A Roundtable Discussion

'Everyone in Healthcare Is a Risk Manager': Achieving Risk-Savvy Cultures

Roundtable Participants

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Joseph Sheffer ***One of the priority actions from the 2015 AAMI/Food and Drug Administration (FDA) Risk Management Summit[1] was to improve recognition "that everyone in healthcare is a risk manager." In what ways have we made progress on that front?***

Jacque Mitchell Our theme at the American Society for Healthcare Risk Management and among the local team at my hospital was that everybody is a risk manager, because the risk manager cannot do it all. Most people are capable of being risk managers because they know what they're dealing with, and they're the ones at the point of care. They're the ones that become aware of issues and report problems. We want everybody in healthcare to look at things differently than we did in the past. Thirty years ago, when I first became involved with risk management, nobody knew what it was. Maybe they thought about claims, but nowadays, people say, "I help with risk management," or, "I'm involved." The perception has certainly changed, but we want to get even more people in the healthcare arena thinking about risk management.

Tom Shoup From a manufacturer's perspective, in the last 15 to 20 years, when design control came into effect, manufacturers have staffed up more to prospectively approach risk management. I spent the first 20 years of my career at HP Medical, which is now Philips, and for a long time there was some guy in regulatory that took care of all this stuff. But in the last 15 years, it's made its way all the way back into design, and there's usually a couple of senior people, maybe with system engineering responsibility, who have taken ownership of creating a risk management file. In parallel, regulatory and quality staff also have increased. There's a whole lot more attention given to complaints, regardless of whether they turn into CAPAs (corrective and preventive actions), and that's a rich field of data that flows back into design.

Aaron Goodstein We've seen a real shift in risk management from it being, as Tom said, "some guy in regulatory" to it becoming a multidisciplinary function. We have people from R&D, quality, complaint handling, manufacturing, regulatory, and medical involved, and they all have distinct responsibilities in the risk management process that complement each other and allow it to be a much more holistic effort focusing on the patient. That's been a culture change, at least from my perspective, during the past 10 years since I first started.

Adam Seiver Being a risk manager is a state of mind; it relates to a level of consciousness throughout an organization as opposed to just a job title. I think we're moving toward that. I don't believe that we're quite there yet, as it takes a while to completely evolve, particularly in large organizations. But I agree that we have moved quite a bit along toward that direction over the past 15 years.

Tina Krenc I teach a risk management class for AAMI, and we've taught hundreds of people, if not more. One of the things that we ask our participants is whether they make decisions at work. And of course, everyone says "yes." Then we ask, "Do you manage risk as part of your job?" And maybe a handful of people will raise their hands. Then we'll say, "Everybody should have their hands raised because anyone who makes a decision is doing it based on risk." The only difference may be that you don't have a systematic documented method for how you're making your decisions. It's really important that we continue to tell people, "If you work in healthcare, every decision you make is a risk-based decision, and it leads to potential product, patient, and user impact."

Tom Shoup Related to what Tina said: Designers do an awful lot of risk management while they're designing, but I don't think it's in the forefront of their consciousness, and they certainly don't record it. For example, if a mechanical engineer is designing a part and deciding on the material, whether they choose plastic, fiber composite, or steel—that alone is actually a risk management decision because it has to do with the strength and other attributes of the part. The same thing is true for electrical engineers. If I'm picking a transistor, does it have to carry 5, 10, or 50 A? I have to size the component so that it's safe. Now, if everybody just wrote that stuff down, then we'd have fantastic bottoms-up FMEAs (failure modes and effects analyses), as opposed to having one or more people go back and perform an FMEA after the design is done. So there's a lot of unconscious risk management done in design—it's just not captured. Risk management would be far easier if people would capture this stuff as they do it.

Tina Krenc Picking up on that: The ISO (International Organization for Standardization) group that works with clinical laboratories is developing a standard aligned with 14971 to help the laboratories understand how important they are to managing risk, because the manufacturer really can't control risk in the pre- and postanalytical phases. Manufacturers can only control the analytical phase, where the labs are actually testing the samples. Lab staff are risk managers as well, because they have to manage the samples in a certain way and they have to make sure that they have solid cybersecurity controls over their data analysis, which then carries over to making the patient results safe for physicians during caregiving.

