A Roundtable Discussion
Usability, Human Factors, and Health IT: Providing Effective Guidance While Nurturing Innovation

Joe Sheffer The concept of human factors as it relates to medical devices is largely well understood. What does human factors mean in the realm of health information technology (IT)? And how does a focus on human factors and usability lead to safer and more effective health IT and ultimately better patient outcomes?

Michael Wiklund I think of human factors as being about creating a positive relationship between people and technology, and we can think about technology broadly. Traditionally, human factors has been applied to medical devices, including patient monitors, insulin pumps, and heart-lung machines, but its application to health IT also matches with tradition. It’s been applied to software user interfaces for decades to make the applications more what people traditionally will call “user friendly.” In the case of health IT, usability matters just as much, and probably more so, than perhaps an application that helps you check your stock portfolio. In addition to usability, the application of human factors is about preventing potentially harmful use errors, such as those that might occur when using an electronic health record (EHR).

Therefore, I see a strong parallel between applying human factors to medical devices and health IT. I think it’s well understood that use errors involving health IT can lead to bad outcomes. We hear horror stories about people putting in the wrong weight for an infant and delivering too much or too little of a medication, for example, and a root cause of this kind of use error being a shortcoming in the EHR’s user interface. Those of us working in human factors engineering seek to make health IT demonstrably safer by helping to avoid those kinds of errors through better design. We also wanted to make health IT usable so that there is no obstacle to getting work done.

We know that many health practitioners out there get very frustrated with the usability problems that create obstacles to getting work done with an EHR. Therefore, I see a strong need to apply human factors to health IT to make applications safer and more usable: two very important goals.

Lana Lowry I agree with Michael’s comments. At this stage of health IT, this is what we know based on the empirical evidence. Through our research, we learned that a human factors focus of health IT is similar to medical devices in terms of preventing “misses,” “near misses,” and adverse events due to use errors. The National Institute of Standards and Technology (NIST) developed the Usability Safety Framework, where we identified “never events,” such as wrong diagnosis, wrong treatment, delay of treatment, etc. These safety-related events are highly connected to usability and human factors. So we know that safety and human factors go hand in hand in the health IT world.
Health IT (and its user interfaces), either associated with medical devices or just medical record systems, are in need of standardization. Critical areas for standardization include patient identification, entering information in the right chart, and medication administration. These all are vitally important usability and human factors issues that have a direct impact on the safety outcome.

Matthew Weinger We spend a lot of time talking about safety issues with regard to usability of health IT, but I want to go a step further and argue that general usability issues are far more important in health IT than in medical devices. The Food and Drug Administration (FDA) has traditionally been less interested in medical device design shortcomings that lead to inefficiency but do not have safety implications. However, with health IT, because of the substantially greater interaction time of clinicians with EHRs and other systems, inefficiency becomes a much greater issue. Potential negative impact can occur when clinicians devise workarounds to overcome, for example, increased documentation burden. It also can lead to general dissatisfaction, avoidance, and diminished interaction with patients when a primary care provider, for example, discovers that the introduction of an EHR into their practice led them to spend 3 more hours each day documenting than they did with the paper chart. That time has to come from somewhere, either during professional time (thereby reducing clinical revenue) or out of their personal time and diminishing their overall job satisfaction. We know that unhappy doctors are less good doctors.

Walter Suarez I would like to take a step back and look at a few terms that have been used: health IT, EHR, and medical devices. These terms generally are believed to be broad concepts that include an array of technologies that allow health information to be captured, collected, stored, managed, analyzed, enhanced, and shared. And I would argue that within the term “health IT,” there is a whole array of technologies, including the EHR itself and many elements associated with the EHR, including clinical decision support, population health management, and other tools.

I see medical devices as a form of health IT. There’s a vast array of different kinds of health IT, and there are a number of common usability and human factor design elements that cut across this very broad term of health IT, including EHRs, medical devices, and mobile medical apps. Some elements are more specific to the usability and human factors design in each of these different types of technologies. So, I think it will be helpful, from a framework perspective, to look at the type of common areas of usability and human factors design across the entire spectrum of technologies that form the scope of health IT, and then look at some of the unique elements of usability and human factor design specifically applicable to the different types of technologies (EHRs, medical devices, medical apps, etc.) that are part of health IT.

Joe Sheffer In terms of putting forth design guidelines and principles: On one hand, we want to provide guidance on safe and effective design practices, but on the other, we don’t want to make the guidelines and principles so rigid that they stifle innovation. What work needs to be done, and what considerations do we need to take into account, to strike the right balance?

