



Making Risk Management Everybody's Business



*Priority Issues from the
2015 AAMI/FDA Risk Management Summit*

Summit Conveners

AAMI

The Association for the Advancement of Medical Instrumentation (AAMI), a nonprofit organization founded in 1967, is a diverse alliance of nearly 7,000 members from around the world united by one critical mission—supporting the healthcare community in the development, management, and use of safe and effective medical technology. AAMI serves as a convener of diverse groups of committed professionals with one common goal—improving patient outcomes. AAMI also produces high-quality and objective information on medical technology and related processes and issues. AAMI is not an advocacy organization and prides itself on the objectivity of its work.

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About this Report

This publication covers the clarion themes, challenges, and priority actions developed by consensus at the summit. The report summarizes summit presentations and provides additional perspectives from experts. This publication is intended to be a helpful information resource, and reflects the expert advice and views of the summit experts. It is not to be construed as an interpretation of AAMI standards, nor does it constitute legal or regulatory advice. The summit agenda, presentations, updates, and reference materials are available at www.aami.org/risksummit.

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PRIORITY ISSUES FROM THE 2015 AAMI/FDA
RISK MANAGEMENT SUMMIT

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A Bigger Tent for Keeping Patients Safe



Dear Colleagues,

For the more than 200 talented professionals who gathered at the AAMI/FDA Risk Management Summit, keeping patients safe is both a passion and a challenge. They know that innovative healthcare technology provides tremendous benefits to patients—and that it also can introduce new risks to patient safety at any stage of the total product life cycle.

Effectively identifying and addressing those risks—and balancing those risks with patient benefits—demands new tools, broader perspectives, and innovative approaches to risk management. The presentations and discussions at the two-day summit in September 2015 inspired participants to develop a compelling action plan that rises to this challenge.

First and foremost, the summit made clear that everyone who's involved with healthcare technology can and should contribute to risk management. Risk management specialists in industry, in healthcare delivery, and at the FDA can't do this alone. Untapped expertise exists, for example, in the ranks of clinicians who use healthcare technology every day.

The many stakeholders of healthcare technology view risk from different perspectives. In the words of summit presenter Susan Nicholson, vice president of safety surveillance and risk management for the consumer segment of Johnson & Johnson, "If something goes wrong with a medical device, all the engineers run to the device, and all the clinicians run to the patient. That's healthy and good."

We couldn't agree more. By engaging all stakeholders to work together in managing risk and considering that risk in the context of benefit to patients, everyone's understanding of both risk and benefit will deepen and grow closer to a 360-degree perspective, which we are confident will improve patient outcomes.

Thank you to all who came to the summit and made it a success. And to the wider audience of readers, we hope that you will consider this report an invitation to learn what happened, what's next, and how you can help.

Sincerely,

Mary Logan
President
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Summit Overview



“With innovation comes great risk.”

—Jeff Natterman

Risk Manager and Associate Senior Counsel
The Johns Hopkins Hospital

Throughout the healthcare community, there is wide recognition that caring for patients can be a risky business. Nowhere is this more evident than in the realm of healthcare technology. The AAMI/FDA Risk Management Summit, the seventh in a series focused on tenacious problems in healthcare, put the challenges in sharp relief.

The summit, held on Sept. 29–30, 2015, in Herndon, VA, drew more than 200 participants from across the spectrum of professionals with a vested interest in healthcare technology, including manufacturers; healthcare delivery organizations (HDOs); regulators; standards-developing organizations; patient safety organizations; clinicians; safety, risk, and quality management professionals; healthcare technology management professionals; and systems engineers.

Informed by expert presentations, participants identified multiple barriers and priority actions for strengthening the discipline and practice of risk management for healthcare technology. The ultimate goal of addressing the challenges is to improve patient safety with the use of medical devices for healthcare.

Increased Possibility Brings Increased Responsibility for Healthcare Technology

Keynote speaker Jeff Natterman, RRT, MA, JD, CPHRM, set the context for the summit’s deep dive into the challenges of managing healthcare technology risks. Natterman

offered a sobering perspective, drawing from his experiences first as a respiratory therapist and now as risk manager and associate senior counsel at The Johns Hopkins Hospital, in Baltimore, MD.

Natterman characterized risk management as a clash that occurs “when an unstoppable force meets an immovable object.” The unstoppable force describes the seemingly inevitable “technological imperative” for

A Broader Perspective on Risk Management

As you read this report, keep in mind that risk management perspectives on healthcare technology—as well as regulations, standards, policies, and processes—differ for industry, HDOs, clinicians, and other stakeholders. In the spirit of the summit, however, the overarching goal for all stakeholders is an invitation to widen our perspectives by embracing a total life cycle approach to managing risk.

rapid innovation. Adoption of advanced healthcare technology is colliding with the immovable object of human culture, whose readiness to manage the risks associated with it is all over the map.

The desire for the latest technology, sometimes called the “shiny object syndrome,” is a potent force in healthcare. To make that point, Natterman shared a sampling of findings from a 2014 WebMD/ Medscape Digital Technology Survey of 1,100 patients and 1,400 health professionals, including 827 physicians:

- A majority of patients (84%) and physicians (69%) embrace technology to enhance and aid the diagnostic process.
- Patients (64%) and physicians (63%) agree that a smartphone can be a useful diagnostic tool for blood tests.

Citing Jacobson (2004), Natterman affirmed that technology is both a savior and a culprit in healthcare. Technology:

- Saves lives
- Improves quality of life and longevity—but provides more opportunity for error
- Can increase medical costs
- Increases exposure to liability
- Increases complexity, which requires more training and cultural adjustments—and creates workflow challenges

Natterman questioned whether all advances in medical devices are truly imperative for patient care. Citing Chandler (2002), he asserted that just because we *can* do something because it is technically possible doesn't mean we *should* do it as a moral imperative, *must* do it as an operational requirement, or inevitably *will* do it in time. Some healthcare technology is so complex that clinicians don't understand how it works or how it applies to patients, which can pose safety risks. “We should seriously consider removing technology that is harmful or not effective,” he said.

Natterman urged summit participants to bear in mind that the increased possibilities of advanced healthcare technology come with increased responsibility:

“One conception of the technological imperative that is important is the one that implies that technology reduces our responsi-

bility toward our actions. I argue that this conception cannot be justified. That is, there is no imperative that frees us from our responsibility for developing, producing, advertising, assessing, implementing, using, and banishing technology in health care. On the contrary, *the increased possibilities provided by technology result in an increased responsibility*. That is, there is no technological imperative, but *technology promotes a moral imperative; in particular, it promotes a moral imperative to proper assessment*” (Hofmann, 2002).

Who's Running the Show?

Right now, the compelling need for greater responsibility—and accountability—in managing risk does not match the reality in healthcare delivery. “Who's running the show?” Natterman asked. “Who's accountable for implementing technology? There's no training, no organization, no methodology for determining effectiveness. People ignore the rules, as though accidents just happen.” He offered these responsibilities for healthcare technology as a starting point:

- Follow the law
- Follow ethical principles
- Secure informed consent for experimental technology
- Know what you know about risk
- Know what you *don't* know about risk

Unclear or nonexistent accountability, ignoring safety rules, and inadequate communication about recalls and adverse events or near misses are flashpoints at the technology/human interface for risk management, Natterman said. “In our facilities, we deal with 200 recalls every month,” he said. “We have to have systems in place for all that,” some of which are still paper based, even in the digital era. “I advocate strongly for electronic systems to monitor products.”

Finally, Natterman shared the risk management strategies used by The Johns Hopkins Hospital, which reflect broad responsibility and accountability for healthcare technology among all stakeholders:

- Training depth and sustainability
- Accountability for deviations
 - David Marx model—three classes of human fallibility:

- Human error (inadvertent)
- High-risk behavior (taking shortcuts)
- Reckless behavior (willful, rare)
- True leadership
- Regulatory partnerships
- Manufacturer relationships

Summit participants responded to this broad perspective on risk management, and all of the multidisciplinary perspectives presented at the event, by identifying **clarion themes**—a comprehensive set of challenges, priority actions for addressing them, and identification of accountable stakeholders within the healthcare community.

Clarion Themes

- 1. Recognize that everyone in healthcare is a risk manager.** Risk management specialists are necessary, but not sufficient, for identifying and mitigating risks associated with healthcare technology. Everyone who designs, develops, produces, markets, implements, uses, monitors, and services healthcare technology has a role to play in risk management. “If you see something, say something” should be the guiding mantra.
- 2. Develop shared understandings of the risks—and benefits—of healthcare technology.** Different stakeholders, including regulators, manufacturers, healthcare delivery organizations (HDOs), clinicians, safety experts, quality and risk managers, healthcare technology managers, information technology professionals, and patients, have decidedly different understandings of even the most basic risks of healthcare technology. Given their shared stake in the safety and effectiveness of this technology, it is time to gain consensus on the meaning of fundamental principles and terminology of risk. At the same time, factoring in the benefits of healthcare technology in risk equations is important.
- 3. Adapt systems engineering principles, practices, and tools for risk management.** Other high-risk industries, such as the aerospace and nuclear power industries, are far ahead of healthcare in managing risk. Although these industries differ substantively from healthcare—and have had some colossal failures—their tried-and-true use of systems engineering to manage risk should be

adapted to strengthen both the mindset of risk management and the multidisciplinary collaboration required to identify and mitigate the risks associated with healthcare technology.

- 4. Engage in a total life cycle approach to risk management of healthcare technology, which is required for effectively managing risk.** Too often, risk management is practiced as a discrete activity that occurs at a fixed point in the life cycle of healthcare technology, typically for manufacturers to meet regulatory approval or clearance processes or for HDOs to configure implementations. Instead, a more progressive approach is actively managing risk throughout the full life cycle of healthcare technology. Leading practitioners are already doing that—and realizing value in terms of patient safety, innovation, and cost.
- 5. Create new practical tools to continue advancing the field of risk management for healthcare technology.** For the medical device industry, risk management is a discipline that has a harmonized consensus process in ANSI/AAMI/ISO 14971. Industry lacks a universal understanding of this process at all necessary levels and sufficient guidance to make efficient use of this standard. Industry and other stakeholders lack a set of robust tools designed specifically for healthcare technology practitioners. Embedding effective risk management into the everyday practices of diverse stakeholders requires practical tools crafted as “risk management for newbies.”

CLARION THEME 1

Recognize that everyone in healthcare is a risk manager.



“The patient safety movement has really made me focus on clients. We want to do enterprise risk management, or ERM, which also stands for ‘everybody’s a risk manager.’”

—Jacque Mitchell

Risk Manager, Sentara Norfolk General Hospital
Past President, American Society for Healthcare Risk Management

Challenge	Priority Action	Accountable
Limited understanding of the purpose of risk management for improving the safety and performance of healthcare technology	Champion the value of risk management for improving patient safety and minimizing risks to patients.	All stakeholders
	Stress that risk management is an indispensable tool for managing the full life cycle of devices, not just a “check the box” compliance activity.	
	Ensure that all industry and healthcare professionals understand how they can contribute to managing the risks of healthcare technology they design, develop, manufacture, market, monitor, or use.	Manufacturers HDOs Professional societies Trade associations
	Incorporate risk management, tailored for particular professions and roles, into the curriculum in engineering and clinical education and training. Leverage and develop risk management skill sets.	Academia AAMI Professional societies
Limited “ownership” of risk management of healthcare technology	Integrate risk management into everyday operations, from the C-suite, to R&D and quality management, to clinical practice.	Manufacturers HDOs
	Broaden and define responsibilities for risk identification and risk management throughout organizations. Increase the participation of end users in risk management.	
Inconsistent risk management processes	Develop consistent processes for risk management within and across organizations.	Manufacturers HDOs

The Blind Man and the Elephant

The discipline and practice of risk management can improve patient safety and clinical practice, the organizational effectiveness of healthcare systems and manufacturers, and regulatory decisions. Risk management also can spur innovation and reduce costs, including the financial burden of recalls and liability when healthcare technology fails to perform as expected.

Limited understanding of risk management constrains these potential benefits, summit presenters and participants agreed. As in the parable of the blind man and the elephant, people perceive risk management narrowly, through the lens of their engineering, software, medical, quality, or legal expertise, for example. All of these perspectives are valuable, but no single one is comprehensive and complete. Organizational and individual roles shape conceptions—and misconceptions—about the purpose and benefits of risk management.

Why does this matter? Complex healthcare technology deployed in diverse settings and connected to unanticipated and potentially uncontrolled equipment and systems could introduce new vulnerabilities to patient safety. Companies and HDOs should be well equipped to identify, mitigate, and manage safety risks.

Instead, in the words of one summit participant, “We’re doing risk management to check a box, file it away, and never look at it again”—an observation that recurred throughout the summit. In the field, though, the risks associated with healthcare technology are constantly evolving, as medical practice, health information technology (IT) systems, and ecosystems of patient care change. These changes necessitate taking a fresh look at potential risks—a key aspect of effective risk management that is often an afterthought, summit participants said. These points are evidence of the need for better education and appreciation of the purpose of risk management activities, within companies’ quality management systems and within HDOs’ enterprise risk management, clinical risk management, and patient safety initiatives.

Too often, risk management also is a piecemeal practice, with individuals doing

their discrete bits in silos. Instead, someone should be responsible for bringing everyone together to synchronize risk management efforts and coordinate cross-functional, cross-organizational expertise. Someone should be responsible for bridging gaps that occur during handoffs from one group or phase to another. Someone should be responsible for synthesizing risk management activities into a holistic picture and promoting risk management as vital to a shared, enterprise-wide mission to improve patient safety.

Instead of a mere compliance exercise practiced for the purpose of checking a box, risk management in companies should be seamlessly integrated throughout the full life cycle of healthcare technology. HDOs should consider risk not just during implementation of healthcare technology but also whenever changes to systems, software, and medical devices occur. Clinicians, health IT experts, and healthcare technology managers in HDOs should provide feedback to companies, contribute to postmarket risk assessment and mitigation, and report any product issues.

Realizing this vision will require leadership, training, responsibility, and accountability—starting with executive champions and extending to the frontline. In the words of AAMI President Mary Logan, “risk management is everybody’s business.”

