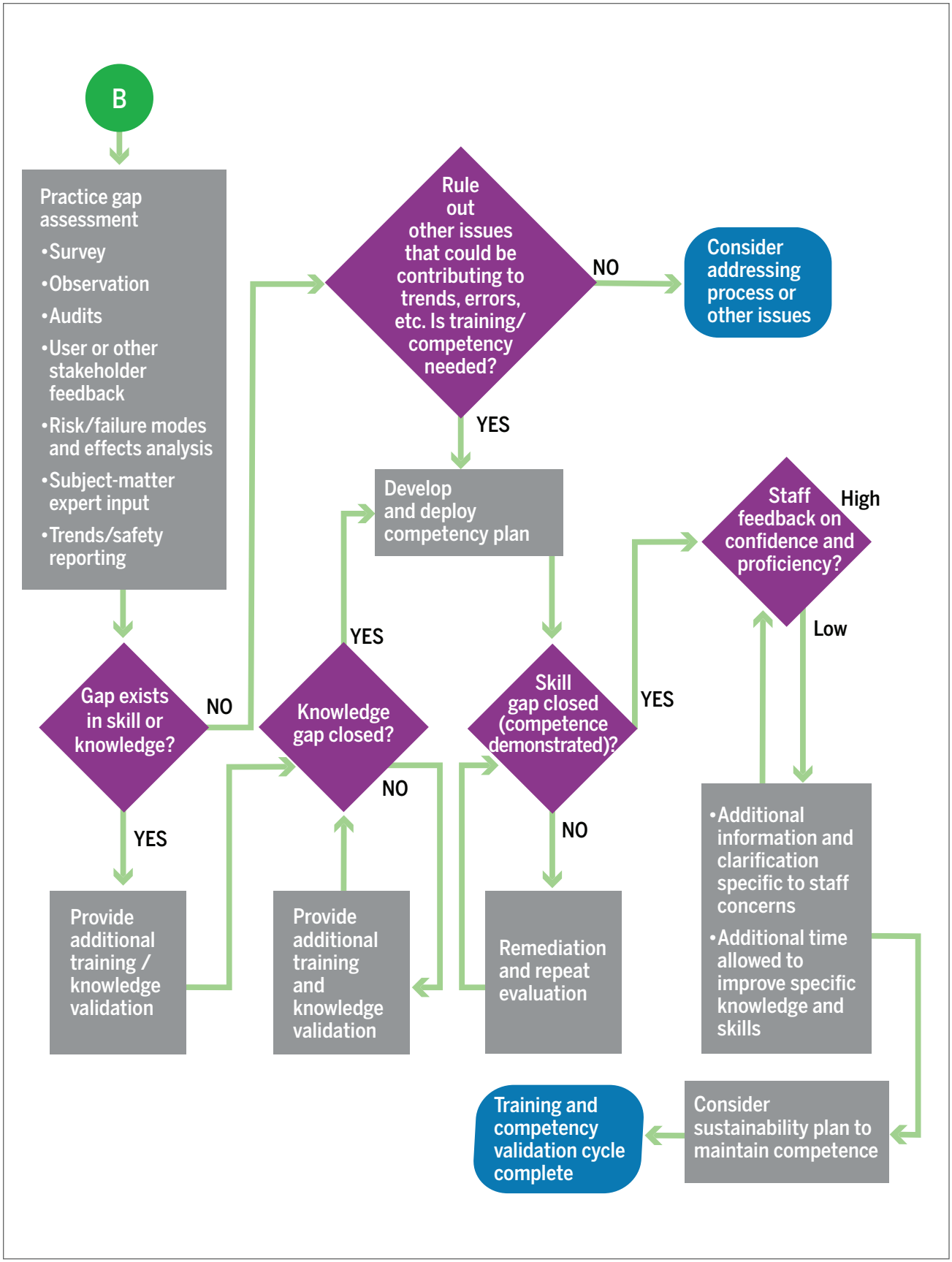


**Figure 4.3.** Competency assessment process for currently used technology.



## Considerations and Resources for Conducting a Competency Assessment for Complex Technology

Risk assessment should be based on an organizational or facility risk assessment process. Trends or safety issues could be identified through internal data, such as quality improvement and safety reporting, and external data, such as manufacturer recalls, Food and Drug Administration communications or databases, and hospital credentialing organizations.

Methods to demonstrate competence are listed on *page 45*, Best Practices and Models. Training and competency plan elements should consider:

- Identification of knowledge/skill gap to be closed
- When and where equipment is to be used
- Patient population
- Target audience for training/use
- Required competency level (basic, intermediate, advanced)
- Critical tasks
- Acquisition of learning objectives
- Performance criteria
- Media for delivery (e.g., in situ vs. simulation environment)
- Type of use (cleaning and storage vs. use on a patient)
- Complexity of use (difficult, average, easy)
- Internal and external quality improvement data
- Validation method
- Time sensitivity
- Resources and time allotted for training
- Other systems, devices, or workflow impacted
- Most likely things to go wrong
- Frequency of use

The next section provides an example of how to use a common risk assessment tool to conduct a competency assessment, along with suggested questions to ask.

## Leveraging and Adapting the SAFER Matrix as a Risk Assessment Tool

The Joint Commission's SAFER (Survey Analysis for Evaluating Risk) Matrix[1] was developed for healthcare organizations as a tool to prioritize their resources and focus their corrective action plans in areas that are most in need of interventions for improvement.

The National Coalition adapted the SAFER Matrix as an option to assist healthcare organizations with risk assessment for competent and proficient use of complex healthcare technology. Dimensions of the SAFER matrix include assessment of the scope of harm versus likelihood to harm patients or staff, which will be based on the established risk criteria and acceptability for an organization or facility process.

Here are some general questions to ask if you decide to use this adapted SAFER Matrix in the process of conducting a competency assessment for the use of complex technology:

- How and where will the technology be used, and on what patient population? (List all possible uses.)
- Is this new or replacement technology, or new use of existing technology?
- What other systems, technology, or workflows will be impacted?
- What things are likely to go wrong and how will they be mitigated?
- What is the probability of something going wrong?
- What is the likely severity of harm to a patient if something does go wrong?

While the SAFER Matrix is generally used for Requirement for Improvement (RFI), this tool also can easily be used to assign risks of technology and help frame what the appropriate level of training and competency should be, as shown in Table 4.1. Again, this is but one example of a tool. Healthcare organizations should make their own risk assessments based on their established risk criteria and risk acceptability.

**Table 4.1.** SAFER Matrix example: defining risk for technology.

| **Difficulty and Criticality Levels** | High difficulty/ high criticality | Average difficulty/ high criticality | High difficulty/ low criticality | Average difficulty/low criticality | Low difficulty/ high criticality | Low difficulty/ low criticality |
|---|---|---|---|---|---|---|
| **Sample Devices** | Smart infusion pump | Peripheral IV insertion | | Cooling/ warming blanket | Cardiac telemetry transmitter | Electronic oral thermometer |
| | Invasive ventilator | ICU bedside monitor system | | | Automated external defibrillator | |
| | Temporary transvenous pacemaker | Patient-controlled analgesia pump | | | | |

**Legend for training and competency**

HIGH FREQUENCY OF USE Self-instruction and review of tip sheets

AVERAGE FREQUENCY OF USE Initial education and skills validation and just-in-time review

LOW FREQUENCY OF USE Initial education, competency validation, and periodic review

## References

[1]The Joint Commission SAFER Matrix.

