

Unintended Consequences of Health Information Technology & Exchange Safety Assurance Factors for EHR Resilience (SAFER) Guides

Summary of In-Person Meeting

September 30, 2013, 8:30 AM – 3:30 PM

Background

This paper summarizes an in-person meeting held September 30, 2013 as part of the *Unintended Consequences of Health Information Technology & Exchange* project being sponsored by the Office of the National Coordinator for Health Information Technology (hereafter referred to as “ONC”), a part of the United States Department of Health & Human Services. Westat, Inc. serves as the prime contractor supporting ONC on this project.

Meeting attendees included members of the project team, along with representatives of industry and organizations that could serve as major users and/or disseminators of the SAFER Guides, including: the electronic health record (EHR) vendor community, the medical malpractice liability insurance industry, patient safety organizations (PSOs), provider organizations, informatics organizations, large health systems, and various agencies of the Federal government, including ONC, the Agency for Healthcare Research and Quality (AHRQ), the Department of Veterans Affairs (VA), and the Centers for Medicare & Medicaid Services (CMS). A complete list of attendees can be found in Appendix A.

Introductions and Meeting Goals

Kathy Kenyon, JD, MA, Project Officer and Senior Policy Analyst in the Office of Policy and Planning at ONC, welcomed attendees and urged them to engage in an open and free-wheeling discussion about the SAFER guides, with a focus on how the 9 guides that have been developed can be effectively marketed and disseminated to encourage their widespread use. (She noted that the project team will also keep track of suggested changes to content, which, while welcome, are not the primary purpose of the session.) The current guides represent the pre-clearance version, as they are going through the clearance process with both the Office for Civil Rights and the Office of the Federal Counsel. Assuming that process proceeds as expected, the guides should be available on the ONC website within several months of this meeting. Following Ms. Kenyon’s remarks, attendees introduced themselves, highlighting their background and interests relevant to EHRs and EHR-related safety issues.

After the introductions, Ms. Kenyon presented a brief video to introduce the guides, which are designed to serve as proactive self-assessment tools that organizations, clinicians, and others can use to ensure that EHR-enabled clinical systems can be used safely and effectively. To that end, the centerpiece of each guide is a checklist to evaluate the degree to which various “best practices” for minimizing EHR-related safety risks have been implemented (i.e., fully implemented, partially implemented, or not implemented). These checklists allow organizational leaders to identify the greatest potential risks and hence prioritize efforts to reduce them. The guides are organized by various principles of safe use of EHRs, and include suggestions about people and/or resources within and outside the organization that can help with both the assessments and efforts to address identified problems.

Available in both downloadable and electronic versions, the guides strive to be as interactive as possible, with liberal use of bookmarks, links, and drop-down boxes. The guides are part of a broader initiative within ONC known as the *Health IT Patient Safety Action and Surveillance Plan*. Published in July 2013, this plan revolves around strategies to use health information technology (IT) to make care safer and to continuously improve the safety of health IT. The upcoming publication of the SAFER Guides will represent a milestone in achieving one of the central goals of this initiative—supporting the development of tools and best practices for the safe implementation of EHRs. The plan also strives to improve knowledge about health IT safety, and the SAFER Guides also advance progress toward that goal. To build on this progress, ONC recently awarded two contracts that begin the process of enriching learning about health IT-related patient safety events. The first, awarded as a one-year contract this summer, will allow the Joint Commission to complete analysis of its sentinel event database to gather information on any events related to health IT. Reports from this analysis should be available in the next several months. The second contract, awarded in August 2013 to Westat, will support a partnership with several PSOs to complete an in-depth analysis of their large patient safety event databases with a specific focus on health IT-related events. The knowledge gained from these two contracts will further inform ONC’s efforts to promote the safety of health IT.

Overview of SAFER Guides

The morning session provided an overview of the SAFER Guides, including what they are and why and how they were developed.

Why Do We Need SAFER Guides?