Improving Ownership and Understanding of Risk Management

Effective risk management starts at the top, summit participants said. Done well, risk management is a value-add, not a burden, for enterprises. For companies, “if a problem costs \$1,000 to mitigate in design, it could cost \$300,000 to \$500,000 later,” said summit presenter Laurie Wiggins, CEO and founder of Sysenex, Inc. “You want to discover risks early on.”

C-suite champions in both industry and HDOs should set the vision and tone for risk management as fundamental to improving patient safety. Organization leaders have the authority to align and integrate risk management with other key initiatives, such as the design, development, and deployment of healthcare technology, as well as safety and quality initiatives. Executives can allocate

“If you are passionate about risk management in your organization, there are ways to get this done.”

—Ginger Glaser, vice president of AMS Quality and FDA Relations at Boston Scientific

“Unless this culture starts with the C-suite, it will never happen.”

—Summit participant

resources and facilitate multidisciplinary coordination across departments or divisions. They also can support training to develop risk management competencies in their organizations. In addition, they can foster a culture that encourages people to speak up without reprisal when safety is concerned.

Training is a sweeping challenge. Even professionals whose primary responsibility is risk management need help keeping up with the rapid changes in healthcare technology or new methods to manage risk effectively and comprehensively, summit participants said. Although risk management specialists need deeper knowledge, the responsibility for risk management should be broadly shared.

Positioning everyone in healthcare to be attuned to healthcare technology risks requires training and a shift in cultural mores.

Beyond adequate training to use healthcare technology competently, clinicians and other healthcare delivery professionals also need training to perform their role in the risk management life cycle. For example, everyone should know who the point person is for communicating safety concerns to manufacturers and the FDA, speak up about safety issues, and contribute to reports about adverse events or near misses.

“I’m not afraid to call my administration and say, ‘This happened and we’ve got to do something about it,’” said Jacque Mitchell,

The Johns Hopkins Hospital

Risk Management in Healthcare Delivery: Training Looms Large

“The biggest issue for risk management in healthcare delivery is inadequate training. It’s the number one issue we face.”

—Jeff Natterman, risk manager and associate senior counsel at
The Johns Hopkins Hospital

Jeff Natterman cited these major training issues at The Johns Hopkins Hospital:

- **Failure to launch healthcare technology.** “Vendor demonstrations don’t equate to adequate training,” he said. The Joint Commission’s Human Resource Standards expect hospitals to define and verify staff competencies, including their skills in using healthcare technology required for patient care.
- **Super users.** Many hospitals use a train-the-trainer model to implement new healthcare technology. In this model, a few clinicians are trained first, then they take the lead in training and supporting others as they learn to use the medical equipment. “Super users become a flotation device,” Natterman said. “If I could get rid of that concept, I would. Others think they can rely on the super users. Everybody else is off the hook. That is an implementation problem. Everybody who touches technology in a hospital is a risk manager.”
- **Institutional scope policies.** Not everyone who has been trained to use a medical device is permitted to do so, which limits clinician proficiency.
- **Academic pursuits vs. application of methods.** An institutional sponsor’s desire for a product to succeed can introduce bias in implementation and monitoring of results for healthcare technology.
- **“It’s just too complex—we have tech support for that.”** Many clinicians do not understand either the functionality or the physiological effects of medical devices on patients as well as they should, which can lead to overreliance and trust in the technology and the technical support staff.

risk manager for Sentara Norfolk General Hospital and past president of the American Society for Healthcare Risk Management. “That working relationship has been there for many years. If you’re always speaking about the patient, you can’t go wrong. In other hospitals, risk management is not so well accepted.”

Even frontline manufacturing workers have a role to play in their company’s risk management system. Medtronic, for example, realized that many of the workers who produce its products had no idea what the products do or how vital they are for patient care, according to Jeffrey Tellman, the company’s director of divisional quality. As a result, Medtronic began providing product awareness training sessions for all workers, who now know how important it is for every component to be exactly right.

Risk management also should be part of the higher education curriculum and training in clinical education and engineering, summit participants said. “When you go to medical school, no one teaches you how to do risk management,” said summit presenter Susan Nicholson, vice president of safety surveillance and risk management for the consumer segment of Johnson & Johnson. Few engineering programs offer specialized courses in risk management, and future engineers are not necessarily required to collaborate with professionals in other disciplines, such as IT experts or clinicians. These shortcomings need to be remedied for risk management to be practiced effectively.

Systems engineering education, which does include risk management, often is a graduate-level course of study, said summit presenter Steven Badelt, managing partner at Suttons Creek, Inc., and industry ambassador for the International Council on Systems Engineering (INCOSE). This means that most engineers in common disciplines for healthcare technology, such as electrical, mechanical, biomedical, and clinical engineers, do not have a depth of knowledge or practical skills in risk management.

Inconsistent Risk Management Processes

Limited knowledge of the purpose and benefits of risk management, as well as inadequate risk management training for specialists and across the spectrum of healthcare, can make for inconsistent risk management processes within and across organizations.

This can be the case in both large and small companies, within regulatory bodies, and in HDOs. Large companies have multiple divisions and departments, and large health-care systems have many hospitals and other facilities. Regulatory bodies are similarly siloed, with experts who specialize in evaluating pre- or postmarket risk or compliance activities. Each group or organization has its own ways of managing risks, making it difficult for them to collaborate and synthesize information. Smaller organizations face a different set of challenges. Startup companies, which are under pressure to get their products on the market as quickly as possible, often see risk management as a hurdle. Small companies and HDOs often don’t have a deep bench of risk management talent or consistent risk management processes.

Clarion themes 2–5 describe specific inconsistencies in risk management processes and offer priority actions to address them.

Few engineering programs offer specialized courses in risk management, and future engineers are not necessarily required to collaborate with professionals in other disciplines, such as IT experts or clinicians. These shortcomings need to be remedied for risk management to be practiced effectively.

CLARION THEME 2

Develop shared understandings of the risks—and benefits—of healthcare technology.



“Why does terminology matter? It enhances our chance of reaching similar conclusions.”

—Randall Brockman
Chief Medical Officer

Office of Device Evaluation, FDA CDRH

Challenge	Priority Action	Accountable
Inconsistencies in risk management terminology, which divert attention from and contribute to misconceptions about risk management processes	Clarify and eliminate inconsistencies between regulatory authority and international standards' use of risk management terminology, including the definitions of "risk," "risk management," "benefit," and "essential function." Consider standardized terminology—but be consistent with international standards and don't add to the confusion.	IMDRF member countries* AAMI Other standards-developing organizations
Imbalanced attention to the risks and benefits of healthcare technology	Consider developing a risk–benefit Technical Information Report (aligned with AAMI/ANSI/ISO 14971:2007, <i>Medical devices—Application of risk management to medical devices</i> , and EN ISO 14971:2012) that will support benchmarking and learning about risk management.	AAMI
Inadequate information about adverse events and near misses related to healthcare technology	Make data publicly available to help guide predictions and updates on severity of risk and incident occurrence rates.	FDA and international regulatory agencies Industry HDOs IMDRF member countries*
	Consider rewarding people for reporting near misses.	Regulatory bodies HDOs Industry

*The International Medical Device Regulators Forum (IMDRF) is a voluntary group of medical device regulators from around the world focused on regulatory harmonization and convergence.

Terminology Matters

Risk management practitioners in industry exert considerable time and effort parsing inconsistent language found in standards, regulatory guidance documents, and other publications, in an effort to understand the expectations for identifying, analyzing, and mitigating risks, summit participants said. Likewise, language trips them up in determining how good is good enough: How far should they take their risk analysis? What's the appropriate degree of acceptability? Differences in terminology and definitions also show up in pre- and postmarket expectations and in U.S. and international expectations.

Confusion over terminology diverts attention from the essential task of keeping patients safe. It wastes time and can result in unidentified risks, gaps in organizational coordination of risk management activities, missed opportunities to link risk mitigation to quality management systems, operational inefficiencies, duplication of work and risk management files to meet international expectations, and delayed decisions. “This can give people an excuse not to do the work,” said summit presenter Tammy Pelnik, president of The St. Vrain Group, a quality systems consultant and a long-time member of

AAMI’s faculty for teaching courses on quality, systems, and risk management.

Summit presenter Robert Menson, owner of Menson & Associates and an AAMI faculty member who teaches industry courses on quality management systems, risk management, and risk assessment, pointed out some of the language discrepancies, as shown in Table 1.

In addition to the terms in Table 1, Menson illustrated the language disconnects between technical and clinical audiences by listing a few terms that meet the requirements for an identified hazard in ANSI/AAMI/ISO 14971:

- A failed capacitor
- A failed component
- An ungrounded medical instrument
- A wrong diagnostic answer

“Which of those hazards can the clinician understand as causing harm?” he asked. “FDA and clinicians need to meet in the middle and understand the terms we are using.”

“If we don’t have common definitions, we use our own definitions. Everyone has an opinion, and mine is always right.”
—Summit participant



Term	Definition in ANSI/AAMI/ISO 14971, Medical devices—Application of risk management to medical devices	Definition in Medical Device Innovation Consortium (MDIC) Patient Centered Benefit-Risk Project Report
Hazard	Potential <i>source of harm</i>	—
Hazardous situation	Circumstance in which people, property, or the environment are exposed to one or more hazard(s)	—
Harm	Physical <i>injury</i> or <i>damage</i> to health of people or damage to property or the environment	An <i>unfavorable effect</i> or <i>undesirable outcome</i> of a diagnostic or therapeutic strategy
Risk	Combination of the <i>probability</i> of occurrence of <i>harm</i> and the <i>severity</i> of that <i>harm</i>	The qualitative notion of the <i>probability</i> and/or <i>severity</i> of a particular harm* (*This definition accommodates how the term “risk” is used in much of the benefit–risk literature and prior FDA CDRH guidance.)
Risk management	<i>Systematic</i> application of management policies, procedures, and practices to the tasks of analyzing, evaluating, controlling, and monitoring risk	—
Other terminology to consider	<ul style="list-style-type: none"> • Risk–benefit: ANSI/AAMI/ISO 14971, <i>Medical devices—Application of risk management to medical devices</i> • Benefit–risk: FDA and MDIC guidance • Premarket estimated risk: ANSI/AAMI/ISO 14971, <i>Medical devices—Application of risk management to medical devices</i> • Baseline risk profile: <i>Risk Principles and Medical Devices: A Postmarket Perspective</i>, an AAMI white paper 	

Table 1. Discrepancies in key risk management terminology. Source: Robert Menson. “Terminology Matters.” Presented at the AAMI/FDA Risk Management Summit, Sept. 29–30, 2015.

“In hardline risk management, risk is risk is risk. I’ve come to the conclusion that risk is contextual. A hazardous situation doesn’t always cause harm. Most customers don’t pay attention to the environment and sequence of events we need to manage.”

—Robert Menson, owner of Menson & Associates



scenario is shown in Figure 2. “It’s really the context you need to deal with to understand what risk management is,” he said. “We need to minimize the possibility that a hazard occurs. If we can’t minimize that, we minimize the situation in which it will occur. And lastly, we want to reduce the probability that it will occur.”

Menson also juxtaposed a beguilingly straightforward diagram of the relationships among risk management terms in ANSI/AAMI/ISO 14971, shown in Figure 1, and the more complex reality of practice.

“In hardline risk management, risk is risk is risk,” Menson said. “I’ve come to the conclusion that risk is contextual. A hazardous situation doesn’t always cause harm. Most customers don’t pay attention to the environment and sequence of events we need to manage.” An example of such a

Regulatory Perspective: Different Terms, Similar Intent

FDA presenter Melissa Torres offered a regulatory perspective on the terminology conundrum and regulatory expectations for risk management for companies. While words may differ, the intent is similar in relevant FDA and international expectations, according to Torres, acting program director of premarket approval (PMA) and humanitarian device exemption (HDE) in the Office of Device Evaluation (ODE) at FDA CDRH. She referenced four sets of documents:

- Quality System (QS) regulation (Code of Federal Regulations [CFR] Title 21 820)
- ANSI/AAMI/ISO 14971
- Global Harmonization Task Force (GHTF) guidance document, *Implementation of Risk Management Principles and Activities within a Quality Management System*
- FDA guidance documents covering benefit/risk

Torres highlighted specific language in the QS regulation, including noting that “**design validation shall include** software validation and **risk analysis**, where appropriate”[from 21 CFR 820.30(g)].

Torres also noted that risk analysis is only part of risk management, as defined in ANSI/AAMI/ISO 14971: “*Risk analysis* is the systematic use of available information to identify hazards and to estimate the risk.”

So, does that mean that the QS regulation only requires manufacturers to follow part of the ISO 14971 process? Not at all, Torres said. She pointed summit participants to the preamble that accompanied the publication of the QS regulation in 1996, well before publication of the first edition of ANSI/AAMI/ISO 14971. At that time, *risk analysis* was considered to be the comprehensive term for the process that is now called *risk management*. In the words of the preamble:

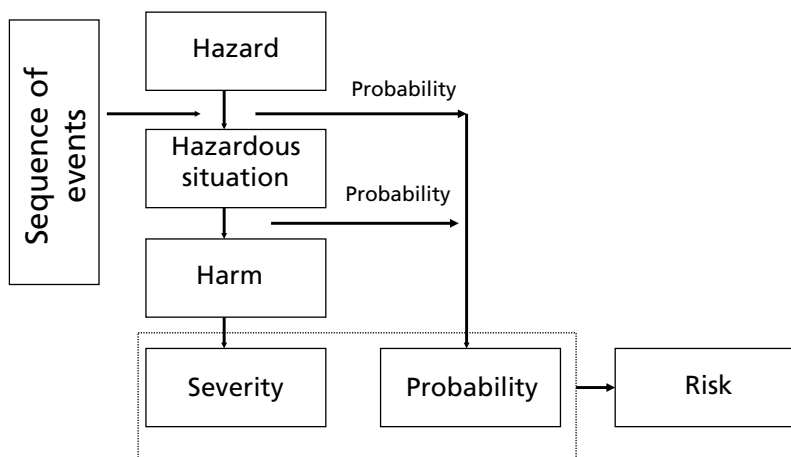


Figure 1. Risk management: relationships among hazards, hazardous situations, harm, and risk. Source: Robert Menson. “Terminology Matters.” Presented at the AAMI/FDA Risk Management Summit, Sept. 29–30, 2015.