# FOCUS: Industry

"Establishing the practices recommended here will help make medical equipment easier to learn and easier to use. It will reduce the time needed for training. Most importantly, it will help to reduce the occurrence of failure modes that accompany the use of complex healthcare technology."

—**Peter Doyle**, senior human factors engineer and National Coalition team leader

Photo: saengsuriya13 – stock.adobe.com

## Overview: Best Practices for Design and Development

Medical product design, development, evaluation, and upgrade activities do not always properly identify and incorporate usability requirements in a manner that results in safe and usable products.

The diversity of complex technology and its safe use with other devices and systems in various work environments demands equipment that is usable—easy to learn, understand, and use. Otherwise, use errors stemming from poor usability result in harm and claims with attendant costs to patients and institutions.

Ultimately, the achievement of safe and usable medical technology depends on a close partnership between manufacturers and healthcare organizations. Each partner has both specific and shared roles in a product's life cycle, starting from needs analysis and concept development to decommissioning and disposal. The deliverables developed by the National Coalition to Promote Safe Use of Complex Healthcare Technology provide guidance for conducting these roles for the sake of improved usability and safety.

To reduce risk of harm, facilitate learning, and promote efficient use of healthcare technology, the proper application of human factors methods and standards is central to the roles of both manufacturers and healthcare organizations. To that end, the National Coalition focused on the application and integration of human factors activities that both partners need to achieve desired usability goals, including guidance on instituting and sustaining human factors programs and

reducing risk of use through proper integration of complex technology in almost all phases of the equipment life cycle. This extends to instruction on how post-deployment communication between manufacturers and users greatly improves product improvements for safety and usability.

Applying the guidance provided here likely will require expenditure of effort beyond "normal" practice. However, once these practices become the norm, the gains achieved will produce benefits and efficiencies in the safe delivery of healthcare that have yet to be realized.

This **FOCUS** section on industry complements the **FOCUS** section on healthcare systems and hospitals, which begins on *page 10* and covers:

1. Best practices, critical aspects, and a detailed template for building the business case for allocating financial resources to improve clinicians' preparation for safe use of complex technologies.
2. Guidance and templates for proper integration of new medical technology.
3. Guidance and best practices for developing risk profiles of complex technology and using these risk profiles to plan clinician training.
4. A new, multi-professional definition of clinician competency, and guidance, algorithms, and tools for conducting competency assessments.

This **FOCUS** section on industry includes:

5. **Human Factors Activities and Associated Standards**—An introduction on how to perform human factors activities through the medical device design process and how standards might best be used for both compliance and efficiency
6. **A Capability Maturity Model to Integrate Human Factors Activities: Guidance for Product Developers**—How to assess the level of integration of human factors in an organization's design and development activities and how to improve it
7. **Learning from Device Use Issues**—How to take a proactive risk assessment approach to inform future design

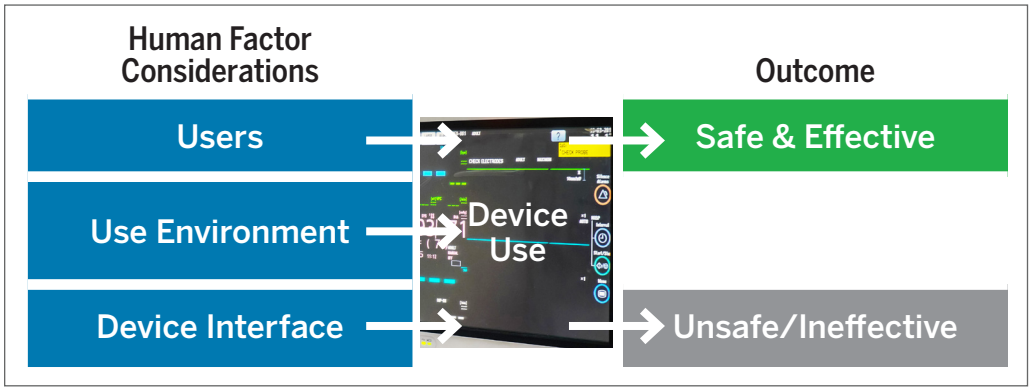
# 5. Human Factors Activities and Associated Standards

## An Overview of Human Factors

Human factors, also known as human factors engineering or ergonomics, is a legitimate scientific discipline supported by formal education. Human factors practitioners study peoples' interactions with products, systems, and environments, and design for human use in accordance with design standards established through human interaction research. The application of this disciplinary knowledge through all phases of the medical device design control process helps ensure development of healthcare technology that is safe and usable for its intended use.

Human factors (HF) practitioners take a systems approach, analyzing the interaction of many elements that affect system performance. Figure 5.1 shows a very high-level view of these considerations for device design.

**Figure 5.1.** High-level factors affecting safe use.




Source: *Applying Human Factors and Usability Engineering to Medical Devices.* (FDA, 2016).

Human factors considerations for users would include, for example, knowledge, skills, aptitudes, training, physical characteristics, motivation, and so on. Other considerations include, of course, influences imposed by the use environment, particularly device and interface characteristics.

To control the elements that affect usability characteristics, human factors practitioners selectively conduct analysis, design, and evaluation activities within a manufacturer's design control process, as shown in Table 5.1. Successful inclusion of human factors activities in that process promotes safe and usable design. Indeed, for complex technology, these activities are a prerequisite. It is beneficial for engineering, risk, and other disciplinary specialists in the design and manufacturing process to be aware of the value of these activities and to have access to the standards and guidance associated with the iterative processes that feed ongoing development efforts.

**Table 5.1.** Human factors activities mapped to design control activities.

| Design Control Activities | Concept Phase | Design Input | Design Output | Verification | Validation |
|---|---|---|---|---|---|
| | Perform studies & analysis | Design requirements | Design specifications | Test output against input | Test against user needs |
| Human Factors Activities | Contextual inquiry | Task analysis | Prototyping/ simulations | Expert reviews | Production units (or equivalent) |
| | Literature reviews | User profiles | Iterative design | Cognitive walkthroughs | Summative usability testing |
| | Complaints analysis | Use environment | Formative usability testing | Usability testing | Field studies |
| | Market research | Heuristic review | RISK ANALYSIS | RISK ANALYSIS | |
| | | RISK ANALYSIS | Cognitive walkthroughs | | |
| | | Usability objectives | | | |

Source: ANSI/AAMI HE75:2009/(R)2018: Human Factors Reference Guide.

Table 5.2 provides a cross-reference matrix of human factors guidance and standards associated with the design control and human factors activities identified in Figure 5.1. The references are mapped to the activities associated with each phase of the device design and development process, enabling manufacturers to readily identify the pertinent guidance and standards for application from concept to validation. Where applicable, guidance and standards in the table are mapped to the design control activities and their associated human factors activities. Hyperlinks are provided as permissible.

A myriad of human factors guidance and standards exist for safe design of medical devices. While not comprehensive, this guidance provides references to lead human factors engineers and others through the activities in the product development process.