Joseph Sheffer ***According to ANSI/AAMI/ISO 14971:2007(R)2016 (*****Medical devices—Application of risk management to medical devices*****),[2] the risk management process involves the need to identify hazards, estimate and evaluate risks, control the risks, and monitor the effectiveness of the controls. What degree of clarity do medical device manufacturers have regarding risk management? If confusion exists, what are some of the causes?***

Adam Seiver I agree that we're doing a lot better in terms of identifying hazards, controlling risks, and monitoring the effectiveness of the controls. But in terms of estimating and evaluating risk, there are better tools. The 14971 standard basically treats risk in a categorical way, using a so-called risk matrix approach. There's an evolving academic literature showing that that sort of approach is really quite flawed.[3] Situations that I come across that highlight shortcomings of the risk matrix approach include cases where there is a very low probability of a catastrophic outcome. Risk matrix categories in such cases don't capture the shades of gray. Another issue that frequently surfaces is the need to categorize a device as either "safe" or "not safe" as opposed to asking, "What is the best thing to do to manage a risk we have identified?" We always face alternatives for managing risks. There are tradeoffs to the interventions, as well as to the existing situation. There tends to be not enough emphasis on comparing the side effects of what we might do to the risk of leaving the device in the field.

Aaron Goodstein That's a very interesting point. I think that manufacturers are very good at determining how their device can fail and what type of hazards might occur, but they're not really good at doing a final evaluation of the risk. When you play that out against what the harm can be from a given hazard—the probability of harm is something

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that is not routinely applied throughout the device industry currently. As a result, you can have instances where you have a very low probability of a catastrophic failure, and their systems can't account for that. They kind of skew the way that they do their risk management, or the way they assess their risk. That's definitely an area that could use some work.

Tina Krenc One of the biggest issues that I've seen is that people tend to only use FMEA. FMEA only deals with failures and can only be done at a certain point in the life cycle of a product. As a result, I think organizations are very comfortable with it. However, they only look at the probability of a failure. They don't look at probability of harm to align with what Tom has said. There is more work that can be done to help them in extrapolating and using other types of tools besides FMEA. But I think there's resistance to move away from what is comfortable for them.

Tom Shoup I think Aaron hit the nail on the head: The toughest thing is often figuring out probability. I've done a handful of risk management files for clients. Thinking of orthopedic surgery: There's a lot of good data on how many surgeries are done, including plenty of data in the FDA MAUDE (Manufacturer and User Facility Device Experience) database, which makes performing risk management easy. But for new products that are doing something a little bit different, it's very, very hard. In the United States, we've taken kind of a medium step backwards. There's confusion with the Annex Zs in 14971 in Europe, and a lot of people in the United States think that you can't do ALARP ("as low as reasonably practicable") anymore. ALARP is part of 14971, and in the U.S., it really makes it easier to get out of this pickle where you can't honestly or accurately assess the probability. Some companies just don't do it because they're happy with the tabulation method, or they think it's not allowed because of all the confusion in Europe over the Annex Zs.

ALARP is a tool that people probably ought to use more. It's a desirable and highly tractable alternative to the two-dimensional matrix for evaluating risk. The whole flap in Europe about ALARP needn't have happened, but it did, and despite about five years passing, people are still confused for European Union clearance. But none of that applies in the U.S.

Pat Baird I see safety assurance cases as being a better way to document our risk files than traditional methods. We've already discussed actions that tie into safety assurance cases: getting folks to write things down as they're doing the design and forcing them to document good design decisions that, in the past, they didn't think to document. I have found that safety assurance cases can work as a stress test on your documentation and will help you find gaps in the documentation. I will find instances where the product itself has a good, safe design, but you didn't document the risk file well enough to actually convince someone that you were doing a thoughtful job.

Tom Shoup I'd be interested to hear from other people: Do your companies use ALARP or safety assurance cases?

Adam Seiver What I've been advocating is a version of ALARP, because I don't think that you can avoid being economically practicable any more than you can avoid the effects of gravity. The European interpretation is really quite extreme. And so, I've been arguing against that.

