A Roundtable Discussion
Elevating the Value and Importance of Risk Management In Healthcare Technology

Roundtable Participants

Mary Logan What is risk management? What does it entail? Why does it matter?

Adam Seiver In our context, risk management is high-quality decision making about the uncertain adverse health outcomes that can result from the use of medical devices. It entails delineating what we know, what we want, and what we can do, so there is clarity about what should be done about device safety. It’s important because high-quality decision making underlies defensible responses to medical device safety issues.

Salim Kai Risk management basically is an ongoing systematic process to identify and prioritize types of risks with the intent to minimize and mitigate undesired effects such as adverse events. It also includes policies and procedures, training and practices, and creating different strategies to continually minimize and mitigate different types of risks.

Jacque Mitchell Our working definition at ASHRM (American Society for Healthcare Risk Management) encompasses enterprise risk management. It promotes a comprehensive framework for making risk management decisions that maximize value protection and creation by managing risk and uncertainty and their connections to total value. Instead of only looking at the clinical aspect, we consider the whole enterprise and all of the risk associated with healthcare.

Stephen Grimes Although it’s found in a standard that applies primarily to manufacturers, a good definition of risk management appears in ANSI/AAMI/ISO 14971:2007. Risk management is defined in that document as “the systematic application of management policies, procedures, and practices to the tasks of analyzing, evaluating, controlling, and monitoring risk.” Risk management is an iterative process: It is risk assessment followed by risk control and risk monitoring, then risk monitoring is used to go back and inform the risk assessment process. One of the concerns I have is that there is a lot of inconsistent use of terminology in our industry, particularly in how people think about and apply risk management in healthcare technology management (HTM) in hospitals.

Susan Nicholson Risk management is an acknowledgment that in the healthcare industry, risk exists. Risk needs to be acknowledged so that risk management can be applied systematically.

Kimber Richter Risk management is a continuous process, though our focus at any given point is on certain aspects, such as dealing with specific defects during device design and development, postmarketing considerations, and how products are labeled and clinically tested. All of those considerations tie into one comprehensive risk management program.
Stephen Grimes Manufacturers generally have a pretty consistent and effective approach toward risk management. Clearly that approach is evolving as the technologies that are being manufactured evolve. From the HTM perspective, the goal is to ensure that clinicians have the right technology, in the right place at the right time, and in the right working order and operated in the right way. Risk management comes into play when you have a failure to achieve any aspect of those goals, which represents a risk to patient care. Paying attention to the risk of failing to achieve those goals enables the HTM professional to identify and prioritize the mitigation based on the probability and severity of risks associated with not meeting those goals.

Mary Logan How does risk management differ from risk assessment? One of my colleagues has noted that we shouldn’t even be talking about risk assessment as something separate because risk assessment is encompassed in risk management. What are your thoughts on how risk management and risk assessment fit together and how they differ?

Adam Seiver Risk assessment really has to do with the informational aspects of decision making—understanding what could happen—whereas risk management is oriented toward what you can do. Risk management often requires you to think about the relative value of the consequences of alternative actions: for example, shortages versus adverse events.

Stephen Grimes Risk assessment is a subset of the risk management process; it’s the first step in the risk management process. It involves both the analysis and evaluation of the risks. The complete risk management process, in addition to risk assessment, includes risk control and risk monitoring.

Susan Nicholson Risk monitoring is key because risk assessment is done iteratively over the life cycle of a given product. That informs whether your risk management program is effective and whether it needs to be adjusted over time. These concepts are woven together through the life cycle of any given product.

Kimber Richter Risk assessment is a subsection of the entire risk management process, and one that has to be performed effectively. Specific information and processes are needed in order for that assessment to generate legitimate conclusions and allow us to really understand the risks.

Mary Logan Let’s compare risk management perspectives between experts in industry and those in healthcare delivery. How are their perspectives the same or different?

Adam Seiver As someone who has worked in both the clinical and industry realms, I find it interesting that risk management is deeply embedded in device manufacturer culture. In most companies with which I’ve been associated, risk management is well recognized and it’s foundational. It is not as embedded into clinical culture, however. There’s certainly a movement toward that. At the top organizational level in healthcare organizations, commitment to risk management clearly exists, but at the level of the day-to-day activities of busy clinicians, I find attention to risk management to be uneven.