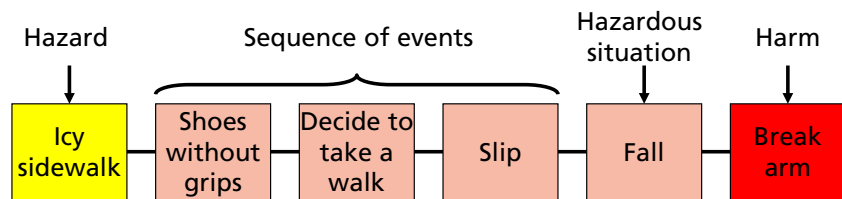


Figure 2. A hazard, a hazardous sequence of events, a hazardous situation, and harm. Source: Robert Menson. “Terminology Matters.” Presented at the AAMI/FDA Risk Management Summit, Sept. 29–30, 2015.

Food for Thought: Two Risk Management Scenarios

Scenario 1

While in the hospital, a patient requires a blood test. After the blood is drawn, a bandage is placed on the patient's arm. Later, the patient develops an infection at the site. Upon investigation it was discovered that a single lot of bandages had broken seals.

- What is the hazard?
- What is the hazardous situation?
- What is the harm?

Scenario 2

A new nurse's assistant takes a child's temperature using a digital ear thermometer. The probe is inserted too far into the ear and the eardrum ruptures, resulting in a partial hearing loss.

- What is the hazard?
- What is the hazardous situation?
- What is the harm?

Source: Robert Menson. "Terminology Matters." Presented at the AAMI/FDA Risk Management Summit, Sept. 29–30, 2015.

"FDA's involvement with ISO TC 210 [Quality management and corresponding general aspects for medical devices] made clear that 'risk analysis' is the comprehensive and appropriate term. When conducting a risk analysis, manufacturers are expected to **identify possible hazards associated with the design in both normal and fault conditions.** The risks associated with the hazards, including those resulting from user error, should then be calculated in both normal and fault conditions. **If any risk is judged unacceptable, it should be reduced to acceptable levels by the appropriate means**" (61 Fed. Reg. at 52620, Comment 83).

Thus, the FDA expects risk management activities to be integrated throughout a manufacturer's quality management system (QMS), Torres said. While U.S. manufacturers are not required to comply with ISO 14971 in its entirety, the process described in the standard is recognized as satisfying both the letter and the intent of the QS regulation. Although the QS requirement for risk analysis is included in the section on design validation, risk management activities should begin early in the design and development process.

The QS regulation and preamble spell out risk-based decisions expected in design controls, purchasing controls, traceability, production and process controls, nonconforming products, corrective and preventive

"Risk terminology may differ. However, expectations are similar between the Quality System regulation, ISO 14971, Global Harmonization Task Force guidance, and FDA guidance documents. Harmonizing terminology may be helpful to ensure consistency in the application of risk management requirements."

—Melissa Torres, acting program director for premarket approval and humanitarian device exemption in the Office of Device Evaluation at FDA CDRH

action (CAPA), and servicing of medical devices. Similarly, the GHTF guidance advises incorporating risk management activities into:

- Design and development activities
- Traceability
- Purchasing controls and acceptance activities
- Production and process controls
- Manufacturing, measuring, and monitoring equipment
- Work environment and personnel
- Process validation
- Servicing
- CAPAs

For more from Torres and others on managing risk throughout the full life cycle of healthcare technology, see clarion theme 4 on page 25.



“I have trouble thinking of risk in isolation. I think of risk in relation to benefits. A benefit is ‘a helpful or good effect, something intended to help.’”

—Randall Brockman, chief medical officer in the Office of Device Evaluation at FDA CDRH

Focusing on the Benefits of Healthcare Technology

Concerns about risks of healthcare technology can sometimes push its many benefits to the background. Summit participants want to see a better balance in focus between risks and benefits.

The FDA is on board with that. “Medical devices are critical to our nation’s health,” said summit presenter Randall Brockman, chief medical officer in the Office of Device Evaluation at FDA CDRH. “The number of devices we regulate is staggering, well into the millions.”

To quantify that point, Brockman cited the 48-million inpatient procedures made possible by healthcare technology—including 1.9 million arteriographs and angiocardiographs, 1.1 million cardiac catheterizations, 902,000 diagnostic ultrasounds, and 676,000 total knee replacements—according to Centers for Disease Control and Prevention data from 2009. By now, those figures undoubtedly are much higher.

The FDA is currently engaged in both pre- and postmarket initiatives with industry and other stakeholders that weigh both benefits and risks of healthcare technology, Brockman said. These efforts fit within the CDRH vision, which states: Patients in the U.S. have access to high-quality, safe, and effective medical devices of public health importance first in the world. That vision also articulates these goals:

- The United States is the world’s leader in regulatory science, medical device innovation and manufacturing, and radiation-emitting product safety.
- U.S. postmarket surveillance quickly identifies poorly performing devices, accurately characterizes real-world performance, and facilitates device approval or clearance.
- Devices are legally marketed in the United States and remain safe, effective, and of high quality.
- Consumers, patients, their caregivers, and providers have access to understandable science-based information about medical devices and use this information to make healthcare decisions.

CDRH’s 2014–15 strategic priorities toward these goals are as follows:

- Strengthen the clinical trial enterprise in the United States. A target to reduce median time to full, appropriate investigational device exemption (IDE) approval from 400+ days in fiscal year (FY) 2011 to 30 days in FY 2015 is within reach.
- Strike the right balance between pre- and postmarket data collection.
- Provide excellent customer service.

Achieving these goals, Brockman said, will require:

- The ability to accurately assess risks and weigh benefits and risks in pre- and postmarket regulatory situations
- Broad input from stakeholders to optimize benefit–risk assessments
- Communication of FDA approaches to help harmonize CDRH and industry expectations and minimize risk to the public when safety concerns arise

In addition to strengthening the clinical trial enterprise, Brockman cited other FDA premarket initiatives that aim to strike a better balance between risks and benefits:

- Innovation for novel devices
- The Expedited Access Pathway (EAP) program for medical devices that address unmet needs for life-threatening or irreversibly debilitating diseases or conditions
- Decisions for premarket approvals (PMAs), 510(k)s, IDEs, and de novo approvals for novel, low- to moderate-risk devices
- Pre- and postmarket data collection

On the postmarket side, “the goal of benefit–risk assessments is to minimize problems in the market,” Brockman said. To that end, the FDA is planning to enhance postmarket activities in partnership with stakeholders with a National Medical Device Evaluation System. In addition to current postmarket surveillance and reporting, the system would make use of “big data” from a variety of sources:

- Medical device registries, which are sponsored by industry, clinician, and other groups, to monitor the implementation and performance of specific medical devices
- A signal management process for identify-

ing, evaluating, and addressing new and unexpected risks associated with a medical device or group of devices

- Unique device identification
- Payer systems
- Electronic health records

The agency also plans to leverage its 2012 premarket benefit–risk guidance, *Factors to Consider When Making Benefit–Risk Determinations in Medical Device Premarket Approval and De Novo Classifications*, in the postmarket space, Brockman said.

The FDA's planned National Medical Device Evaluation System could help alleviate another challenge summit participants see: inadequate information about adverse events and near misses. Without this information, accurately identifying and effectively mitigating risks is difficult. More publicly available data would inform risk predictions and updates to the risk profiles of healthcare technology.

A related challenge is that HDOs, clinicians, and other healthcare professionals don't always have the incentive or time to report device issues. Streamlined, easy-to-use reporting systems could help alleviate that challenge—as could improved training, responsibility, and accountability for risk management throughout healthcare, as discussed in clarion theme 1. Summit participants also advocated for rewarding people who report near misses.

For more information on the FDA's plan for a National Medical Device Evaluation System, see clarion theme 4 and the November/December 2015 issue of AAMI's journal, *BI&T* (Vockley, 2015)

“There’s a built-in conflict of interest regarding safety. That is, to a great extent, the interests of patients, clinicians, healthcare institutions, and manufacturers converge in regard to safety. But the instant something goes wrong, those interests diverge, at least in the short term.”

—Al Taylor, associate director in the Office of Science and Engineering Laboratories at FDA CDRH



Cost–Benefit Analysis

THE LEARNED HAND RULE, TWO WAYS

Keynote speaker Jeff Natterman of The Johns Hopkins Hospital summarized the legal genesis of risk management, cost–benefit considerations, and their interpretation in healthcare today.

1. In *United States v. Carroll Towing Co.* (1947), Judge Learned Hand issued this precedent-setting cost–benefit analysis for determining negligence and liability:

Probability of harm (P)

Severity of harm (L)

Burden of adequate precautions (B)

$B < PL$

If the burden (cost) is less than the probability and severity of harm, then it is your duty to mitigate the risks.

2. Modern risk management as it is often practiced today puts a different twist on the calculation:

Probability of harm (P)

Severity of harm (L)

Benefit of adequate precautions (B)

$B > PL$

Does the benefit of mitigating risk outweigh the cost of doing so, given the probability and severity of harm?

Source: Jeff Natterman. “In the Matter of: Technology v. Risk Management.” Presented at the AAMI/FDA Risk Management Summit, Sept. 29–30, 2015.

However, this modern risk calculation misses a central tenet of ANSI/AAMI/ISO 14971, as Al Taylor, associate director in the Office of Science and Engineering Laboratories at FDA CDRH, pointed out. In the standard, reasonably foreseeable risks that are not broadly acceptable must be mitigated to the extent practicable (as far as possible). Then, the benefits of using a device are weighed against those risks for which no practicable mitigation could be identified. This reflects societal values concerning risk. Substantial risk is accepted to gain the benefit of things people want or need, but a harm that is reasonably foreseeable and preventable is never acceptable.



CLARION THEME 3

Adapt systems engineering principles, practices, and tools for risk management.



“One can only understand the safety and effectiveness of a product by considering how it interacts with the system implied by its intended use.”

—Al Taylor

Associate Director

Office of Science and Engineering Laboratories, FDA CDRH

Challenge	Priority Action	Accountable
Inconsistent rigor, efficacy, and efficiency in risk management processes	Learn from leading industries and innovators in healthcare that use systems engineering routinely and successfully to manage risk. Adapt the structure and discipline of systems engineering to meet the unique challenges and complexities of the medical device industry and HDOs.	Industry HDOs AAMI INCOSE
A “siloed” approach to risk management	Use systems engineering perspectives to develop a holistic view of the risks—including cybersecurity risks—of medical technology interacting with other systems in different healthcare environments and in different contexts. Develop a closed-loop system in which risk findings are used to improve medical technology safety and performance.	Industry HDOs
Inadequate communication, coordination, and consistency in risk management activities and decisions	Use systems engineering principles, practices, and tools to focus and optimize the risk management activities and decisions of multidisciplinary teams across organizational business units, departments, and specialties.	Industry HDOs

Why Add a Systems Engineering Approach to Risk Management?

Companies and HDOs compete on state-of-the-art healthcare technology. To keep patients safe, shouldn't they back that technology with state-of-the-art risk management?

Systems engineering is a well-established discipline that is underused for risk management of healthcare technology, and it could help solve key challenges identified by summit participants. Right now, risk management processes are uneven in rigor and focus. Absent robust thinking and protocols, risk identification amounts to unstructured brainstorming and guesswork. This might produce improbable “sharknado” scenarios, in the words of summit presenter Pat Baird, director of engineering at Baxter Healthcare. However, it won't necessarily identify all of the probable risks that can and should be mitigated.

Steven Badelt of Suttons Creek, Inc., underscored this point with levity, as shown in Figure 3. He characterized systems engineering as “the scientific method of engineering,” which provides sound methodology, practical tools, *and* a structure for productive interactions and multidisciplinary collaboration in risk management processes.

Risk management is sometimes practiced inconsistently, in silos, and with inadequate communication and coordination among organizational experts, divisions, and departments, summit participants said. That “siloed” approach to risk management—and the assumption that quality and safety can be

“We need to look at the complexity of combining products in different environments.”

—Jason Amaral, vice president of program management and systems engineering at Thoratec Corporation



“tested in” to healthcare technology—has made risk management and compliance with ANSI/AAMI/ISO 14971 appear to be a barrier and a cost, said summit presenter Michael Robkin, president of Anakena Solutions Inc. However, “if you solve problems early in the process, it's a lot cheaper than fixing them in the field,” he said.

“Why bother adding systems engineering to the toolbox?” asked summit presenter Jason Amaral, vice president of program management and systems engineering at Thoratec Corporation. First off, standards and guidelines now expect systems approaches to risk management, as shown in Figure 4. Quality System (QS) and Good Manufacturing Practices (GMP) regulations are based on systems engineering practices as well, Robkin added.

Just as relevant, the days of stand-alone medical devices have given way to healthcare technology systems. Amaral grounded his remarks with this example: A Thoratec left ventricular assist device is a power-intensive system with multiple components, including the implanted medical device; an external, wearable system with a small controller,

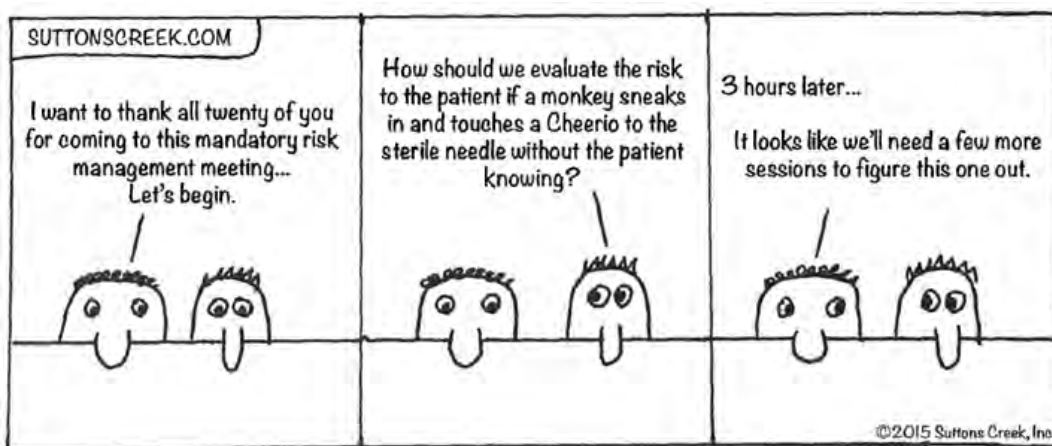
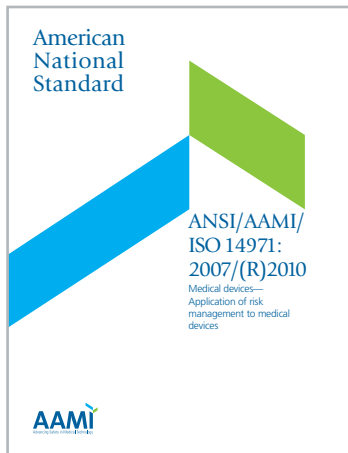


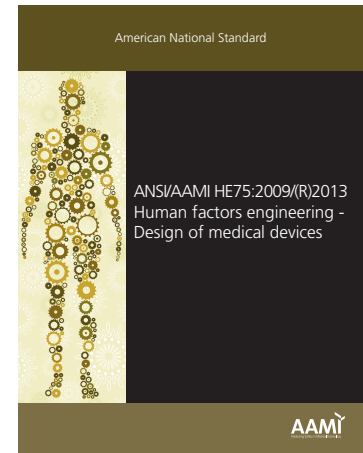
Figure 3. A lack of practicum to the point of panic. Source: Steven Badelt. “Learning from Other Industries.” Presented at the AAMI/FDA Risk Management Summit, Sept. 29–30, 2015.