Dean F. Sittig, PhD, Professor of Biomedical Informatics at the University of Texas Health Science Center at Houston, discussed the various factors behind the decision to develop the SAFER Guides. The need for these guides is perhaps best illustrated through the many problems that routinely occur in health IT systems throughout the country, particularly with EHRs. For example, less than a month ago, Sutter Health System experienced a significant system outage shortly after spending \$1 billion to upgrade its EHR system. Such outages occur frequently, particularly in organizations that have comprehensive health IT systems that perform many functions. But organizations that use health IT only for specific functions (e.g., results reporting, scheduling, billing) also routinely fall victim to problems.

Unplanned downtime can happen anywhere at any time. In fact, a recent survey of members of the Scottsdale Institute (a group of sophisticated organizations committed to health IT) found that the overwhelming majority had experienced at least one unplanned downtime in the past three years, with over three quarters (79 percent) having an outage lasting eight hours or more and 13 percent experiencing one lasting 24 hours or more. Two of the surveyed organizations had a patient or staff member experience an injury during the unplanned downtime, while another experienced such an injury during a planned downtime.¹ A separate survey of 369 risk managers and lawyers in hospital systems conducted in August and September 2012 found that over half (53 percent) had experienced at least one serious safety event related to EHRs in the past five years, and 10 percent had experienced more than 20 such events. Common events include incomplete, missing, or misleading data (experienced by 52 percent of respondents); open or incomplete patient orders (51 percent); ineffective procedures and policies (46 percent); failure to follow up on abnormal test results (44 percent); confusing one patient

with another (43 percent); relying on inaccurate or incomplete patient data (39 percent); and intentionally or accidentally subverting clinical decision support (CDS) systems (34 percent).² Common causes for these events include system interface problems (e.g., between computerized physician order entry or CPOE systems and pharmacy systems), incorrect input, software/system configuration issues, retrieving the wrong patient record due to duplicative names, and software functionality issues.³ These anecdotes and statistics make it clear that national initiatives are needed to support organizational leaders and front-line clinicians in their efforts to ensure the safe implementation and use of EHRs. These individuals remain unaware of best practices in this area, particularly in identifying and addressing errors embedded in flawed interfaces between components of the EHR. To address these issues, improvements cannot focus only on the technology itself. Rather, success requires that close attention be paid to the many people and processes involved as well.⁴

The SAFER Guides in Brief

The SAFER project includes nine separate guides, as outlined below:

- **Foundational guides:** The first of these two guides (entitled *High Priority Practices*) reviews roughly 20 best practices thought to be most important. The second (entitled *Organizational Responsibilities*) lays out the various people and processes that need to be involved in the effort.
- **Infrastructure guides:** These three guides focus on critical error-prone topics related to how EHR systems work: **system configuration** (e.g., so as to avoid the loss of test results), **system interfaces** (an area where problems frequently occur, often leading to “finger-pointing” by departments and people not accustomed to communicating with each other), and **contingency planning** in the event of system outages (which inevitably occur).
- **Clinical process guides:** These four guides cover important, error-prone processes related to EHRs, including **patient identification** (where errors can lead to catastrophic problems such as wrong-site surgery), **CPOE aided by decision support** (where problems can lead to patients receiving dangerous medications or procedures), **test results reporting and follow-up** (an area often plagued by delays and lost information), and **clinician communication**.

Methodology for Developing the SAFER Guides

Joan Ash, PhD, MLS, MBA, Professor and Vice Chair of the Department of Medical Informatics and Clinical Epidemiology at the School of Medicine at Oregon Health & Science University, described the development process for the SAFER Guides. This process combined the gathering of evidence from the limited amount of published literature on the topic with the solicitation of input from experts and stakeholders in the field through expert panel and stakeholder meetings, in-depth visits to carefully selected sites, cognitive in-person and telephone interviews (to review drafts of the guides), and pilot testing. Stakeholder engagement involved presentations, teleconferences, and webinars with representatives of various professional societies and associations, PSOs, the Joint Commission, the Institute for Healthcare Improvement, and government agency sponsored panels and workgroups. The site visits consisted of nearly week-long visits by a team of five to eight researchers (including experts in

cognitive and behavioral sciences) who observed those using the guides and engaged in interviews and discussions about them. These visits provided an opportunity to do the following:

- Learn about best practices to avoid unintended consequences.
- Discover variations across different kinds of sites (which were purposely selected to include both large and small entities).
- Identify those interested in using the guides and understand how and when they would do so.
- Find out which aspects of the guide are most useful (and which are not).

