Using Data-Based Decisions to Transform Health Technology and Improve Patient Care

**Bradley Schoener** How well is the healthcare technology field using data generated by technology to make clinical decisions? What’s your assessment?

**Rich Zink** One of the challenges we still have with healthcare technology data is linking it to patient data. Right now we can say, for example, that there are fewer alarms being generated but we don’t know things such as what the patient outcome will be if we reduce the length of stay or reduce the number of readmissions.

**Karen Giuliano** Healthcare technology provides us with a wealth of important information, but linking data from various sources into one place is a continued challenge. For healthcare technology to have optimal impact, clinicians need to have all the data they need in one place and easily accessible. While there have certainly been improvements in the past decade or so, we still have a long way to go.

**Loretta Dorn** The first hurdle for getting data generated is inputting the data in a manner that provides the information needed to make a decision. When entering data, healthcare providers don’t always understand why we are asking for certain types of data. They may leave gaps that make the data inaccurate. For example, if I want to determine what my cycle time is for any given patient task but the electronic health record (EHR) marker is being changed by the provider to match expectations of the organization, then the data become invalid.

**Michelle Jump** It is also important to understand the reliability of each data source when aggregating data that will be used to inform clinical decisions. Not all data are validated for the purpose of clinical decisions. If less reliable data are used in conjunction with other, more robust data, this can skew the validity of the recommendation. In other words, if you combine data with different levels of accuracy or reliability, the recommendation can only be as good as the least reliable data.

**Bradley Schoener** Can you characterize the maturity of the life cycle? Are we at an “adolescent phase” or a “senior citizen” phase? Do you feel like we’re still on a very steep curve, or do you think we’re making some real headway?

**Berkman Sahiner** It’s still a pretty young industry with many data sources that could be incorporated, including data from imaging, devices that collect biomedical signals, or devices that generate and analyze genomics data. All of these sources are producing huge amounts of data that could be utilized in healthcare. There is still a huge potential for growth.

**Pat Baird** We’re in the early teens—looking forward to having the driver’s license and all the freedom that the future is going give us but not realizing the responsibilities or the hard work that’s going to go into getting that driver’s license. We still have big bright eyes about how wondrous the world is and how great the future is going to be, and we’re just starting to realize that getting there isn’t going to be a snap of the fingers.

**Martin Ho** We are enthusiastically exploring different options, but we don’t own the car keys! We think about the outside world and how wonderful it is. But the problem is that while I have some access to a car, my access to the keys is restricted. All of these data systems are being developed for specific purposes. They are not being designed to be shared and used as an ecosystem, which would benefit patients.
**Michelle Jump** We are certainly still in school, learning the ropes but trying new things. The great thing is that the people involved are also still exhibiting the exuberance of youth! That means that we have some great potential and exciting innovation that should come out of this. The key here is that we stay in school long enough to graduate with a good understanding of the fundamentals.

**Bradley Schoener** What are some of the obstacles that get in the way of drawing these different datasets together for clinicians to make decisions?

**Rich Zink** We still have thousands of data sources from which we’re pulling data. And with all the disparate data and the size of the data, linking it all up, as well as linking it to the patient, is one of the biggest challenges that we still have.

**Pat Baird** All these different data sources are not only in their own silos—the silos themselves are on different islands! There are a lot of barriers to getting and connecting two of those data sources together. Our healthcare system wasn’t designed that way. We have a lot of distributed ownership of this data.

What do I mean by that? Different vendors are developing and optimizing their products to get the maximum use and utility for a particular kind of therapy, one that is particular to their medical device function. There hasn’t been a strong motivation to work together. For example, think of the continuum of care—when patients are discharged or need follow-ups, the responsibility for the care is handed off amongst different people who are working on different systems.

Contrast this with healthcare in countries outside of the United States and with industries outside of healthcare. In the aircraft industry, a manufacturer is responsible for the entire design of the airplane, even though it may subcontract some of the work. They are a single entity responsible for integrating the system and making sure things work smoothly. We don’t have that in healthcare in the United States.

**Martin Ho** I would go a step further. Even as a patient, I am very empowered to get my hands on my own data. But the ownership is so unclear that every time I ask my provider to get it, they always provide different types of barriers. Needless to say, other competitors or providers would like access to my data.

The ownership, and what that ownership means in terms of access, is yet to be clear.