**Table 5.2.** Standards and guidance for human factors and design control activities.

| Design Control Activities | Human Factors Activities | Standard/Guidance |
|---|---|---|
| **Concept Phase:** Perform studies and analysis | Contextual inquiry | *Applying Human Factors and Usability Engineering in Medical Devices* (FDA, 2016), 6.4.1, 6.4.2, pp. 15–16 |
| | Contextual inquiry | ANSI/AAMI HE75:2009/(R)2018: Human factors engineering—Design of medical devices, Introduction, p. 8; Section 4, p. 16; Section 5, pp. 33, 42; Section 9, pp. 116, 120, 123, 125 |
| | Complaint analysis | *Manufacturer and User Facility Device Experience (MAUDE) Database* (FDA) |
| | Market research: Predesign controls | ANSI/AAMI HE75:2009/(R)2018: Human factors engineering—Design of medical devices, Section 4, pp. 14–28, p. 120 |
| **Design Input:** Design requirements | General principles: User Interface | ANSI/AAMI HE75:2009/(R)2018: Human factors engineering—Design of medical devices, Section 4, pp. 14–28, p. 120 |
| | Usability engineering process | ANSI/AAMI IEC 62366:2007/(R)2013: Medical devices—Application of usability engineering to medical devices, Sections 5.1-5.7, pp. 7-11; D.2.6, p. 38; D.3.3, pp. 43–44; D.4, pp. 44–51; D.5, pp. 53–57 |
| | Residual risk evaluation | I ANSI/AAMI/ISO 14971:2019, Medical devices—Application of risk management to medical devices, Sections 7.3. p. 15; 8, p. 16 |
| | Design input | AAMI TIR59:2017: Integrating human factors into design processes, pp. 13–16 |
| | Task analysis | *Applying Human Factors and Usability Engineering in Medical Devices* (FDA, 2016), p. 14 |
| | Primary operating functions | ANSI/AAMI IEC 62366:2007/(R)2013: Medical devices—Application of usability engineering to medical devices, Sections 5.4, p. 9; D.5.7, p. 56; H.2.2, p. 82 |
| | Risk control and residual risk acceptability | ANSI/AAMI/ISO 14971:2019: Medical devices—Application of risk management to medical devices, Sections 7, pp. 14–14; 8, p. 16 |
| | Residual risk acceptability | ANSI/AAMI IEC 62366:2007/(R)2013: Medical devices—Application of usability engineering to medical devices, Section 6.4, p. 13<br>ANSI/AAMI IEC 62366:2007/(R)2013 Medical devices—Application of usability engineering to medical devices, Sections 4.3, p. 7; 5.3.2, pp. 8–9; D.4.3, p. 46; D.4.6.4, p. 51; D.5.2, p. 53; D.5.4, p. 54; D.5.9, p. 54; D.5.14, pp. 55–56; D.5.17, pp. 56–57 |
| | Identification of hazards | ANSI/AAMI/ISO 14971:2019, Medical devices—Application of risk management to medical devices, Section 6.4, pp. 12–13 |
| | Identification of characteristics related to safety | ANSI/AAMI/ISO 14971:2019 , Medical devices—Application of risk management to medical devices, Section 5.4, p. 12 |
| | Heuristic review | *Applying Human Factors and Usability Engineering in Medical Devices* (FDA, 2016), Sections 6.3.2, p. 15; A.2.4.2 p. 21 |
| | Heuristic review | *Heuristic Evaluations and Expert Reviews*. (Usability.gov) |

**Table 5.2.** *(continued on page 59)*

**Table 5.2.** Standards and guidance for human factors and design control activities *(continued)*.

| Design Control Activities | Human Factors Activities | Standard/Guidance |
|---|---|---|
| **Design Output:** Design specifications | Design output | AAMI TIR59:2017: Integrating human factors into design processes, pp. 17–19 |
| **Verification:** Test output against input | Usability verification | ANSI/AAMI IEC 62366:2007/(R)2013 Medical devices—Application of usability engineering to medical devices, Sections 5.8, p. 11; D.5.2, p. 53; D.5.4, D.5.6, D.5.8, p. 54; D.5.15, p. 56; 4.3, p. 7 |
| | Verification activities | ANSI/AAMI/ISO 14971: 2019, Medical devices—Application of risk management to medical devices, Section 7.2, pp. 14–15 |
| | Usability testing | ANSI/AAMI HE75:2009/(R)2018: Human factors engineering—Design of medical devices, Section 9.0, pp. 116–138 |
| | Design verification | AAMI TIR59:2017: Integrating human factors into design processes, Section 11, p. 21 |
| | Cognitive walkthroughs simulated-use testing | *Applying Human Factors and Usability Engineering in Medical Devices* (FDA, 2016), Section 6.4.3.1, p. 18 |
| **Production and Post-Production Activities** | Human factors validation testing | *Applying Human Factors and Usability Engineering in Medical Devices* (FDA, 2016), Section 8, pp. 20–29 |
| | Usability validation plan | ANSI/AAMI IEC 62366:2007/(R)2013: Medical devices—Application of usability engineering to medical devices, Sections 4.3, p. 7; 5.6 pp. 10–11; D.4.4, pp. 47–48; D.4.7.3, p. 53 |
| | Risks for which probability cannot be estimated | ISO 14971:2007, Medical devices—Application of risk management to medical devices, Section D.3.2.3, p. 37 |
| | Usability validation | ANSI/AAMI IEC 62366:2007/(R)2013: Medical devices—Application of usability engineering to medical devices, Sections 5.9, p. 12; D.5.13, p. 55; D.5.15, p. 56 |
| | Design validation | AAMI TIR59:2017: Integrating human factors into design processes, Section 12, pp. 21–22 |
| | Post-market field studies | ANSI/AAMI/ISO 14971:2019, Medical devices—Application of risk management to medical devices, Section 10, pp. 16–18 |
| | Post-market surveillance | AAMI TIR50:2014/(R)2017: Post-market surveillance of use error management |

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# 6. A Capability Maturity Model to Integrate Human Factors Activities: Guidance for Product Developers

Photo: patrikslezak – stock.adobe.com

"Keep it simple—and don't rely on education to make the device safe."

—**Connie Barden**, a clinical nurse specialist and chief clinical officer of the American Association of Critical Care Nurses

While the proliferation of healthcare technology is a great boon in many ways, it can be onerous in that clinicians must learn to master and safely use an ever-growing list of complex technologies.[1] Complex medical devices that require a notable training effort impose a burden on clinical resources. Moreover, devices that are used infrequently could introduce additional safety risks.

User training, warnings, and cautions are not the preferred means to limit risk or assure fail-safe operation.[2] Properly incorporating users into device design and other design activities that comply with human factors principles and precepts is, in contrast, a more reliable means for achieving the goal of safe use. Sound human factors activity also is likely to provide other benefits for manufacturers, including the ability to:

- Identify issues requiring redesign early on, thus reducing the number of iterative design cycles.
- Specify products that satisfy specific user needs and use environments.
- Achieve faster regulatory approval for deployment.
- Enable higher levels of customer acceptance, thereby improving marketability.

Incorporating a well-integrated human factors program throughout product conception, design, development, verification, validation, testing, and post-deployment support activities facilitates the production of technologies that can be used safely in intended environments. Because the role of human factors is relatively new in healthcare, integrating that role into the product development process likely varies widely across suppliers, depending on company size and other factors.