Throughout the development process, the team continually refined the guides, iteratively making changes in response to input as it was received. Ultimately, the team gathered over 2,000 pages of information that informed the development process. Key lessons that emerged from this effort are outlined below:

- **Organization:** The guides should be organized around overarching principles, with specific practices within each. In addition, a rationale must be articulated for each practice, focusing on the risks of not doing what is recommended.
- **Implementation and use:** The guides should be designed to be used by multidisciplinary teams within an organization. The focus should be on self-assessment so as to help organizations improve rather than on “scoring” practices against peers. In addition, the self-assessment scale should be as simple as possible; this finding convinced the team to reduce the number of items on the scale to three (from five). Finally, the guides needed to include practices that apply both to standalone ambulatory centers and large health systems.
- **Content:** One of the guides should cover high-priority practices, giving users a place to start the effort. This guide helps users identify the biggest problem areas before diving into the more detailed guides to address them. The guides also need to include references so that users can know the source of the recommendations (even if it is expert opinion).

After the data-gathering process had been completed and the initial guides drafted, the team pilot tested them at five additional sites (i.e., not those used for the site visits), with the goal of answering the following questions:

- Who is in a position to respond to the questions included in the self-assessments? (As noted, completion of the guides usually involved a multidisciplinary team of individuals.)
- Is the guide user-friendly?
- Are the questions user-friendly?

This testing process elicited additional input, which led to further changes. The testing found that each guide took a team about 20 to 30 minutes to complete, depending on the number of people involved.

Generally, the process worked better if a “point person” took charge of the guide, sitting with individuals as they filled out their portion of the guide.

Conceptual Models Underlying the SAFER Guides

Hardeep Singh, MD, MPH, serves as the Chief of the Health Policy Quality and Informatics Program at the Houston Veterans Affairs Health Services Research & Development Center of Excellence within the Michael E. DeBakey VA Medical Center and the Baylor College of Medicine, and as Director of the Houston VA Patient Safety Center of Inquiry. Dr. Singh reviewed the conceptual models that serve as the basis for the guides.

Recognizing that the design, development, implementation, use, and evaluation of health IT is complex and prone to failure, the team searched for new scientific “conceptual models” to help “get it right.” Some models proved more useful than others, and the ultimate goal was to create a model that was practical and useful to the field, and that clearly communicated the intended messages. Ultimately, the team created the eight-dimensional *Socio-Technical Model of Safe and Effective EHR Use*. Depicted in Figure 1, the model incorporates eight dimensions that each must be addressed to succeed-- **hardware/software**; **content** (e.g., knowledge, logic); **user interface**; **personnel** (including clinicians, IT personnel, system developers, and patients); **organizational policies, procedures, and culture**; **workflow and communication**; **measurement and monitoring**; and **external rules and regulations**.

