A Roundtable Discussion
Forging a Path toward Seamless Health IT

Roundtable Participants
Sean Loughlin is vice president of communications at AAMI. Email: sloughlin@aami.org

Gerard Castro, PhD, MPH, is project director for patient safety initiatives in the Office of Patient Safety at The Joint Commission in Oakbrook Terrace, IL. Email: gcastro@jointcommission.org

David Classen, MD, is chief medical information officer at Pascal Metrics in Washington, DC. Email: david.classen@pascalmetrics.com

Joe Lewelling is vice president of emerging technologies and health IT at the Association for the Advancement of Medical Instrumentation in Arlington, VA. Email: jlewelling@aami.org

Sean Loughlin Let’s start with everyone grading the current state of health information technology (IT), as well as your thoughts on why you gave that grade.

Michael McCoy I would give it a C+. We have come a long way from the beginning of the incentive programs, the HITECH era, and we have a reasonable level of adoption in the clinician practices and a very good level of adoption in the hospital settings. However, the reason I wouldn’t give it a higher mark is that we still have a challenge with broader physician adoption, and beyond the traditional hospital setting and physician office setting, we still have the continuum of care gap that still needs to be addressed more robustly.

Michael Marchlik We have to look at health IT as an enabler of the ultimate goal: a patient-centered healthcare system. From that perspective, I think health IT rates about a B–. While we have enabling technology out there in the hands of many providers, like Mike McCoy said, not everyone has it yet. More importantly, we’re being asked to pivot away from adoption to concentrate on outcomes. And that’s where we have the most significant opportunity to improve both the processes and technologies that will help deliver that patient-centered healthcare system. It will be important to avoid policies that get too deep into standards versus setting broader policy goals that let industry innovate to meet these objectives.

David Classen I would say right in the middle of C. We’ve been successful at adoption, more wildly successful than I ever could have thought, but we haven’t been successful leveraging that adoption for significant broad-based benefits yet. However, I think there is great potential to get benefit, as Mike Marchlik just said.

Mark Segal I’m going to be a little more optimistic and give it a B. If you look at the rate of growth of adoption, and the ensuing extent of digitization, it’s very high. And my understanding is we’re actually exceeding, at this point, many European countries. So, I think you have to look at where we are relative to where we’ve been. Clearly, there are more opportunities, and those are emerging every day, so I’ll rate it a B rather than an A. I also think we have to be mindful of some of the user frustrations that we’re seeing, many of which have to do with product improvement, but also very much with how product development and requirements for use by providers have been driven by regulatory requirements—whether it’s meaningful use or long-standing requirements such as those related to E&M (evaluation and management) code documentation—that have really soured some providers on their use of health IT.

Addressing the many dimensions of this frustration is a real challenge that we have going forward.
Gerard Castro I would give it a B−. As others have said, the incentive programs have successfully put the technology in the hands of providers. But I think more work is required to fully realize and optimize quality and safety improvements. That’s not to say that the technology is not there; it is there. We have the ability to do these things, it’s just really marrying the technology with the workflows and processes in the clinical setting.

Lana Lowry I would give a grade of D−. The reason is because I was the one who was leading the project on empirical data collection. I got to see first hand the struggles that the end users were having with these systems. But most important, they have no help that they need in order to have successful interactions. There are certain things that are not standardized, and certain things that should never, ever be present in safety-related systems, but they’re there. One example is hard stops. The hard stops are crucial; they should not be there. The last decision has to be up to the user, not the computer. For these reasons, I would grade it very low, but I do agree with what I just heard. All of the potentials are—they are great potentials, and the technology is present. It’s just the point of making this technology functioning and safe.

Sean Loughlin What’s the single biggest challenge to realizing a seamless and interoperable health IT system?

Michael McCoy I would say it’s business practices. Until we have alignment of incentives that really make it worthwhile for clinicians, hospitals, and systems to share information, it’s more in their business interest to keep the data where they have the most benefit. The move to payment reform and portability of patients and data will help align incentives for better care of the individual rather than the data within a particular organization. Until that (payment reform) happens, there is little incentive for that (interoperability) to take place. Although there are technical challenges, the greatest challenge is related to business practices.

Lana Lowry I would say that the lack of standardization is the greatest challenge.

Michael Marchlik I tend to agree with Mike, in that the biggest challenge isn’t the “how” but the “why.” A lot of work has gone into creating new, innovative standards, and they hold a lot of promise. We need to clearly understand what the objectives are going to be, so we don’t go down a path where five...
years from now, we’re “interoperable,” but we have missed the mark in delivering a patient-centered healthcare system. We need to have a clear understanding of what we want to achieve with interoperability beyond meeting the latest technical standards.