## Assessing the State of Human Factors in Industry

Results of an AAMI online survey to inform the work of the National Coalition to Promote Safe Use of Complex Healthcare Technology provide a glimpse of the degree to which the medical device industry is integrating human factors activities into their organizational, design, and development practices.

Feedback from a small sample of quality and human factors engineers, hardware and software engineers, and corporate, project, and marketing managers helped the National Coalition identify some of the ways in which industry currently employs human factors capabilities. Due to the small sample size, it is not possible to paint a comprehensive picture of the manner in which human factors is involved in healthcare product design. However, the following qualitative observations can be made:

- Not all respondents claimed a level of familiarity with the discipline of human factors as it pertains to product development.
- A high-level executive/manager does not always champion proper integration of human factors in the full development cycle.
- Some non-human factors staff see the role of human factors as fully legitimate and routinely include a human factors specialist in design decisions. However, some believe that human factors as a discipline is not well understood by other disciplinary specialists. As a result, sometimes human factors staff struggle to be included and to make sure teams fully consider human factors principles in their processes and designs.
- Some but not all project teams rely on a person dedicated to usability or user research to gather feedback during product development and ensure all user requirements are addressed. In some cases that person has academic training in human factors/usability engineering. Some companies rely on external, trained human factors/usability engineering consultants at specific product development milestones.
- Different companies initiate human factors efforts at different times during product development—some at project start, others in mid-cycle or not until product testing.
- Some participants perceived that insufficient resources are provided for human factors activities.
- Some project teams do not refer to usability design criteria based on human factors standards to address issues identified.
- Some participants expressed difficulty doing good user research to support design and translating that research into usable designs.

These observations suggest that, in at least some cases:

- The roles and responsibilities associated with human factors have not been well defined by management because the discipline of human factors is not well understood.
- Management may not value human factors equally with other activities or see human factors as an essential activity.
- A lack of good research and inability to translate findings into good design hinders development of usable products.

While a survey with a much larger sample would yield a better profile of human factors in the healthcare industry, even this small sample indicates considerable variation in how human factors is integrated as a systems engineering discipline in terms of organizational support, staffing, and methods. These observations raise questions about whether the human factors role is well integrated into design and evaluation activities.

Integrating the human factors discipline more deliberately and comprehensively into product development would help organizations (and ultimately patients) realize the benefits of the discipline. For example, when human factors activities begin only late in the development process, opportunities to make products more useful and usable may be lost. This could result in relying on user training, warnings, and cautions to reduce risk. Instead, earlier human factors involvement could prompt design properties that prevent risk by eliminating it, rather than by simply attempting to control risk at the sharp end.

## A Model for Integrating Human Factors Activities in Product Development

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This guidance presents a model for integrating human factors activities into product development programs. Also, and importantly, this guidance addresses how to institutionalize these activities to sustain a mature human factors program.

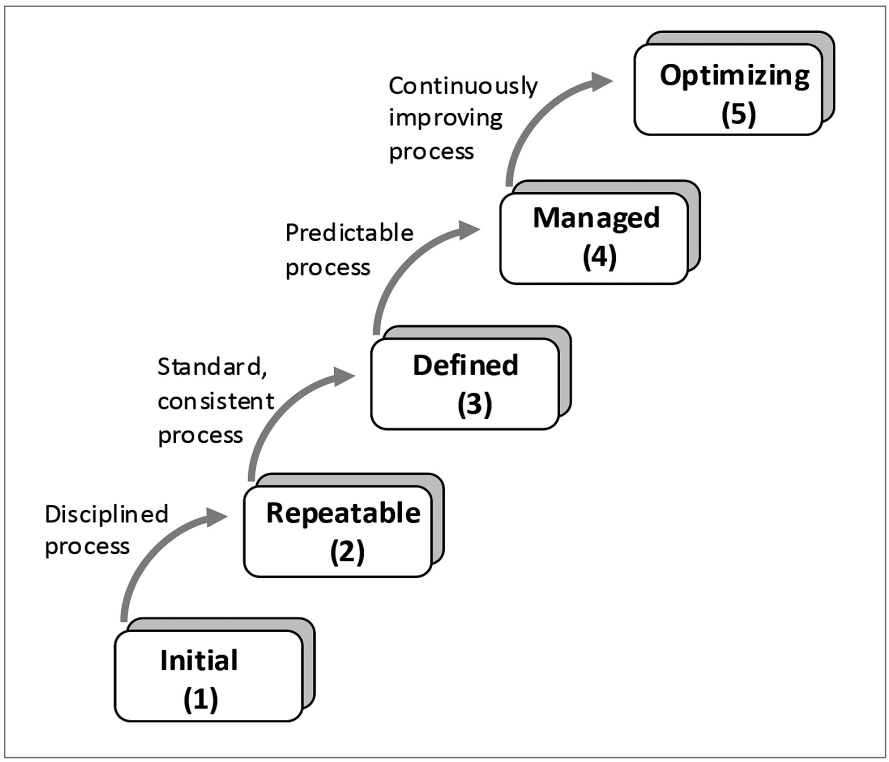
To manage risk through development of safe and usable designs, integrating a mature human factors program with unconditional management support is a necessary fundamental. Optimizing the contribution of human factors activities to produce and upgrade safe and usable products requires a fully matured organizational approach to integrate this role into the corporate culture.

To achieve that end, the National Coalition looked to the Capability Maturity Model for Software, Version 1.1 (CMM®), for guidance in establishing an organizational structure and approach.[3] Here's the backdrop: In 1986, the Software Engineering Institute at Carnegie Mellon University and the MITRE Corporation initiated a process for improving the management of software development processes. This evolved into the Capability Maturity Model for Software (CMM(SM) v1.1).[3]

The model defines five graduated levels, from "initial" to "optimizing," to characterize the maturity levels of organizations in managing the software development process,[3] as shown in Figure 6.1. In this context, maturity refers to "the extent to which a specific process is explicitly defined, managed, measured, controlled, and effective ... and ... indicates both the richness of an organization's software process and the consistency with which it is applied in projects throughout the organization."[3]

The graduated levels provide a maturity framework that "establishes a project management and engineering foundation for quantitative control of software processes" as a means of continuous improvement.[3] The model is generalizable to many organizational activities as it provides guidance for developing or improving processes that meet the business goals of an organization.[4] Hence it is used with permission here to help identify goals for successful integration of human factors activities into medical device development organizations.

**Figure 6.1.** Capability Maturity Model for Software: Five Levels of Software Process Maturity. CMM® (CMM(SM) v1.1.)[3]

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## CMM® (CMM(SM) v1.1) and Integrating Technology in Healthcare Settings

Over time, aspects of the CMM® (CMM(SM) v1.1) model have been adapted for making process improvements in various, non-software-based projects.[4] The National Coalition guidance relates how the model can serve as a reference for assessing the integration of human factors activities into the process of medical device development.

First, we examine the descriptions of the five graduated levels in the model presented by Paulk et al. as they might be used to assess the optimization of human factors design in product development.[3] The five levels can be used to determine how well organizations integrate human factors activities.