Michael Wiklund This is one of my favorite topics because I was heavily involved in a team effort, sponsored by NIST, to develop guidelines for EHRs and health IT. In my opinion, guidelines are a great thing—an important resource for user interface designers. I see them not as rules to be followed blindly or inflexibly, but rather as a great resource that will help people take what they know from their own studies and experiences and augment it with information that they otherwise might not have regarding what constitutes good design. No designer will be all-knowing about what works and doesn’t work in terms of health IT interface design.

I see guidelines as a real assist to those designers. It doesn’t have to stifle creativity any more than teaching an artist certain painting techniques limits their artistry. There are plenty of guidelines on how to oil paint, and there are plenty of guidelines on how to design a safe, effective, and usable
“One thing that I would like to see more of is the communication of the user-centered design methodology—the iterative cycle that involves continual reviews with end users. It’s this methodology that impacts usability along with guidelines, but if we have one without the other, it doesn’t serve our customers.”

—Amanda Mander, senior manager of user experience design at GE Healthcare

user interface—but it still requires an analytical mind, following a creative process, and paying a lot of attention to user needs and preferences to get it right. Guidelines are a very good starting point for establishing requirements for health IT and user interfaces, without necessarily shutting down avenues of creativity.

Guidelines prevent people from committing design flaws that have induced user errors in the past. Lana spoke about the importance of making sure that patient-related information perhaps is accompanied by the patient’s name. This is a lesson drawn from real-world experience and from usability tests. So, if you have a guideline that says, “Put the patient’s name on top of patient-related information,” I can’t see anything bad about it, and don’t think it limits creativity.

Amanda Mander I also think it’s really important to have guidelines and principles and to share usability studies that have been done in the past. But one thing that we have to be careful about is having guidelines that are too specific, because sometimes those guidelines don’t really work across a variety of scenarios. One thing that I would like to see more of is the communication of the user-centered design methodology—the iterative cycle that involves continual reviews with end users. It’s this methodology that impacts usability along with guidelines, but if we have one without the other, it doesn’t serve our customers. So, it’s important to have some general guidelines, such as having the name on the patient record. But also a methodology needs to be followed, so that we can make sure that the designs are meeting our users’ needs. If we do that, then we can strike the right balance. But, if we get too prescriptive and say that every patient banner has to look like this and have these colors, these fields, and this much spacing between each label, then that gets to be too confining for companies to be able to be innovative.

Matthew Weinger I’m sensitive to what Amanda said; however, I think that one needs to distinguish among those areas where innovation and creativity are appropriate and those where there are clear safety implications and some constraints are appropriate.

Let’s talk about our automobiles. There’s tremendous innovation in the automobile industry, but nobody is going to consider introducing a new automobile where the gas and brake pedals are reversed or perhaps a different mechanism is used for steering, because such changes would be inherently unsafe due to negative transfer of training.

We need to identify through empiric evidence those aspects of health IT where it is simply safer to standardize across the industry. To some extent, the order and content of patient headers are one such area. We have some evidence to support this. In even the most specific national and international medical device standards, there’s always a clause that says if you as an individual company have evidence to support an alternative design, you have the right to do that.

The same should be true of the applications that Amanda mentioned. Even if a particular guideline specifies a design approach, a vendor would be free to design something different. But, they’d need to document that user performance with that design was equivalent to that expected with the guideline-specified alternative.

Michael Wiklund Currently, the AAMI Health IT Committee on which I serve is developing exactly what Amanda described—a set of guidelines that would not be too prescriptive. We expect the guidelines to preserve opportunity for creativity but nail down the stuff that is well known to ensure they’ve been effective interactions. A lot of the guidelines will be drawn from evidence collected over decades regarding what makes software “user friendly.” In addition to that, we will suggest a good user-centered design approach that involves determining user needs, assessing the risk of potential use
errors that could occur working with a health IT application, and performing validation usability testing. Both of these work products will build off of similar products originally developed for NIST. They will be taken forward and expanded upon to ensure that they represent an industry consensus.

**Lana Lowry** I implicitly agree with Michael’s overview of the use and usefulness of the human factors guidelines, and of course, that the design guidelines should be less prescriptive so that innovation is not stifled. It should not be a requirement; it’s just a good practice. If other creative and innovative solutions are found that are not in the guidelines, then they should be justified. I also agree that in the core of good user-centered design is an application of human factors methodology. For me, the most important statement was made by Matt: that the guidelines are a just a “volunteer guide to a better design.”