I also would like to comment on the thought that there are situations where you cannot estimate probability. There is a school of statistics, typically called the frequentist school, where a lack of data precludes the ability to assess a probability. But there's actually a much older school that views probability as a "state of information" or, philosophically, as a state of mind. It's known as the Bayesian school and offers tools to quantify uncertainty even when data is limited. That's the sort of approach that I've been advocating within the businesses that I work with at Philips.

Joseph Sheffer ***The FDA recognizes 14971, but do manufacturers and the FDA have a shared understanding of the principles described in the standard? What, if any, trouble spots exist to realizing this shared perspective?***

Tina Krenc I think that using the FDA term is very broad because there are different organizations within FDA. I would say that the

The Advantages of ALARP

Following the 2015 AAMI/FDA Risk Management Summit, AAMI published *Premarket Risk Management for New Medical Device Companies.* Authored by Tom Shoup, the book explains risk management concepts in practical terms, providing guidance on creating a compliant risk management file for a medical device. Although the title addresses the book to new companies, it also can help existing companies that may be struggling with risk management.

The book provides detailed background and guidance on the "as low as reasonably practicable" (ALARP) approach. ALARP involves a three-level acceptability approach to assessing hazardous situations. Risks that fall into the green area are not further mitigated, whereas those in the red area are subject to risk control measures. For risks that fall in a middle gray area, each one is reviewed individually and a decision is recorded as to whether further risk reduction is practicable. The advantage of ALARP is that it recognizes that risk evaluation doesn't lend itself to a strictly two-dimensional matrix, given that the boundaries of the gray area may lie in different places for each hazardous situation.

Premarket Risk Management for New Medical Device Companies is available in the AAMI Store (**www.aami.org/store**).

reviewers are very familiar with product safety risk management because it's part of so many submissions. And there's understanding among some, but maybe not all, of the compliance folks who do the inspections. I think the MDSAP (FDA's Medical Device Single Audit Program) process is going to increase that because ANSI/AAMI/ISO 13485:2016[4] has called out 14971. It calls for risk management throughout the entire standard. Some of the regulators are on the standards committee, including Melissa Torres (associate director for international affairs at the FDA Center for Devices and Radiological Health). But the understanding of risk management may still need to get out even further to more of the FDA employees, especially as new ones come on board.

Aaron Goodstein From a pure risk management standpoint, being able to speak the same language with the FDA usually works fairly well. There is a shared understanding. I think where there's more of a disconnect, quite honestly, is when you have to have the conversation with the FDA, and then have the same conversation with European notified bodies and competent authorities, which take a very different tack, specifically around the whole ALARP concept. It can be a challenge when you're working with both at the same time because they may not be approaching it in the same way. But generally in my experience, during conversations with the FDA, there has been pretty good shared understanding from an overall risk management perspective.

Tom Shoup For established manufacturers, such as GE, Philips, Siemens, Medtronic, Abbott, and so on, they know what they're doing; they speak the same language as the FDA. However, startups or other companies that are new to medical devices may be a bit lower on the learning curve. My experience has been that a lot know that there's this big matrix you're supposed to create, and they try to create it by brainstorming. And that's probably the worst way to do it. So they don't have a shared understanding. In general, they're not really up to speed on the purpose and use of standards anyway, so not just 14971, but electrical safety, sterility, and others. That was another outcome from the 2015 AAMI/FDA Risk Management Summit, and I was involved in that. So, established companies are doing well; it's the companies new to medical devices that tend to be struggling.

Tina Krenc I would agree with that, especially related to standards and little things like the total product life cycle on FDA.gov. The small companies may not even realize how much information is out there that links back to their risk management process.

Tom Shoup In addition, independent of whether it's a new or established company, my experience has been that the companies are still struggling a little bit with how to assess risk related to software. Whether the software is the device, or the software is embedded in the device, people still treat software as though it's this mystical thing—more art form that engineering or science. And I find that to be just crazy. It's not that hard to do a software FMEA. It's not that hard to do an FTA (fault tree analysis) early on to figure out what could go wrong with your software. The profession of software engineering actually has very good tools and processes. It seems to be much harder to do good risk management related to software than it needs to be.

