SAFER Guides Transcript

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Presentation

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Hello. Welcome. My name is Kathy Kenyon, and on behalf of the Office of the National Coordinator for Health IT, I'm very pleased to moderate this webinar on the SAFER guides. I was ONC's project officer for their development, and so I hope that you've already gotten on our website and taken a look at them.

In the next hour or so I will offer a brief policy context for the SAFER guides and introduce the developers, Dean Sittig, Joan Ash, and Hardeep Singh. They will describe some of the reasons for the SAFER guides, and the development process, as well as showing you how they are intended to be used. You can submit questions through the Q&A box on your screen. We will have time at the end to answer questions.

[Slide: ONC and Health IT Patient Safety; 00:01:00]

In 2009, when Congress created the Meaningful Use EHR Incentive Program, part of the reason was the enormous potential for EHRs to reduce errors and improve the safety and quality of health care. ONC, while diligently shepherding meaningful use along, knew that there would be unintended consequences, and planned for that. The SAFER guides project is part of an ONC contract on the unintended consequences of the rapid and widespread adoption of electronic health records.

Early on, ONC turned to the Institute of Medicine for recommendations on the Health IT safety. The IOM, as I'm sure most people remember, ignited a nationwide effort to improve patient safety, in part by calling attention to the magnitude of the problem in the paper based system about a decade ago, and pointing to the potential for electronics systems to fundamentally change and address safety problems.

So in 2011, the IOM report that was sponsored by ONC, called “Health IT and Patient Safety, Building Safer Systems For Better Care,” made a number of recommendations, among them urging the need for more research on health IT safety, and better tools on health IT safety for the users of EHRs. The IOM report helped launch the research that has led to the SAFER guides.

Building on the IOM report, ONC, in July of 2013, issued to health IT Patient Safety Action and Surveillance Plan, which is the department's blueprint for moving health IT safety forward. It's based on two objectives: using help IT to make care safer, and continuously improving the safety of health IT. The SAFER guides, as you will see, are about both of those objectives.

ONC knows that health IT safety requires leadership first in the health care organizations that use EHR. And we know that health care organizations are serious about improving patient safety. We believe the serious commitment that already exists among health care providers to patient safety will drive use of the SAFER guides.

We also know that health care organizations cannot fully use and optimize EHR safety using the SAFER guides without a close partnership with others, including the EHR technology developers. The SAFER guides require shared responsibility for patient safety, and they suggest specifics about what that might be. The SAFER guides are based on the best evidence available.

[Slide: SAFER Guides -- Development; 00:04:10]

They were two years in development, and with that, let me introduce the SAFER guides' content developers. Over the past two years, I have come to appreciate this team. Their combined skills and experiences just made all the difference. You can read their credentials here, but let me give you some of the relevant additional details.

Joan Ash is a professor of informatics at Oregon Health and Science University. She began her career in library science. She led the team, for instance, that wrote the research appendix to the IOM report on health IT and patient safety.

Before this project, Joan, with Dean, had a multi-year NIH grant where they did research in dozens of small and large health care organizations, where they went into the practices and actually observed what was going on on the impact of computerized provider order entry. And the result was a book on the unintended consequences of CPOE.

Joan is recognized for her work on qualitative methods for studying health IT. She is a disciplined listener, and that has been very important in this project, which included field research and building a tool that is user friendly.

Dr. Hardeep Singh is an internal medicine physician. He actually began his career using paper records in solo practices in rural east Texas, then moved to the VA clinic in Houston, where he experienced the transformative power of a good electronic system. He now leads research programs at Baylor College of Medicine, and at the Houston Veterans Affairs Center.

Dr. Singh was recently named as one of the recipients of the Presidential Early Career Awards for scientists and engineers in part for his work on health IT safety. As a clinician he understands and is deeply committed to using health IT to improve clinical diagnostic processes, and in general the safety and quality of health care as experienced by clinicians as well.

Dean Sittig has worked on the healthcare informatics for 30 years at healthcare organizations that have led on EHR development. He worked at Partners Healthcare in Boston, at Vanderbilt, at Kaiser Permanente while he was in Portland, Oregon, doing some of his work with Joan Ash

there and he's worked at Intermountain Healthcare. He understands the technology, how it should work, why it sometimes does not, but most important to him, he understands that you cannot understand the technology alone. It must be understood in the real world in which it is used. Dean is now a professor of informatics at the University of Texas in Houston, where he is affiliated with Memorial Hermann Medical Center. With that, let me turn it over to Dean.

Dean Sittig, PhD – Professor – School of Biomedical Informatics, The University of Texas Health Science Center

[Slide: Why We Need the SAFER Guides; 00:07:29]

Thanks so much, Kathy. It's really great to be here, and to have a chance to talk to everyone about the SAFER guides, which Hardeep deep and Joan, and I have really put our hearts into for the last year and a half or so. So it's good to have people finally getting to see what we're doing, and learning how we develop them.

[Slide: SAFER Project Goal…; 00:07:45]

So with that, I'll just remind you that when we started this project with the SAFER tools, we were really trying to develop and validate some proactive self-assessment tools. And so the idea was that organizations could review themselves and try to understand where they stood in terms of recommended practices. And so the goal of these tools is to make the EHR safe and effective to use, and also to make sure that you're using it safely and effectively.

[Slide: Agenda; 00:08:17]

So today the three of us are going to go over these guides, and we'll start with a little bit about the need for the guides. I'll do that, then Joan is going to review some of the research and development methods that we used while we were developing these, and then Hardeep will be describing how and why the guides are organized as they are.

And then I'll come back and show you a little bit of an example, walk through some of the guides and show how they're organized, and what they look like. And at any time during then you can feel free to write questions into the thing, and there should be plenty of time at the end for us to have a good, lively, interactive discussion about sort of what the guides are, and what they mean, and how they're used.

[Slide: Health IT Risks Exist; 00:09:04]

So not to pick on anyone particularly, but one of the most recent and large scale electronic health record downtimes was this past summer, when Sutter Health Care System in California had a big downtime. And their system crashed, and in the previous times when people were doing electronic health records, or even the paper based records, we had crashes before. So that's not new.

What's really new now is that the systems are on a much larger scale. And so when Sutter had their problem, it was about 30 hospitals that were affected, and probably hundreds of outpatient clinics that were using their systems. And so we see these failures can be on a much larger scale, and affect a lot more patients and a lot more providers.

[Slide: Be Prepared!; 00:10:04]

And so part of the reason we're developing these guides is to help organizations learn how to be prepared for the types of events that we know can happen. So the other point to think about this is that the more health IT you have, the more you need these guides. And so the more prepared you need to be, because people that have just started, and just have sort of a results review system, for example, aren't truly dependent on their EHR. But as you get to using your EHR for admission and discharge, and transfer, and your order entry, and you results review, and your clinical documentation, and you've got a bar code medication administration system, the hospital becomes more and more dependent on this method of communication, and moving information, managing information. So you have to be very particularly careful to make sure that you're really using the system as it was intended to be used, and you're prepared to use it in the event that something happens to your electricity, or your network, or your database servers, or something like that.

[Slide: This Can Happen Anywhere; 00:11:03]

So with that, we were trying to get an idea of just sort of how widespread problems with sort of down time activities could be. And so we did a survey of the Scottsdale Institute membership, and for those of you who aren't familiar, the Scottsdale Institute is a group of about 60 very large organizations that are either on the cutting edge of health information technology, or are really committed to being on that cutting edge. And so these are places like the Mayo Clinic and partners, and Memorial Hermann Health System that really have made a serious commitment over the last 5 or 10 years to developing these systems long before meaningful use was even a concept. And the majority of people in the Scottsdale Institute are at a HIMSS adoption level of four or greater. And so usually once you get to four, you're pretty much dependent on your electronic health record system.