At the same time, health IT safety–related usability should prevent inadvertent use errors, and that can be translated into preventing critical safety events. Again, I would like to repeat that those critical areas must be standardized, such as patient identification. Just recently, we completed a study on the usability of “copy and paste” functionality. We learned from the research findings that “copying and pasting” in certain error-intolerant interfaces, such as a blood bank, should not be allowed and that safety-related feature must be a standardized to prevent critical errors consistently across all applications.

**Walter Suarez** I am in agreement with the principles and concepts around designing and defining guidelines, as well as standardization. The concern I want to raise is that too often, I have seen how those same guidelines tend to make it into federal requirements and mandates, whether they are regulations, subregulatory actions from federal agencies, or even the use of federal contracting as a vehicle to mandate the adoption and use of these guidelines. So, the caution point I would make is that although the guidelines are valuable in terms of voluntary adoption, use and testing, and standardization, when they tend to move into the federal requirement side, then we are at risk of stifling innovation.

**Michael Wiklund** The health IT industry can learn a lot from the manner in which the medical industry has embraced ANSI/AAMI HE75:2009, *Human factors engineering—design of medical devices*. It became one of AAMI’s best-selling standards. It’s still in wide use today and is being updated by AAMI’s Human Factors Engineering Committee. In the case of this standard, they have not been imposed on manufacturers as regulation, but rather they have been used where helpful to create better designs. There has been no migration from guideline to regulation.

**Zach Hettinger** Some of the work that our team at MedStar’s National Center for Human Factors in Healthcare is doing is to look at the needs of the EHR vendor communities in this space. There is a huge thirst for data around EHR-related safety events and EHR design. Whether you call them guidelines or principles, it is very challenging for any individual healthcare organization or vendor to do the research and have access to enough data to really understand the best way to design safer systems. These types of guidelines and principles that are based on the best evidence that’s out there, subject matter expertise, or a large enough data sets can really help us improve our understanding of how best to design EHRs without affecting innovation in a collaborative manner. Those efforts highlight the real advantages of applying human factors principles, which are needed by those individuals who are tasked with anticipating and designing around known EHR issues and predictable errors. This will help to prevent repeating the same errors and safety events in different healthcare systems across the country. That’s kind of where we’re at right now. We make the same mistakes over and over again, when we could be anticipating the mistakes and designing them out of the system, rather than leaving each individual EHR vendor or healthcare...
AAMI Human Factors and Usability Standards

AAMI has long been a leader in developing usability and human factors standards for medical devices. As part of its Health IT Standards Initiative, AAMI has begun drafting a new standard, AAMI/HIT 1000-4, Health IT software and systems — Part 4: Application of human factors engineering, and expects to release this document as a provisional standard for trial use in late 2017 or early 2018. AAMI’s current body of medical device human factors/usability standards and guidance document is as follows:

- ANSI/AAMI/IEC 62366:2007(R)2013, Medical devices—Application of usability engineering to medical devices (Includes Amendment 1)
- ANSI/AAMI/IEC 62366-1:2015, Medical devices—Part 1: Application of usability engineering to medical devices
- AAMI TIR49:2013, Design of training and instructional materials for medical devices used in non-clinical environments
- AAMI TIR50:2014, Post-market surveillance of use error management
- AAMI TIR55:2014, Human factors engineering for processing medical devices
- AAMI TIR61:2014, Generating reports for human factors design validation results for external cardiac defibrillators

organization to “innovate” on safe and effective design by themselves. That’s where we see the real value around applying usability and human factors.

Amanda Mander I have a question for us. Are we thinking that the guidelines and principles, as well as conveying a methodology, are enough in terms of supporting companies that don’t have any user experience or usability people on staff? Because I would say that there’s a whole discipline around usability, user experience, and design that would be missing if we just had a list of guidelines and principles without practitioners who are qualified to implement those best practices in a good way.

I’m wondering what other people think about the fact that we have these various professions that really should be embedded as best practice into companies that are doing this kind of software for patients and physicians.

Michael Wiklund I believe that human factors engineering should be a core competency at any health IT firm of significant size. Just as programmers are necessary, I believe that good user interface designers are necessary, but not only folks who are good at graphical design and, more broadly, information design, but also folks who are skilled at traditional human factors methods: establishing requirements, assessing use-related risks, applying established user interface design guidelines, and performing iterative usability tests. That said, there are plenty of firms out there, mine and many others, that can help product development teams if human factors is not yet a core competency.