“...to enable the early identification of hazards and hazardous situations in **complex medical devices and systems...**”



“...increasingly, medical devices are being combined with other equipment...to create **systems...**”



“...HFE areas of special importance relate to...the role of humans in **complex systems...**”

Figure 4. Standards approaches are systems-oriented. Source: Jason Amaral. “A Systems Engineering Approach to Risk Management.” Presented at the AAMI/FDA Risk Management Summit, Sept. 29–30, 2015.

driveline, and batteries; monitoring equipment; and battery chargers. Furthermore, “combining our device with others in a system creates complexity,” he said.

Amaral underscored that healthcare technology is complex and has many dimensions, including:

- The technology ecosystem, with healthcare technology—both medical and administrative—and consumer technology in the mix
- Multiple use environments, including clinical, nonclinical, and in-transit settings
- Diverse users with wide-ranging competencies, including clinicians, patients, and caregivers, and people of all ages
- Different geographies, from developed to developing countries
- Different time zones and distances to healthcare providers

While a systems approach to risk management is implicit in standards, guidelines, and regulations, “complexity creates implementation challenges,” to meet that expectation, Amaral said. A case in point: Electrical, mechanical, and ergonomics engineers and other experts each focus on

identifying risks of the components they know best, such as the electronics, functionality of parts, or human factors. He refers to this as a “divide-and-conquer” approach.

“Divide and conquer” makes the work tractable, in the sense that the discrete parts seem doable, but it does not go far enough. “How can you think about dividing the elements of risk apart and think of risk through different combinations?” Amaral asked. “Consider putting the elements into different environments, as well as changes in the environments. Don’t just think about dividing, but about combining things together.”

That’s where systems engineering can be particularly helpful. Indeed, this is what safety assurance cases—arguments for safety based on claims, evidence, and reasoning—are all about, and why the FDA has advised the infusion pump industry to use this model, according to Erin Keith, director, Division of Anesthesiology, General Hospital, Respiratory, Infection Control and Dental Devices in the Office of Device Evaluation at FDA CDRH.

Systems can produce “emergent properties,” or unanticipated behavior, which can introduce new risks—including cybersecurity risks,



which are a growing concern in healthcare as in other industries, Amaral said. Systems engineering supports a holistic approach that takes into account emergent safety risks—and can foster safety as a desirable emergent system property as well. Systems engineering tools can help risk managers:

- Focus on interfaces and interdependencies
- Consider diverse users, environments, use cases, and system components
- Evaluate dynamic change and human/machine controls
- Focus on architecture and appropriate system decomposition
- Determine technology readiness levels and appropriate program timeline commitments
- Manage configuration and system integration

Robkin of Anakena Solutions highlighted the organizational benefits of systems engineering, which he defined as “a cross-industry, interdisciplinary, universal, and all-inclusive methodology meant to provide technical and managerial discipline to a project wherever and whenever it is found lacking. The methodology intends to strongly persuade and bring about a *determined* plan of action for establishing accountability, order, logic, and coordination wherever and whenever it is needed throughout an entire project life cycle—resulting in the project’s end product, system, or service successfully meeting the customers’ expectations and fulfilling formalized need statements.”

A systems approach to the design, development, implementation, and use of healthcare technology empowers organizations to identify and solve problems, Robkin said:

- **Systems thinking** ensures that the entire system is included in the problem
 - Ask the right questions
- **Systems analysis** helps to break down the problem into its components
 - Find the simplest correct answer
- **Systems engineering** helps to manage complexity through processes and feedback
 - Deliver the right solution

He shared an example of a hazard and risk analysis of a “simple” device interface (Figure 5) that has multiple systems and hazard and risk analyses (Figure 6).

Systems engineering brings together

“Successful risk analysis begins first with a rigorous, structured process for risk identification. The application of this process has improved risk identification rates by a factor of 10.”

—Steven Badelt, managing partner at Suttons Creek, Inc., and industry ambassador for INCOSE

multiple engineering and management disciplines, and it adds value to existing standards and techniques, Robkin said. With a systems approach, risk management is more than compliance with ANSI/AAMI/ISO 14971. Quality management is more than compliance with ANSI/AAMI/ISO 13485:2003, *Medical devices – Quality management systems – Requirements for regulatory purposes*. Safety and effectiveness are more than compliance with the IEC 60601, *Medical electrical equipment*, series of standards for basic safety and essential performance.

Learning from Other Industries

Risk management is a core discipline of systems engineering that has long been practiced—and practiced comprehensively—in high-risk industries outside of healthcare and healthcare technology. In the Federal Aviation Administration, Badelt said, risk management is integrated horizontally and vertically into every phase of a product’s life cycle, including:

- Conception
- Integrated technical planning
- Requirements management
- Functional analysis
- Synthesis with regulations, standards, legacy systems, and other technology

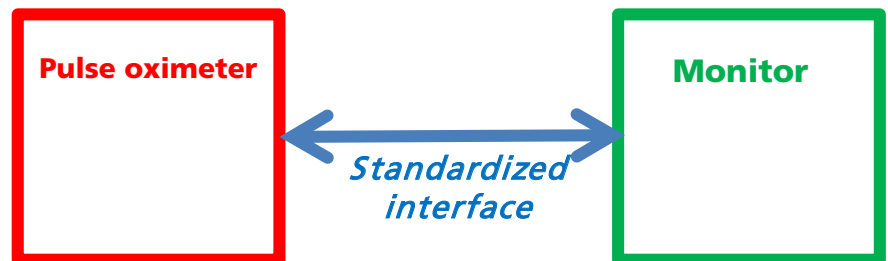


Figure 5. Two medical devices: What is the system? Source: Michael Robkin. “A Systems Engineering Approach to Risk Management.” Presented at the AAMI/FDA Risk Management Summit, Sept. 29–30, 2015.

“Medical technology focuses on hazards and how they affect risk management. I encourage you to expand your scope on that.”

—Laurie Wiggins, CEO and founder of Sysenex

- Interface management
- Specialty engineering
- Validation
- Verification
- Life cycle engineering
- Maintenance

Healthcare can learn from other industries, where prioritizing the likelihood and consequences of risk is similar in focus to healthcare technology, as shown in Figure 7 with a risk matrix and Figure 8 with “risk

triplets,” both from the National Aeronautics and Space Administration (NASA). Risk triplets are *accident scenarios* involving hazards, associated *frequencies*, and associated adverse *consequences*.

“Risk management in healthcare is narrowly focused on safety and efficacy,” Badelt said. That’s problematic. According to NASA, technical risk management alone is much broader:

- “Risk is defined as the combination of (1) the probability that a program or project will *experience an undesired event* and (2) the consequences, impact, or severity of the undesired event, were it to occur.
- The undesired event might come from technical or programmatic sources (e.g., a cost overrun, schedule slippage, safety mishap, health problem, malicious activities, environmental impact, or failure

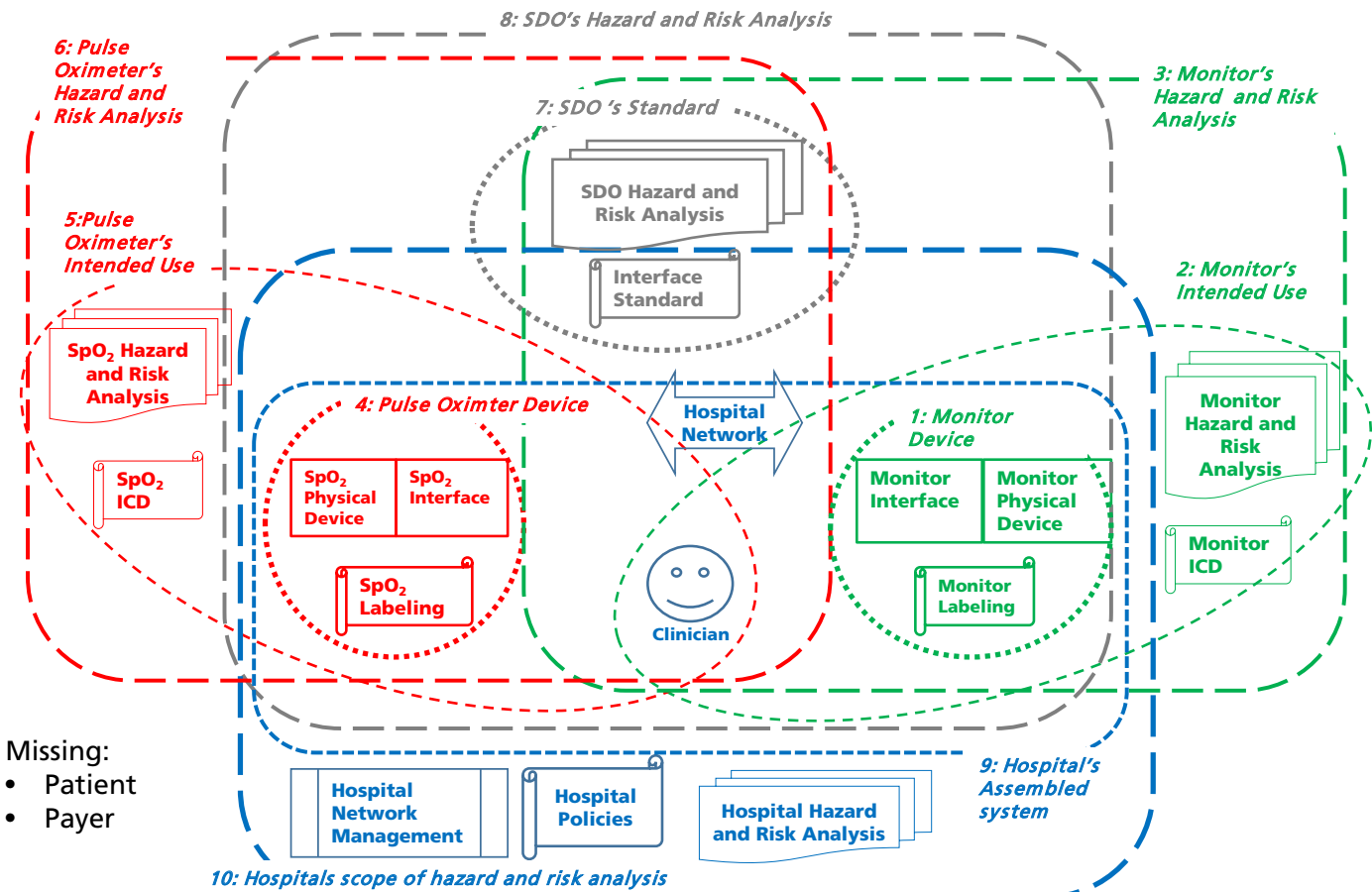


Figure 6. A standards developing organization's hazard and risk analysis of a pulse oximeter connected to a monitor in a hospital. Source: Michael Robkin. “A Systems Engineering Approach to Risk Management.” Presented at the AAMI/FDA Risk Management Summit, Sept. 29–30, 2015.

What Is a System? (And Other Head-Scratching Topics)

The FDA's Al Taylor is a regulator. He also is an engineer, and he spoke with that hat on to clarify points of confusion about risk management from a systems engineering perspective.

First, what is a system? According to the ISO 9000:2005 definition, "a system is a set of interrelated or interacting elements." But Taylor emphasized that "medical devices do not operate in a vacuum—a device needs an environment."

Next, from a legal and regulatory perspective, manufacturers need to answer two questions about their products:

- Is my product a "device" under the law?
- Is the device reasonably safe and effective in clinical use?

From an engineering perspective, the questions are a bit different:

- Has my design ensured that, to the extent foreseeable and practicable:
 - risks are mitigated to an acceptable level?
 - the product will consistently perform as intended in the intended use environment?

Assessing the safety and performance of a product necessitates examining the safety and performance of the *de facto* system. "Every intended use of a product has a context," Taylor said. "Elements within that context of use that interact with the product constitute a system. You have to consider how your product interacts with all the elements that surround it."

to achieve a needed scientific or technological objective or success criterion).

- The concept of "value of information" is central to making the determination of what analysis is appropriate and to what extent uncertainty needs to be quantified."

Risk-informed decision analysis occurs throughout the continuous cycle of technical risk management—identifying, analyzing risk, planning, tracking, and controlling risk, Badelt said. Similar comprehensive risk management occurs in the defense industry. Other industries also use physical modeling, functional modeling, and use cases to analyze risk.

Important differences do exist between healthcare technology and other industries, Badelt noted. The defense industry, for example, follows a top-down process, with the prime contractor driving requirements and specifying how technical program processes, including risk, are managed. In healthcare, manufacturers drive the requirements and risk management processes, which are communicated only to regulators. Menson

noted that ANSI/AAMI/ISO 14971 does require that, "for residual risks that are acceptable, the manufacturer shall decide which residual risks to disclose and what information is necessary to include in the accompanying documents in order to disclose residual risk." In practice, manufacturers do this in their instructions for use.