Figure 1 Socio-Technical Model of Safe & Effective EHR Use

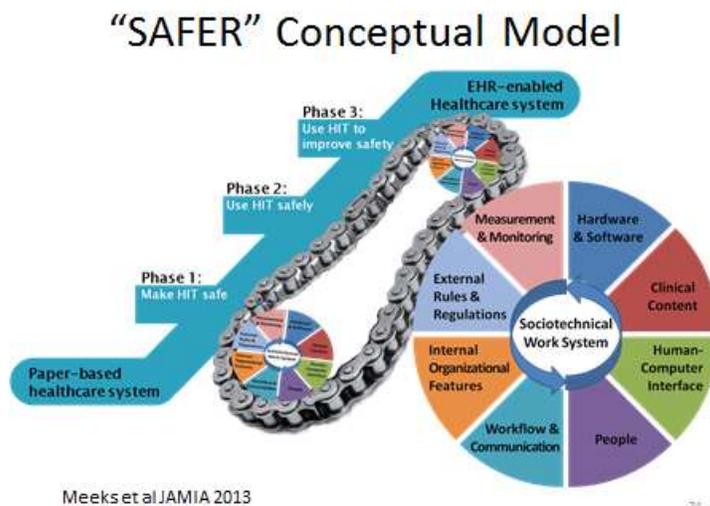


Underlying this model is a conceptual agreement on the appropriate evolution of EHR-related safety, which envisions three phases, as outlined below:

- **Safe health IT:** The first phase addresses safety concerns unique to EHR technology, with a focus on safety events that manifest early in the implementation process. Principles underlying this phase include data availability, data integrity, and data confidentiality.
- **Using IT safety:** Once safe implementation has occurred, the focus turns to optimizing use of EHRs to avoid inappropriate use of the technology and/or unsafe changes in workflows that could emerge from its use. Principles underlying this phase include complete and correct use of EHRs and system usability.
- **Using IT to monitor and improve patient safety:** The final phase focuses on how IT can be used to measure and improve safety, such as through triggers embedded in EHRs to help identify safety events and monitor healthcare processes and outcomes, with the goal of identifying potential safety concerns before they arise or cause harm. Principles underlying this phase include safety surveillance, optimization, and reporting.

Putting this all together, the SAFER Conceptual Model (see Figure 2) depicts the evolution from a paper-based to an EHR-enabled system, including the role of the eight dimensions in moving through this evolution effectively.

Figure 2 SAFER Conceptual Model



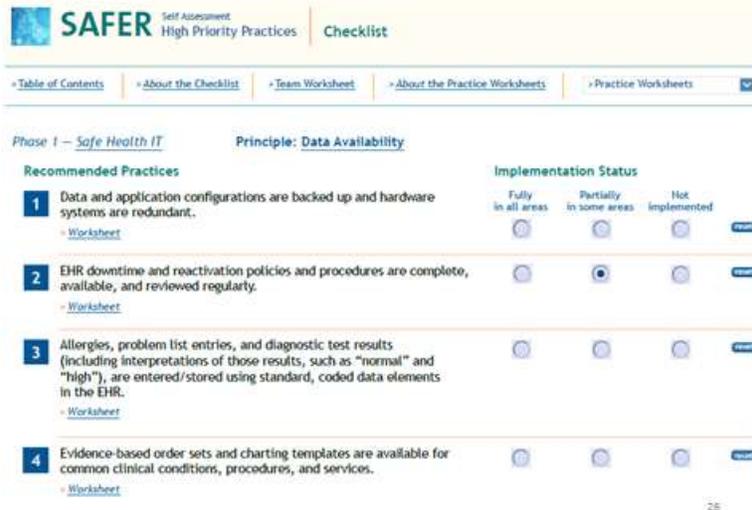
Once the model and principles were in place, the team focused on developing recommended practices that were not controversial in nature (i.e., acceptable to all key stakeholders), using diplomatic language and as few specifics as possible so that few if any stakeholders could argue with them.

“Deep Dive” into One of the Guides

To illustrate how each guide works, Dr. Sittig provided a “deep dive” into one guide: *High Priority Practices*. Like all the guides, this one is meant to be customizable at the local level, and can be used not only during the initial implementation of the system, but also several times a year to monitor progress in various areas.

As alluded to earlier, the *High Priority Practices* Guide represents a logical place for many organizations to start their efforts, as it helps to identify the biggest problem areas. Dr. Sittig briefly described each of the 18 practices deemed to be the highest priorities for most organizations, beginning with the phase-one issues described earlier—i.e., data availability, integrity, and confidentiality. As depicted in Figures 3 and 4, the guide includes summary pages that briefly list the practices and provide a place to assess the degree of implementation (full, partial, or not implemented), along with a more detailed page for each practice that includes a brief rationale explaining the importance of following this practice (and/or the consequences of not doing so); suggested sources of input to complete the assessment; and examples of specific sub-practices and scenarios. Dr. Sittig reviewed each of the 18 practices included in the *High Priority Practices* Guide; additional details can be found in the guide itself.