**Michael McCoy** I agree, and adding to that, one challenge is defining what’s necessary for interoperability. It’s not the entire universe and every bit of data that has to flow. It’s the critical priority data elements or data domains, as have been defined. That’s really what’s important clinically.

**Gerard Castro** At the risk of vastly simplifying this, I would say the ultimate goal is to provide actionable information when it’s needed most by the provider. By focusing on that, the other aspects will fall into place.

**Mark Segal** I agree on the importance of the business case, and I’d focus it less on people having incentives not to exchange. I think the most powerful piece is shifting so that people have positive incentives to invest their time and resources in exchange. And as Gerard suggested, exchange should be prioritized based on what information is necessary. To Lana’s point, my sense in talking to people is that generally, we have the standards that are needed for exchange. In addition to a more robust business case, the major opportunity is standardized implementation of those standards.

**Sean Loughlin** *What are the problems, challenges, and trends in addressing safety and security today? How are organizations and authorities approaching this?*

**Michael McCoy** It’s really not sufficient to just have good “cyberhygiene,” though that is clearly critical. There are additional layers of security and privacy that are important to ensure the safety of the data within hospital systems. Even if you have good, robust systems, there still will be targets painted on every hospital’s back, insurance company’s back, etc. As shown with the recent Department of Homeland Security and FBI breaches by hackers, even the federal government and OPM, with more resources available, have had breaches and hacks. We have to become a little more focused on the overall concept of how to address safety and security of the data so that patients are comfortable with the data, where it resides, and that organizations that are enforcing policies and best practices actually do exist.

**Lana Lowry** Safety of the data and safety of the system: these are two different things. We need to look into the reports that are coming out of the patient safety organizations. Establishing safety standards and harmonizing them with industry would be a huge step forward. A lot of users will feel relieved if the systems would become safer to use. The biggest challenge I see is transparency. I do not believe we currently have any databases or systems in place where people can report misses or near misses and feel safe doing it. We can certainly learn lessons from these reported events like we do, for example, in the aviation industry.

**David Classen** I personally have been through scenarios where safety and security standards conflicted, where my password expired and I couldn’t get into the system to place a critical order on a patient. And that happens not infrequently, with my passwords usually expiring every 90 days. So I really believe that we need to reinvent the security system to make sure we are not in a situation where a critical order could not be entered for a patient because a password has expired or does not work. I do not know where the evidence base came from to justify this password change every 90 days, and when users deal with multiple systems and multiple different passwords, it can get really burdensome and unsafe. This password process is an example of the problems that can occur when user-centered design isn’t effectively used.

**Michael Marchlik** A lot of new challenges have been emerging in the patient-centered environment, where patients own their data.
Patients are going to increasingly be in a position to contribute their own data. They're going to have the right to choose when, with whom, and how that data is shared, and we are going to have to build security models that support all that. We’re also adding complexity with policies that are requiring the use of restful APIs (application program interfaces) as a means to share data. At the end of the day, we have to always remember that interoperable doesn't mean secure. That’s the challenge that we’re facing going forward as we try to extend what we currently have and move away from siloed data.

**Sean Loughlin** What are the challenges and opportunities for today's health IT system in terms of health IT regulation and governance?

**Michael McCoy** There is an opportunity to realign the needs of consumers of technology, so it's physicians, hospitals, and patients. Unfortunately, some of the realignment requires, literally, legislative changes. For example, meaningful use is an example of something that can't just magically go away. Regulatory relief is going to be needed in addition to realigning various measures and constraints that are placed on the EHR development in order to make users of the system happier, to decrease the documentation burden, and to realign the way we do things with health-enhanced outcomes rather than check boxes for process measurements.

**Mark Segal** Meaningful use has been enormously successful in many respects. But it has also led to some significant challenges: The program sought to program, at a very microlevel, how physicians and hospitals have to use their technology in ways that none of us would really appreciate if our employers, for example, were doing that. Likewise, we’ve seen in many cases that the federal advisory committees, ONC, and CMS have attempted EHR and health IT product management, and I think in many respects, that approach has created real challenges for developers and end users. Looking ahead, CMS is aiming to create more flexibility for meaningful use, some of which will require legislation. I think it is also really important that ONC, as it’s moving forward within its own statutory authority, looks to lighten the regulatory burden around the certification process. I have a bit of apprehension about a situation where there’s appropriate lightening up on the provider side and perhaps a doubling down on the product side, which I think will have negative consequences for everyone.