And so these places were what we'd call leaders in health information technology. And when we asked them if they had any unplanned downtimes in the last three years, 95% said they'd had at least one. And then we asked them how long those had happened, I said like, have you ever had one that's lasted at least eight hours, almost 80% of the organization said they'd had at least one unplanned downtime of at least eight hours. And this was pretty shocking to me, because in most organizations an unplanned downtime of eight hours puts a significant crimp on the lifestyle and the workflow of the people in the organization. There was just a report of a hospital in Florida, and they described it as chaos in the hospital when things go down, because we've gotten rid of a lot that people that used to do a lot of sort of paper shuffling, transcription, reporting type activities, and we replaced that all with a computer system. And when the computer's not there, there's just no one to really do the work.

The other interesting thing was that 13% of those people mentioned that they'd had a downtime greater than 24 hours. And 24 hours really starts to eat into the practice of the hospital, because you start having problems where you start wondering whether you should keep the hospital open, a lot of times the emergency rooms have to go on divert, and you sort this stop doing-- what are those called? the surgeries, elective surgeries, and you only do the emergency surgeries. And so really, it gets to some serious impacts on your organization.

It was interesting that one of the organizations mentioned that they had an injury to a patient or a staff member during this downtime, and it's difficult to really assign blame for the down time and the injury, but in general, the things you can think of is when the computer is down, laboratory results can be delayed, and so that means people may not get treatment that they need in the timely manner. Or it may be that they don't get the medications they need in a timely manner, and so these kind of activities can cause a problem. We've also seen problems when the computer comes back live, where sometimes things that were in process when the computer went down can sort of get lost, and sometimes get assigned to the wrong person. And so it's very possible that people can be injured during these times.

[Slide: We Did a Survey of ASHRM and AHLA Members; 00:14:29]

And we have a paper that's under review right now, describing this study in more detail. But in general, there were about 370 or so respondents to this other survey we did with the Association of Hospital Risk Managers and the American Health Lawyers Association. And so this was, and instead of asking the IT people, which was more of the Scottsdale Institute respondents, this is more of the health risk managers and the lawyers. And these are people that have a bigger view of the organization, and sort of see the effects of these kinds of down times. And we asked them about things like how often these events are happening in your organization, what type of factors are affecting these, and did they have some best practices that they could recommend to help people avoid these kind of things?

And then finally we asked them about what kind of measurements they were tracking, and who they were reporting those measurements to. And there's a paper in the Journal of Health Risk Management that describes this study, that will be coming out this spring.

[Slide: Frequency of Serious Safety Events in the Last 5 Years; 00:15:30]

So when we asked these people this study, in this study, 53% of the people admitted to at least one serious safety event in the last five years. And so just to give you a feel for survey research, the last one with the IT people that weren't so scared, but these people were the lawyers and health risk managers, and so I would have expected them not to be, let's say, as forthcoming with us about what had happened as the other people. But still over half of them said that they'd had some problems, and 10% experienced more than 20 of these events and in the last five years.

And so these kinds of things are happening, and they are important, and people that think that this kind of stuff won't happen to you, you're wrong. They will happen to you, and they can happen to anyone.

[Slide: Type and Frequency of Healthy IT-Related Safety Events in the Past Five Years; 00:16:14]

So when we asked them about the types and frequency of different health related events in the last five years, the number one thing that they all mentioned, and they could click on more than one of these type things, but they talked a lot about data that's incomplete, missing, or misleading.

And this is a common occurrence in electronic health records, were people enter orders and forget to sign them, or don't hit Return at the right time, or put them in a hold, and no one seems to activate them. It's very easy to get the orders into a place where it seems like you've done everything you're supposed to, but the order action hasn't made it. If you think about Amazon.com, this is when you forget to hit that button to say ship me the thing, or confirm your order. And so you think you've ordered the book, and it hasn't come for you. And so that's always annoying, and it can be life threatening at a hospital.

We also saw a lot of people with these open or incomplete patient orders. And this is very similar to the first one, so it's hard to separate the two of these, and it's a very significant problem, where people think that they've completed something, and they just haven't quite gotten confirmation that something's gone through. And this is very akin to when you send email to someone, and then you don't hear anything back, and you don't know whether you should assume that they hate you and they're never going to speak to you again, or whether your email didn't get through, or it got in their spam filter, or something like that. And so it's very important that we always close the loop on these types of communications.

And then we had different people where they talked about policies and procedures being ineffective, and a lot of times the policies and procedures really need to mirror what's happening in your computer system. And that can be a problem.

We've had a lot of trouble with failure to follow up on abnormal test results, and Hardeep and I have had several grants on that subject all by itself, just trying to figure out how to improve these systems to make sure that once we get these abnormal test results, we get the results to the right patient, and we get the appropriate follow up actions.

And as you can see, there's problems with more incomplete data, people that have trouble with different types of clinical decision support. And I know in a lot of the organizations, we have a lot of trouble with overriding clinical decision support, or ignoring the drug-drug interaction checker, for example, that seems to be putting up a lot of irrelevant data. And so a lot of organizations are working on that, and we consider that an error because not only is it putting up something that someone that has expertise has deemed not relevant, but it's also bothering them right at an important time. And so it's very easy that they can make a mistake at that

time. And you can see the rest of these with prolonged downtime, and the different legal mandates.

[Slide: Results of the ECRI Deep Dive; 00:19:09]

So then we looked at some more data that came from the ECRI organization, where they did a review of the patient safety events that were reported to their organization. And this you can see that they categorized these in some different ways, and they said that there were a lot of system interface issues. And this is either the user interface, or the interface between different systems. It's not exactly clear.

They talked about a lot of wrong input data. They talked about some configuration errors, where people just set up the system incorrectly, and so this could have happened, for example, when you forget to send the results back to the ordering provider and the primary care physician, for example. And then we had problems with a lot of software functionality, and wrong patient errors.

[Slide: National Initiatives Should Be Accompanied by Guidance for the Frontlines; 00:20:03]

So then when we started these guides, we were hoping that the SAFER guides would sort of help clinicians and institutions learn about some of the best practices for safe and effective EHR implementation that has been developed over the last 20 or so years. So a lot of people are brand new to this area. The meaningful use has drawn them in, just like it was supposed to, and they're just not aware of how much knowledge and experience has been gained over the years. And that's one of the best parts of these guides, I think, is it tries to pull that together.

It also can be very difficult to identify errors that are embedded, sort of, in these interfaces between system components. And so we want to make sure that people are very aware of that, and how to test those kind of systems.

And then to remind people that we can't fix these solutions just by fixing our IT. This isn't something that you go to your IT vendor or your IT department and yell at them to make things better. This is something that, really, the entire organization has to work on and concentrate on, and really strive to fix.

[Slide: SAFER: Safety Assurance Factors for EHR Resilience; 00:21:09]

So the different guides, there's nine guides, and we organize them in terms those of two of them that are what we call foundational. The first one is the high priority guide, which sort of takes some of the most important items from each of the other eight guides, and then there's an organizational responsibilities guide. And this one really focuses on the people and the practices, and the policies that need to be implemented in your organization to make this thing work. And then we have three guides that are really focused on the computing infrastructure. And so one of these is about how to configure your system to make sure you have test

environments, and make sure your printers are connected to the right computers, and things like that.

We have system interface guides of trying to make sure that your interface between the EHR and your lab system, or your EHR and your pharmacy system are working in detail. And then we have a contingency planning guide that helps you to prepare for these inevitable down times. And then we have four guides that are focused more on clinical processes that our research showed to be particularly dangerous.

And so one of these is patient identification, making sure that we've always got the right patient, and we're ordering the things on the right patient, or the patient we expect to be ordering them on, and that the results are on the right patient. We have one on computerized provider order entry with decision support, and talking about how that needs to be implemented safely and completely. One on test results reporting and follow up, and I mentioned that already. And then one on clinician to clinician communication, and probably the take home message from this one is to make sure we always get a confirmation whenever we send a message, that we get a confirmation that the message has been received, and it's agreed upon.

And with that, I think I'll turn it over to Joan Ash, and let her talk to you about the methods that we've used in this project.