**Karen Giuliano** In addition to the various constraints already mentioned, manufacturers invest a great deal of time and money into their own products and systems. While manufacturers may be open to both sharing their own data and hosting other manufacturers’ data, there are often competing proprietary or economic concerns that can really get in the way of open sharing, and these may not be small issues.

Consider a physiologic monitor. The manufacturer hosts a variety of physiologic measurements. Some they may have developed themselves, whereas others involve partnerships with different manufacturers. Each partnership will have its own individual licensing or partnership agreement, which outlines how their data can be used.

**Rich Zink** Here’s another example of silos. In the healthcare system where I’m a patient, the doctors are on one EHR system and the hospitals are on another. When I show up at the hospital and they ask me what my prescription list is, I tell them it’s “in the system.” But then I’m told that I have to tell them all over again.

**Loretta Dorn** The biggest challenge we have is sharing of data as mentioned previously. If a patient is seen at an urgent care center with a high A1C (average blood glucose level), but the primary care physician isn’t aware of it, then the data can’t be used to change the medication or treatment. Patients very seldom remember lab results unless they happen to bring the discharge paper with them to the next provider. We cannot provide truly reliable care if our data systems don’t talk.

This includes knowing if patients pick up medications prescribed after discharge from the pharmacy or if they didn’t bother to pick them up because of cost or transportation.
Michelle Jump Others have mentioned the silos that exist in the current industry practices, and those are certainly obstacles. However, some of those silos can be broken down as manufacturers and developers partner with other vendors with strong data-handling experience. We’ve also seen manufacturers collaborating on projects. Manufacturers can no longer develop their products in a vacuum with an assumption that others will integrate them.

Bradley Schoener What about data-based decisions is exciting to you? What’s on the leading edge where health technology is driving decisions?

Karen Giuliano I recently visited a large hospital system that has implemented intravenous (IV) smart pump integration with the EHR. While the integrated process requires barcode scanning and still involves more manual steps than I would have imagined, it is certainly a giant step in the right direction for decreasing IV medication administration errors. Orders for IV infusions are sent directly from the EHR to the IV smart pump channel that has been designated by the nurse caring for the patient. This is called autoprogramming, and it eliminates all the manual programming steps previously required to start an IV infusion. In the case of autoprogramming, once the order is received by the pump channel, all the nurse has to do is make sure that the correct bag is connected to that pump channel, verify that the order is correct on the pump, and initiate the infusion by hitting the start button.

One example of improved safety is the elimination of mistakenly hanging two bags of the same medication. In the old system of complete manual programming, in caring for a critically ill patient, it would not be unusual for a nurse to be simultaneously managing eight to 10 infusion pumps, all with different medications and fluids infusing at different rates. If the nurse mistakenly hung two bags of dopamine in two separate lines, there is no way of electronically detecting that inadvertent error. With integration and autoprogramming, that error would be automatically detected and the nurse would be alerted, avoiding a potentially serious IV medication administration error.

Martin Ho I’ve heard from different vendors that they are providing services for individual health systems to use a different type of machine learning, or intelligence (AI), to try to identify certain high-risk patients and the things they can do to improve performance as a hospital or care provider. At that point, we are still at a very siloed type of learning in the sense that each system holds what they’ve learned close to the chest while trying to learn as much as possible. A lot needs to be done and can be learned, so that patients can tap into these benefits.

Berkman Sahiner I’d like to add to the types of machines that use machine learning. Devices that use imaging data or results from diagnostic devices or monitoring devices to improve patient diagnosis and treatment options are one example. Bigger data promises larger patient datasets, which means that these devices can be more accurate. There can also be more data for each patient coming from different sources. With data diversity and bigger data, I see a big push and even a bigger potential.

Pat Baird A decade ago, I spent the entire summer doing observational studies, touring hospitals throughout the United States and Canada and watching healthcare providers work across different hospitals and different care units. I would talk to them about what’s changed in the past decade or so. Overwhelmingly, the response was, “I got into this field because I wanted to take care of people, but now all I do is take care of technology. I spend all of my time with computers and not enough time with my patients. And that’s not the world that I signed up for.”

That was the snapshot back in 2006. As I was talking to a doctor a few weeks ago, he said that he’s looking forward to machine learning and AI because he doesn’t get to spend much time with the patient anymore because of the technology. Now he’s looking forward to the day when the technology will present him with everything he needs to
know to do that quickly. Then he can spend more time with patients. I love the irony of it: When you only have some technology, you spend time with the technology, not the patient. With sufficient technology, you spend more time with the patient, not the technology.