Stephen Grimes It’s clear that a gap often exists in what is considered risk management between two key stakeholders in healthcare delivery organizations (HDOs): clinical professional risk managers and HTM professionals. Generally speaking, I think there’s a lack of understanding among HTM professionals about what constitutes a truly effective risk management program. One of our biggest challenges is helping them understand the elements and benefits of an appropriate risk management process. Professional risk managers within HDOs are challenged in different ways. They need to better understand the significance of risks associated with how the technology is being acquired, used, maintained, supported, and ultimately disposed of.

Jacque Mitchell Unfortunately, risk management practices vary in a lot of different systems. Some risk managers only perform root-cause analysis, while others are only concerned with regulatory issues. One aim of risk management is to expand the focus into all aspects of healthcare, because risk managers have the critical-thinking skills. We are spread quite thin, and some hospitals or systems are better at
incorporating risk management into the various processes. However, usually there’s one risk manager for one hospital, and they have to keep their fingers on seven to eight different domains at once.

Jean Cooper Manufacturers operate in a more controlled environment, where they can focus on the process of building their product, while hospitals are operating in a more chaotic environment with patient care. Therefore, the tools that you would use in these different settings vary because you’re dealing with different frameworks.

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Jacque Mitchell In the uncertain environment of healthcare delivery, it’s important to have your risk management person sitting at the table asking questions about a certain process or piece of equipment that will affect other systems. One important perspective is assessing human factors engineering. And so we can ask those questions about design and functionality. We need to undertake a process of identifying the uncertainty, assessing risk, responding to that risk, and evaluating how effectively the risk was controlled.

Adam Seiver In my experience, the efforts on the part of manufacturers of medical devices to improve product safety have been perhaps an order of magnitude greater than efforts from clinicians dealing with the use of the devices within the complicated process of delivering care. Although the Institute of Medicine report, To Err is Human, has helped increase awareness, clinical practice of risk management to address care communication and coordination issues still lags behind industry activities oriented toward safe medical device use.

Michael Fales Both healthcare organizations and medical device manufacturers broadly focus on the same things: patient safety, user safety, and environmental impact. The big differences are that medical device manufacturers are focused on engineering controls, training materials, and labeling, while healthcare organizations focus on user skills, clinical workflows, quality control practices, and clinical communications. All of these areas need to be managed effectively for a comprehensive safe environment to result. Unfortunately, in healthcare, we’re relying on humans to do a lot of critical thinking, and errors can occur as a result.

Stephen Grimes In recent years, we’re seeing much more technology being acquired by hospitals compared with 10 years ago. In addition, the technology itself is becoming increasingly complex, as well as integrated within a larger technology ecosystem. Now, if an integrated component fails, it’s more likely to have wide-ranging effects and severe consequences. These increased complexities make effective risk management all the more daunting and necessary. As we integrate increasingly sophisticated systems, our approach to assessments and testing to ensure that we have accounted for and mitigated all possible errors also needs to become more sophisticated.

Susan Nicholson A key opportunity exists for sharing information between those two owners of risk management—manufacturers and hospitals—because it’s really about a system. Medical devices don’t exist in a vacuum; they are part of a system of care, and it’s critical that information from clinicians is relayed back to manufacturers, and vice versa.

Jacque Mitchell Unintended consequences are a major concern for hospitals. For example, we have about 40 systems that feed into our registration system. A change in one of those systems could affect the performance of the overall system, and unexpected adverse events could arise. Troubleshooting these consequences beforehand would be optimal, but “you don’t know what you don’t know.”

Adam Seiver When we move beyond just physical devices into areas like electronic medical records (EMRs), we see a new level of complexity. EMRs are sweeping across the country, and integrating these complex systems across large organizations is a major challenge.

Salim Kai Several years ago, at the University of Michigan Health System, UMHS Risk Management, the Office of Patient Relations, and the event review management team from
Quality Improvement merged into one unit. Those three groups were combined to form the Office of Clinical Safety. Basically, we look at everything across the spectrum of healthcare delivery. The goal is to prevent harm to patients and staff, as well as continuously monitor for potential threats and unsafe conditions, then try to mitigate them by creating meaningful and sustained change. We seek to ensure that patients receive the care and services they need, that they are treated with respect and dignity, and of course, that they are not harmed by healthcare technology or medical devices. In terms of hospital staff, our goal is to make sure clinical and information technology systems are running safely and reliably and that when issues are found, they are fixed efficiently. We also want to ensure that the fixes are not workarounds but rather robust solutions that will prevent problems from recurring, especially when there is harm. Ultimately, it’s really about creating a safe, high-quality, and highly reliable work environment for everyone.