Joseph Sheffer ***Another priority action from the 2015 summit was for manufacturers to engage in a "total product life cycle approach to risk management" in order to "improve the effectiveness of risk management, from initial product conception in premarket to final decommissioning and disposal in postmarket." Has this total product life cycle approach to risk management gained sufficient traction with manufacturers? Or is it still seen as a box to check to satisfy regulatory requirements?***

Tom Shoup I think it gets into the culture of the company. When I worked at established companies, it was just a cultural thing that once we shipped a new product, we constantly got feedback from users through multiple channels: service installations, repair, experience on the manufacturing line, and so on. And so that all got folded in, which is a huge economic driver. That's not the only reason manufacturers are interested

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—Aaron Goodstein, senior director of medical safety operations at Johnson & Johnson in Fort Lauderdale, FL

in it, but it is a big driver. So again, for established companies, looking at it through the whole life cycle is pretty easy. For new companies that are struggling with a lot of processes that they're not used to doing, it's just one more hurdle. I've seen new companies struggle with receiving, for example. You need standard operating procedures for what the people on the receiving dock should do when material is delivered. If they're not even used to working under the ISO 9000 family of quality management systems standards, they're certainly not going to be able to come up to anything near what 13485 would require. So this isn't isolated to just risk management, but it's the same effect.

Joseph Sheffer ***Switching gears a bit: What degree of clarity do health delivery organizations (HDOs) have regarding risk management for medical devices? If confusion exists, what are some of the causes?***

Tom Shoup A recent article in *BI&T* on the care and handling of medical devices[5] included the importance of understanding what chemicals are in your cleaners—that's a risk management thing. Given the examples in the article, it seems that some HDOs don't know that they ought to read the label. They need to worry about what types of solvents, such as ether, acetone, or alcohol, are in cleaners. Manufacturers range from doing a good to a bad job of testing a few cleaners, and they put it in the labeling. But nobody reads the labeling. And there's just not an awareness that any old cleaner off the shelf may actually harm your product.

Adam Seiver I'm always astonished that the medical device manufacturers are trying to do things like Six Sigma and worry about 1 in 10,000 or 1 in 100,000 events. And then you walk into a hospital, and you're really in an environment where there's maybe one or two Sigma. So there's a complete mismatch between the standards to which medical device manufacturers and HDOs hold themselves. I'm not advocating that manufacturers would have a different standard, but I think that HDOs have a long way to go to not be the weak link in the chain.

Tina Krenc I'm not sure that every company is entirely clear on what risks they're transferring to the user, to the hospital, and to the clinical laboratory because residual risk always remains. But I'm not sure they're very clear saying, "Okay, we're counting on you to do this." Related to what Tom said about the materials used in cleaners: that's an example of manufacturers potentially transferring risk to clinical users. I don't think we're very clear about the limitations and warnings of the procedures. They may be in the labeling, but having to go through and find that information can be challenging. Years ago, CLSI (Clinical and Laboratory Standards Institute) was trying to develop a standard that included a methodology where manufacturers were required to inform clinical laboratories of all leftover risk so that they were aware what was transitioning to them. Well, that didn't go over very well; it never was published. But it's something that HDOs and manufacturers need to consider. How do we communicate that without heavy liability issues for the manufacturer? How do we make sure that any mitigations the user must manage to maintain the safety of the device is clearly shared with the users? How do we make sure that we're very clear about that?

Aaron Goodstein That's a very good point, and it's something that's not necessarily taken into account all the time by manufacturers, from a mitigation standpoint. How do you ensure that you get the best possible outcome from the use of your device and that you have the most standardized application and use of your device? Companies are starting to explore methodologies that would enhance labeling. They emphasize key points and elements regarding the use of a device or a procedure to try to highlight areas of residual risk for healthcare providers, so that they can take the appropriate action and get the best possible use of their devices. That's something that probably needs to be looked at and more widely implemented across industry.