Summit participants elaborated on the ways in which healthcare and healthcare technology are different from other industries. A sampling of the remarks:

- The aviation, space, defense, and nuclear power industries face the potential of massive-scale disasters. "An accident that can kill hundreds or thousands of people is different than the situation most of us are dealing with in medical devices," one summit participant said.
- "Every single care area in every single hospital is its own system," said another. "There aren't 40,000 different systems in a power plant."
- Highly trained professionals fly airplanes and spaceships and operate nuclear power plants. The skill sets of people who use

“We’re not so different, you and I.”

—Steven Badelt, managing partner at Suttons Creek, Inc., and industry ambassador for INCOSE

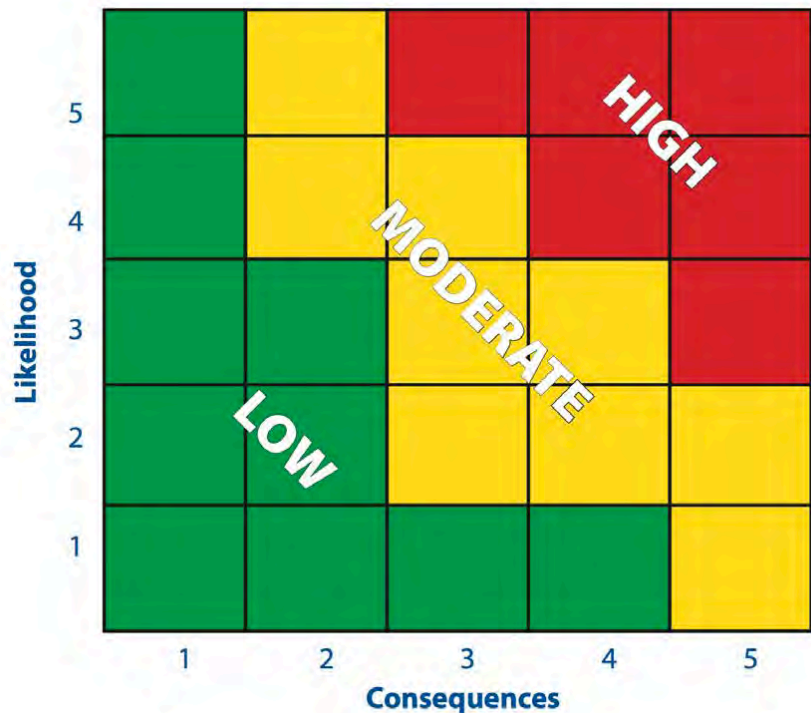


Figure 7. NASA risk matrix. Source: NASA and Steven Badelt. “Learning from Other Industries.” Presented at the AAMI/FDA Risk Management Summit, Sept. 29–30, 2015.

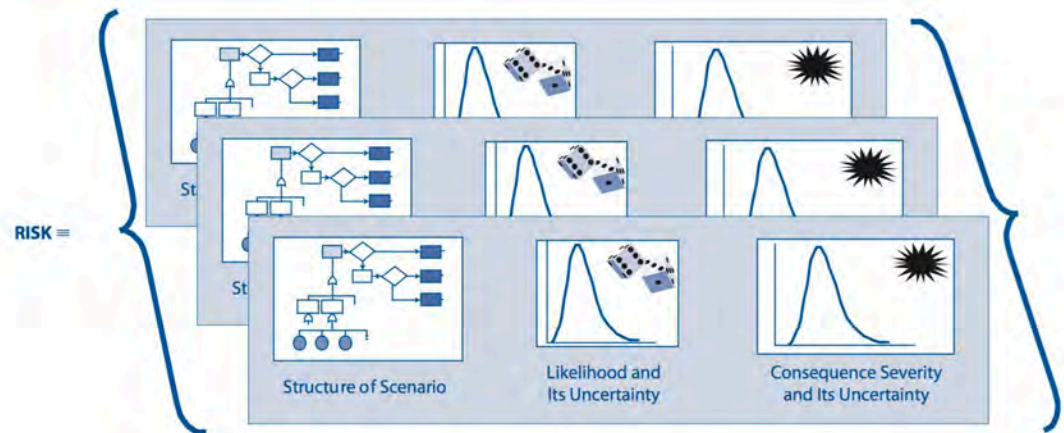


Figure 8. NASA risk triplets. Source: NASA and Steven Badelt. “Learning from Other Industries.” Presented at the AAMI/FDA Risk Management Summit, Sept. 29–30, 2015.

healthcare technology are extraordinarily diverse, with experts and nonexperts alike at the controls.

- “It’s discouraging to do risk management for mobile apps,” one summit participant said.
- “Scaling this great body of knowledge from larger industries with lots of money in a way that will work for small companies,” would be worthwhile, said another.

Despite the industry differences, summit presenters and participants agreed that there are important takeaways from other industries that could, and should, be adapted to healthcare and healthcare technology.

Learning from Another Industry’s Failures

Laurie Wiggins, CEO and founder of Sysenex and a member of the INCOSE risk

management working group, offered a counterpoint perspective on learning from another industry, aerospace: It's not perfect, but its failures are instructive, because they correspond to challenges with healthcare technology.

- **Waiting is expensive.** The aerospace industry faces an increasing trend of cost and timeline overruns and performance problems. Addressing risks late in development (rather than early on) is expensive—300% to 500%+ more expensive—and time-consuming.
- **Risk management processes aren't effective enough.** An industry survey found that although 75% of organizations surveyed have a risk management process in place, 51% of them reported a risk-related loss or failure.
- **No one is pushing the “equals key.”** Different groups within an organization address different risks—technical, safety, financial/business, strategic—but no one is summing them all up. That skews decision-making processes, and organizations don't know how much risk they actually have.
- **Risk management is subjective.** The information and opinions of those at the highest levels and with the biggest voices often take priority.
- **Standards say “what” to do but not “how” to do it.** Organizations are on their own in carrying out risk management processes.
- **Risk identification methods are ad hoc, not comprehensive.** The industry survey found that 83% of organizations rely on personal experience and 67% use brainstorming to identify risks, compared with 41% that report using probabilistic risk assessment, a comprehensive and systematic analysis tool.
- **Not much help is available.** Of more than 50 commercially available risk management tools, none of them identify risk, according to a Systex/George Mason University study.

To size up the problems more carefully, Sysenex culled through hundreds of programs and analyzed their risks and outcomes. A set of common risks and common underlying program problems emerged—despite having many faces depending on a specific product or service. The risks are grouped into six areas, as shown in Figure 9. Notably, while current risk identification focuses on technical risks,

risks actually can be found throughout organizations and externally.

“This is an innovation,” Wiggins said. “These common risks can be used to diagnose as-yet-unidentified program problem.” Sysenex has developed a web-based software tool, Program Risk ID, that can be used to identify risks of one program with trending over time or across many programs to compare risk across programs.

218 Risks in Six Areas

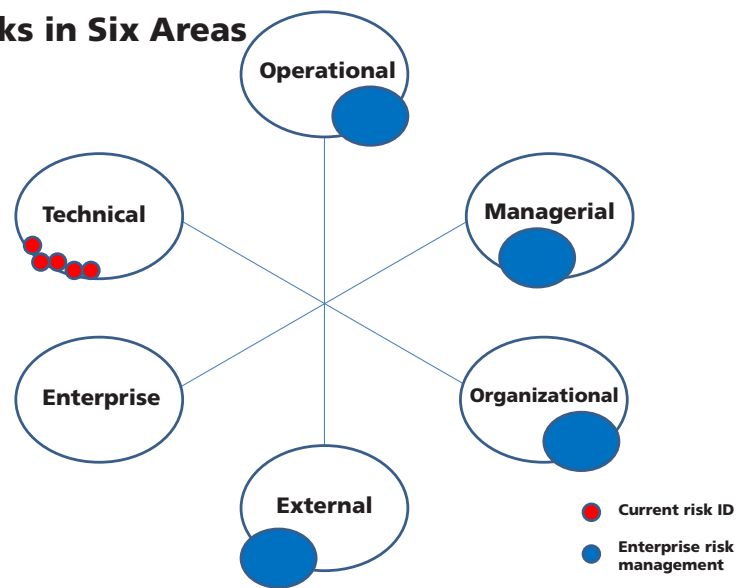


Figure 9. Radical risk identification. Source: Laurie Wiggins. “Radical Risk Identification: Moving Risk Management into the 21st Century.” Presented at the AAMI/FDA Risk Management Summit, Sept. 29–30, 2015.

LEARNING FROM LEAD INNOVATORS

Philips Healthcare Applies Decision Analysis, a Systems Engineering Tool, to Mitigate Risk



“The act of a recall itself can introduce risk to patients.”

—Greg Lancaster, senior reliability engineer at Philips Healthcare

Philips Healthcare took an unconventional approach to gain compelling insights into postmarket risk associated with an automated external defibrillator (AED), a device that treats sudden cardiac arrest by delivering a shock to the chest to restore heartbeat. A component of the device had a low failure rate, but a failure could be deadly. “An AED can sit dormant for many years, but when it’s needed, it must work,” said Greg Lancaster, senior reliability engineer at Philips Healthcare. The risk was discovered during periodic diagnostic tests of the devices by a fraction of customers. Sometimes, however, the diagnostic tests did not detect the problem.

Philips identified two options to mitigate the risk:

- Replace the component with a higher reliability component
- Change the software to better detect the defect

With more than 500,000 AEDs deployed worldwide, Philips determined that physically retrieving the devices to replace the component could introduce risk to patients.

The best practice approach to risk management is to use a risk matrix to assess the severity and probability of harm occurring. Risk matrices might be easy to understand, but descriptions of probability can be qualitative and subjective, Lancaster said, and lead to arbitrary decisions. Risk matrices also don’t take into account the full range of factors relevant to patient outcomes, which include clinical severity of device failure, user behavior, reliability, failure effect, and device design mitigations.

To take all of those factors into account, Philips used decision analysis, a systems engineering approach, to inform its decision. Decision analysis clearly frames the decision, includes the full range of factors relevant to patient outcomes—not just device failure. Philips used mathematical models to simulate the effects of alternative courses of actions to patient outcomes, quantify outcomes in terms of standard units of health risk, and assess uncertainty factors. The mathematical models included an event tree, Markov model, influence diagram, and fault tree.

Decision analysis represents a change from traditional methods of defining acceptable risk thresholds to modeling alternative actions, which can be a challenge in terms of becoming familiar with new techniques, obtaining probability assessments from engineers and clinical experts, and incorporating cost when valuing patient outcomes. But model analysis can focus attention where further data are needed, which requires input and review from systems, design, and reliability engineers, clinician specialists, and quality and regulatory experts.

CLARION THEME 4

Engage in a total life cycle approach to risk management of healthcare technology, which is required for *effectively* managing risk.

“The risk management life cycle is a continuum that doesn’t stop.”

—Tina Krenc
Director, Quality Assurance
Abbott Medical Optics



Challenge	Priority Action	Accountable
Outdated regulations for risk management of medical devices	Modernize the regulatory approach to make use of risk management standards, essential requirements, and conformity assessment. Take a risk-based approach to compliance and enforcement, using a tiered response based on the level of potential risk of the device.	FDA
Inadequate focus on risk management throughout the product life cycle	Use ANSI/AAMI/ISO 14971, <i>Medical devices—Application of risk management to medical devices</i> , to identify the hazards of medical devices, estimate and evaluate the associated risks, control the risks, and monitor the effectiveness of the controls for all stages of their life cycle.	Industry HDOs
Lack of transparency about pre- and postmarket risk management expectations	Complete works in progress with clarifications and guidance on pre- and postmarket requirements.	FDA
	Leverage the postmarket risk initiative in development now.	FDA AAMI Industry
Complexity and confusion over multiple, different forms companies use to notify HDOs of product recalls	Create a standardized recall notification form.	AAMI

“Management owns the quality system. Risk management should be incorporated across the entire life cycle of healthcare technology and into the quality system.”

—Summit participant

Life Cycle Risk Management: Regulations and Reality

Regulations, standards, and guidance documents call for risk management to occur throughout all phases of the healthcare technology life cycle, from initial conception to final decommissioning and disposal, and throughout the quality management system, as discussed in clarion theme 2.

However, it is still common practice for manufacturers to assume that failure modes and effects analysis (FMEA) is the be-all and end-all in the implementation of quality and risk management principles. Risk analysis is too often conducted as a “one-and-done” activity to meet regulatory requirements for premarket approval or clearance.

Linking postproduction information back into premarket risk assessment sometimes falls apart as well. Postmarket activities—collecting and analyzing data, reporting any issues, and taking any necessary corrective or preventive actions—do not always use all available information about performance of medical devices in the field to reassess risk and improve device design, safety, and quality. Without a closed-loop system that leverages postmarket information for continual improvement, risk analysis and postmarket monitoring are proxies for risk management. But these are just parts of a comprehensive system.

The FDA’s Melissa Torres noted that the GHTF risk management guidance document describes four phases of risk management activities:

- **Phase 1:** Determining levels of risk that would be acceptable for the device (risk acceptability criteria)
- **Phase 2:** Identifying hazards that may occur due to characteristics or properties of the device during normal use or foreseeable misuse (risk analysis)
- **Phase 3:** Comparing estimated risks with the risk acceptability criteria (risk evaluation)
- **Phase 4:** Risk control and monitoring activities (risk control/production and postproduction information)

Although the product regulations, standards, and guidance apply to manufacturers, similar shortcomings in managing risks are common in healthcare delivery, summit

presenters and participants said. For example, risk analysis takes place with implementations of new healthcare technology but does not necessarily continue as changes in systems and the environment of use occur. Summit presenter Tina Krenc, director of quality assurance for Abbott Medical Optics, listed changes that can affect the risk profile of healthcare technology after it’s in the market:

- Intended design changes (including packaging and labeling)
- Manufacturing process changes
- Manufacturing material changes
- Transportation route changes
- Supplier changes
- Change in intended use
- Change in intended users
- Change in clinical workflow or policies
- Software bug fixes
- Field service actions
- Removal of product from field

In the current state of practice, “risk management and risk decisions are totally disjointed” in the product life cycle, Krenc said. There’s no integration of risk-related activities and decisions, including FMEA for products and processes, manufacturing failure risk assessments, customer complaint risk assessments, and audit, supplier, and resource decisions.