[Slide: Developing the SAFER Guides; 00:22:52]

Joan Ash, Ph.D., M.L.S., M.S., M.B.A. – Vice Chair – Department of Medical Informatics and Clinical Epidemiology, Oregon Health & Science University's School of Medicine

Thanks, Dean. I'd first like to emphasize that our goal was not only to develop the self-assessment guides, but even more important, we wanted to make sure that we were developing tools that would really get used and be useful.

[Slide: Methods We Used for Developing Truly Useful Guides; 00:23:19]

So as far as methods go, we started with a solid literature review to gather the published evidence. We'd done one for the Institute of Medicine HIT Safety Report, but we updated and expanded on that. And then we have to figure out how to fill the many, many gaps to identify best practices, and also to discover what kind of guidance in what format was needed.

So we sought expert advice in a couple of ways. We gathered a panel of experts, and we started by holding an in person meeting right at the beginning of the project to prioritize the topics for the guides, and let them advise us about the content and the format. And we continued to use that hard working panel throughout the project. We did teleconferences and emails, and had them review individual guides as we went along.

We also had a technical expert panel. We involved a long list of stakeholder groups for more help, and finally, the most labor intensive part was we filled gaps in research by conducting some of our own. We did ethnographic research at five different sites, and completed cognitive interviews walking through the guides while we were at the sites. And finally, we pilot tested the use of the guides at five different sites.

And really, for those of you who are listening who are part of this, we give you a great big thank you.

[Slide: Stakeholder Engagement Has Been Ongoing; 00:24:46]

Now, a little bit more on the stakeholder engagement piece. This was a really important part of the development. We met with all of these stakeholder organizations to not only get their help and advice, but also to inform them about the guides, let them know they're under development, and hopefully they would use them and recommend their use. And thanks to the funding we were given, we were able to travel to organizational professional meetings, and do teleconferences and webinars with all of these groups.

We did focus groups with some. We did roundtable discussions and presentations with others, whatever was most applicable. And very often we spoke to them more than once, so this was an iterative process.

[Slide: The Purpose of Site Visits Was To…; 00:25:40]

And as far as the site visits go, the purpose was to identify best practices primarily. And we traveled to five really carefully selected sites to see what was actually being done about EHR safety now, and learn about best practices at different types of places, all with reputations for doing things well.

Now, we had done prior research, and we knew that not every place does everything well, or even the best places don't do everything well. So we knew that we could learn best practices only if we went to different kinds of organizations. These places, however, were really reputed to have good cultures of safety. So they were our picks.

We gathered lists of best practices and saw a lot of differences across the organizations, and found out who why, how, and when these guys might help these organizations. And we kept making the guides better as we visited them.

[Slide: We Gathered a Lot of Data; 00:26:48]

We gathered a lot of data. Depending on the size of the place, from two to eight researchers descended upon the sites. The sites ranged from one provider practices to large integrated health care systems, with Geisinger and Partners, of course at the large end, a group of safety

net clinics, and a 100 provider private practice in the middle, and four independent Colorado practices ranging from 1 provider to 11 at the smaller end.

We conducted observations and interviews, we did both semi-structured interviews, more open ended, and these cognitive interviews I mentioned, and we gathered over 2,000 pages of data. Again, each visit helped us refine the guides.

[Slide: We Pilot Tested the Tools at Five Sites; 00:27:38]

And finally, we pilot tested the guide when they were fairly finished.

Again, at five places, but different places to try to find out who could answer the questions, usability issues, the time for completion of each of the guides, and whether it works best to send the guides to people to do them asynchronously, in private, in the quiet of their offices, or to have folks sit down together to do them, and we found out definitely the latter method is best.

[Slide: Lessons Learned; 00:28:11]

And finally, we learned a lot. We learned that some people want generalities, and others want specifics. So we tried to provide both, and hopefully make everybody happy by offering high level principles, and some more detailed recommended practices, and then some even more detailed examples.

We've offered rationales outlining risks for not doing each thing we've recommended. We found out that multi-disciplinary teams are needed to complete the guides. Scoring wasn't exactly popular, but self-assessment scales were. We were told the guidance is needed for all kinds of organizations, both ambulatory and in-patient, large and small. We were urged to develop a high priority guide to include references. And finally, we discovered lots of best practices to include in the content.

The biggest decisions we had to make along the way were that these would be pretty much one size fits all guides for all types of healthcare organizations. That they would allow drilling down from the general to the specific, and that the practices should be reached goals. Not the lowest and easiest things to do, but the ideal towards which you'll want your organizations to be moving.

And now I'll turn it over to Hardeep to describe the conceptual underpinnings of the guides.

Hardeep Singh, MD, MPH – Internist – Michael E. DeBakey VA Medical Center

[Slide: The Conceptual Evolution of the SAFER Guides; 00:29:40]

Thanks, Joan. So I came into this as a clinician who uses electronic health records. I was always a health services researcher in informatics, and so in health services research, we like to use a lot of conceptual models.

[Slide: Multifaceted Approach Needed; 00:29:58]

Any time we find things that are very complex – and I think most of you will agree with me that the design, and development, implementation used in evaluation of health IT – the entire life cycle is really complex and prone to failure.

There's many things that can go wrong, and so what we wanted to do as a group was to do use strong, conceptual framework so that we could get guidance as to how to approach this complex topic. So I'm going to walk you through a couple of these frameworks to explain to you how we actually integrated them with the guides' development.

[Slide: 8-Dimensional Socio-Technical Model of Safe and Effective EHR Use; 00:30:31]

So the first model is what we call this eight dimensional sociotechnical model of safe and effective electronic health record use. We actually published about this model a few years ago in *Quality and Safety in Health Care*. And it has eight dimensions, and you can see those eight dimensions on your screen and how they interact with each other.

The interesting thing to note here is, you really need to account for all of these eight dimensions in anything in the life cycle of health IT. So if you want to have an evaluation or implement health IT and you want to make it safe and effective to use, you really need to address each of these eight dimensions. And that's what we've learned in our work over the last few years.

The first dimension is hardware and software. Everybody will agree that you need to have a computer that is available and safe to use. Content means things like decision support, the logic, the knowledge in the computer, the alerts, the reminders. With user interface, a lot of the other dimensions are quite intuitive, but the interesting thing here is, this is not only about technology. This is also about the social, and the organization, and environmental contexts in which the technology is embedded.

One of the dimensions I like to emphasize here is that of measurement and monitoring. And the reason we have that as a dimension in our conceptual model is because we often do things, we implement things in practice, but we then don't evaluate how they are doing: are they having the right consequences or are they having some unintended consequences we need to know about?

And the reason we seek certain rules and regulations that are on the right hand side is because those are the things that really affect us. So things like meaningful use, things like ICD-10, all of

the Joint Commission things. So all of these things are affecting how we are performing within this complex sociotechnical environment that we're implementing electronic health records.

[Slide: Evolution of Safety- (and Risks) Phases; 00:32:43]

So in the next slide, I want to walk you through the model that is when we say health IT related patient safety, this model sort of explains it. And we published in the *New England Journal* in 2012. And we call it the evolution of health IT related patient safety. So when we say health IT patient safety or electronic health record related patient safety, we actually mean three things which need to be understood.

So the first thing we need to put into context is that, IT needs to be safe by itself. So that means that, some of you might remember in the National Health Service in 2006, there was an incident in which, because of a computer glitch, quote unquote, patients were prescribed Viagra instead of Welbutrin, and the only way they found out was because women started showing up in the pharmacies with Viagra prescriptions.

And so that's because of a computer glitch. So that's the first phase off our second model is having safe IT. And this pretty much relates to making sure the technology is safe.

The second phase of our model that we used is using IT safety. So you can have the best technology in the world, but then if you don't use it correctly, we could still have problems in patient safety. An example would be too many alerts. So we could have a wonderful electronic health record system but we are sending too many alerts to our providers and they're all getting overwhelmed and ignoring them. Or if you're having too much copy and paste, then that's harming patients, so that's also unsafe. So that is using IT safely phase of this model.