### Level 1: Initial

Organizations functioning at this level do not have a disciplined process for integrating human factors activities into the design process. There is no stable environment or executive champion who properly supports and integrates human factors activities into the design process. Engineering staff or others not well trained in human factors methods and standards may be substituting for a capable human factors staff or consultancy. Design decisions may be based on the input of managers, marketing, or development teams unduly influencing design. If usability goals are met in any measure, that may be due to the work of a few individuals who are staffed on only a subset of projects or tasks or of individuals who have some level of aptitude for usable design.

To supersede this initial level of functioning:

1. Establish a systematized approach to integrating human factors activities into product development with the ongoing support of an executive manager.
2. Initiate formal processes for the conduct of human factors methods.
3. Emplace qualified human factors staff in the human factors role.
4. Include human factors staff in all analysis and design activities.

This will help to legitimize the role of human factors in the organization and reduce the degree of variation in the methods used, lending more control to the process of designing for efficient use and safety.

### Level 2: Repeatable

At this level, leadership works towards establishing policies and management controls for integrating good human factors analysis and design activities. This supports learning at the organizational level for a more disciplined approach and "foster(s) more systemic patterns of thinking."[5] This can be achieved when:

1. A strategy for integrating human factors processes into design activities is established.
2. Leaders or executive champions work together with empowered committees to establish human factors policies that are used consistently across projects.
3. Management assures that all parties exercise discipline across projects with regard to schedule and cost, and tasks are allocated appropriately across project personnel, to include human factors personnel.
4. A qualified human factors staff is established, as evidenced by academic training in human factors and, perhaps, by appropriate certification(s). Opportunities for certification are offered by the *Board of Certification in Professional Ergonomics* and *Human Factors International.*
5. The human factors staff size reflects the size of the company and number of products. This staff could be partially or totally supported by external human factors consultants, provided the activity is appropriately integrated into the product development cycle. Larger companies would likely have senior staff overseeing junior specialists.
6. Training is provided to management and other product development staff on policies defined for human factors.

### Level 3: Defined

This level centers on documenting standard processes. For this level, both human factors and management activities are addressed. Defining processes helps others in the organization understand how human factors activities are to be integrated into projects. At this level:

1. Management develops processes to ensure integration of human factors activities in iterative design, development, testing, risk management, and product support activities, to include post-rollout upgrades addressing product use and safety.

2. Management defines processes for the conduct of all human factors activities, which comply with external criteria identified in guidance from the Food and Drug Administration6 and in ANSI/AAMI risk management and human factors engineering standards:[7,8]
    a. Methods for analysis of stakeholders' use and maintenance requirements
    b. Methods to identify risk
    c. Development of test methods and criteria
    d. Derivation of design requirements from human factors standards[8]
    e. Traceability of those requirements to product specifications
    f. Establishment of means to gather and respond to user feedback. (See *Learning from Device Use Issues* on page 70.)

    (See also *Human Factors Activities and Associated Standards* on page 56.)
3. Processes can be tailored as needed at the project level. This may include the use of instructional systems design methods in addition to classic human factors methods to develop good product labeling and training materials.[9]
4. Training is provided to enable staff to perform in accordance with documented processes.
5. Once processes are defined, they are regularly followed.

**Level 4: Managed**

Attaining this level requires the determination of quantitative goals and reviews to assess compliance with the documented processes referenced in Level 3 to assure productivity and quality. As a matter of routine, measurements are made to assess products' human factors design for safe use—and to assess the quality of the processes to achieve that goal. This enables a company to identify and address any anomalies affecting quality. Controls at this level assure that:

1. Human factors, engineering, and managerial oversight activities produce quantitative assessments of compliance with defined processes and standards.
2. Evidence is used to assess whether the human factors staff consistently participate in product development activities and contribute to design decisions.
3. Evidence is used to verify that human factors design contributions comply with professional practice.
4. Evidence is used to verify that risk assessment activities comply with professional practices.
5. Designs are validated by assessing usability and safety post-implementation.
6. Recall and upgrade activities include human factors assistance in analysis and redesign.

### Level 5: Optimizing

At this level, emphasis is on continuous process improvement and elimination of defects in organizational processes, as defined in Levels 1–4. Management provides support to enable both sustainability and continued improvement of all team processes relevant to human factors and safety outcomes. Managerial assessments are made regularly and continually to validate the value of human factors in development activities.

Reviews are conducted to assure continued compliance with good human factors practice and to avoid the development of unsafe products or those with poor usability. In addition:

1. New human factors processes and practices are evaluated and implemented where beneficial.
2. Process defects are identified and lessons learned are applied throughout.
3. As part of continuous improvement, human factors and engineering staff benchmark designs against other products and stay current with developments of tools and techniques in their respective professions.
4. Finally, a path for conflict resolution can be provided to ensure that senior management can aid in resolving design conflicts that persist between human factors and other staff.

From a usability and safety perspective, achieving Level 5 status should contribute to the development of superior products. From a managerial perspective, investments in achieving Level 5 status should facilitate an orderly and more efficient development process due to reduction of rework to meet design goals.

## Guidance for Institutionalizing Practices for Developing Usable Devices

There are many relevant standards and methods for those practicing human factors engineering.[7,8,10] (See also, *Human Factors Activities and Associated Standards*).

These standards and methods provide the techniques to properly understand users and their needs for the sake of achieving user-centered design. They also provide a foundation for design decisions that support user requirements. However, simple use of the standards and methods does not guarantee production of safe and usable products. Human factors activities must be purposefully integrated into the organization's structure and practices. Indeed, for best and continuing benefits, the human factors activities must be fully institutionalized in a manner that favors a user-centered approach over a technology-driven one.

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For best and continuing benefits, the human factors activities must be fully institutionalized in a manner that favors a user-centered approach over a technology-driven one.

Eric Schaffer and Apala Lahiri of Human Factors International provide a how-to guide in their book, *Institutionalization of UX: A Step-by-Step Guide to a User Experience Practice*. As in the CMM® (CMM(SM) v1.1) model, Schaffer and Lahiri espouse the need for an executive champion in setting up, organizing, and preserving institutionalization. Properly setting up a human factors program requires a strategy that includes an "infrastructure to support ongoing work," a "user-centered design methodology integrated with the general system development life cycle," and "supportive resources such as design standards, user profiles, ecosystem models and tools."[11]

Close attention to human factors training and certifications are other aspects of the setup phase. Schaffer and Lahiri cite governance of user-centered design as a major challenge because of a possible resistive culture and barriers to a thorough user-centered mentality. They promote training for all team members as a means to overcome resistance and ensure that teams adhere to standards. They also address staffing and organizational structure issues, noting that "routine practices and perspectives must change throughout the organization" for successful institutionalization.[11] Also, efforts must be directed at preserving and maintaining institutionalization for long-term operations. Avoiding the tendency to revert to a technology-driven model, in which hardware and/or software engineers alone drive design decisions, is critical to maintaining a user-centered approach.

## Final Thoughts

Safe products are developed by:

- Successfully integrating qualified human factors specialists early in the development process.
- Using appropriate methods and standards.
- Adhering to creditable, documented processes; and consistently applying managerial support and oversight.