Pat Baird When it comes to activities related to cybersecurity, for example, the manufacturer can't control everything. Manufacturers will highlight how an HDO's firewall and other attributes of its IT network relate to cybersecurity. That's just part of risk

management. So, although we do that for cybersecurity risks, we really don't have similar mechanisms for communicating other types of risks.

Tom Shoup Two high-level parties are involved in this. Manufacturers are disclosing residual risk and helping users understand sources of harm that they have some control over. The other side is that HDOs have the responsibility of operating the device in a safe way. I'm not in a position to judge what the pull is from the responsible organization, but "responsible organization" is actually a term in the standard. So, manufacturers could disclose everything. But if there isn't a certain amount of pull from the HDO, which includes creating an awareness among users, then that's only half the job done. So I think there's 50/50 shared responsibility here, and we should be asking the question, and this is what Tina brought up: Can manufacturers disclose more? On the other hand, the responsible organization should step up and take more responsibility to, if nothing else, push awareness down in the organization about having a risk management mindset when using devices.

Joseph Sheffer ***Focusing now on cybersecurity: Are cyberthreats being adequately factored into the risk management process for either manufacturers or HDOs?***

Aaron Goodstein From my perspective, cybersecurity was the buzzword of 2017.

Risk Stratification in a Real-World Healthcare Setting

Loretta K. Dorn

The Lake County Health Department and Community Health Center provides primary care and behavioral health services to vulnerable and uninsured patients in Lake County, IL. Our goal is to provide high-level quality of care through wraparound patient-centered care.

Given patients' complex health and social issues, a risk stratification model was developed based on ANSI/AAMI/ISO 14971:2007/(R)2016 to identify patients who were most at risk for poorly managing their health conditions. High-risk patients are less likely to control diabetes, hypertension, obesity, and other chronic conditions when combined with the various social determinants of health. Currently, patients are given a questionnaire that uses three categories of risk: 1) high or acute need, 2) medium or chronic need, and 3) low or supportive need. The probability of a hazardous situation leading to harm (referred to as P2 value) has been incorporated into the questionnaire. As such, high risk assumes critical or catastrophic harm, medium assumes moderate harm, and low assumes minor or negligible harm. This produces a three-level P2 value for the severity of the harm.

The tool has been programed into the electronic health record. Therefore, after the questions related to comorbidities and social determinants of health have been entered by the patient-centered medical home team nurse, the tool automatically calculates the score. A patient in the high-risk category then becomes a case-managed patient, and a care plan with patient-centered achievable goals is created. From the identified risk factors, we created a red/yellow/green table to identify where the patient falls in the stratification.

- **Green** is considered "good to go." These patients may need a referral to reduce smoking or for simple health maintance procedures but do not need specific interventions beyond the normal primary care physician (PCP) visit.
- **Yellow** is considered "watchful." These patients need close review by the PCP in case the condition worsens, another chronic conditon is added, or an increase in hospitalization is noted.
- **Red** is considerd "act." These patients are enrolled in case management.

The goal of our organization is for all new patients to have a complete risk assessment. Use of the tool to manage high-risk patient means less hospitalization and better control of chronic conditions. Use of the 14971 approach combined with comorbidities and social determinants of health allow us to understand when patients need more help managing their conditions. Although we continue to test and review the tool, ultimately, we anticipate that the data will demonstrate that proactive risk management increases the management of health conditions in individual patients.

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Manufacturers are very much concerned and aware of cybersecurity threats both from the standpoint of how does it impact the performance and safety of our products, as well as how does it impact the safety and reputation of the company itself. Nobody wants to be on the front page of the news after being hacked or held ransom, with a bunch patient-identifying information compromised. For manufacturers, cybersecurity has been built into the processes and people are more than well aware of it.

Pat Baird I agree: Cybersecurity is all over the news. It's getting serious attention both in terms of potential harm to patients and concerns regarding privacy.

Joseph Sheffer ***How do human factors or systems engineering considerations contribute to a risk-savvy culture, in either manufacturing or HDO environments?***

Adam Seiver We're doing a lot more in terms of human factors testing and formal outside consultation with human factors companies to put our devices through rigorous evaluation. I think there is more that we could be doing. It would be nice if we had ready access to an environment where we could put our devices into the field and observe their use in realistic situations. There's obviously a lot of complexity to doing research with experimental or developmental devices in real-world patient care settings. But there are limitations (in addition to advantages) for testing in simulated environments.