“The worst-case scenario is where the quality system is totally disconnected from the risk management process,” said Krenc, who also teaches a risk management course at Northwestern University and at AAMI and is a member of the ISO Joint Working Group responsible for ISO 14971. “The best state is where risk management is the bigger picture and the quality system fits within it. All decisions are based on understanding safety of the product and of patients.” Krenc shared methods within the quality system to support risk-based changes:

- Identifying, linking, and maintaining essential design outputs through risk management activities
- Maintaining risk management files with production and postproduction information
- Understanding and managing suppliers as holders of many essential design outputs

Krenc offered this advice for effective life cycle risk management:

- Use all sources of data, including original risk management files, as a starting point for decisions during production or postproduction, such as:
 - Failures (deficiencies)
 - Harms (medical device reporting)
 - Hazardous situations (supplier CAPA, nonconformances or deficiencies)
 - CAPA
- Use the same decision makers or functional areas throughout the product life cycle/quality system
- Communicate, communicate, communicate

Steven Badelt of Suttons Creek, Inc., provided a succinct representation of continuous risk management from NASA, as shown in Figure 10.



Figure 10. Continuous risk management. NASA and Steven Badelt. “Learning from Other Industries.” Presented at the AAMI/FDA Risk Management Summit, Sept. 29–30, 2015

Applying Disciplined Thinking to Life Cycle Risk Management

To understand the shortcomings of life cycle risk management, Pat Baird, director of engineering at Baxter Healthcare, applied risk management tools to examine the risk management process itself. “Any process can fail, including risk management,” he said.

Fault tree analysis is one method used to determine how things can fail. He used this tool (illustrated in Figure 11) to show that the risk management process can fail if it is incorrect, incomplete, or ineffective.

LEARNING FROM LEAD INNOVATORS

Boston Scientific’s Quality Journey

Boston Scientific Corporation (BSC) has undergone a dramatic shift in quality performance, including risk management, since receiving a corporate warning letter from the FDA in 2006, according to summit presenter Kristen Hastings, quality systems manager for global design controls and risk management at the company.

“Risk management must be considered a thought process, not just a bunch of tasks to complete.”

—Kristen Hastings, quality systems manager for global design controls and risk management at Boston Scientific Corporation



Through Project Horizon, the company has built a quality system with world-class compliance and effectiveness and continues its journey toward efficiency and continuous improvement, Hastings said. The initiative has entailed a “Best 4” approach to quality:

1. Compliance

- Evidence of risk reduction during design process
- Documentation of product risk acceptability

2. Outcomes

- A “One BSC” scaled system to meet all product complexities and business models
- Consistent decision making across similar product types

3. Efficiency

- Safety risk input to design configuration
- Process flexibility for product risk benefit, with low, medium, and high risks assessed for three levels of product complexity (simple, normal, and complex)
- Capability to leverage documentation and reduce rework
- Increased risk knowledge and competence

4. Agility

- Easier to integrate new technologies and acquisitions
- Alignment within related quality system processes such as CAPA and complaint handling

The company has shifted its thinking about risk, from reacting to product issues in the field to considering “what happens” when things go wrong—in other words, analyzing the risk of failures for design. Now, it is beginning to use risk information during design and development to ask “how can” questions: How can we design products to reduce risk? “Risk management can be the cornerstone of design control,” Hastings said. Boston Scientific’s quality journey required a culture change, with overlapping risk assessment, risk communication, and risk management and decision-making processes.

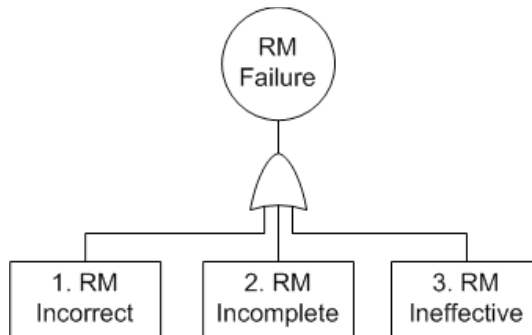


Figure 11. Fault tree of risk management (RM) failure. Source: Pat Baird. “Life Cycle Risk Management.” Presented at the AAMI/FDA Risk Management Summit, Sept. 29–30, 2015.

Baird pushed the major failure modes of incorrect, incomplete, and ineffective risk management processes through each of six major product stages (design, verification and validation, design transfer to manufacturing, production, monitoring, and change management) to develop a scorecard to assess the correctness, completeness, and effectiveness risk management throughout the product lifecycle. Baird also suggested using another standard risk management method, an FMEA, to determine shortcomings in ANSI/AAMI/ISO 14971 itself.

Finally, Baird shared eight common myths and misunderstandings about risk management from his experience in the field.

Special Challenges and Complexities in Managing Life Cycle Risk

Several summit presenters honed in on the challenges of managing risk at different stages of the product life cycle, for specific types of devices, and for software. Here’s a roundup of the remarks:

Design Changes

The QS regulation (21 CFR 820.30[i]) addresses manufacturer requirements for design changes. Summit presenter Lorie Erikson, consumer safety officer for the Cardiovascular Devices Branch in the Office of Compliance, Division of Manufacturing and Quality, at FDA CDRH, cited these relevant passages:

“Each manufacturer shall establish and maintain procedures for the identification, documentation, validation or where appropriate verification, review, and approval of design changes before their implementation.”

Documentation of design changes creates a history of the evolution of the device’s design, which is invaluable to failure investigations, invaluable to the design of similar products in the future, and prevents repetition of errors during design activities (preamble comment 87).

Product development is inherently an evolutionary process, by which change is healthy and necessary, quality is ensured when change is controlled and documented throughout the process, and change is appropriate for the device’s design (preamble comment 88).

What Does “Incorrect” Risk Management Mean?

Incorrect risk management is that from which the results are not as they should be. Examples include:

- Data sources used are not the best ones available.
- An analysis has an incorrect conclusion.
- An issue in the production environment.

What Does “Incomplete” Risk Management Mean?

Incomplete risk management is that which might be correct but is not complete. Examples include:

- Missing information (e.g., some hazards have been identified, but not all).
- Risk controls are not traced to design and verification.
- The postmarket monitoring system is not using all data sources available.

What Does “Ineffective” Risk Management Mean?

Ineffective risk management is that which might be correct and complete but is not effective in performing proper risk reduction. Examples include:

- A design that has not reduced the risk to an acceptable level.
- An implementation is not as effective as originally anticipated.
- Failure to take action (e.g., not acting on a postmarket trigger).

“Risk management is all about Murphy’s law. Anything that can go wrong will go wrong.”

—Pat Baird, director of engineering at Baxter Healthcare

“There’s an underlying theme—controls need to be in place during the design process,” Erikson said, and all design changes after initial FDA review must be documented. Why? Because design changes can introduce risk, in terms of improper device performance/function, introduction of an unsafe device for use, or introduction of an ineffective device for use.

From the FDA perspective, manufacturers encounter special challenges managing design changes associated with purchased products, accessories to devices, and how a device is used over time, which Erikson referred to as “use evolution.” In one instance, a device change created incompatibility with device accessories—the result of a lack of communication during the device modification, she said.

Postmarket Changes

In addition to design, process, and labeling changes by manufacturers, external changes can affect risk at any stage of the product life cycle, according to summit presenter Weiping Zhong, director of risk management at GE Healthcare. For example, new findings about changes in the use environment; regulations, policy, standards, including the good clinical practice quality standard; and science and technology could require a fresh look at risks.

Zhong shared a case study about the evolving change in premarket assessed probability of risk with a single-use lancing device (i.e., an in vitro diagnostic product). Before the product was marketed, the company identified the risk of blood-borne diseases if the lancet were to be reused on multiple patients. This risk, assessed as serious in severity with a medium probability, was mitigated with labeling in the user manual stating that the lancet was intended for single use only and that only the specified lancet should be used for the diagnostic purpose. This reduced the premarket assessed probability of risk to low and the risk to acceptable after mitigations.

Postmarket information, however, revealed that single-use lancets were being used on multiple patients, Zhong said. Based on this information, the postmarket risk analysis indicated that the probability of risk had changed from low to high—an unacceptable

Eight Common Myths and Misunderstandings about Risk Management

1. **Myth:** FMEA is our risk management file.
2. **Misunderstanding:** hazard, hazardous situation, harm
3. **Misunderstanding:** mitigating “sharknado” scenarios
4. **Misunderstanding:** implementing but not validating
5. **Myth:** postmarket surveillance = complaint handling
6. **Myth:** Investigation is not needed unless the device is returned.
7. **Misunderstanding:** Complaints tell the whole story.
8. **Myth:** Users are responsible for use error (not design).

Source: Pat Baird. “Life Cycle Risk Management.” Presented at the AAMI/FDA Risk Management Summit, Sept. 29–30, 2015. From the spring 2015 issue of AAMI *Horizons* (Caines et al., 2015).

conclusion. By law, that required new risk mitigations. The company added a new sticker on the device with the message: “Do Not Use on More Than One Patient.” The labeling also included a fill-in-the-blank line, “User Name,” to discourage reuse. This reduced the postmarket assessed probability of risk back to low and the risk to acceptable after mitigations.

Further along in the life cycle of the lancet, new information and regulations prompted another update to the postmarket risk assessment. “The reality is that some devices, such as lancets, are used on multiple patients, particularly in assisted-living facilities, even though that is not an approved use,” Zhong said. In addition, new regulations called for single-use-only devices for assisted-care settings. Multiple-use devices had to adhere to reprocessing requirements, including demonstrated validation and verification of cleaning and disinfection of products between uses. Recognizing that labeling changes would be inadequate to mitigate the risks and that reprocessing requirements would be complex, the company decided on design changes to make the lancet a disposable product that could be used only once.

“Changes can happen at any stage in the healthcare technology life cycle. Postmarket risk assessments are required when there are elevated or new risks.”

—Weiping Zhong, director of risk management at GE Healthcare

Lessons learned for postmarket risk mitigation: Design changes are the most effective, whereas labeling is the least effective, according to Zhong. Protective mitigations are an option as well. He recommended these methodologies to manage postmarket risk:

- Reevaluate severity, probability, and acceptability of risk
- Consider:
 - Clinical uses, particularly if they deviate from intended uses
 - Changes in regulations
 - *Risk Principles and Medical Devices: A Postmarket Perspective*, a 2015 white paper developed by AAMI and the FDA, which outlines six risk principles and 60+ risk factors. (For more on this paper, see page 32.)
- Make sure decisions on changes encompass mitigations, increased risks, reduced risks, and compliance

Software Changes

“Software continues to be a growing challenge, not only in medical devices but in many industries,” said summit presenter Donna Haire, vice president and head of medical care global regulatory affairs at Bayer HealthCare. That’s because software is different than other products, and it needs to be treated differently.

Software challenges begin in product development, which typically is done sequentially—developing and then evaluating the first phase, the second phase, and so on, which Haire termed “the waterfall method.” Software development might not occur until later in the design process. It should be done in parallel with product development, and software risks should be as rigorously evaluated as electromechanical risks, for example.

Healthcare technology makes use of common operating systems such as Windows, iOS, and Android, proprietary software, and other software for necessary functionality, such as antivirus software. Keeping that software up to date provides benefits, such as enhanced cybersecurity safeguards, the latest antivirus protections, and bug fixes. But postmarket software changes, which typically occur more frequently than other product changes, also can introduce risks that must be managed.

Pre- and postmarket challenges require added flexibility (an “agile” approach) during software development processes, Haire said (see also: AAMI TIR45:2012, *Guidance on the use of agile practices in the development of medical device software*). In addition, it’s not always clear whether postmarket software changes need regulatory approval.

The FDA has responded to that challenge with *Proposed Guidance for Industry and FDA Staff: Deciding When to Submit a 510(k) for a Software Change to an Existing Device*. This guidance uses a risk-based approach, addressing new hazardous situations, risk control, and modifications to risk controls. The FDA’s *Guidance for Industry: Cybersecurity for Networked Medical Devices Containing Off-The-Shelf (OTS) Software* also addresses when cybersecurity patches do and do not need regulatory approval.

Still, managing software changes remains challenging, largely because there’s inadequate assessment and distinction between low-risk or no-risk changes and high-risk changes. Haire posed these questions:

- How can postmarket software defects/anomalies be effectively assessed?
 - No risk or low risk/acceptable risk to health (i.e., device system crash at startup)
 - High risk/unacceptable risk to health (i.e., device system crash during procedure)
 - May not manifest itself or be visible to the end user (i.e., device service log not recording data)
- Is a field corrective action necessary for nonsafety or low-risk (acceptable risk to health) software defect/anomaly?
- When field corrective action is needed, how best to implement?
 - Implementation method (options?)
 - Implementation timing (options?)

“Postmarket software anomalies are one of the greatest challenges we have in industry,” Haire said. “A significant number of firms’ field corrective actions are associated with software changes that are low risk or no risk. We have to assess the risks on a case-by-case basis. One size doesn’t fit all.” She advocated for using a risk-based approach with streamlined processes and regulations specific to the evaluation of postmarket software anomalies and defects, especially those

deemed low risk or no risk to public health. That would include addressing software verification and validation limitations.

Special Challenges: Changes to Combination Products

Postmarket changes to medical devices that combine with drugs and/or biologics, known as combination products, pose special challenges, according to summit presenter Lee Leichter, president, P/L Biomedical. “Drugs, devices, and biologics are distinct products with distinct functions that have more differences than similarities,” he said.

Chief among the differences is the tolerance for change for drugs and devices, Leichter said. For pharmaceuticals, change is feared; companies want to bring any deviations back into compliance. For medical devices, change tends to be considered innovative and beneficial. “Pharmaceutical companies are predicated on change prevention,” he said. “Medical devices are predicated on continued improvement.” Thus, there’s a tension in “risk tolerance,” exemplified in the risk scenarios such as complaints or failures that will be tolerated before companies take the business risk to make changes.

In addition, two companies might be involved in combination products: one responsible for risks associated with drugs and the other for risks associated with devices. “Risk is owned by the drug company, but risk assessment and risk management are primarily on the device company,” Leichter said. The companies also abide by different standards and regulations. “The patient risk gets lost” as companies try to assess the different regulatory and other risks, he said. Coming to agreement on whether changes to combination products are necessary can be difficult. So, too, is determining whether drug or device changes are minor or not. Securing regulatory approval for major changes is a costly process, which could involve clinical trials, he said.