**Sean Loughlin** What role do quality systems and risk management have in establishing a healthy health IT ecosystem?

**Michael Marchlik** Looking at quality systems and risk management is important. They’re necessary and critical components, but they’re not sufficient to deliver high-quality health IT to support a patient-centered healthcare system. We have to make sure that they’re designed to promote and work with a highly innovative, agile industry and are subject to continuous improvement.

**Joe Lewelling** When talking about safety and security, it’s important to remember that those are characteristics of the system. When defining the health IT system, it is essential to understand the components of the system—the roles of all of the people and software involved in that system. Quality systems and risk management can help delineate those and delineate what is expected of individuals who participate in the system, as well as the technology that is used.

**David Classen** At the hospital level, we run a pretty complex ecosystem with lots of different vendors and products involved, and we have not had a clearly identified place to turn for health IT risk management and quality management best practices, in terms of maintaining that complex ecosystem. So I think this will play a critical role in giving us guidance at the hospital level and how we safely operate that complex health IT ecosystem.

**Gerard Castro** A well-functioning risk management system would proactively identify risk across the care continuum—the different roles and the different components. That is what we’re ultimately looking for: to actively seek to reduce those risks and hazards.

**David Classen** Building on that, we are proactively building surveillance to detect risks as soon as they occur or even before they even occur.
Mark Segal
It’s also important to recognize that these kinds of approaches and standards really will need to be tailored to the kinds of organizations that are affected. Approaches to risk management are going to be different for a physician’s practice or small hospital versus a very large, multispecialty practice or large hospital organization. Having flexible approaches to development and deployment of these kinds of programs is going to be important.

Sean Loughlin
What about user-centered processes and design guidelines for health IT? What does that mean?

Lana Lowry
User-centered design is a process that involves bringing user requirements and needs into the system specification and the design of the functionality. For example, when the system is about to be designed, there are certain technical requirements for the system. In parallel with the technical requirements, the user requirements are created, and then during the process, these requirements are validated and the system is tested iteratively in a formative way to inform design of user needs and ensure that they are met. Finally, at the end of the process, usability testing is done to establish the pass/fail criteria and determine whether users can or cannot interact with the system successfully and safely. This is the standard process as defined by ISO and by the national standards.

My opinion is that it’s very important to understand that the design guidelines and principles should be voluntary, because if they are rigid, it will stifle innovation. It is very important to provide guidelines for safe practice and best design practice, but in my opinion, it’s not very wise to enforce them, because that is how innovation starts—by thinking outside the box. Only safety-related features shall be enforced.

Mark Segal
There’s a science to user-centered design, and much of that is reflected in the kind of standards that Lana discussed. There’s also an art to it, which comes in how the process is applied, and this is something that GE Healthcare is very committed to. I’d also like to emphasize that because so much of the end-user experience with health IT is a function of implementation, the configuration decisions made by the provider’s organization is important. As organizations, hospitals, clinics, and others make decisions around how to implement and configure, they should be guided by user-centered design processes. You can’t just stop at product development.

David Classen
That’s a critical point, because the goal of what we’re developing here is something that’s applicable at both the vendor and the healthcare delivery organization level.

Sean Loughlin
I’d like to turn now to the work that AAMI is doing with its health IT Initiative, which I think everyone on this call is involved in. Joe, could you please provide an overview?

Joe Lewelling
AAMI has long involvement in developing standards for the safety of medical technology, including health IT systems. In the last decade, we specifically addressed health IT systems through our work with ISO and IEC developing the 80001 series, which deals with risk management for IT networks incorporating medical devices. That work is continuing, and international standards will eventually be developed that address all aspects of health software and health IT systems safety, security, and efficacy, including usability, risk management, quality systems, governance, and more. Developing this body of standards will be a long-term process. We’ve also recognized a distinct and separate need for standards here in the U.S. to bring conformity and consistency in the application of quality systems and risk management in the health IT ecosystem. Certainly, health IT
vendors, hospitals, and others use quality systems already—many of them also use risk management—but we’re trying to develop standards that ensure that these are applied in a consistent manner, because as mentioned before, safety and security are the characteristics of the system and you cannot ensure safety or security by addressing these only at the component level. We are developing two standards, one that will deal with quality systems practices for health IT and one that will deal with risk management processes for health IT. These are not aimed at vendors or at the users separately, but rather at the system as a whole. The goal is to define the roles, responsibilities, and expectations of the various players in that system. We’re hoping to have the first editions of these available in 2017, and we expect this to be an iterative process. The standards will be revised over time as we learn more and are able to further develop health IT systems and associated practices. AAMI is also considering proposals that the association develop guidelines for user-centered design processes and for good design of user interfaces.