Tom Shoup Adam, there's the investigational device exemption (IDE) to put significant-risk devices into the field, and you just need institutional review board approval to put a non–significant-risk device into the field. I know that's more time and more money, but are there other hurdles to using those two programs?

Adam Seiver The IDE always causes a visceral reaction in management, but I agree that we need to work through that and do it the right way.

Tom Shoup One of the easy things to do, though I'm usually astounded when my clients won't do it, is to bring in doctors, nurses, or whoever's representative of the intended user group into the factory and have them use and operate a prototype. You're probably not going to do heavy-duty orthopedic surgery in a simulated environment like that, but a lot of times, just positioning the patient, moving equipment, holding it, operating the controls, and stuff like that—you gain a wealth of information. And if you don't do it, you're running an unforgiveable business risk of being surprised either late in the game or after introduction. I had a client who I begged to do this, and I never understood why they wouldn't. They launched a new product, and it was a flagship product, and the very first surgeon who got their hands on it, after a week said, "Take this back." And there was just a flaw. And it wasn't really a patient safety flaw. It was a usability flaw that they would have caught if they'd had a couple of surgeons come in and "play doctor" with this equipment. It cost them hundreds of thousands of dollars and a chink out of their reputation because of that.

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Aaron Goodstein That's a great comment about bringing in representative healthcare professionals. A lot of times, companies have an overreliance on the opinion leaders when they do this type of work. The bottom line is that medical devices are going to be used by a wide array of healthcare professionals with varying levels of skill. An overreliance on key opinion leaders can sometimes skew the results of your human factors analysis. So, ensuring that you have a representative population doing that work is really important for getting the most bang for your buck.

Tom Shoup The other thing to recognize is the fact that a manufacturer often draws conclusions from only key opinion leaders. One time, when I was vice president of R&D at a company where we had a Class 3 product, we had to do a postintroduction study to demonstrate to the FDA that normal users could get the same result that our key opinion leaders had gotten in our clinical trials. They initially wanted to set it up as an experiment, and I pointed out you couldn't withhold a cleared or approved device from somebody. So we turned it into just monitoring. But we spent probably $1 million collecting results from "average" physicians

to demonstrate that they could get the same results as the key opinion leaders had gotten. And I think there's a mildly spoken push to be more proactive in getting market feedback on the quality of results from devices. And that should be a data stream that manufacturers should really be going after.

Jacque Mitchell I agree that it's important for clinical end users to try out products. It's amazing how people, after they've been educated and trained, will then go about doing it their own way. They'll find workarounds to doing things. So I think it's really important to learn how people may find workarounds. And I also think it's important to partner with your healthcare people to make sure that they know that they can have a voice back to you. From working in a large organization, I found that we would report back to the manufacturer. But I think in the smaller companies, you're not going to get that feedback because they don't think they are empowered to give feedback to the manufacturer. Learning about potential workarounds would be a huge benefit of user testing. If the human factors aspect doesn't factor in the humans who would be using the device, then I think you're going to have a lot of potential for workarounds, which could result in harm because somebody skipped some vital step along the way.

Pat Baird The medical practice is so diverse in this country. There's a saying: "If you've seen one hospital, you've seen one hospital." We may know what Mayo Clinic does, but what about the HDO in Sioux Falls, South Dakota? There's a diversity of approaches in these things. About a decade ago, I was in Boston doing some observational research, and a pharmacist told me, "No matter what, your product has to do X. We need a feature to do X." Later that same week, I was in San Francisco at a hospital. A pharmacist pulled me aside and said, "No matter what, don't ever do X. Never do X at all." I therefore have conflicting user needs: The product must have a feature and also must not have that same feature.

Aaron Goodstein In the healthcare community, we have a standing joke: What do you call the person who graduated last from medical school? Doctor. So, you have the full gamut of people. You have the people who graduated at the top of their class and those who graduated by the skin of their teeth. And they're all allowed to do the same thing. So, we have to make sure that the device performs and gives the same outcome in the hands of anyone who's licensed to practice.