Patient-focused risk management is an effective tool for managing risks in both drug and device areas, Leichter said. At the same time, it can be difficult to ascertain the root cause of complaints or failures, which complicates decisions on whether risk mitigation should address the drug or the device that delivers the drug.

A Life Cycle Approach to Regulating Healthcare Technology

Reflecting best practices in risk management, the CDRH Office of In Vitro Diagnostics and Radiological Health (OIR) “is one of the few offices in FDA that actually looks at products from a total product life cycle perspective,” said summit presenter Jean Cooper, associate director of OIR. OIR has made a deliberate effort over more than a decade to integrate work on premarket submissions, postmarket surveillance, and compliance activities.

“Cybersecurity is critical, yet we have to rely on hospitals and their security systems to protect us. Having access to our systems is predicated on their security systems. We can’t control how the medical device industry interfaces with health systems. Who owns cybersecurity?”

—Summit participant

In practice, that means that OIR staff have learned to look at risks and benefits across the life cycle of healthcare technology. Most OIR staffers in that office work in two of the three major areas of FDA oversight; elsewhere in CDRH, regulators specialize in just one area. Cooper summarized the FDA’s risk management expectations at key points in the medical device life cycle from that unusual vantage point.

Premarket assessments of risk management processes

Supports design specifications, validation, and verification for 510(k), PMA, HDE, de novo, and IDE submissions

Indirect assessment

- Adequacy of the acceptability criteria
- Adequacy of hazard identification
- Adequacy of mitigations/control measures

Direct assessment

- Risk management documentation in a subset of submission pathways

Risk management documentation in premarket submissions

- Special 510(k): Partial risk analysis
- Special controls that require risk analysis
- Other examples (safety assurance case for infusion pumps)
- Rates of erroneous results with in vitro diagnostics

- De novo guidance requests risk analysis
- For PMAs, 30-day notices for changes in manufacturing process or methods that affect safety or effectiveness
- Original PMAs

PMA and risk management

- Postmarket staff in the CDRH Office of Compliance (OC) and OIR perform reviews of manufacturing procedures and processes, including 21 CFR 820
- ODE/OIR (premarket) review benefit and risk per the intended use

PMA and benefit–risk review

Worksheet for benefit–risk determinations:

- Assessment of benefits of device
- Assessment of risks of device
- Additional factors in assessing probable benefits and probable risks of devices
- Do the probable benefits outweigh the probable risks?

Assessment of risk management processes during inspection

- Design controls 21 CFR 820.30
 - Assessment of risk analysis procedures and activities throughout the design and development process
 - Investigators do not assess the substantial equivalence/safety and effectiveness
 - CAPA
 - Assessment of CAPA procedures for conducting failure investigations and the linkage to the risk analysis process
 - Assessment of the rationale for determining the need for CAPA, including linking the decision-making process to the risk analysis
- Risk-based decisions
- Implementation of procedures

Cooper also pointed out that risk management is very useful in determining if a device meets the predetermined acceptability criteria or not at any point in the product life cycle. “However,” she said, speaking about the benefits of medical devices, “continued marketing of a given manufactured lot of medical devices is not always as clean as ‘acceptable or not.’ This is particularly true when determining what is best for the patient in the postmarket phase of the life

cycle. The classic example would be a recall situation that could result in a shortage. In this case, removing the product from the marketplace may cause more harm than having access to nonconforming product.”

That scenario of changes in risk underscores the need to update the risk assessment throughout the life cycle of a medical product. “The determination of what is acceptable theoretically would allow for a range in the final device performance,” she said.

CDRH and Industry Collaboration on a Postmarket Risk Framework

In the midst of a unique FDA CDRH–industry initiative aimed at developing a proposed, common risk–benefit decision-making framework to assess risks and benefits in postmarket compliance situations, a summit panel provided updates and perspectives on the work to date. AAMI is the neutral convener of the initiative and put together the representative panel of industry/FDA experts, with input from industry trade associations.

The backdrop is a longstanding regulatory–industry divide on product recalls that occur when postmarket risk goes beyond baseline, accepted risk determined at the time a device is cleared for the market. Pulling products from the market can deprive patients of access to these devices, which also can put patients at risk.

Industry, other stakeholders, and the FDA share the goal that a common framework is needed to improve everyone’s understanding of risk–benefit assessments, increased risk–benefit considerations in CDRH decisions, and improved tools. For the first phase of this work, AAMI published a white paper, *Risk Principles and Medical Devices: A Postmarket Perspective*, in August 2015, which sets out six risk principles in the following categories that may be useful for both CDRH and industry postmarket risk assessment:

1. Informed judgment in risk and benefit evaluations
2. Loss-of-benefit assessment
3. Populations
4. Use environment and clinical assessment
5. Communication
6. Risk control and recovering loss of benefit

Learning from Other Industries

TOWARD A QUALITY SYSTEM MATURITY MODEL

In a project sponsored by the FDA, MDIC benchmarked other industries that use maturity models, which “help organizations assess their operations consistently and reproducibly” (MDIC 2015) and improve performance.

The intent is to leverage maturity models in other industries to develop an industry-specific model to use across the medical device industry, according to summit presenter Nicole Schumacher-Crow, senior manager of life sciences at Deloitte & Touche.

The research identified Capability Maturity Model Integration (CMMI) as one model that has been implemented many times and fits well with the medical device industry. CMMI incorporates 22 process areas and defines five “maturity levels” and three “capability levels” that are important to build products or provide services.

Based on the research, MDIC plans to implement a Quality System Maturity Model based on CMMI for the medical device industry that is focused on promoting product quality and patient safety, Schumacher-Crow said. Already, the CMMI model has been aligned with the QS regulation and with ANSI/AAMI/ISO 13485:2003, *Medical devices – Quality management systems – Requirements for regulatory purposes*. MDIC has leveraged that work to develop a model for medical devices. MDIC plans to pilot the model in three to five companies in 2016.

Schumacher-Crow cited these benefits of implementing a maturity model:

- **Impact on product quality and patient safety:** Promote the development of actionable strategies to improve operations and quality; encourage self-improvement and QMS sustainment.
- **Consistency:** Standardization of assessments and benchmarking of operations across all medical device companies regardless of size or product type; promote a strong functional orientation that can be used to drive improvements.
- **Effectiveness:** Working toward higher maturity levels can help improve capabilities, promote more effective processes and governance, and reduce variability that leads to increased cost of quality.
- **Alignment with the FDA:** The FDA is an active participant in developing the model and will be a key to the pilot program; plans are in place on how the agency will be able to leverage a model construct.
- **Change agent:** Promote culture improvement by holistically evaluating the QMS across people, processes, and technology with metrics that link to organizational talent.
- **Value to business:** Track and monitor progress and ROI to improve clarity and communication with executive stakeholders; shift the quality focus so it aligns—rather than conflicts—with speed and cost objectives.

The white paper also identifies shared risks factors that industry and the FDA could use to better manage postmarket risk, as well as suggestions to AAMI that could inform the upcoming revision of ANSI/AAMI/ISO 14971 (see pages 14–18 in the white paper).

For the second phase of the initiative, four working groups have been tasked with recommending specific improvements to postmarket risk activities, as shown in Figure 12. Goals and deliverables for each of these working groups, summarized below, were scheduled for December 2015.

Working Group 1

Project goal: Develop a Postmarket Risk Universal Assessment (PRUF) form, which would be a reference for, but not a replacement of, the Health Hazard Evaluation Form.

The PRUF form would benefit industry and the FDA with a consistent way to communicate, with documentation of relevant data and analysis to support clear action and a structured assessment of postmarket device issues, regardless of whether there is a recall. The working group also is developing a plan for pilot testing of the new form and a plan for training stakeholders to use it.

Working Group 2

Project goal: Assess postmarket risk mitigation today and develop a plan for improvement, if needed.

This working group identified two primary disconnects in postmarket risk mitigation today: recall classification and what action should be taken. To address these issues, the working group has developed a concept and flowchart for a common process that includes correct notification about the product problem, risk assessment prior to mitigation, correct classification of the problem, a correction strategy based on a risk–benefit ratio, and ongoing information gathering. Templates, checklists, and examples would become tools for using the process. The working group also has a white paper in development.

Working Group 3

Project goal: Clarify the threshold of a recall.

This working group plans to recommend new recall thresholds for FDA postmarket action, based on risk–benefit analysis, which industry hopes will help solve a current problem of overusing recalls for minor, technical violations. Decision flowcharts, checklists, and examples would create a reference and tools that both industry and the FDA could use in making decisions, which would contribute to greater consistency, and transparency.

Working Group 4

Project goal: Explain a common framework that industry and the FDA can apply when assessing risk and weighing benefit and risk in quality and postmarket safety issues.

This working group will provide recommendations, process flowcharts, and examples. If it is adopted, it is intended to improve predictability, consistency and transparency with a common framework for addressing postmarket risk that enables industry and the FDA to arrive at decisions that are beneficial to patients.

Already, the postmarket risk initiative has proven fruitful in identifying “eye-opening” disconnects between the FDA and industry, in terms of motives, data, and methods, according to summit panelists:

- **Motives.** Interactions with the FDA over

Process overview and subgroup alignment

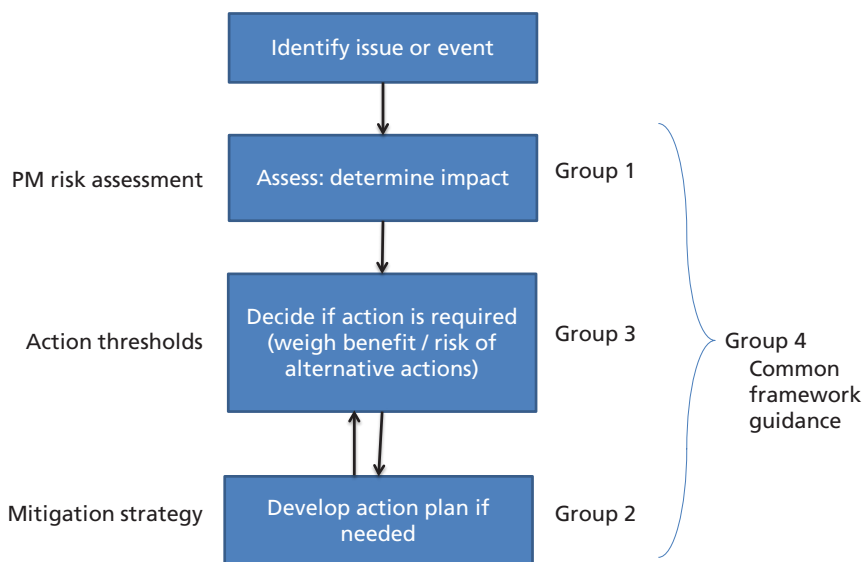


Figure 12. Postmarket risk framework initiative: process overview and working groups. Source: Ginger Glaser. “Risk Framework Initiative.” Presented at the AAMI/FDA Risk Management Summit, Sept. 29–30, 2015.

postmarket decisions sometimes occur “under tense circumstances,” said summit panelist Thomas Morrissey, MD, vice president of quality assurance at Edwards Lifesciences. Through the initiative, he has learned that the FDA wants to help companies through these decisions. “The benefit of having the FDA participate on this team with industry has been eye-opening to me,” he said.

- **Data.** “In early meetings, I was somewhat frustrated,” said panel moderator Ginger Glaser of Boston Scientific. “We do have all of this analysis and data from premarket submissions. The FDA said, ‘But we don’t have access to all of that information from premarket data.’ That was an eye-opener.”

“I always thought the FDA had a bunch of information we didn’t have,” said summit panelist Susan Nicholson, MD, FIDSA, vice president of safety operations and compliance at Johnson & Johnson. “I learned that they think we have a lot of information they couldn’t see. We have the same challenges. We’re looking at data differently and without the same algorithm. The intention is the same: to reduce the grey areas as much as possible and see agreement in these data. In the end, we have the same challenges. If we get this worked out, we’ll both be much better off.”

- **Methods.** “We’re delving into recall policy and field action decision making and having an open dialogue about areas that have caused some frustration on both sides,” said Tony Carr, vice president of global quality at Boston Scientific. Clarifying recall policy is a win-win proposition. It will enable the FDA to more efficiently classify recalls and industry to communicate more effectively with customers, and it will enable better decision making all around.

“The FDA recognized that we were trying to make decisions based on information that we had in the postmarket space. When we talked to industry, we realized they would make different decisions. We realized our thought process was not being shared in a way that was resonating. Industry really didn’t understand our recall process and the things we do. Our goal is to make our decision making transparent because we know that that will improve decision making in the postmarket space and improve patient safety.”

—Capt. Diane Mitchell, MD, assistant director for science at FDA CDRH



Participation by federal agency representatives in this voluntary initiative does not constitute endorsement by the federal government or any of its agencies. Also, it should be noted that this summary of the initiative is a snapshot in time. The work is ongoing; therefore, later developments may call for reshaping of the information outlined during the summit. The information presented should not be construed as being etched in stone.

CLARION THEME 5

Create new practical tools to continue advancing the field of risk management for healthcare technology.



“Risk management as a discipline should be available for any reasonable, professional adult. It shouldn’t be so restrictive than anybody can’t get involved.”

—Tammy Pelnik
President
The St. Vrain Group

Challenge	Priority Action	Accountable
Understanding risk management processes and implementing risk management standards	Create “Risk Management for Newbies” and “Systems Engineering Guidebook for Medical Devices” tools.	AAMI INCOSE
Difficulty implementing risk management processes efficiently, effectively, and consistently in organizations of different sizes and for products of different levels of complexity	Create risk management tools and templates that can be easily used by both small and large companies, for simple and complex products, with the same level of rigor.	AAMI
Inability to track risk management activities and decisions across systems	Create user-friendly risk management software that integrates information and methods from many different risk management systems.	Industry partners

The Missing Ingredient in Effective Risk Management: Practical Tools

Throughout the summit, presenters and participants made clear that they want to improve patient safety with effective risk management of healthcare technology. They also emphasized the need for practical tools to carry out this work, so that everyone can play their part in strengthening the discipline and practice of risk management.

The healthcare industry is not lacking in sources of inspiration. Pockets of excellence, best practices, and wisdom in risk manage-

ment exist in healthcare and beyond. Other industries have longer histories, deeper knowledge, and well-developed tools for effective risk management, including systems engineering and life cycle approaches. While those industries are not a perfect match with healthcare, their experience and methods could be adapted to empower healthcare technology stakeholders to improve their risk management activities.