Amanda Mander I would say that there’s also a lot of confusion on terminology around usability, human factors, user experience, interaction design, visual design, and all the different disciplines. For example, my team is not a human factors engineering group, but it is a user experience group. We all have advanced degrees in usability and design. To me, the most important advice to give a company that wants to build usable and safe healthcare products is to make sure that whomever they hire has credentials and follows the user-centered methodology along with any safety requirements. We might have to be a little bit more general and not just say, “only human factors engineers.” The point is that this could be a source of confusion for people when they’re trying to figure out what they need to do to make their products better.

Matt Weinger I wholeheartedly agree with Amanda. The danger in the informatics space right now is that a lot of software engineers have been designing user interfaces generally without formal training. I fancy myself a bit of a designer but also have a professional interaction designer on staff to keep me out of trouble. I don’t think it matters what you call the interface design people in your organization; what is important is whether they have the necessary training, experience, and abilities to design and evaluate the function of the user interfaces.

Zach Hettinger It is important to note that formal human factors training provides key knowledge and skills in basic user interface design, which our team has dubbed “context-independent design”: the colors, the font size, contrast, and placement of things on the screen. This is something that’s been understood for many years within human factors, and so if you’ve got that background and training, that is going to be less of an issue. However, beyond the basic design elements there is “context-dependent design,” where based on different healthcare specialties or locations, the design or location of specific elements and workflow in the EHR will have a major impact on the safety and efficiency of the system.

Thus, good user-centered design is not something that even a well-trained human factors person can just do from behind a desk. They need access to the clinical sites, and they need to collaborate with healthcare organizations and subject matter experts that have access to data and knowledge to meet the needs of the user. Regarding the earlier discussion around patient identification in the EHR: The basic interface design will only get you so far if the staff are being interrupted in the middle of their workflow and accidentally place an order on the wrong patient. Therefore, anticipating interruptions and designing strategies into the system is different than just making sure that the demographic bars are

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present, which is still critical and needs to be addressed initially. But the level beyond the basic design—the context-dependent design level—needs to be taken into account, and there needs to be collaboration among human factors professionals, EHR vendors, and healthcare organizations.

Matt Weinger To augment something I said earlier: One thing I’ve learned is that designers and engineers, particularly in the user interface space, are rarely excellent at both activities. You need people who are artistic, creative … truly designers—they will introduce the design innovation. And then you need individuals who are human factors engineers or others with expertise in usability testing who can evaluate the results. Often, you want those to be different individuals or teams to reduce bias in the process. Further, front-end user research may also require a skillset that is different from those of either designers or evaluators.

Joe Sheffer The 21st Century Cures Act has provisions clarifying the roles of the FDA and Office of the National Coordinator for Health Information Technology with regard to oversight of EHRs and health IT. What do we know about how this will change the regulatory landscape for these technologies, and what is still unclear in this regard?

Lana Lowry Usability and human factors are mentioned in the 21st Century Cures Act, mostly in terms of postmarket surveillance and determining when user performance actually fails due to critical errors. To achieve this goal and being able to evaluate how the system performs in preventing use errors, we need to establish these pass/fail benchmarks. These benchmarks need to be set against the standards.

Joe Sheffer What words of advice would you give to frontline healthcare technology management (HTM) professionals—clinical engineers and biomedical equipment technicians, for example—to help them remain current on key issues pertaining to usability of health IT?

Matt Weinger I think that HTM professionals, at least the older ones, have kind of shied away from this space. They do so at their own risk, because as more and more devices become part of a “network of everything” and software becomes an increasingly important, an HTM who is not well versed in informatics and, in particular, connectivity and network-related matters, is going to be finding themselves obsolete.

Joe Sheffer I would go a step further and argue that human factors engineering ought to be a core competency of HTM professionals and a skill that they can bring to bear in their local facility, because few healthcare facilities can afford to hire a full-time human factors engineer. Yet, because facilities are expected to customize and implement health IT, they need that expertise, and bringing it in via outside consultants may be far less cost effective than having internal individuals who are familiar with that environment and can bring that expertise to bear.

Zach Hettinger Adding to what Matt was saying, I think that HTM professionals can serve a critical role in identifying hazards and near misses by mining data like help desk tickets, “malfunctioning” equipment that could be due to poor design, or patient safety event data. These sources of data may be reported to separate groups but can be critical for understanding how the health IT systems are impacting the care of patients.

—Zach Hettinger, medical director and director of cognitive informatics at MedStar Health
files or date/time stamps, or look for other instances in the patient safety event system that are similar, then we start to get a much richer picture that this isn’t an individual provider’s error. Rather, it’s the design of the system that is leading them down a path that is either causing the error or not facilitating the recognition of the error before it reaches the patient.