**Sean Loughlin Any thoughts on what Joe has outlined?**

**Mark Segal** I have a couple of thoughts. One is that it’s certainly critical for us, and I think much of the industry in general, to have really good alignment between U.S. and international standards. Secondly—and this would apply in particular to the proposals related to usability standards—I think that in many respects our problem is not a lack of standards. We have to be careful to make sure that standards development is needed and not duplicative. I’m very impressed with the careful way that AAMI is approaching these decisions.

**Joe Lewelling** I just want to reiterate that we are doing this: the domestic work is in tandem with the international work.

**Michael Marchlik** AAMI is doing a very good job of managing this process. It’s especially difficult because what we’re trying to do is to develop standards that span an entire life cycle of products, and recognize all the entities that are involved with that. It will take a lot of input from a lot of different parties to make sure we get this right. We’re looking at it holistically.

**David Classen** The AAMI initiative is ambitious, but I think it’s necessary because the health IT ecosystem is very different than other things that we regulate, and it requires a holistic solution.

**Sean Loughlin Before we get to the final question, are there any additional points that anyone would like to mention?**

**Michael McCoy** I would like to emphasize the balancing that’s needed between regulatory oversight versus the free market and innovation that occurs. We don’t want to stifle innovation. We want to encourage innovation, and often there are unintended consequences from a regulatory environment and oversight. So hopefully we can find the right industry-led balance. Particularly, that’s what AAMI is doing as a way of moving forward. And again, internationally, it’s absolutely appropriate.

**Sean Loughlin How will health IT look 10 years from now? What will be different?**

**Michael Marchlik** If you look at IT in general, we all know that there’s a logarithmic growth curve. So if you look back at the past 10 years, in the area of network, storage, mobile computing—we know that 10 years from now, it’s going to be a very different environment. There’s going to be technological capabilities out there that we can’t even imagine. The real question is whether we go chasing after that shiny new object for the sake of using that new and innovative technology, or if we purposefully and judiciously use that technology to improve healthcare delivery and patient care. At the end of the day, we have to keep the

There’s going to be technological capabilities out there that we can’t even imagine. The real question is whether we go chasing after that shiny new object for the sake of using that new and innovative technology, or if we purposefully and judiciously use that technology to improve healthcare delivery and patient care.”

—Michael Marchlik, vice president of compliance and regulatory affairs at McKesson
objectives in mind because it’s all about improving patient outcomes and better enabling patients.

**Mark Segal** As I look at where technology is going, I think some of the clichés that we’re hearing, the buzz words, are in fact going to be critically important. I think we’re going to have much more technology deployed through the cloud; I think we’re going to have much more of a focus on modular or app approaches to develop particular types of health IT designed for particular use cases that folks have. I think we’re going to have a focus on interoperability and data liquidity that’s also very tailored to what a clinician might need in a particular instance—the data elements they need at a given moment to make a clinical decision—as well as the data elements that are needed for quality measures.

**Gerard Castro** I have a 13-year-old son, so in 10 years from here, he’s going to be 23. I think about how he will be accessing all technology, including health technology. I wouldn’t be surprised if he didn’t even have to go to the doctor’s office anymore. Today we have the wearable technology that measures heart rates, and many other kinds of physiologic data that data can be shared with clinicians remotely. And that’s a trend we see in telemedicine—healthcare is moving away from the brick-and-mortar building. Clinicians will have more and more data, but what they need is actionable information. Can we solve that problem? The extent to which we solve that problem will inform the degree to which the future vision I described is achieved.

**Michael McCoy** I hope that we see a patient-centered and individual-activated health system, with emphasis more on the “health” than the “care.” I hope we get there in 10 years. It’s an audacious goal, but I think it’s doable.

**Lana Lowry** Well, it took aviation 60 years to become safe. So, I’m hoping that 10 years from now will be the time when health IT has become completely safe.

**Mark Segal** As we’re looking ahead, I want to emphasize that health IT is a means to an end. It’s a tool. As the system matures and societal challenges emerge, I’m looking forward to a day when health IT can be rapidly deployed to help address challenges like the emergence of the Zika virus. We learned a lot from how the users of health IT handled the Ebola crisis, and it’s important to look at conversations that are occurring now around the precision medicine initiative and the national cancer “moonshot.” It would be great to get to a point where the health IT infrastructure that we’re all investing in will be able to be deployed seamlessly to handle those kinds of challenges.