Figure 3: SAFER Guide Checklist



SAFER Self Assessment High Priority Practices Checklist		Implementation Status		
Recommended Practices	Fully in all areas	Partially in some areas	Not implemented	Team
1 Data and application configurations are backed up and hardware systems are redundant. Worksheet	<input type="radio"/>	<input type="radio"/>	<input type="radio"/>	<input type="button" value="Team"/>
2 EHR downtime and reactivation policies and procedures are complete, available, and reviewed regularly. Worksheet	<input type="radio"/>	<input checked="" type="radio"/>	<input type="radio"/>	<input type="button" value="Team"/>
3 Allergies, problem list entries, and diagnostic test results (including interpretations of those results, such as “normal” and “high”), are entered/stored using standard, coded data elements in the EHR. Worksheet	<input type="radio"/>	<input type="radio"/>	<input type="radio"/>	<input type="button" value="Team"/>
4 Evidence-based order sets and charting templates are available for common clinical conditions, procedures, and services. Worksheet	<input type="radio"/>	<input type="radio"/>	<input type="radio"/>	<input type="button" value="Team"/>

Figure 4 SAFER Guide Planning Worksheet

SAFER Planning Worksheet

Recommended Practice	Implementation Status
<p>2 EHR downtime and reactivation policies and procedures are complete, available, and reviewed regularly.¹⁴ more</p> <p>Checklist</p> <hr/> <p>Principle: Data Availability</p> <p>Rationale for Practice or Risk Assessment Failure to prepare for the inevitability of EHR downtimes greatly increases the potential for errors in patient care during these difficult times.</p> <hr/> <p>Assessment Notes</p> <div style="background-color: #e0e0ff; height: 100px; width: 100%;"></div>	<p style="text-align: center;">Partially in some areas</p> <hr/> <p>Suggested Sources of Input</p> <p>Clinicians, support staff, and/or clinical administration</p> <p>Health IT support staff</p> <hr/> <p>Examples of Potentially Useful Practices/Scenarios</p> <ul style="list-style-type: none"> • Policies describe: <ul style="list-style-type: none"> • When a "downtime" should be called (including when the EHR is functionally unavailable [e.g., very slow response time]). • Who will be in charge during the downtime, • How everyone will be notified, and • Who is responsible for entering data collected during the downtime. • Hospital personnel are trained (and tested annually) in these procedures. • The organization regularly conducts tabletop downtime and reactivation simulations or "drills." <p><small>See the Contingency Planning Guide for related recommended practices.</small></p>

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Key Points from Discussion about Opportunities to Improve SAFER Guides

Following the team’s presentations about the guides, attendees engaged in an interactive discussion about potential opportunities for improvement. These discussions identified the need to consider development of the following:

- **Phase-zero materials:** There may be a need to develop materials for “phase zero”—i.e., before implementation. These might include an organizational readiness/cultural assessment tool (since cultural issues are critically important to successful implementation and safe use of EHRs); a short piece to convince senior administrators within the organization of the need to pay attention to EHR-related safety issues; a video or webinar that provides an overview of the guides as a package; and/or a “guide-to-the-guides” written piece that serves as a prequel to the material. Ms. Kenyon noted that some foundational materials are being developed as part of other ONC contracts. For example, ONC has a contract with RAND to assess implementation-related risks. As part of this work, RAND is collaborating with ECRI to examine six hospitals and four physician practices that have embarked on quality improvement projects designed to mitigate the unintended consequences of EHRs. Dr. Sittig and Dr. Singh are involved in this work, which includes a pre-assessment survey phase focused on cultural issues related to safety.