**Martin Ho** I’ve studied shared decision-making tools in different health systems. Most of the time, what they’re complaining about is not the effectiveness of the tool, but rather whether they are in the way of their work processes or workflows. Can we find a way to incorporate this without hindering or slowing them down? Definitely. I think the physicians and the providers are now more open to it.

**Michelle Jump** One of the exciting areas to leverage data-based decisions and analysis is personalized medicine. This becomes extremely important with complex diseases such as Parkinson’s disease or cancer. To understand the next level of treatment for these complex diseases often requires following many variables to ensure the best treatment. The potential for reaching the next level of healthcare by truly customizing care is exciting and game changing for our patients.

**Bradley Schoener** Let me bring us back to one of the comments that was made earlier, which was around unstructured sources of data and the sheer volume of healthcare data that is being generated from these sources. **What technologies are helping our industry realize the healthcare data revolution?**

**Berkman Sahiner** I would bring up natural language processing because nowadays, most of the medical records or the data generated by physicians is still captured in text files and in a not-so-structured manner. Natural language processing has the potential to turn these text-based or narrative documents into standardized documents from which it may be much easier to extract information.

**Rich Zink** We’re getting a lot of help from the computer science and IT world. There are a number of big data projects doing things like critical, statistical, mathematical, and algorithmic techniques. In addition, software is being added to support emerging data analytics applications and large clinical data repositories. They’re improving privacy models, setting this up for being able to replicate databases, redoing queries so you can get the same result as you did before, testing, etc.

**Berkman Sahiner** One can be “data rich” and “information poor.” Appropriate methods to extract information from that rich data source—which is increasingly being accomplished by machine learning and deep-learning algorithms—will be helpful in bringing that data together in a more useful, informative way.

**Martin Ho** To me, the most challenging part is that as a patient, it’s not easy for me to accumulate all the information that is related to me. That’s particularly difficult when switching providers. I second Berkman’s comment that if we can access the dataset, that would be wonderful. But still, we have a problem there. I know that there’s been a lot of work trying to make use of different data sources and draw some conclusion from them. But if we all only have access to a piece of the information, the technology wouldn’t be able to help us too much because it can be, one way or another, biased, in its prediction or suggestions, depending on the context. Therefore, it would be helpful if technology enabled patients to keep their information—carry their own data, so to speak—from one provider to another.

**Pat Baird** Back when I was working on a manufacturing line, one of our major quality controls was the ability to perform quality audits and assess the quality of incoming raw materials. When we got a batch of raw plastic, for example, we could ensure that the batch met key criteria. Otherwise, it could affect the quality of the products we were making.

As a software engineer, I don’t really have to think about raw materials. Now when we’re talking about big data, we’re talking about all these different data sources and asking what can go wrong. This is similar to asking what controls I have for an incoming
inspection in the manufacturing lines—similar concerns, but in an information domain.

Can we take some of those existing structures and develop a guidance document on what’s good data hygiene, what should you look for, what are some of those key principles? There’s definitely an opportunity to have some papers in the future to help guide people on how the data can be wrong and what makes for good data.

I’ve seen incidents where data had “gone wrong” or wasn’t understood as well as people thought it could be. For example, I learned that if I found an adverse event or a near miss and the patient was either given twice as much drug as they should or only half as much, then I could guess that that patient was in the United States and was a teenager. Because, in the United States, a child’s weight is in kilograms and adult’s weight is in pounds. Teenagers are sometimes sent to a pediatric unit, and other times they are sent to an adult unit. As clinicians administer a weight-based drug, they will type in the patient weight but may not notice if it is in pounds or kilograms—they just focus on the number. A person that weighs a 100 lb is only 45 kg. If someone didn’t notice that a weight of “45” seems to be a little funny for this patient, then they type in the wrong value.

So, when you’re taking and importing the data (e.g., the patient’s history), you need to not just grab the numeric value from the weight field. You also need to grab the units. A worry that I have is that a programmer in another country (because the rest of the world uses kilograms for everybody) wouldn’t know this subtlety in the data. They might import patient weight in a numeric value and not include the unit’s value. This use case has popped up enough that I’ve learned to look for it.