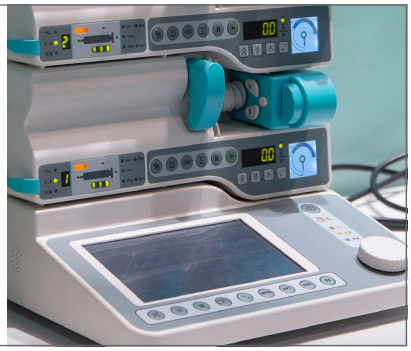

Photo: DmyTo – stock.adobe.com

The discipline of human factors is rightfully gaining more recognition for its importance in the design of medical devices. Its application in the design of safe products is far more complex than the use of common sense, focus groups, or survey results. For life-critical systems especially, assigning someone who is not a human factors specialist to a human factors role can invite significant risk to patients, users, and manufacturers.

Use of metrics to manage and control human factors programs helps to achieve sustainability and foster continuous improvement. Achieving the objectives in the five levels of the Capability Maturity Model will enable the development and integration of proper human factors programs that are essential to healthcare's journey toward high reliability.

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# 7. Learning from Device Use Issues

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A strong partnership with and good communication between those who build products and those who use them is a hallmark of mature industry.

## A Partnership for Proactive Identification and Control of Design Risk

Clinical experience with complex healthcare technology promotes mastery for safe use and affords opportunities to identify and communicate information regarding clinical system performance during use. A strong partnership with and good communication between those who build products and those who use them is a hallmark of mature industry.

In the healthcare industry, this relationship has yet to be standardized to ensure that critical user feedback is routinely provided to those who design, develop, and update complex healthcare devices. Following the example of other complex industries that seek highly reliable, safe system performance, the National Coalition to Promote Safe Use of Complex Technology provides a strategy here for capturing use errors encountered by medical device customers and communicating them to product developers. Such a strategy, when used in ongoing transactions between product developers and users, will greatly expand upon clinical evaluation results in the premarket phase, ensuring that benefits from user experience become an important part of a learning partnership.

## Predicting Use Errors for Communication to Manufacturers

The strategy offered uses an approach outlined by the Department of Veterans Affairs (VA) to proactively focus on "what could go wrong" in each major process step associated with use of a medical device.

This proactive risk assessment approach is common to conducting a Failure Mode and Effects Analysis (FMEA), as outlined in the FDA guidance document, *Applying Human Factors and Usability Engineering in Medical Devices* Realizing the value of the FMEA approach, the VA's National Center for Patient Safety adapted it in 2002 to create a *Healthcare Failure Mode and Effect Analysis* (HFMEA)—with a guide book and simple step-by-step guide updated in 2021. The proactive steps are described below.

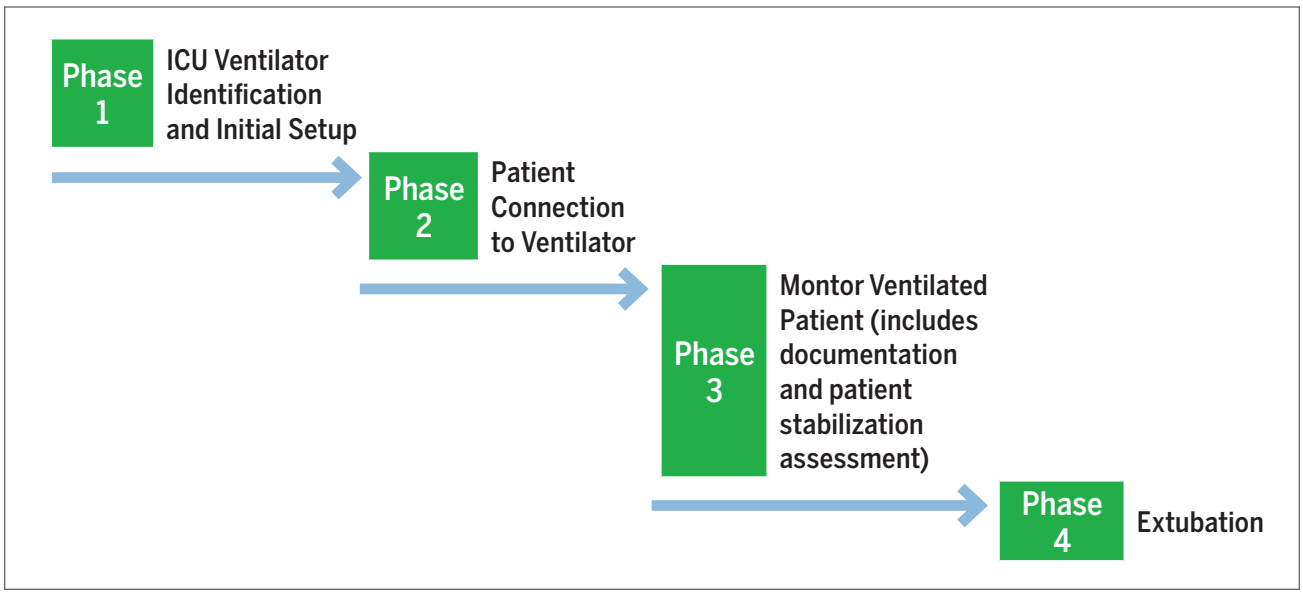
This proactive approach differs from a reactive one, which gathers feedback only retrospectively from events in which patients were harmed. A proactive approach helps to identify particular aspects of device use that seem to be the most challenging in delivering safe and effective patient care—and that could contribute to near-misses or adverse events. Being proactive

enables targeted attention to the riskier steps of device use, with the goal of minimizing unwanted outcomes by instigating procedural, hardware, or software upgrades. The HFMEA approach should inform updates of healthcare technology.

How can patient safety staff at healthcare institutions and manufacturing design teams carry out this approach? The first phase involves activities by the healthcare institution to develop a set of design considerations for safety. Such a list of design considerations or features forms a basis for discussion with manufacturers to use in modifying or upgrading specific medical devices. Opportunities for improvements within the user community may also be identified. To conduct this process, healthcare institution staff would:

- First, identify a complex medical device, such as an intensive-care unit (ICU) ventilator—the example used here.
- Then, study the device's use in a healthcare environment—for example, in transport, in the operating room (OR), during magnetic resonance imaging (MRI) scanning, or in the home.
- Next, identify and examine the phases of use for ICU ventilators, as shown in Figure 7.1, and identify all the steps users would need to take to properly operate this ventilator in one these phases, as shown in Table 7.1. This is an important undertaking. (The example below focuses on the 15 steps required for the Identification and Initial Set Up phase for ICU ventilators. Similar analyses could be done for the other three phases: Patient Connection to Ventilator, Monitor Ventilated Patient, and Extubation.)
- Next, for each identified step that the user would perform, break out the tasks associated with it—and consider the diversity of users and potential use errors. Analyze, discuss, and document the characteristics of:
  - ~ the range of users who might perform each task;
  - ~ the use conditions or environments for the task; and
  - ~ the likely use errors.

**Figure 7.1.** Four phases of device use for an ICU ventilator.



You can use techniques common to the HFMEA method to examine opportunities for error.

- Then, conduct use testing with any similar device or simply walk/talk through the tasks with a number of representative users. For each step, use errors can be identified by walking users (in this case, respiratory therapists, pulmonologists, and nurses) through the steps and querying them on the user-device "dialogue" needed to complete tasks. This would include analyzing actions required (menu-based and other control inputs), control and display labelling, device feedback (including alarms), the sequence of steps, interfaces with other devices, the work environment, and so on.
- Compile the use errors for later use in developing and communicating recommendations for the user community and manufacturing industry.