Tom Shoup Pat used a very interesting term: "observational research." During my career in various management positions, anytime an engineer asked to travel to a technical conference or visit a vendor, we required that they spend an extra day and ride around with either a sales person or service engineer, just so they could see where our equipment was going, meet the people who used it, and see how it was used. Everybody always came back astonished by something they had witnessed. Adam raised the point about how hard it is to simulate an environment in the factory. And, you know, there's always time and budget crunches to putting equipment out in the field. But just observational research can be a huge benefit for the design team, and I don't just mean the engineers. Sometimes even the product managers, manufacturing engineers, and others—if they can see the environment where their equipment is going, it can really help round out their understanding of what they need to design.

Pat Baird I used to have a rule for staff who reported to me: "To better understand our customers, you have to visit one hospital per year." But then, the following year, I changed that to "You have to visit either zero or two hospitals every year." I was having problems with people going to just one hospital and thinking what they observed was the only way that hospitals worked. In this case, a sample size of one was worse than a sample size of zero.

Joseph Sheffer ***Before we conclude our discussion, does anyone have other thoughts on risk management that they'd like to share? If you could "sound the alarm" regarding one aspect of risk management, what would that be and why?***

Tina Krenc During the last six months, I have been encouraging anybody who's involved in risk management, no matter where they are, to use all available sources of data. People tend

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—Pat Baird, regulatory affairs specialist at Philips Electronics North America in Pleasant Prairie, WI

"We need to empower our clinicians to give feedback and assure them that manufacturers do listen to it. But moreover, it's important to establish better relationships other than just the vendor trying to sell you a product."

—Jacque Mitchell, former risk manager at Sentara Norfolk General Hospital in Norfolk, VA

to feel that when they're looking at a product, wherever it is in the life cycle, they can only use certain data. But they really should open their eyes and find all available sources of data, whether it comes from complaints, talking with physicians, or looking at things that are considered noncomplaints, like service records. There's so much information out there in addition to the total product life cycle and the FDA publications. Looking at all available data is critical to making good decisions, but many people are afraid or simply don't know how to do that. Currently, there is no good standard or methodology available on how to best collect or analyze data. However, the committee for ISO/TC 210, Quality management and corresponding general aspects for medical devices, is working on a guidance document on how to best collect data. We're trying to fill that gap. The guidance should help people determine where to look for information, as well as how to evaluate it.

Adam Seiver From my involvement in risk management activities, it seems that people sometimes mistake the process for the end. There may be a lot of attention on dotting the i's and crossing the t's, and people feel that that's risk management. It is important, but it's a means to an end. A large part of risk management is being skeptical and having a questioning attitude, where you're trying to make sure that you've thought things through to the point that you've gained a deep understanding. For example, have you looked at all potential sources of data, as Tina mentioned? What do the patients feel is an acceptable risk for that device? Including a free-ranging analysis and thought process in your overall risk-benefit analysis is an area that we should focus on more as manufacturers.

Jacque Mitchell Looking at the clinical side, I'd like to highlight the importance of partnering with the end users and getting more feedback from them, both before and after the product comes out. We need to empower our clinicians to give feedback and assure them that manufacturers do listen to it. But moreover, it's important to establish better relationships other than just the vendor trying to sell you a product.

Tina Krenc It's really important for manufacturers to clearly document the benefit of their product, and how they've translated that into their product. Because that's going to come back in the postmarket phase, when they're trying to evaluate risk and benefit, or even during the process of the product life cycle, early on in developing the product. We spend a lot of time on the risk, but we don't spend as much time solidifying the benefits.

Adam Seiver I like that point because frequently, as a chief of medical affairs, I get asked, "Is this risk acceptable?," as though the world existed in black and white. The only answer I can give is: "Acceptable compared to what?" You have to balance the benefit against the adverse consequences, whether they're certain or uncertain. You also have to balance leaving something in the field, versus introducing something, and versus what is the alternative that's out there? And benefit considerations are clearly a large part of that. ■

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