So, there are lots of ways that HTM professionals can start actively looking for problems in their system. As Matt said, that might require some degree of human factors training to really get to the root of the problem, but even mining the data or digging deeper into problems can be critical for uncovering some of the system-based issues. If no one’s looking for those issues, they’ll just continue to be hidden in the data that already exist.

Joe Sheffer In addition to what we’ve already discussed, what other challenges are we facing related to usability, human factors, and health IT?

Matt Weinger One area worth exploring is the huge effort, costs, and implications of local implementation of commercial systems. At Vanderbilt, we’re in the middle of a multiyear implementation costing hundreds of millions of dollars. There’s a huge amount of customization that occurs locally and has huge safety and efficiency implications. The guidance provided by the health IT vendor is somewhat limited. Consultants charge a whole lot of money, but they don’t have the local knowledge necessary to customize wisely.

With health IT implementation, standardization across an enterprise becomes critical, yet many facilities have difficulty doing that. That’s very different from medical devices. When the FDA regulates a medical device, for the most part, the product that the company puts forward to the FDA is the product that everyone ultimately uses; there isn’t a lot of customization that occurs locally.

With health IT, the vendor sells an out-of-the-box system and says, “Well, you can’t really use this system—you have to do all this extra work.” And the final product at one hospital is largely different from the product in any other hospital. Who’s responsible for those differences? How do human factors and usability play into that?

At our institution, the people who are responsible for implementation have followed the roadmap provided by the vendor and consultants, and this has not included, for example, formal usability testing. What do other people think about this implementation issue?

Zach Hettinger A critical issue is the implementation and optimization piece, specifically the design decisions that are delegated to the healthcare organizations. Having participated in some of these health IT implementation teams, sometimes it’s not necessarily the safest or the best designed that is selected, but rather the individual who’s the loudest or most persistent in the room. There is often limited data around how the decisions will impact workflow or evidence from prior implementations, and this decision-making process has major ramifications.

Building off of what Matt said earlier regarding the need for human factors training for HTM professions, our team performed safety work around a glucometer, where the manufacturer of the device delegated the customization of the critical result error messages (if the patient had either a critical-low or critical-high glucose) to the local lab managers. The actual messages that were implemented by someone with no human factors training ended up causing result misinterpretation and patient harm. This is just one example of where customization without training and data, even just 20 characters, can have a major impact on the safe use of a device or interface, even though everything on the device has been tested and approved.

Amanda Mander This gets back to having professionals in those important spots where those decisions are being made. But another thing we need to think about, which is part of our profession as usability, human factors, and user experience people, is to listen to our customers and know our audience, providing workflows and feedback that support their work tasks. As we create guidelines, principles, and ways of doing things, we need to be cognizant of our audience, which are software companies. The software process—getting to market, etc.—sometimes...
does not coincide with the perfect usability and human factors flow of activities. That seems to be a reality that I’ve experienced in my career. So as we suggest certain ways of doing things, we have to really think about the software process, think about the companies and how they work, so that we are able to provide really effective guidelines and methodologies that could fit within the software process.

Matt Weinger About 30 or 35 years ago, we were having some of the same kinds of conversations about medical devices: there was publicity about use-related safety problems and that most manufacturers were not adequately addressing usability or had rigorous user-centered design processes. That’s when the FDA stepped in and told manufacturers, “You really need to do this.” There was a lot of complaining that this was going to stifle innovation. AAMI and others stepped up and developed standards and training to help the medical device manufacturers. The FDA strongly supported this in a public-private partnership. Over time, we’ve made huge strides, and now established medical device manufacturers maintain rigorous user-centered design processes. They’ve even developed mechanisms to incorporate human factors methods into agile software development approaches for regulated medical devices.

Now, it’s 30 years later and the health IT industry is going through the same thing. We need to be supportive and provide the guidance that the industry needs to move in the right direction. It’s going to take time. Also, it’s worth noting that a typical enterprise EHR or health IT system is far more complicated than even the most complicated medical device (e.g., a CT scanner). Some aspects of an enterprisewide informatics systems really need the same level of rigorous human factors, user-centered design as a medical device (e.g., aspects of medication management). Meanwhile, others probably don’t need much at all. If we continue to help the health IT industry move forward as a whole, we’ll figure it out.

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—Matthew B. Weinger, professor and vice chair of anesthesiology and professor of biomedical informatics and medical education at the Vanderbilt University School of Medicine

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