**Table 7.1.** Steps for use in Phase 1 for an ICU ventilator.

| 15 Steps for an ICU Ventilator Identification and Initial Setup | |
|---|---|
| 1. | Select vent. (If this is a rental ventilator, users need to go through all safety checks—e.g., electrical, data integrity/malware, system performance/maintenance history.) |
| 2. | Select humidification device. |
| 3. | Select appropriate patient ventilator circuit for patient (e.g., neo, ped, adult). |
| 4. | Connect inspiratory and expiratory limbs of circuit. |
| 5. | Verify tubing and connections. |
| 6. | Connect heated wire adapters to humidifier. |
| 7. | Verify performance check. |
| 8. | Move ventilator into patient room. |
| 9. | Connect supply sources (e.g., electricity, compressed gas, communications to electronic medical record, Wi-Fi). |
| 10. | Power-on ventilator. |
| 11. | Confirm self-test was good. |
| 12. | Confirm battery backup. |
| 13. | Initiate humidification. |
| 14. | Set initial vent settings for patient. |
| 15. | Vent can now be in standby awaiting patient arrival from OR. |

## Establishing a Partnership Between Developers and End Users

The next phase in this proactive risk management strategy is to develop and document issues that should be addressed by the user community and industry. These can be in the form of technical requests addressing:

- Novel failure modes.
- The conditions contributing to novel failure modes.
- Recommendations for procedural, hardware, or software upgrades for consideration.

In this way, patient safety staff in healthcare institutions can initiate a dialogue with device developers to identify worthy—yet feasible—mitigations to eliminate or control newly identified risks. Establishing such a partnership enables communication of a safety "wish list" which can mature into design specifications for the next device upgrade opportunity or for Instructions for Use (IFU) revisions. Feedback with a large user population helps to identify events that were not anticipated and promotes changes that improve the safe and effective use of technology.

Returning to the ICU ventilator example, more than three dozen critical and important technical requests were generated from use errors and insights discovered from respiratory therapists, pulmonologists, and nurses in the user community, as shown in Table 7.2. Ideally, such information would be shared across manufacturers or to specific device groups that could influence changes in a standardized manner.

## Benefits of this Approach

Identifying and analyzing the steps and tasks required to operate an ICU ventilator, and conducting walk throughs or use testing, resulted in many recommendations for ventilator design enhancement, as shown in Table 7.2 in the many issues identified using this process.

This demonstrates the value of adopting a task-focused structure as opposed to learning only from actual events of patient harm and close calls. Addressing each substep of a task can elicit rare but significant limitations of use and identify how the "usual" clinical process needs to be improved for safety. This strategy can be conducted for any medical device—and it could be used to frame industry standards for other devices as well as ventilators.

By sharing the information learned with your health system and others, the benefits multiply as more users become aware of latent errors to be avoided.

**Table 7.2.** Technical requests for improvements to ICU ventilator setup, Phase 1 device use: ICU ventilator identification and initial setup.

| Technical Requests for Improvements to ICU Ventilator Setup | |
|---|---|
| **Requests of Critical Importance for User Community** | |
| **1.** | Create a *Consumer Reports*-type of chart that highlights what features differ among ventilator models. This would help avoid use error by heightening awareness of subtle differences among models. |
| **2.** | Develop "standards" for the ventilator industry for successful task performance. |
| **Requests of Critical Importance for Industry** | |
| 3. | Use bar codes to ensure compatibility of circuit with ventilator; hospital standardizes ventilator at the unit/facility, or to ensure clear inability to use an incompatible vent/circuit. |
| 4. | Standardize circuits to fit the two kinds of heaters. |
| 5. | Standardize select circuit interfaces so connections could be universal. |
| 6. | Standardize and clearly label HME (Heat Moisture Exchanger) so users can easily see how much water is produced per liter. |
| 7. | Standardize the labels for modes across the industry. Have the user "select" the inspiratory pressure or have them select the PIP (Peak Inspiratory Pressure). Industry needs consistency across devices for the end users. |
| 8. | Ensure high tidal volume alarm functions as a cycle and an alert. |
| 9. | Ensure that when switching between "volume" and "pressure" modes that the initial settings, per the order, are retained and not cleared when returning to initial mode. |
| **Important Requests for the User Community** | |
| 10. | Determine how to document proficiency metrics for specific ventilators rather than rely on a "trust, trained, and ready" approach. |
| 11. | Determine how to standardize the order process and create a standard tag to denote order. |
| 12. | Determine how to identify clean devices (e.g., standard cues or separate spaces). |
| 13. | Standardize label stickers with font, color, and text to easily confirm mode and patient type supported by the device. |
| 14. | Determine how to package accessories with the device with evidence that hoses, quick connects, and power cords meet standards and are fit for safe use. Put the pieces together with the circuit, assemble the dry line and circuit together, and clearly label all. |
| 15. | Standardize signage/signal, date and time, and initials of who and how the ventilator was used (which procedure). |

**Table 7.2.** *(continued on page 75)*

**Table 7.2.** Technical requests for improvements to ICU ventilator setup, Phase 1 device use: ICU ventilator identification and initial setup *(continued)*.

| | |
|---|---|
| 16. | Develop training modules to present worst-possible scenarios a respiratory therapist might encounter. |
| 17. | Ensure facilities can assure a quick means to have equipment delivered from central supply. |
| 18. | Request that inventory management systems can confirm availability and location of clean circuits of appropriate type (e.g., active humidity). |
| 19. | Be aware that turbine-driven vents need longer dry line to ensure cool gas. Label and co-package them with humidity indicator. |

### Important Requests for Industry

| | |
|---|---|
| 20. | Standardize filters and adapters for universal use in circuits, or do so as much as is feasible. |
| 21. | Make limbs easily discernable as inspiratory/expiratory. Wiring is different, but mismatch can still happen. Consider unique inspiratory/expiratory connectors or unique wiring connectors to avoid misconnections. Consider changing transfer chamber so it only accepts appropriate limb. |
| 22. | Assure connection or orientation of limbs to the device enables the user to feel if loose. On successful connection, provide feedback (e.g., a détente, click, light, or speech indication) so user knows it's connected. Perhaps the IFU should require a pre-op leak test. |
| 23. | Provide materials compatibility information on the cleaning processes that have been tested and approved. This information is much needed because changes are frequent. |
| 24. | The technology should perform internal checks in a rapid manner to verify readiness prior to use on the patient. If checks fail, the system should inform which element failed. |
| 25. | Have automated health check so users cannot proceed until the required step is performed. |
| 26. | Design plugs so they can only go into sockets/circuits that match the load, etc. |
| 27. | Need to display battery status (charged, hours left) as clearly as mode so users know what to expect. |
| 28. | Means to describe battery life should be standard across the industry. |
| 29. | Standardize the icon/check process for confirming charge of backup battery—green/yellow/red, vs. "%" charge. |
| 30. | If vent can have multiple backup batteries, there needs to be individual component health, not cumulative charge status. |
| 31. | Consider forcing function that needs to confirm user checked battery status. |
| 32. | Provide confirmation of availability of power if connection to main power source is lost (e.g., during transport). |
| 33. | Provide light indicating that vent is operating on external, not internal, battery power. |