And the last phase is the one that we actually envisioned our electronic health records to do. We wanted electronic health records because we wanted to improve patient safety. We wanted to measure how safe and high quality our care was. So this is a third phase, and this is the phase in which we really want to monitor health care processes and outcomes.

And we want to proactively assess outcomes, and improve before harm occurs. So that's the third phase of our model.

[Slide: "SAFER" Conceptual Model; 00:34:54]

And putting this all together now, this is what we call our SAFER conceptual model. And this is based on David Blumenthal's notion that, going from a paper based health care system to an electronic health record system, it's like an escalator. And you climb on the escalator. So we actually published this in JAMIA last year where we show how each of these phases is important, and you really need a sociotechnical approach, and a sociotechnical model in each of these phases in order to guide your progress upwards.

[Slide: 6 Principles in 3 Phases; 00:35:29]

So now let's talk about making this a bit more practical. When we started our guide development we thought, OK, so the models are good, but we really need to start putting things in perspective of health IT, so we decided that every phase would be accompanied by some inarguable principles that would be useful for us to develop practices that would then be useful.

So these are explained in a lot more detail in the SAFER guides. So I'm not going to walk through each one of them, but in phase one, for instance, data availability, integrity, and confidentiality would be the three really important things you need to be thinking about when you think of safe health IT.

In terms of phase two, using the EHR correctly and completely, in the lines of how I mentioned earlier, and of course EHR system usability is in this phase as well. And in the phase three, like I emphasized earlier, monitoring is really, really important because it tells us how we are doing, how we are performing, what is it that we need to change in order to go forward. And these are the principals that guided us in our SAFER guide development.

[Slide: Practices; 00:36:45]

So let's come to the practices. Each of the guides has practices which are anywhere from 10 to 25 recommended practices. The practices pretty much tell you what to do to optimize the safety and the safe use of EHR. And so when we developed these practices with all the methodology that Joan just went over, we wanted to make sure that they are not considered either guidelines, or policies, or regulations.

We're not coming up with guidelines, policies, or regulations. These are just self-assessment practices that people could consider within their own system. And they are the right things to do. And so, what we wanted to make sure was they're applicable broadly. So if it's relevant to the outpatient setting, it's relevant to the inpatient. So it's a good thing to make sure that you follow up on the abnormal test results, and that is a practice that could be relevant to both inpatient and outpatient settings.

So that was the way we came up with practices. I think the scoring system, as Joan talked about, we did consider whether you should score yourself or not and then compare yourself over the next year or two years.

[Slide: Planning Worksheets; 00:38:05]

But we decided that we would leave that up to the institutions, and so the next thing we wanted to do was to come up with some sort of a planning worksheet, if you will, that can help the practices or the organizations that are doing the self-assessment to set some goals and track some progress as to what they can do.

We want to give every practice rationale as to why is it important, why is it needed. Many times on our site visits, people say, yes, that's a good idea, but can you tell us why is it that you need it. Why is it that would need this practice? And so we also gave references, a lot, many of them at times, at to where the evidence came from. We also give examples. And I want to make sure that there's a distinction understood between practices and examples. Practices are something that we really think every organization should self assess to make sure that they are paying attention to it. You could go through a SAFER guide in our 25 practices, figure out that you're only doing 20, but the five that you're not doing, you might decide as an organization or practice that you only need to do two of those five, because the other three are right now really not relevant in your context and in your setting.

So how you get those practices implemented is through an example. We only gave some examples, and you could argue whether we say it's a banana, it's a fruit, and you might say, well, apple is a fruit too. And so as long as you can make sure that the practice requirements are been met, it doesn't really matter what kind of example you use. The only reason we gave examples was to get people to think about the things that they need to do. And yes, it might require some kind of more development in terms of technology to make sure some of the practices are being met, but that's the whole point of innovation. So we thought that the examples would have people think about the things they could do in their environments to meet the practice requirement.

[Slide: Where to Begin; 00:40:05]

And so where do you start? I think a high priority SAFER guide would be a good place to start, because it really comes together from a lot in any other guide. It would be great to get a multidisciplinary safety team together to do these. Although, you know in our preliminary field work, we found that the CMIOs who really know the institution really, really well were able to go through the CPOE guide quite well in about 30 to 40 minutes, and they were able to answer most of the questions without asking too many other people.

But a lot of institutions might require to have answers from a diagnostic service, or a pharmacy, or the EHR developer. So in our SAFER guides, we've actually put in pointers as to who you could ask to see if you're meeting the practices or not. And what are the next steps to take.

It does require engagement of people, both within your own practice and outside your practice environment, and so we thought that this could begin the start of a meaningful conversation on improving health IT related patient safety between the organizational stakeholders, for instance the risk management people, the quality people, the administrators, the CEO, the leadership team, the board, and of course the clinicians and the users. And so we think this could be a nice way to start conversation on, here are the things that we could do better within our EHR system.

[Slide: SAFER Checklists; 00:41:36]

And so now I'm going to turn it over to Dean to walk you through how to use the guide if you're just thinking about using this in your practice or your organization, how you could walk through the guidance. And over to you, Dean.

Dean Sittig, PhD – Professor – School of Biomedical Informatics, The University of Texas Health Science Center

All right, thanks. So what you're looking at now is a screen print of one of the guides. And I'm told by our instructors that there's a green icon at the bottom of your screen that should give you a link right to the SAFER guides. They're also available on the Healthit.gov website under the SAFER project. So you can look at there and they're all available for downloading or online use.

And so I'm looking at a screen print of a PDF that's available for downloadable use. And these are what we call interactive PDFs. So they allow you to fill them out as Hardeep mentioned. So you can see at the top, we're in the recommended practice, this is a phase one item of the high priority checklist.

If you look at the first recommended practice, it says data and application configurations are backed up and hardware systems are redundant. And then you can reach over there and say, oh, that's fully implemented in all areas. You can click on that, keep track of where you are, and go to the next recommended practice, for example, and see the downtime policies and procedures are complete, available, and reviewed regularly. And someone says, you know, we're doing pretty good on that. I'd say we're partially implemented. We don't really have a good system for the lab, for example.

Then you go to the third recommendation and it says something about allergies, and problems list entries, and diagnostic test results have normal and high values associated with them and are entered using standard code and vocabulary elements. And you wonder, I wonder what that means, exactly. And so one of the things you can do is, you can click on the worksheet link and you'll be taken right to the back of the guides.

[Slide: SAFER Worksheet – Practice 3; 00:43:34]

And so usually, the guides are about one or two pages of the recommendations in the front, and then in the back, there's one page for every one of the recommendations. And on this worksheet, you can see the practice again, and then you can see the rationale that we talked about where, if you click on that, you can see that it says that free text data can't be used by your decision support. So it's important if you want to let the computer try to help you, you have to use some coded data elements. And that shows an example like Hardeep mentioned, why we would do this kind of a practice.

And then we also can see the sources of input. And so it may be that you're having a little trouble wondering, I'm not exactly sure if we're using that in the lab. And so when you click on

these suggested sources of input, you see the people that we would expect that you would need to ask to get clarification on this. And so for this, we'd expect clinicians would know stuff about this, or support staff. Maybe someone in clinical administration, someone in the lab department, or maybe you'd have to go all the way to your EHR developer to tell you how this information is stored in the computer system.

So then the other things we can do on this guide, we can see some of the examples that Hardeep mentioned. And like I said, these are just examples, and these are things that you should think about. And so we would recommend that RxNorm is a good way to code your medications, and it's good to use the NDF-RT coding system for different medication classes. So if you want to have decision support that says if the patient's on an antibiotic, I want to do something special, the NDF-RT can help list all the antibiotics, as opposed to someone having to go through and select all the medications that are in your formula that there are actually antibiotics.

We recommend SNOMED CT for coding the allergens and the reactions, and severity. SNOWMED CT or ICD-9, or soon to be ICD-10 for coding your clinical problems and diagnoses, and so on.

And we try to give you some examples of the way that you could implement these practices. And a lot of times, these examples are sort of the best way to really understand what we were trying to get at with the recommendations.