Mary Logan Are we at a point where healthcare technology is outpacing our ability to manage the risks? How can we continue to expand the discipline of risk management to consider the “system of systems”?

Salim Kai Generally speaking in the past, when a problem was found with a particular device or system, it could be resolved by one individual. Today, interdisciplinary teamwork is needed among multiple departments, as current issues are becoming very complex in nature and span across areas such as information technology (IT), medical devices, clinical care, and environments of care. More disciplines, such as clinical, nonclinical, and administrative, need to collaborate and communicate to create long-term solutions within this complex environment.

Stephen Grimes In response to Mary’s first question: Yes, technology is outpacing our ability to effectively and safely implement it. The goal is to prevent harm to patients and staff, as well as continuously monitor for potential threats and unsafe conditions, then try to mitigate them by creating meaningful and sustained change.
Increasingly, a multidisciplinary approach will be needed to manage risk. As new technologies come out, we need to be very careful about weighing the benefits and risks before implementing them. We feel pressure to be early adopters of the latest technology, but we don’t always fully consider the risk-to-benefit ratio. We need to make sure we’ve sufficiently vetted these technologies before adopting and implementing them.

**Michael Fales** Clinical decision support or artificial intelligence, which is starting to be incorporated into IT systems, is an area that involves increased risk. When the technology starts to make decisions for clinical practitioners, it will really change the landscape. We will need to manage that new risk together.

**Adam Seiver** I agree that there will be challenges as use of technology increases, but I tend to be optimistic that we will rise to face the challenges and make good decisions, such as in the use of clinical decision support. New technology has the potential to improve clinical outcomes, but if it’s not deployed correctly, it can certainly be detrimental.

**Kimber Richter** With these new technologies, it’s very difficult for regulatory agencies to anticipate issues that lie ahead and determine the best strategy going forward. When we talk about how these products are used in healthcare environments, an opportunity exists for voluntary leadership from industry, standards organizations, and other groups to step forward and help ensure that medical devices used in systems are compatible and that issues are anticipated.

**Jacque Mitchell** My experience has shown that nowadays, hospitals and clinicians are more likely to work with manufacturers and have more of a relationship. Whenever we have concerns with a piece of equipment, we contact the manufacturer and expect feedback from them. Twenty years ago, we would have said, “We can’t do anything about this. It’s a big manufacturer; they’re not going to listen to us.” There’s more of a feedback relationship now between clinicians and vendors.

**Jean Cooper** On that note, a comprehensive life cycle approach to risk management would be optimal. A life cycle approach assumes an active feedback loop and helps with learning. How close are we to achieving that ideal? What is needed to make it a part of the DNA for HDOs?

**Adam Seiver** On the industry side, we need much greater consistency between the techniques that are used for pre- and postmarket analysis of risk. A further leap forward would be to have risk analysis integrated across the entire care continuum so that healthcare institutions and industry have a single coherent approach.

**Salim Kai** More transparency and data sharing are needed among healthcare facilities, manufacturers, and regulators. Currently, part of the challenge is that no clear method exists for determining whether devices are safe before they are put on the market. Oftentimes, safety is not sufficiently considered during the design phase. However, when a device is being used and problems are encountered, then we ask how it can be made safer through various workarounds. If manufacturers shared more with healthcare facilities, then a lot of these problems would be solved.

**Stephen Grimes** Manufacturers have become more consistent in how they approach FDA requirements and risk management. And they do produce a risk management file; they’re required to. Sharing key information from that file would be very helpful in kick starting the risk management process on the healthcare organization side. Opportunities exist for manufacturers and healthcare organizations to work together to develop new standards and tools that could be very effective in applying risk management to the technology life cycle.

**Susan Nicholson** The unique device identifier is going to be a major game changer with regard to life cycle management. It’s going to help us understand the result of using a particular...
device, particularly for implantables but less so for capital equipment. Moreover, nothing motivates a manufacturer more than thinking that a competitor or health authority is gaining information or insight before they do. That mechanism will incentivize manufacturers to get very good at analyzing risk data and using that analysis to proactively anticipate potential risk events, design out risk more effectively, or at least to make better next-gen products.