**Table 7.2.** *(continued on page 76)*

**Table 7.2.** Technical requests for improvements to ICU ventilator setup, Phase 1 device use: ICU ventilator identification and initial setup *(continued).*

| | |
|---|---|
| 34. | Locate "power on" indicator in common (i.e., standard) physical location using common switch design (same user action—toggle, switch, etc.). |
| 35. | Supply power on switch with the universal on/off symbol. |
| 36. | Be able to replace batteries on the fly. |
| 37. | Need system to detect and warn if bypassing circuit tubing compliance step. Annunciate to users to remind them of consequences (e.g., "Are you sure you want to bypass this?). It should force you to bypass the step if necessary, user should need to opt OUT, not opt IN. |
| 38. | Make sure the connectors indicate whether they meet ISO standards and if the wrong connector is used, annunciation should occur. |
| 39. | Provide an alarm for low end pressures. |
| 40. | Provide sensor detection of water in air hose/line. |
| 41. | Provide test/indicator to confirm alarm is active and wires connected correctly. |
| 42. | Provide capability to automatically test the EMR/EHR (Electronic Health Record) connection. Perhaps vent/hospital has default alarm settings. |
| 43. | Self-check currently differs by brand; consider having self-check or diagnostic/human confirming the steps. Consider user ability to bypass the check. |
| 44. | Separate power for heater might lead to user forgetting to turn it on; consider confirmation of "heater power on" as part of pre-op ventilator check. |
| 45. | Determine an easy means to confirm proper temp is set. |
| 46. | Provide common logic/strategy for measuring relative humidity rather than judging by condensation. Currently one must trust the algorithm without a way to confirm it's working correctly. |
| 47. | Ensure vents monitor Heat Moisture Exchanger status so the user can confirm the configuration is "good." |

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# Raising Awareness and Highlighting Best Practices

## The Call to Action
2017

*Developing the Business Case for Purchasing Healthcare Technology*

The AAMI Foundation recognized that executive leadership in healthcare organizations would be essential to promoting the safe use of complex healthcare technology. At the kickoff meeting of the National Coalition, two experts gave presentations on the implications of product liability, malpractice, and incidents related to adverse events. This summary of presentations can be used to make the business case for effective management of the full life cycle of complex healthcare technology.

## Patient Safety Seminars
2017–18

The AAMI Foundation hosted three patient safety seminars (webinars) that showcased best practices and insights on the safe use of complex healthcare technology. The Foundation offered Certificates of Participation as a continuing education credit for each seminar.

*Fail Safe Use of Complex Medical Devices—Memorial Hermann Health System, Houston, Texas* • 2017

**Patricia Hercules**, BSN, MS, RN-BC, director of System Clinical Programs

**Teresa Ryan**, RN, BSN, CPHRM, risk management manager, Memorial Hermann Southeast Hospital

**M. Michael Shabot**, MD, FACS, FCCM, FACMI, executive vice president, and system chief clinical officer

*Go with the Flow: Insights into Complex Infusion Delivery Systems* • 2018

**Robert Butterfield**, Becton-Dickinson Engineering Fellow (retired) and principal, RDB Medical Instrument Consulting

**Nathaniel Sims**, MD, cardiac anesthesiologist and physician advisor to Biomedical Engineering at Massachusetts General Hospital and assistant professor of anesthesiology at Harvard Medical School

*The Challenges of Ensuring a Safe and Competent Workforce in the Use of Medical Devices in Healthcare* • 2018

**David Williams**, RGN, medical devices clinical lead in Clinical Engineering, Medical Physics and Clinical Engineering at Nottingham Universities Hospitals NHS Trust

# Going Deeper

Articles and Case Studies from AAMI and the AAMI Foundation 2017–18

### *BI&T (Biomedical Instrumentation & Technology)*, AAMI's peer-reviewed journal

*Frontlines: Curbing Medical Device Misuse*
Sheffer, J. (November/December 2017)

*Case Study: Overcoming User-Centered Challenges with Complex Health Technology*
Doyle P & Vockley M. (January/February 2018)

*Review: Use of Simulation-Based Training to Aid in Implementing Complex Health Technology*
Devers V. (January/February 2018)

*Nurse Executives Seek to Address Burden of Complex Technology on Workforce*
Stifler K. (July/August 2018)

*Handled with Care? Protecting Medical Devices from Harm*
Stern G. (November/December 2018)

*Roundtable Discussion: Gaining Proficiency in the Use of Complex Health Technology Requires a Multifaceted Training Approach*
(November/December 2019)

### AAMI News

*Industry, Nurses Grapple with Technology Training* (Feb. 1, 2016)

*Experts See Need for New Way of Thinking to Tackle Complexities of Healthcare* (May 9, 2016)

*AAMI Foundation Launches Initiative to Address Complexity of Healthcare Technology* (April 17, 2017)

*Industry, Nurses Address Barriers to Clinical Training on New Technologies*
(Jan. 13, 2018)

### Podcasts

**Episode 33**: Human Factors in the design of medical equipment part 1 (April 13, 2020)

**Episode 34**: Human Factors in the design of medical equipment part 2 (June 19, 2020)

### Press Release

*Press Release: AAMI Foundation Launches Initiative to Address Complexity of Healthcare Technology*

## Conclusion

The National Coalition to Promote Safe Use of Complex Healthcare Technology took a classic approach to solving a complex set of problems, which has resulted is an exceptional collection of wisdom, guidance, and practical solutions that will help keep patients safe.

Coalition members identified the issues and consolidated them into a shared definition that shaped their work. They listened to a diverse group of stakeholders to understand everyone's interests. They consulted research, and identified best practices, tools, and resources. They narrowed their focus to the most pressing issues and agreed on a scope of work that could make the most impact on patient safety.

This National Coalition produced a body of work that both healthcare delivery organizations and companies will find compelling ... emphasiz(ing) the importance of partnership and collaboration across sectors.

Photo: Chaikom – stock.adobe.com

This National Coalition produced a body of work that both healthcare delivery organizations and companies will find compelling. Healthcare systems and hospitals will realize value from developing a business case for effective acquisition, properly integrating new medical technology, using risk profiles to plan training and introduce complex technology, and strengthening competency assessments. Companies will benefit from integrating human factors activities into every aspect of product development and design; creating a mature, sustainable, and user-centric human factors program; and learning from device use issues in the field.

The National Coalition's work emphasizes the importance of partnership and collaboration across sectors. Healthcare delivery organizations need corporate cooperation and support at critical junctures, from the acquisition process to technology integration to training and competency assessment. Likewise, companies need strong relationships with healthcare systems and hospitals to support user-centric product design, development, and testing and to learn about device performance in clinical settings.

The AAMI Foundation is grateful for sustained engagement of the National Coalition, industry sponsors, and the many advocates of patient safety who contributed to this body of work. We encourage you to use the resources in this Anthology to enhance your patient safety efforts.

# National Coalition to Promote Safe Use of Complex Healthcare Technology

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# National Coalition to Promote Safe Use of Complex Healthcare Technology

## Corporate Sponsors

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- *Nihon Kohden*

**Gold Level**

- Baxter
- Crothall Healthcare
- Vivenix
- Smiths Medical

**Bronze Level**

- VitalSims

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