**Karen Giuliani** As a researcher, data cleaning before performing any analyses is a very important part of the process. Once I have a complete dataset, the first thing I do is run descriptive analyses to look at the data for values that do not make sense. Because
I know the expected range for each variable in my dataset, I look through each data column for outliers and obvious data entry errors. For example, in a study I did on sepsis, when I looked at the temperature column, the numbers did not make sense. Upon review, I realized that some of the entries were done in degrees Fahrenheit and other were entered in degrees Celsius. This allowed me the opportunity to consolidate the data into one unit of measure and correct the variable. If the opportunity to review and correct data in large datasets is not readily available, that certainly limits its use.

Martin Ho At the Food and Drug Administration (FDA), we have a precertification program for manufacturers of software that is being used as a medical device. The program works like the Transportation Security Administration’s PreCheck for certain manufacturers who have great practices in terms of building software. Their products can go through a streamlined review process or even waived if the product is below a certain risk level. In other words, if the data is coming from a high-quality source or manufacturer, then you would have a higher confidence in the quality, like a “Good Housekeeping Seal of Approval,” so to speak.

We are in the process of developing these guidelines and key performance indicators. We will have a minimum viable program to announce at the end of the year. We are focusing on the manufacturer level and the individual product level performance. Another step would be looking at the data quality or input.

Berkman Sahiner You can have the best imaging equipment, but the output can be degraded by a patient who is uncooperative and moving around or has a metal implant that affects the image. Data acquisition issues can occur in other devices, such as a biomedical signal acquisition device or an electrocardiogram where the electrodes do not have full contact, for example. There are many sources of poor data acquisition or noise. And if we don’t clean the data before we pass it to other processing systems, then we’ll be in trouble.

Bradley Schoener Who’s responsible for the data, who owns it, and how is it protected? How can we make strides in this area?

Berkman Sahiner It’s a shared responsibility among multiple stakeholders: healthcare facilities, the device manufacturers, and the patients themselves. For example, healthcare providers take devices built by manufacturers but have to deploy them correctly in their environment to protect patient information. Likewise with the device manufacturers, if there are risks and hazards associated with the cybersecurity of their medical devices, then the patient information might not be safe. Finally, patients must be vigilant about protecting their data. They are the most important owner of the data because it affects their health and other aspects of their lives. But also, the healthcare facility has to use that data for patient care. They need to access it and in a sense own the portion that they access.

Martin Ho When we’re talking about ownership, we are implicitly thinking that when we own something, then we have access to it. That’s not necessarily the case in healthcare, unfortunately. I agree with Berkman that the patient should be the ultimate owner of the data. At the same time, there are different views as to who is responsible for maintaining access to it and who is storing it.

Loretta Dorn Who owns the data is a good question. Is it the provider, the institution, or the patient? The rules that determine the protected status of the data vary by data type. Is it protected or aggregated? Do patients know with whom their data are being shared? Hospital systems get very proprietary about data because of competition.

Karen Giuliano Here is an example from my visit to the hospital system using IV smart pump integration with autoprogramming. Completing the transition from manual programming to autoprogramming integration was a huge effort involving ongoing collaboration with both the EHR and IV smart pump vendors. As you can
imagine with a project of this magnitude, there were a number of hiccups along the way. In most instances where the data were not transferring between the EHR and the IV smart pumps as expected, the EHR vendor blamed the IV smart pump vendor and the IV smart pump vendor blamed the EHR vendor. The clinician project manager from the hospital had to play the role of mediator in order for the two vendors to collaborate and get the system to work. This is a place where vendors, especially in an environment where there are two systems working together, need to step up and consider issues as they arise in collaborative projects as a joint responsibility. And we need to hold individual vendors accountable in a meaningful way. Otherwise, it is just too tempting for each to shift blame.

Michelle Jump When looking at data aggregation, AI, analytics, and other data-trending–type activities, it changes how we think about who owns the data and who’s responsible for it. This is because the patient ultimately owns data that are identified and associated with them. However, when you deidentify that data and start to aggregate it for clinical decision support–type activities, it becomes less clear. As this field matures, you will also see that data from different sources is merged, and the sources can become harder to track. This is why it is important for manufacturers and vendors to be clear about data ownership and usage allowances and ensure that they are outlined specifically in literature and agreements.

Bradley Schoener Can you talk a little bit about how to increase trust in this area and whether trust is at the core of some of the data sharing? Are there other hurdles that need to be managed to move forward on this?