[Slide: Interactive Section of Worksheet; 00:45:55]

So then if we scroll down on that page, we can see this worksheet that Joan mentioned.

And so it may be that you want to write something in the follow up actions section, and you want to tell someone, you know, we need to talk to the lab, and we need to get with our EHR vendor and discuss what's going to happen. And then you might want to set someone responsible for this. We say, you know, Joan, you're the one that's supposed to do this work. Report back to us at next week's meeting.

And then there's also a link to some references, and so Hardeep mentioned those.

[Slide: SAFER Reference Page; 00:46:22]

And so we usually try to link to all the scientific literature that we were reading, and some of it that we've written ourselves that sort of explains why we're doing the things we're doing, and why we think they're so important.

[Slide: Interactive Section of Worksheet; 00:46:36]

And then we also have links back to those phases and principles.

[Slide: SAFER Phases and Principles; 00:46:45]

And so Hardeep mentioned those, how we try to remember the different phases, and think about why we're doing the things we're doing. And so this is another way to sort of help explain what we're trying to get at, and what the meaning of these guides, recommended practices are, and where they came from, and why we think they're so important. And so you can see here we talk a lot about data availability, data quality and integrity, and data confidentiality. Sort of the three key items for all data management systems.

[Slide: SAFER Phase 2; 00:47:14]

And then we also have the different principles for phase two and phase three, where we're constantly trying to get everyone to use the system as completely and correctly as possible, and make sure that the system is usable, and it fits in with the workflows that people are trying to do.

And then finally, we're big fans of this idea of using the EHR to sort of monitor what's going on in your organization, and use it to sort of develop some surveillance and reporting. And then when you get those reports, you can optimize your system to get the outcomes in patient care that you're really hoping to get.

[Slide: Interactive Section of Worksheet; 00:47:49]

And so then we can go down, and we see that we also have some other links on the guides.

[Slide: HIPAA References; 00:47:58]

And so some of the recommended practices are adaptations, or come straight from the HIPAA guidelines. And so if you're having a hard time convincing someone that patient ID is important, or patient confidentiality is important, and role based access is an important thing in your organization, you can be reminded that that's part of the HIPAA security rule, and it takes you right to that place, and the rule of where that is. And so this can give you some more little impetus of why you're going to do this. I guess I should mention that just because you do the SAFER guides, the few items that we have in the SAFER guides from HIPAA doesn't mean you're in total compliance with all of the HIPAA guidelines, which, you know, are several hundred pages themselves. And so this is just some of the things that we think are particularly important from those guides in relation to patient safety.

[Slide: SAFER Worksheet – Practice 13; 00:48:46]

And then we have more guides for like, phase two, where we're trying to use our IT safely. In this one we're trying to make sure that we're using EHR for ordering all the medications and diagnostic tests, and procedures in your organization. And these are three of the most important ancillaries, and we think this will go a long way towards improving patient safety

once we get complete use throughout your organization, and have the decision support in place.

[Slide: Interactive Section of Worksheet; 00:49:20]

I remind you that you can always scroll down on these guides and see the worksheets at the bottom. And then some of these come, like that one I just mentioned, comes right from the meaningful use guideline.

[Slide: Meaningful Use References; 00:49:28]

And so you can see that in meaningful use, stage one you were trying to get 30% of all your orders through CPOE, and now in phase two we're trying to get up to 60%. The guides go a little further than that, and they would recommend that virtually all your orders should go through CPOE. Now, we recognize that there's always a few cases where it's appropriate to do a verbal or a written order if someone's not at a computer, or not available at a computer system. But in general, the goal is 100% CPOE to the extent that you can possibly do that. That's the safest way to do it, I think.

[Slide: SAFER Worksheet – Practice 17; 00:50:05]

And then we get into phase three, where we're trying to monitor the safety of our system. And so one of things that's really important is we want to really make sure that the safety hazards that are identified either in your organization or in your EHR are reported to responsible parties, and the appropriate steps have been taken to address them.

And once again, we can see some examples of things that you should do. And so you should have policies and procedures for how to address EHR safety hazards, and someone to prioritize them, and someone to be responsible for talking with your vendor, or someone to be responsible for talking with your IT department about how we're going to get this fixed.

Make sure that these reports of hazards are reported, and where they're appropriate to maybe senior leadership in your organization, or the boards of directors of your hospital, even. Sometimes it takes things going to a very high level in the organization to get the kind of response that's needed. And so that's sort of how we use those examples. We recognize that not everyone would do that, or not everyone would go to the board, but that's the type of example that we're putting in place here.

[Slide: SAFER Project Team; 00:51:15]

And with that, I'll certainly open it up to questions. This is where you can reach us, Joan, Hardeep and I, and also a link to the SAFER guides, and we'd be happy to answer any questions you might have. Thank you very much.

Kathy Kenyon, JD – Senior Policy Analyst – Office of the National Coordinator for Health IT

OK. This is Kathy Kenyon, and while I wait for the meeting organizers to send me the questions, let me start by a little bit more on the conclusion that the recommended practices and the SAFER guides work for both small practices and large health systems. And Joan, I know you talked about that a bit, but it is a question that we get. So how did you come to that conclusion?

Joan Ash, Ph.D., M.L.S., M.S., M.B.A. – Vice Chair – Department of Medical Informatics and Clinical Epidemiology, Oregon Health & Science University's School of Medicine

Well, actually at first we thought that we might have to do different versions of the guides, but once we went into the field and visited the sites, we realized that with the different levels of granularity, so we talked about higher level principles, and then more specific practices, and then very specific examples, we decided by organizing it that way, we could have practices that were generalizable across all different types of organizations.

So once you get into the examples, you'll see things that are more relevant to ambulatory, or more relevant to larger organizations. But by and large, the practices themselves are applicable to any kind of organization, because they're general enough.

Kathy Kenyon, JD – Senior Policy Analyst – Office of the National Coordinator for Health IT

What about the organizational responsibilities guide?

Joan Ash, Ph.D., M.L.S., M.S., M.B.A. – Vice Chair – Department of Medical Informatics and Clinical Epidemiology, Oregon Health & Science University's School of Medicine

Well, that one in particular, the practices are very generalizable across all of the organizations. And for example, we tried to use terminology when we described the practices that would fit. Different kinds of organizations.

One example I can give is that we had originally used the word governance a great deal when we had drafted the practices for the organizational responsibilities guide, and when we got into the small practices, they said, well, that's not a term we would ever use. That doesn't mean much to us. Don't you mean decision making? And so we tried to use terminology in the guides that was applicable to everyone.

Kathy Kenyon, JD – Senior Policy Analyst – Office of the National Coordinator for Health IT

OK. I now am beginning to get some questions. The first is when Sittig, et all looked at various practices, to what extent did they find that some of these problems were more predominant than others? So Dean, do you want to take that one?

Dean Sittig, PhD – Professor – School of Biomedical Informatics, The University of Texas Health Science Center

Yeah. And so we try to make the guides, we try to make a guide, when we found out that some practices were particularly dangerous, like the idea of identifying the patient, for example, we tried to make an entire guide for that.

Then within the guides, we didn't really prioritize the items within the guides. We think they're all important, but I think that's something that an individual organization would work on as trying to figure out what they're going to address first. And so that's sort of a trade off between their capabilities of what they can address, and what they have the time, and the human resources, and the financial resources to address.

And so in general, if you know in your organization that you're having a lot of trouble with wrong patient errors, like you're getting a lot of calls, for example, to your help desk, saying I entered some orders on the wrong patient, can you move them to another patient, or get a lot of complaints that orders aren't being received by the pharmacy, you might want to look into your system interfaces and try to see if there's a problem there.

And so a lot of this depends on sort of what's going on in your organization, and how that relates back to your guides, because not everyone has the same sort of problems. Some people are doing a great job on their down time, but their system interfaces aren't working very well.

Sometimes their interfaces are working, but they don't have the right people or organizational structures in place, and so this is something I think each individual organization sort of has to work through.