Mary Logan Unique device identification (UDI) will be a very challenging transition for industry, as well as for HDOs. Industry is incentivized to implement UDI based on a regulatory requirement. I believe that UDI is a fantastic risk management tool for HDOs, but they have not fully grasped how valuable it will be. A good example to demonstrate this is the speed with which a tainted bag of spinach is pulled from grocery shelves. UDI would confer a similar benefit to HDOs.

Adam Seiver A practical issue along those lines is for device manufacturers to receive full clinical information following adverse events. It’s not enough for manufacturers to learn that a problem occurred; detailed clinical information is needed to determine the cause and consequences of the failure.

Susan Nicholson That relates to something we talked about earlier, which is this idea that manufacturers and healthcare institutions have a shared responsibility around risk management. They need to communicate. Another key stakeholder is the healthcare provider; often, he or she is the person holding the information needed by manufacturers. Unfortunately, a strong incentive does not exist on the part of those users to provide detailed information to manufacturers. There’s not even a sense of shared responsibility. So I think we have an opportunity for a culture shift, in which every stakeholder agrees that they own this responsibility collectively, because each person holds a piece of the puzzle.

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responsibility collectively, because each person holds a piece of the puzzle and we don’t really get the picture unless everybody contributes.

Salim Kai Certain stakeholders are so involved in what they do and so detached from clinical care that the patient is forgotten. It’s all about the patient and being able to provide patient-centered care. We have partnered with patients or families and, as such, have included them on some of our committees, in order to solve some of the most challenging problems and continue to provide safe care. Moreover, among the stakeholders, each one wants to solve their piece of the problem, but in the end, it’s about the patients. When patients present to the health system, a clinical encounter exists; they are sick and scared and want to be involved in the decision making. The last thing they want or expect is to be harmed. So, the patient is at the center of all this.

Mary Logan How do we make a business case for the value of risk management? For industry, it might be a little bit easier because it’s a regulatory requirement. But, in general, what is the strongest way to make a business case that risk management really pays for itself and isn’t a cost center, so to speak?

Salim Kai First, it needs to start from the leadership in the organization. Leadership has to lead by example and explain the necessity for risk management and the value it brings. More importantly, risk management programs need to be evidence based and data driven, because you need to show and be able to measure their effectiveness and cost savings.

Adam Seiver The movement toward pay for performance (P4P) is capturing people’s attention. P4P has become a prominent topic at a lot of medical meetings. Previously, meetings that were only focused on clinical topics are starting to emphasize areas such as reducing readmission rates and complications. I see P4P making financial demands on the clinical side, and these demands will be passed on to industry.

Stephen Grimes Selling leadership on risk management is critical. When we go into an organization or hospital, often we’ll start by picking one or two critical systems and performing a risk management and vulnerability assessment process. After we have identified the risk of failures, as well as the probability and severity of consequences, we then share that information with leadership and explain how to mitigate those risks. That has proven to be effective in demonstrating the value of the risk management process.

Jean Cooper Currently, risk management is not part of the education curricula for physicians and nurses. As with any scientific discipline, making these health professionals aware of the value of risk management early in their education or careers would help elevate its value and importance and improve the use of these concepts in patient care.

Susan Nicholson One risk for manufacturers is having to remove products from the market. Such end-field corrections can result in customers losing faith in a manufacturer’s product. So one major value of a rigorous risk management program would be avoiding these field removals. A compelling argument is determining how many field removals can be avoided and the resulting cost avoidance for manufacturers.

Mary Logan My last question is for Kimber: What is going on at CDRH regarding its approach to risk considerations from a regulatory standpoint?

Kimber Richter We’re focusing more and more on balancing benefit and risk instead of focusing only on the risk. We’re also working on tailoring assessments to specific devices and situations, as well as clarifying the processes for conducting good benefit/risk assessments. We’re also looking at ways in which we can be more transparent about these processes and how we can include input from other stakeholders when we make benefit/risk-related decisions. We are working actively to harmonize our approaches with those of industry and ultimately to incorporate information pertaining to patient preference and other information as well.