Rich Zink I don’t know if it’s a gap in the technology stream today or not, but there are groups that are sharing healthcare technology data among themselves. That’s a good thing because they’re learning from each other, benchmarking each other, and not having to reinvent the wheel. Yet, there are other groups that can’t participate in that type of organization due to concerns at the legal, contract, or risk management level.

If you’re sharing, then generally you’re trying to improve patient care everywhere. One of the cool things about this industry is that in general, people are trying to share data and not keeping it like it’s intellectual property. Some of the vendors are tighter with their data than others. But from the clinician level, they’re trying to share data to improve patient care.

The Healthcare Technology Foundation, a 501©3, was founded in 2002, on the principle that achieving improvement in the safe use of healthcare technology requires diverse stakeholders to come together in order to utilize their collective knowledge on the design, use, integration and servicing of healthcare technology, systems and devices.

The many issues surrounding Data through Decisions provide an excellent example of the need for such broad collaborations, and we are therefore enthusiastic in our support of this issue of Horizons.

Strategic initiatives, publications, board membership, and donation instructions can be found at http://thehtf.org/
**Loretta Dorn** I am not sure I agree that institutions are willing to share data across hospital systems in competitive environments. If they were open to sharing, we would have a platform for all systems to be able to share data. In fact, if one provider sees a patient and orders a procedure and then the patient goes to a different institution with a different EHR, the ordering provider must request the data, and in some cases, the patient has to request that the data be shared.

**Michelle Jump** This comes back to communication surrounding intent for the data being generated. If data are being gathered from various sources, then the entity gathering that data has an obligation to ensure that the sources are valid and that it may be used that way. Data gathered for one purpose does not always translate to it being used for a different purpose. At the same time, there needs to be more global discussion on the tradeoff between greater data protection and benefits from using data aggregation practices. No one wants to see privacy violations, of course. However, the potential for using data for good may start to push up against the edges of data ownership and trust.

**Berkman Sahiner** There’s a huge potential for savings in healthcare costs, and some of it is already being realized. For example, reducing readmissions by analyzing a patient’s data, and then identifying what type of patient may require some intervention to reduce readmission. Healthcare facilities have already seen a lot of returns from this type of data analysis. Likewise, identifying and managing high-cost patients (e.g., those with chronic conditions) can be a big cost saver. Or improving physician performance, not only in terms of better patient care but also in terms of better workflow; saving time for physicians by data analysis approaches has a huge potential. If you can analyze the data to optimize the uses of a hospital’s staff and resources, ensure that the patient is sent to the correct unit, and overall inform management about the state of patient care—that again has a potential for huge savings.

**Martin Ho** Our conversation has focused on patients so far. But the best medicine is often prevention itself. Another very promising area these days is wellness devices (e.g., Apple Watch, FitBit). These can nudge people toward a more healthy lifestyle and prevent them from becoming patients in the first place, as well as help those who are recovering from illnesses or other conditions. It’s still very early, but we already see that some people are embracing wearable devices and walking more than usual.

**Michelle Jump** Martin’s point is a great one. It highlights one of the largest challenges of our healthcare system today. The cost of treatment for “lifestyle diseases” is crippling the healthcare system. But people love collecting data and digitally tracking information. Right now, most of these data sources are external and not always accurate. The movement toward gathering physiological data and tracking that data for factors such as insulin levels can be game changers for patients with diabetes. But imagine if we had more information on the everyday health of our bodies, such as blood chemistry, and could closely track the impact of our everyday activities back to that. Your average patient may get their blood tested annually or even less often, depending on their diligence. A year’s worth of habits can have a big impact and lead to disease. If we can help people get in front of that, we can help adjust habits before they become ingrained.

**Bradley Schoener** If you were advising the leadership of a health system, what steps would you be recommending right now to improve access using data?

**Martin Ho** The Centers for Medicare & Medicaid Services (CMS) is doing a good job of providing some information about choosing the right provider, such as comparing...
hospitals, on its website. Some people disagree with the methodology used by CMS, but the intention is clear—it provides a performance-based measurement of individual hospitals.

Also, consider the Internet service OpenTable, which is an independent way to make a reservation at a restaurant for dinner or lunch. In the future, with a similar platform for healthcare, people could make an appointment and the platform would give individual providers the patient’s information along with the scheduling. This is future looking. If the technology can reach the point that everybody recognizes the importance of providing an accessible platform for patients to see their providers, that would be wonderful.