Kathy Kenyon, JD – Senior Policy Analyst – Office of the National Coordinator for Health IT

OK. We've got a question here about using a variety of settings in order to ensure a broad coverage of EHR vendors. They noted that in the slide that Joan had up, that there were four or five different vendors. How important was a particular vendor to what you found?

Dean Sittig, PhD – Professor – School of Biomedical Informatics, The University of Texas Health Science Center

I guess I'll take that again. Basically, the way we developed the guides was we went out and talked to provider organizations. So some of these organizations would tell us either they had problems in the past with certain items with their EHR, and they wanted to make sure that other people had those addressed, or else they were still having those problems.

And so the items we have identified are not really particular to one EHR vendor. These really cross all vendors. And so for example, one of the items in the patient ID guide says the patient's name, and their date of birth, and their gender ought to be on every screen in the EHR. And so

that's something that every EHR vendor, I think, would agree that they have strived, and they were trying to do.

Now, it's very easy with these new systems, with multi-windows to sometimes have a window that pops up that doesn't have the patient ID on it, and some of the vendors would say, well, the patient ID's on the screen right behind it. But sometimes these windows can be maximized, and we can sometimes lose track of what patient we're working with.

And so in that case, these are problems that cross all vendors. Potentially cross all vendors. I don't think there's really any one vendor that we're singling out for any problems, or any one vendor that's particularly solved all of the problems.

Hardeep Singh, MD, MPH – Internist – Michael E. DeBakey VA Medical Center

I'd like to add that this is not just about technology. There's lots of things that are organizational, workflow related that are just not about technology. So you might want to keep that in mind, too.

Dean Sittig, PhD – Professor – School of Biomedical Informatics, The University of Texas Health Science Center

Yeah, I guess I should add with that, and then there's the interaction between those two things. A lot of times health care organizations buy an EHR from a vendor, and then they have the option of configuring it. And you can configure it so it's not as useful as, or not as safe as it was when it was designed.

And so that's an important part of this, is how do you make sure that the system is sort of implemented as it was designed, and implemented and tested safely? And so a lot of the items on the guides span that continuum that Hardeep talked about, from the technical all the way to the organizational, and everywhere in between.

Kathy Kenyon, JD – Senior Policy Analyst – Office of the National Coordinator for Health IT

I've got a question here. Are you aware of work being done or published about how to monitor the safety of EHR systems, either with software alone, or by people.

Dean Sittig, PhD – Professor – School of Biomedical Informatics, The University of Texas Health Science Center

Well, there's quite a bit of work going on in different areas. So like at the technical level, I would think that everyone would be monitoring what we'd call the uptime of their system and reporting that to, I think, the CEO and the board of directors of the organization ought to know what their up time is. And I wouldn't say just the planned uptime, but I'd talk about the total up time.

And so if someone's taking your system down for an hour every night, I would say that that's probably unacceptable unless you're a small practice and you're closed except between 9:00 and 5:00 during the day. But in a big hospital that has an emergency department, and ICUs, and surgery that's going on all night, it's not acceptable to be down during the night.

So I think you should be monitoring the uptime of the system, I think you should be monitoring the response time. So we saw a lot of places where sometimes the system runs so slow that the clinicians would say it was down even though technically it was not down. And we called that functional down time. So the system's just working so slow that you couldn't really use it.

And then there's people that are working on – so, Jason Adelman from somewhere in one of the New York hospitals –

[INTERPOSING VOICES]

Dean Sittig, PhD – Professor – School of Biomedical Informatics, The University of Texas Health Science Center

– looking at trying to identify wrong patient errors where he monitors how many times orders are entered, and then discontinued, and then re-entered on a different patient. The same order on a different patient. And in his research, that was probably 50% or 60% correct for a wrong patient error when someone did that.

And so you can look into your system that way. People are monitoring what percentage of your orders are entered, for example, in free text. And so if you have a high percentage of free text orders, that's a problem. Or if you have a lot of –

Kathy Kenyon, JD – Senior Policy Analyst – Office of the National Coordinator for Health IT

Yeah, and I actually think that this list is in the organizational responsibility guide.

Dean Sittig, PhD – Professor – School of Biomedical Informatics, The University of Texas Health Science Center

And there's also a very nice resource on the American Health Lawyer Association website where Elizabeth Belmont led a project that came up with some very nice recommendations on what should be measured as well.

Kathy Kenyon, JD – Senior Policy Analyst – Office of the National Coordinator for Health IT

Right, in conjunction with the American Society of Healthcare Risk Managers, ASHRM.

Hardeep Singh, MD, MPH – Internist – Michael E. DeBakey VA Medical Center

But I think it's important to note that some of the measures are being proposed and some of them are still under development. There's a lot more that needs to be done. We've done some work in the VA. We're trying to monitor follow up of test results as well on an automated basis. So there's a lot of exciting work which is still under development. A lot of it.

Dean Sittig, PhD – Professor – School of Biomedical Informatics, The University of Texas Health Science Center

I guess we should also add this is what we'd call phase three of one of those models that Hardeep mentioned. And so you've got to make sure the system is working correctly first. You've got to make sure they're using it. And then this is the final phase in most organizations, even the leading organizations are just starting to make headway into what I call these phase three activities of trying to monitor your system and monitor the safety of the system.

But certainly this is where we want to go, and it's why we developed EHRs and it's where the big benefits are going to come from. So this is what we're going to be working on, I'd say, for the next five years at least.

Kathy Kenyon, JD – Senior Policy Analyst – Office of the National Coordinator for Health IT

OK. A question here that I think probably is for Hardeep related to – Well, the question is, is there a desirable target for decision support being overridden.

Hardeep Singh, MD, MPH – Internist – Michael E. DeBakey VA Medical Center

Well, you can propose one and see how that works. I don't think there's a target per se.

Dean Sittig, PhD – Professor – School of Biomedical Informatics, The University of Texas Health Science Center

Yeah. So I would say the target is, we shouldn't be overriding more than 50% of the alerts we put up. But I don't know of any organization that's achieved that, like Hardeep said. And so most of our organizations were overriding well over 90% or 95% of our alerts, and sometimes higher.

So certainly that's something that needs to be worked on, and we're working on it in every organization I've ever been associated with of how to improve the sensitivity and specificity of those alerts. And so that's something that's going to be an ongoing battle, and I hope that, by publicizing it and making people understand the risks of too many alerts that we can start addressing this problem, come to some agreement.

Kathy Kenyon, JD – Senior Policy Analyst – Office of the National Coordinator for Health IT

So Hardeep, how do you deal with that in the SAFER guides?

Hardeep Singh, MD, MPH – Internist – Michael E. DeBakey VA Medical Center

How do I deal with what?

Kathy Kenyon, JD – Senior Policy Analyst – Office of the National Coordinator for Health IT

Over-alerting.

Hardeep Singh, MD, MPH – Internist – Michael E. DeBakey VA Medical Center

Well, I mean, we propose in at least two of the guides that organizations should be monitoring the amount of information that is flowing into the inboxes of providers. Both the test results guide and the communication guide address things like information overload. So some of the systems currently are reporting providers getting in their in-baskets more than like 100 alerts a day, and these are the asynchronous notifications.

They also get the other types of alerts, such as drug-drug interactions. So I think we've got to have a monitoring strategy in place to figure out who's getting what. Most organizations that agree we are aware of. Since they're not monitoring the amount of information that is flowing into the docs' inboxes. It'll be shocking, I think, when people start to see the real numbers. And we've seen some of those numbers in research settings, and I can tell you they're very, very large.

Joan Ash, Ph.D., M.L.S., M.S., M.B.A. – Vice Chair – Department of Medical Informatics and Clinical Epidemiology, Oregon Health & Science University's School of Medicine

And if I can just add, the organizational responsibilities guide is quite clear that there has to be a decision making organizational structure in place so that decisions can be made about individual alerts and again, the specificity of alerts before the monitoring can start, the ability to make judgments about how to decrease the number of alerts.