Several summit presenters focused on the unique challenges with risk management to startup companies. Given the key challenges

identified in the summit, however, companies of all sizes seem to need the same kinds of practical tools. Summit presenter Tom Shoup, principal of Foxburg, LLC, a consulting firm, identified these challenges that both startup and established companies face:

- Risk management is not perceived as an engineering benefit. “It’s just paperwork” that’s often viewed as a quality assurance, quality engineering, or risk analysis task, not as a design task.
- Standards compliance is not part of formal training, and there’s confusion about laws, regulations, standards, and best practices.
- There’s an assumption that risk analysis has to identify a lot of unacceptable risks, and lack of understanding that safety can be inherent by design.
- There’s a lack of clarity on the role of test labs, which certify compliance to standards, but don’t “approve” anything.
- There’s a lack of understanding about the anatomy of the risk management file.
- It’s difficult to define meaningful measures of probability and levels of severity.

Startups may have to hire risk management consultants, which looks like an added cost, Shoup said. Schedules are mostly focused on the technology. Startups get little help from their investors with risk management. “Even serial entrepreneurs think it’s just paperwork,” he said.

Startups, like all companies, are dealing with considerable external forces on their businesses, including highly complex devices, rapid technology advancement, extensive compliance requirements, and country-to-country regulatory differences, according to summit presenter Mark Leimbeck, program manager, UL EduNeering. “You always have to be thinking about the next thing, and you cannot anticipate how other technologies impact the risk profile of your device,” he said. Companies also face “watershed changes” in standards, such as the shift from assessing “basic safety” to also assessing “essential performance” in the IEC 60601, *Medical electrical equipment*, series of standards.

Startups, and other companies, also lack understanding about their responsibilities, roles, and “the basics” of risk management, Leimbeck said.

Tammy Pelnik of The St. Vrain Group itemized these typical startup constraints:

- Investors reward *results*, in terms of a working prototype, not risk management.
- Budgets are tight. Time frames are tighter.
- Subject matter experts know the product’s technology and science, not risk management.
- There may be little commercial GMP expertise, including design controls, on staff.

Standards, guidance, and technical reports about risk management provide a huge body of knowledge. “But if you are a startup, if you have no expertise, is that enough?” Pelnik asked. “I’d say no. As an industry, we really haven’t provided the right kind of support for people to do this in the right way.”

“Why Don’t We Have ...?”

“Why don’t we make risk management less of a specialist’s domain?” Pelnik asked. “Why don’t we develop risk management checklists to support inexperienced organizations? Why don’t we have:

- Better communication, making the business case for risk management, with a clear analysis of return on investment that connects with investors, and the same clear analysis for quality management system compliance staff?
- Better resources for first timers with tools to get started before they can afford a risk management specialist, plus real-world examples in the public domain that show what risk management really looks like?
- More guidance for specific high-risk product categories, such as life-sustaining cardiac and respiratory devices?
- More guidance for combination products, both for development and postmarket risk management?”

Summit presenters and participants generated a number of ideas for other practical risk management tools that would improve the field, including:

- “Risk Management for Newbies” and “Systems Engineering for Medical Devices” guidebooks
- Systems engineering tools, such as for mathematical modeling and decision analysis
- FDA guidance equivalent to guidance on design controls

“We need to make it easy to understand the steps of risk management.”

—Tom Shoup, principal at Foxburg, LLC

- Risk–benefit analysis tools
- A handbook or course correlated with ANSI/AAMI/ISO 14971
- A sample risk management file
- Publicly available data to help guide predictions about severity and occurrence rates
- Practical tools for managing risks associated with mobile apps
- Job descriptions for systems engineers
- User-friendly risk management software that integrates information and methods from different sources and covers the full life cycle of healthcare technology

Heat Maps: A Tool to Visualize and Communicate Risk

Some people are “practiced journeymen” as risk managers, others are brand new to the discipline. Heat maps are tools for people of varied expertise to talk about risk, visualize and communicate risk, and understand changes in risk, according to summit presenter David Sine, chief risk officer for the Veterans Health Administration’s Office of Quality, Safety & Value. Figure 13 illustrates changes in severity and frequency of risk. Figure 14 shows risks color-coded by likelihood of occurrence and severity of impact. Figure 15 shows how relative risk can be compared visually.

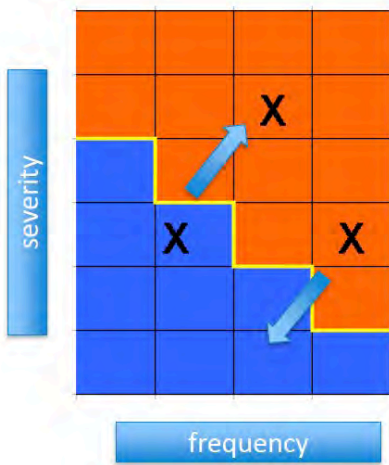


Figure 13. Motion within risk map is of interest. Source: David Sine. “Managing Risk While Managing Design or Other Changes: Special Challenges and Complexities.” Presented at the AAMI/FDA Risk Management Summit, Sept. 29–30, 2015.

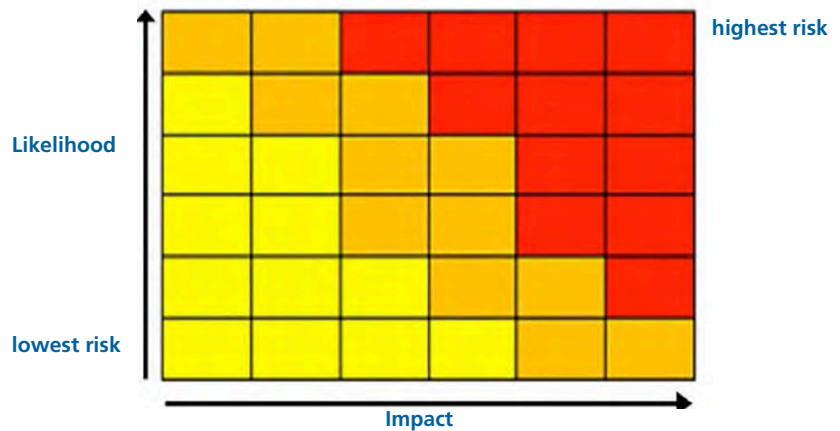


Figure 14. Heat map of risk results. Source: David Sine. “Managing Risk While Managing Design or Other Changes: Special Challenges and Complexities.” Presented at the AAMI/ FDA Risk Management Summit, Sept. 29–30, 2015.

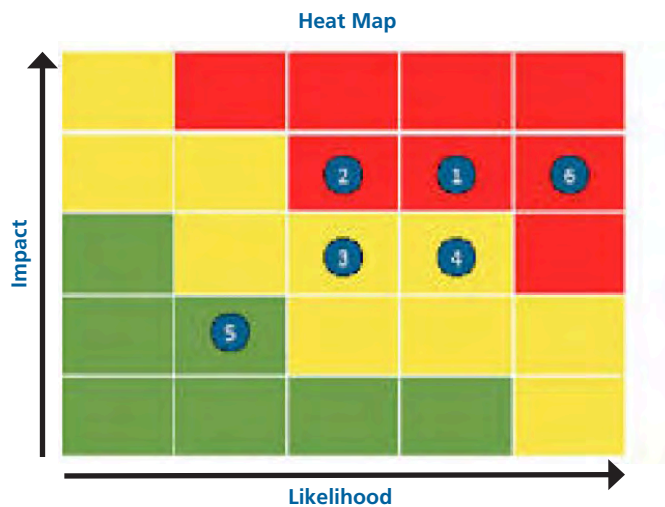


Figure 15. Heat map of relative risk. Source: David Sine. “Managing Risk While Managing Design or Other Changes: Special Challenges and Complexities.” Presented at the AAMI/ FDA Risk Management Summit, Sept. 29–30, 2015.

Learning from Lead Innovators

ADDRESSING STARTUP CHALLENGES

“It’s not always clear when mitigations are adequate when you don’t have a lot of clinical information out in the field.”

—Al Crouse, senior director of quality assurance and quality systems at CVRx



The limitations of time, talent, and resources made risk management a challenge for CVRx, a startup company that makes an implantable device now on the market to treat hypertension and heart failure. Al Crouse, senior director of quality assurance and quality systems at CVRx, enumerated other risk management challenges the company faced, including:

- Performing work early enough in the development process to make changes
- Clearly identifying all harms and hazards for patients, users, and facilities or the environment
- Estimating the risk a new product and therapy in terms of severity, probability of occurrence, and detectability
- Identifying the benefit of device, since animal or small clinical studies would not likely provide quantitative support
- Identifying a reasonable level of risk control by defining criteria for acceptability of mitigations prior to performing the work

With new products and therapies like the CVRx device, knowledge and access to knowledge about risks and benefits can be limited. In addition, “it’s unclear when mitigations are adequate,” Crouse said. The company took these steps to address the challenges:

- Hired people experienced with related devices and used contracted physician reviewers to confirm and support decisions

- Performed work early enough in device development to make changes, which saved time because only critical requirements had to be verified and validated
- Clearly identified all harms and hazards by looking at similar devices and procedures and conducting a literature search and early animal/clinical studies
- Took a qualitative, rather than a quantitative, approach to estimating risk (i.e., improvement required, improvement desirable, no improvement necessary)
- Defined the product benefit with animal and acute human studies to support feasibility clinical trials, with the results supporting randomized studies and marketing efforts
- Identified a reasonable level of risk control by defining safety level specifications early that could be largely proven through product testing and supported with animal and clinical studies

From these experiences, Crouse recommended these changes to support startups:

- Create industry harm and hazard rate publications
- Identify well understood risk mitigations that are transferrable (e.g., for infections from implantable devices)
- Change the mindset that risk analysis is a postdesign and -development activity

Learning from Lead Innovators

TAKING A STRATEGIC RISK MANAGEMENT APPROACH TO A DEVICE DEPLOYMENT DECISION

What's the best way to safely and effectively deploy a potentially life-saving device in under-resourced, but diverse, communities? To find out, a global health funder turned to Applied Strategies, which used prescriptive analytics to model scenarios and build decision-making tools that led to a tiered solution.

About 85% of the 260,000 annual deaths from cervical cancer occur in low- and low-to-middle income countries, said summit presenter Craig Shaffer, managing director, prescriptive analytics, Applied Strategies. When caught early, cervical cancer is curable, most efficiently and effectively with screening and treatment with gas cryotherapy. "This strategy is optimally achieved in a single visit and can be carried out by competent physicians and health professionals, including nurses and midwives, Shaffer said. "Cryotherapy is considered safe. The only real 'risk' is providing sufficient treatment efficacy at all settings in which it is deployed and not reaching as many screened-positive women as possible."

Applied Strategies assessed the treatment situations and risks in target countries, analyzing factors such as the size, location, and distribution of healthcare facilities and at their capability to effectively screen and treat women after training with a cryotherapy device. This strategic risk management approach to the deployment decision:

- Provided a systematic way to capture, quantify, understand, and manage inherent uncertainty
- Enabled consideration of both upside potential and downside possibilities when generating alternatives
- Minimized "unexpected" outcomes, since uncertainty of outcomes was better understood and accepted
- Delivered clarity in the recommendation for strategy implementation and operational management, with customized strategies for each country and coordinated rollout of equipment

Based on the predictive analysis, the initial deployment strategies focused on "protecting" the health benefit using a three-tiered approach:

- Tier 1 small community health centers would screen and refer women in need of treatment to a Tier 2 facility
- Tier 2 district hospitals or larger health centers would screen and treat women
- Tier 3 regional or national hospitals would screen and treat women

For women screened and in need of treatment at Tier 2 and 3 facilities, the "screen and treat" protocol would occur during a single visit, to minimize the risk of patient attrition after screening for follow-up treatment.

Conclusion

Participants and presenters at the AAMI/FDA Risk Management Summit took a broad perspective on how to improve the discipline and practice of managing risk associated with healthcare technology. The summit laid out the challenges with risk management and developed consensus on a focused agenda to overcome them.

This is what it will take and what can be achieved when the priority actions identified at the summit are addressed:

- Recognizing that everyone in healthcare is a risk manager will build understanding of the purpose of risk management for improving the safety and performance of healthcare technology, broaden “ownership” of risk management, and improve the consistency of risk management processes.
- Developing shared understandings of the risks—and benefits—of healthcare technology will harmonize in risk management terminology, create a more balanced focus between the risks and benefits of healthcare technology, and improve access to information that will expedite risk assessment and mitigation.
- Adapting systems engineering principles, practices, and tools for risk management will improve the rigor, efficacy, and efficiency of risk management processes and strengthen communication, coordination, and consistency in risk management activities and decisions.
- Engaging in a total product life cycle approach to risk management will

improve the effectiveness of risk management, from initial product conception in premarket to final decommissioning and disposal in postmarket.

- Creating new practical tools will continue advancing the field of risk management for healthcare technology with rigorous resources for satisfying regulatory requirements, implementing standards and best practices, and streamlining risk management activities.

“System safety and security should be built into healthcare technology from the beginning.”

—Michael Robkin, president of Anakena Solutions Inc.

This focused agenda can be achieved with broad stakeholder perspectives and involvement. Already, leading practitioners and leading industries point the way to solutions for improved risk management of healthcare technology. AAMI and the FDA are committed to working with industry, HDOs, healthcare providers, and other stakeholders to leverage the innovative ideas generated at the summit, with the ultimate goal of benefiting patients. Together, we can create a safer, more secure environment in which healthcare technology and patient safety thrive.

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RELEVANT STANDARDS AND GUIDANCE

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ANSI/AAMI/IEC 80001:2010, *Application of risk management for IT Networks incorporating medical devices*

ANSI/AAMI/ISO 13485:2003/(R)2009, *Medical devices – Quality management systems – Requirements for regulatory purposes*

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MDIC. Medical Device Innovation Consortium (MDIC) Patient Centered Benefit-Risk Project Report. http://mdic.org/wp-content/uploads/2015/05/MDIC_PCBR_Framework_Web.pdf

International Medical Device Regulators Forum guidance documents

- Software as a Medical Device (SaMD): Application of Quality Management System. www.imdrf.org/docs/imdrf/final/technical/imdrf-tech-151002-samd-qms.pdf
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