Another possibility is with big data—we can produce some good predictive analytics that can help manage the care of patients and perhaps customize their care accordingly. If we can collect patients’ habits and create behavioral profiles, then we can develop strategies to help their adherence to their treatment regimens and better understand these patients in general. To leverage big data, we want to have some meaningful subgroups to leverage the group-level data as well.

Karen Giuliani Adding to Martin’s point, hospitals should consider investing in systems that eliminate multiple sign-ons as much as possible. I just started at Northeastern University, and they have a single sign-on system. This allows me to navigate freely throughout all the systems connected to Northeastern without having to remember a different password or reenter my password. It certainly saves a lot of time.

Berkman Sahiner I don’t know if it is exactly data or not, but I just wanted to mention telemedicine, remote monitoring, and mobile device apps as ways of improving access, especially at remote locations. These are all devices that are helping to exchange data, of course, so in that sense, the data make it possible to bring care to patients who cannot physically come into the clinic.

Rich Zink It’s important to consider more than just data, hardware, and software. There are people involved, and there are processes. If you automate a bad process, you just make the same mistake faster.

Pat Baird Even though I have a software background, and I love data and algorithms, I know that the big challenge is going to be organizational. Consider infusion pumps and drug libraries. To build the drug library that the infusion pump is using, different parts of the healthcare organization that never really talk to each other very much had to sit down
in the same room and come to an agreement on some level of standardization and consistency across different medical orders.

The true benefit may come from the fact that the people had to cooperate and be more integrated with each other, with the technology being a secondary benefit. I’m wondering if the same thing will happen here. If we can get people to better understand how the whole system works, that will be a great benefit.

**Bradley Schoener** What is the state of regulation for AI and predictive analytics? What do you think is needed here for regulation accreditation standards?

**Pat Baird** We need to develop something—or several somethings—in the future. I don’t know that I want to jump into starting to write standards now. Instead, I think some papers and some guidance documents in which learning is shared would be beneficial. This is something that’s being noticed globally, and several other countries are working on publishing their versions of guidance.

**Martin Ho** We hope there is regulatory guidance that can answer the majority of our questions, but we are not there yet. To develop useful regulations, I would like to see some consensus building among professional societies and scientific organizations on what would be a good practice or good research practices related to those issues. I ask that because if the guidance is not consistent with the state of art or state of science, then that guidance wouldn’t be robust.

**Berkman Sahiner** I agree that we need to develop something, but it doesn’t always have to be guidance. At the beginning, it can be a good practices document or a white paper. I understand that the International Organization for Standardization and International Electrotechnical Commission have only recently started a working group to tackle issues related to AI and standards in AI.

**Michelle Jump** Traditional regulations and standards are not ideal for AI for several reasons. The biggest is the time taken to develop them. The pace at which the industry is moving in many aspects of emerging technology is challenging that paradigm for managing these risks. I’d like to see more of what FDA has been doing, in the form of high-level guidance paired with engaging workshops and meetings. We have existing quality and risk standards that can help vendors make sure their fundamentals are solid, but trying to regulate this right now is going to be tough. That doesn’t mean that the regulators should be outside of this conversation—exactly the opposite, actually. We need the regulators to understand AI and learn from the industry. At the same time, those vendors working in the AI space need to see the regulators as part of their stakeholder group, not as an enemy to avoid. We all have the best of intentions to bring cutting-edge technology to our patients. But it will take the whole village to do so safely and effectively. We live in exciting times. We can maintain that excitement as long as we are also considering the patient lives that are depending on this technology.

**Bradley Schoener** Does anyone have closing thoughts on this topic that they’d like to share?

**Loretta Dorn** I would like to see a shared EHR data platform that can track medications from any pharmacy, emergency room visits, hospitalizations, and behavioral health encounters for patients, in order to create better clinical outcomes.

**Martin Ho** I’d like to repeat the importance of patient-centric database ownership that facilitates use and access to patients’ own data. Patients should be able to access their own data seamlessly when moving from one provider to another. Second, the state of the science of AI research is still evolving and consensus on good AI research practices has yet to be firmed up among different professional societies and research organizations. If there is an organized and harmonized effort to develop such a consensus, then that would greatly facilitate the development of guidance for regulators.

**Rich Zink** Standards are like toothbrushes. Everybody has one, everyone likes their own, and nobody will use anyone else’s.

“We all have the best of intentions to bring cutting-edge technology to our patients. But it will take the whole village to do so safely and effectively.”

—Michelle Jump