Dean Sittig, PhD – Professor – School of Biomedical Informatics, The University of Texas Health Science Center

Yeah, that'd a good point. So I work with Memorial Hermann Health System, and we have a monthly meeting with representatives from all 13 of the hospitals that we work with – a multidisciplinary team just like Joan mentioned – and we have arguments about what alerts we can turn off and which ones we can't.

And you'd be surprised the difference of opinion between the pharmacists, the physicians, the nurses. Then you get to the risk manager and the chief medical officer and the medical information officer. There's a lot of different opinions. And then when we finally do it, someone says, well, you know, we've had three lawsuits on that very alert. I'm not sure that's the one we should turn off, even though we're getting a lot of overrides on that.

And so, as Joan mentioned, these are very difficult decisions, and there's a lot of important data that you need to collect, and there's a lot of negotiation that goes on, and that's why you need these high level oversight committees that that organizational guide really focuses on.

Kathy Kenyon, JD – Senior Policy Analyst – Office of the National Coordinator for Health IT

OK, I'm getting a bunch of questions that have to do with basically validating the tool or creating benchmarks for the recommended practices. I'll note that that was not part of this contract, but if you want to comment on that, I'll open that up because it's of interest.

Hardeep Singh, MD, MPH – Internist – Michael E. DeBakey VA Medical Center

Sure. So we've talked to certain organizations, and one example I like to give people, people are interested in benchmarking. And certainly there's work that could be done in doing something. We've thought about getting aggregated data at either a national or regional level.

So for instance, ACP has this medical home builder where you could go in and input data, and they can create benchmarks. And we've talked to them about potential interest in trying to create a centralized platform where organizations could enter data and then compare themselves to see where they stand.

Every system is different, obviously. Every organization's different, as you saw from the eight dimensional model. I think we're going to have to do a little bit more work on the scoring system before we open it up to benchmarking, but I think, as Kathy said, it wasn't part of the original contract and original work, and the one and a half to two years we had, we didn't approach that, but that certainly is on our mind to do it the next step.

And I want to emphasize that there are certain things that are still under evolution. What we developed is certainly a version one of the guides. I think these are going to evolve, the practices are going to evolve over the next few years. We're hoping there'll be a version two and maybe more. This is just the beginning. So I would say draft one, and certainly we can do a lot better in trying to create benchmarks, and validation, and more field work.

Dean Sittig, PhD – Professor – School of Biomedical Informatics, The University of Texas Health Science Center

So the other way to answer that question is, we're hoping that different patient safety organizations will take this up and start collecting data like this from their members. And so I

know that ECRI is trying to start up a collaborative that they're trying to work with both EHR vendors as well as health care provider organizations to start bringing these reports of what's going on together and trying to work these out.

Joan and I have written a lot of papers about the need to start these conversations between the different people that are working, and so many times these get into adversarial arguments about who's responsible and who's going to pay.

And if we think about it, the goal is to try to make health care safer for patients, which are people like us, if they're not us. We really want this to happen. And so sometimes we need to bring these people together in a non-threatening way where we can just start talking about how we're going to fix this, what we should be doing. We can't constantly be telling the vendors they've got to fix it and the vendors can't be telling us you've got to train your people better, because neither one of these has really worked very well. We're going to have to work together to get this to work.

Kathy Kenyon, JD – Senior Policy Analyst – Office of the National Coordinator for Health IT

So that's a great segue way to a next question, which is, can you describe how you see health care providers working with their EHR developers when it comes to actually using the SAFER guides? Doing a self-assessment?

Dean Sittig, PhD – Professor – School of Biomedical Informatics, The University of Texas Health Science Center

Well in a smaller organization I think that you'd want to have them on the telephone when you're going through the guides, because they would be the only ones that could answer a lot of these questions for you, because they're in a small practice that's using a cloud based EHR. The EHR vendor controls a huge amount of what happens there. And so the vendor can either answer these questions, say we're doing that, or usually they'll say something like, that's in our next release, and we anticipate having that out early this summer.

And so these things that we're talking about are not a long-- if they are in the future, they're not very far in the future. These are things that almost every vendor I know has either completed, or is working on actively. So in a larger organization I think that you would be talking to your IT people, because in a larger organization, you do a lot more configuration and customization of the EHR on site. And so a lot of these things are maybe what I'd call local configuration parameters that can be adjusted. So for example, we have one of the items in a guide says that you shouldn't have more than one medical record open on the same computer screen at one time. And I know a lot of the vendors, almost all of the vendors allow more than one patient on the screen, but usually that's a configurable parameter, and that's something the organization needs to work through itself to decide how many they're going allow. And so –

Hardeep Singh, MD, MPH – Internist – Michael E. DeBakey VA Medical Center

I would say that providers should probably focus on the practices after you do the self-assessment, and we've given sort of resources where the people who would give you that information to do the self-assessment – once you've decided what's really important for you, I think the providers should sort of focus more on the practice rather than the example. And they could work with the developers on anything that would work to satisfy the requirements of the practice itself, not necessarily the examples that we've given in the guides. So I think you guides, what we're hoping would be quote unquote a guidance document, because providers like things like guidelines, and evidence, and benchmarks, and all that stuff.

So it'll be a starting point, because right now providers really don't know exactly what all they should be asking. But I think the practice section of the SAFER guides should really stimulate their thinking as to I think that's a really good idea as to the importance on my practice, on my organization, I need this. And so make that a point of conversation.

Kathy Kenyon, JD – Senior Policy Analyst – Office of the National Coordinator for Health IT

Hardeep, we've got one question that says regarding test results follow-up process, did you have recommendations for enabling clinicians to acknowledge urgent and critical test results, and to ensure patients are electronically alerted?

Hardeep Singh, MD, MPH – Internist – Michael E. DeBakey VA Medical Center

Yeah, so, very important question. So I think it's a two part question, and I'll try to take the first part first, which is do you have any recommendations for enabling clinicians to apologize urgent and critical? So I think one important thing that should be recommended is that the abnormals have some type of a structured data attached to it. So for instance, we need to be able to figure out from the EHR which ones are abnormals, and which ones are criticals. If you don't have structured data attached to it, then there's no way that the EHR would know. We recommend a whole lot of sort of sociotechnical practices in order to do that, in order to get the information about the abnormal test to the right provider, including using CPOE, for instance.

So if I order the test, I need to be the one getting the test back in my inbox. And that test then should be flagged in certain fashion. So we're also recommending sort of flagging off criticals and urgents, and some institutions around the country, including the VA are already doing this type of flagging.

We think acknowledgement is good. Acknowledgement is probably not enough by itself, because you can certainly click on the alert, and it might go away, and you may not still take any action on it. So we certainly recommend that there ought to be some backup processes to make sure that people are taking follow up actions on the abnormals that are sent within the EHR. It's sort of lots of recommendations in order to do that.

And then most importantly, organizations ought to be monitoring how many of their results are getting acknowledged, especially the abnormals and the criticals. We're working on some of the recommendations within the VA. Actually, if they're life threatening criticals, those really need to be verbally communicated. We should not rely on the EHR to communicate life threatening critical results. And so those have to be verbally communicated.

So we'll have to put into process a lot of these procedures in order to get things done.

The second part is more about getting results to patients. We did consider adding sort of patient notification of test results, or making a separate guide to this. That part is a lot under evolution right now. So there's evidence based, and there's research, the strength of the evidence. The experience from the field wasn't as mature as sort of the provider notification part. We do think that patients ought to receive test results, whether it's electronically or by phone, or whatever, as soon as possible. And we've put some sort of hints along those lines along in the provider notification guide as well. But I think there needs to be a follow up in maybe a year or two as people started releasing electronically these results to patients. Especially, I think the question was mostly talking about abnormals, as to how they actually will take – how do we make sure that patients get those results on time, they take follow up on them, understand the, et cetera. So we haven't worked on that yet. Certainly a work in progress.

Kathy Kenyon, JD – Senior Policy Analyst – Office of the National Coordinator for Health IT

OK, and so as Hardeep knows, that patient engagement is a real issue of mine. The SAFER guides at this point, we do not have a SAFER guide on patient engagement. But that isn't because it isn't important. It's because we haven't gotten to it yet at this phase. And so the next question is have you received feedback on the guides from the HIMSS EHRA association, or vendors?

And I'll take that one. We have. And in fact, I think it's posted. The EHRA sent a very nice statement commending the development of the SAFER guides, and they also sent significant comments on the SAFER guides, which we welcome.

The EHRA has taken a position of embracing shared responsibility, and I think what we're hearing is that they will use and work with their clients who are interested in using the SAFER guides. I can tell you that at ONC, we are very interested in hearing from people about the engagement between users of the SAFER guides and the EHR developer community. But the initial feedback we're getting is positive from EHRA.

Dean, Joan, and Hardeep, I think you have a list of questions. Are there any on there that you would like to answer that I have not asked you? And while you're looking, I'm gonna ask you –

Hardeep Singh, MD, MPH – Internist – Michael E. DeBakey VA Medical Center

Sure, I can start with one. One of them is have you talked to the CLIAstaff at CMS, or the lab reporting work group at SI on lab data safety issues? We've been actually in conversations with CDC'S lab informatics work group. And actually, we've got feedback. I was on that workgroup the last two years, and we've got feedback from them, and overwhelmingly very supportive.

They're going to be doing some other things in the near future based on our guides. And actually, as of this year, I got appointed, but I'm officially now on CLIAC which is the federal advisory committee. So you'll definitely see more sort of evolution of lab and lab related safety issues coming out from the SAFER guides.

Kathy Kenyon, JD – Senior Policy Analyst – Office of the National Coordinator for Health IT

OK, there's one, and Joan, this is a good one for you. How much time do you estimate an organization or practice will spend doing an adequate job completing this assessment?

Joan Ash, Ph.D., M.L.S., M.S., M.B.A. – Vice Chair – Department of Medical Informatics and Clinical Epidemiology, Oregon Health & Science University's School of Medicine

Well, that's a good question, and we deliberately designed the high priority guide as a starting point. So it would probably take – and again, it depends on the size of the group you get together. We heard in the small practices that they're fairly familiar with filling out self assessments for other purposes, and they'll get everyone in the practice together to complete it.

But it still may only be four or five people, so it's going to take less time. And the judgment was maybe 20 minutes for the high priority guide in that kind of organization. And the larger organization, it might take longer just because you have more people at the table. But the high priority guide is the starting point, and then it's up to the organization to decide which of the other guides they really want to spend time using.

Our recommendation would be that they pick a few to start with, and make a schedule. Do some planning. We'll do a couple of guides this year that seem to be our weakest areas, and then we'll do a few more the next year, and we'll do others the following year. It really, really depends on the organization. But we did see that the guides could be done in 20 to 40 minutes each. But it depends on how many people are –

Kathy Kenyon, JD – Senior Policy Analyst – Office of the National Coordinator for Health IT

And that was for the checklist portion, not the worksheet with the follow up, and all of that, I assume?

Joan Ash, Ph.D., M.L.S., M.S., M.B.A. – Vice Chair – Department of Medical Informatics and Clinical Epidemiology, Oregon Health & Science University's School of Medicine

Yes. Yes. Because certainly the planning process will be a much greater effort, and it may be that it's part of the HIT planning process in general. So it's really hard to estimate that.

Dean Sittig, PhD – Professor – School of Biomedical Informatics, The University of Texas Health Science Center

Yeah, I think what Joan was getting at is you could pick one of the recommendations for the guide, and that could become a year-long project. I wouldn't ever – you know, at Memorial Hermann Hospital System we had a large downtime, and we realized we weren't really prepared for that after we'd recovered from it. And our CMO convened a 90 day a high priority task force with over 100 people from 13 different hospitals, and gave us a deadline of 90 days to figure out how we were going to address this so next time it wasn't such a big fiasco for our system. And so we came up with standard paper charting forms, we reviewed data center procedures, reviewed all the policies and procedures.

I mean, this was a huge undertaking, and Hardeep has mentioned over and over, this is a sociotechnical process. And so we went all the way from making sure we had redundant servers in our data center and different configurations of air conditioning so we could handle the hear in the data center, all the way up to how we were going to communicate once the telephone system was down. And so were we going to have walkie talkies in the organization? Or were we going to have cell phones? And what were we going to do?

And so that was a rushed process. We were meeting on a weekly basis, 100 people for 90 days to solve that problem. So I wouldn't say solving the problems of the SAFER guides is done in 30 minutes. I would say going through the recommendations is 30 minutes.

Kathy Kenyon, JD – Senior Policy Analyst – Office of the National Coordinator for Health IT

OK. Hardeep, you might want to look at part six of the Q&A list. There's a question for you and I'm not quite sure what it means.

Hardeep Singh, MD, MPH – Internist – Michael E. DeBakey VA Medical Center

Sure, I can look at it. I'm going to try to understand. I think I understand what this person's asking. But the question is I expect the results to be sent to physicians, which is only the inpatient hospital model. In ambulatory settings, the physician of service could leave the organization, the patient is a part of an ACO, but that patient, I guess, remains at the office. And then what?

You know, the goal is to create backup and redundant systems. And we say that over and over again in the SAFER guide as well. We could have that even in an integrated model like the VA,

where, if I'm a PCP, let's say I ordered the test. And if I'm gone, we need to have a backup system to get that test to somebody else.

So we recommend escalation procedures in our SAFER guide, which mean, if I haven't really acknowledged – somebody was asking what acknowledge meant – if I have not acknowledged the result in my inbox for, let's say, three days, that would then be escalated to another person. It basically just means they'll be forwarded to my partner that remained, or my colleague, or whatever that might be.

Again, I want to emphasize, we're only going to be able to do so much with the technical solutions. We're also going to need to have a lot of workflow and organizational interventions. A lot of the organizations we went to and have talked to, there's not even a clear cut rule as to who's responsible for follow up of an abnormal result.

And so we really think that it's just not going to be the technical part that I'm going to send you an alert, and you take follow up action, and that finishes the story. But I think a lot more than people envision. And so I think we've given examples in the SAFER guide, and there's a lot that will be institutional contacts. And in your organization, you might decide that there will be a case manager, for instance, that's going to get a back-up of all the results that were sent by Dr. X before he left the organization or the ACO.

Dean Sittig, PhD – Professor – School of Biomedical Informatics, The University of Texas Health Science Center

Yeah. So I think I'd like to reiterate what Hardeep was saying about the importance of working through these issues. If you think about this from the patient's standpoint, if I went to the doctor and got a test result and nobody got that result, it doesn't really matter to me what the reason is that that organization couldn't do that. That's a failure from the patient's standpoint.

And so, from a health care provider standpoint, the challenge is to solve that problem. And so the reason we have hospitals is because we take our sickest patients there and we've created systems to manage these complex patients and the complex flow of information. As we move more and more care to the outpatient setting, we have to set up these similar types of systems and backup procedures like Hardeep mentioned.

And we have to have surrogates in place and sign outs. And so, just like when I'm on vacation, I should set my email to have an out of office response. And I should say if, there's anything important, call Hardeep, and list his home phone number even. I mean, I have to be responsible when I leave the organization and he has to be responsible for picking up when someone leaves the organization.

Hardeep Singh, MD, MPH - Internist - Michael E. DeBakey VA Medical Center

We mentioned surrogate procedures like Dean s but also one thing that is coming down is, most institutions are now going to be releasing all types of test results within, like, three to seven days to patients electronically anyway. So that would be, obviously, the ultimate backup system. And that goes to show the patient engagement point that Kathy was talking about.

Kathy Kenyon, JD – Senior Policy Analyst – Office of the National Coordinator for Health IT

But we still expect our doctors to look at it and to get to it. We're at 4:30. I am extremely appreciative to Dean, Joan, and Hardeep for developing the SAFER guides. We thank the participants, the people who are listening in, for their questions. If we did not get to your question and you need an answer to that, could you please get in touch with me. My name is Kathy, and my email address is kathy.kenyon@hhs.gov, and I will get back to you with an answer. So thank you very much.