- **Cost and/or cost-effectiveness estimates:** Using these guides to promote the safety of EHRs requires both time and money. At the same time, this effort might lead to reduced liability costs, since delayed diagnoses are the most common reason for medical malpractice lawsuits, and some of these delays stem from lost or delayed test results. Consequently, it would be helpful to give users a sense of the costs of working through the self-assessment guides and the potential savings and benefits that might accrue from doing so. (This material could also be part of phase zero as outlined above.)

- **More digestible materials:** Consideration should be given to making the guides more digestible, including shortening them and migrating away from paper-based materials and downloadable PDF files posted on the Web, with more of an emphasis on interactive electronic materials.
- **Questions to ask vendors for those purchasing systems:** Existing material could potentially be repackaged to create a list of questions that organizations should ask of vendors before purchasing an EHR system. Many phase-one issues and some issues that arise in other phases can be addressed through system design, so it makes sense to ask the right questions of vendors upfront (before the purchase). Dr. Sittig noted that he and his colleagues are currently writing a paper on this topic, and he is intrigued by the idea that vendors could even be pre-qualified as “SAFER-compliant.” As noted, however, many EHR-related safety issues have to do with people and processes (not technology), and hence purchasing a compliant system is not enough.
- **Guidance related to additional devices that connect to EHRs:** Many clinicians now use handheld devices to collect patient data that then gets input into the EHR. These devices may create additional safety risks related to data integrity and stewardship. The current guide covering system interface issues does not address use of these devices.
- **Documentation guide:** Consideration should be given to creating an additional guide covering documentation issues.
- **Regular updates:** Just as other tools—such as surgical checklists—are refined over time (often by those adopting them), these guides will need to evolve as well. However, the general principles underlying them should remain the same.
- **Easy access to additional tools and resources:** Potential users, particularly small physician practices, will need additional tools and resources (beyond the guides) to support successful implementation and use of EHRs. As noted, the versions available on the ONC website will include the ability to download references and related resources.
- **Illustrative examples for smaller organizations:** Small practices cannot be expected to take the same steps as larger ones that have more resources. Consequently, the details included within the write-up of each general practice should make an effort to include examples and illustrations relevant for smaller organizations. For example, the appropriate contingency plan for a small practice might be to close during a system outage, a step that a tertiary hospital cannot take.
- **Information on patient notification of test results:** Given the advent of patient portals and meaningful use (MU) requirements related to patient access to their medical records, consideration should be given to whether the guides can address this issue. Dr. Sittig noted that

the team considered including content on this subject, but to date the evidence base related to reporting results to patients is not well developed. Over time, it might be possible to develop some guidance and best practices as the evidence base evolves.

Dissemination and Use of the SAFER Guides: Group Discussions

The afternoon session focused on how different stakeholder groups can promote the dissemination and encourage the use of the SAFER guides by ambulatory practices and large health systems, including the role of professional associations, vendors, and others.

Promoting Dissemination and Use in Ambulatory Practices

Michael S. Barr, MD, MBA, FACP, Senior Vice President of the Division of Medical Practice at the American College of Physicians (ACP), led a discussion on how to promote dissemination and use of the SAFER Guides in ambulatory practices, including drivers and/or leverage points that could encourage such dissemination and use. The conversation focused on smaller practices (10 or fewer physicians), which make up the bulk of ACP's membership. The vast majority (80 to 90 percent) of these smaller practices have implemented EHRs.

Strategies and Activities to Promote Dissemination and Use

This discussion highlighted the following potential strategies and actions for promoting dissemination and use of the guides by ambulatory practices:

- **Liability insurance discounts and insurer-facilitated dissemination:** Medical malpractice liability insurers could create a financial incentive for clients to work through the guides to reduce EHR-related safety risks. For example, they could tie a portion of the rebate to completion of the guides. While hard data are not available, carriers generally feel that improvements in this area could lead to a reduction in claims, particularly the many claims related to delayed diagnosis. In addition, the Physician Insurers Association of America (PIAA, a coalition of medical malpractice liability insurers) could serve as a vehicle for disseminating and promoting use of the guides, as could representatives of individual liability insurance companies during regular meetings with clients.
- **Continuing education and/or maintenance-of-certification (MOC) credits:** Professional associations could give nurses and physicians continuing education and MOC credits for working through the guides.
- **Written and other materials by national professional associations:** Since medical students, residents, and nursing students do not learn much about practice management during training, professional associations need to disseminate information about EHR-related safety risks and the SAFER Guides as a mechanism for identifying and reducing them. Associations that could assist in this effort include those focused on primary care, such as the American Academy of Family Physicians (AAFP) and the American Board of Internal Medicine (ABIM), along with specialty societies (e.g., American College of Surgeons) and nursing associations (e.g., the

American Academy of Ambulatory Care Nurses). These organizations can spread the word through their publications, webinars, and other normal activities.

- **Briefings at local hospital staff and medical society meetings:** “Teaser” material to introduce the SAFER Guides could be distributed and briefly discussed at hospital staff meetings and regular sessions held by local chapters of medical societies.
- **Dissemination through EHR developers/vendors:** Vendors have a strong interest in promoting the safe and effective implementation and use of their systems, and hence represent a natural partner in disseminating the SAFER Guides, particularly to smaller practices who do not have staff dedicated to patient safety or health IT. Many vendors host regular user-group meetings and other educational sessions that represent a potential opportunity to disseminate and discuss the practices in the guides. Vendors can also assist their clients in promoting the safe and effective use of EHRs (including working through the guides and implementing recommended practices). However, they typically charge a fee for these value-added services.
- **Incorporation and/or linkages to external and/or regulatory requirements:** ONC did not develop the SAFER Guides with the intention of mandating their use as part of regulation requirements or certification. That said, several attendees suggested that ambulatory practices would be much more likely to pay attention to the guides if they were an explicit part of MU requirements and/or *Health Insurance Portability and Accountability Act* (HIPAA) regulations, or were incorporated as part of accreditation and/or recognition programs run by the Joint Commission and National Committee for Quality Assurance (NCQA). Short of these organizations taking that step, there may be opportunities to highlight for would-be users how the SAFER Guides can help in complying with existing regulations and requirements from these and other entities. To that end, ONC has conducted a “crosswalk” between the recommended practices in the guides and MU and HIPAA requirements.
- **Dissemination through existing EHR coalitions:** Existing coalitions focused on EHRs represent an important vehicle to spread information about the SAFER Guides. In particular, the Physicians’ Electronic Health Record Coalition (PEHRC) may represent a valuable partner. PEHRC brings together more than 20 medical societies representing over 600,000 physicians who work primarily in small and medium-sized practices. Members routinely share information to support the safe and effective use of health IT. Since many physicians do not have time to read journals and/or attend meetings sponsored by specialty societies, organizations like PEHRC may represent an effective mechanism for reaching this audience.
- **Dissemination through regional extension centers (RECs):** As long as they exist, RECs represent a potential vehicle to promote dissemination of the guides to ambulatory practices.

- **Dissemination through health plans:** Health plans and their associations (e.g., America’s Health Insurance Plans) routinely push out educational materials to provider organizations, and hence represent another potential vehicle for disseminating the guides.
- **Integration into medical, nursing, health management, and allied health professional schools:** There may be opportunities to convince medical, nursing, health management, and allied health professional schools and training programs to integrate material about the safe and effective use of EHRs into their curriculum. To that end, material in the SAFER Guides may need to be repackaged to allow faculty to drop this material into an existing syllabus.
- **Coordination with Institute of Medicine (IOM) initiatives:** The guides might fit in well with IOM-led activities and initiatives, such as its program focused on learning healthcare systems.

The Right Message

In addition to discussing potential strategies and vehicles to promote dissemination and use among ambulatory practices, attendees also highlighted the importance of crafting the right message. Key points are outlined below:

- **Develop congruent message and marketing:** Given the multitude of requirements and issues facing ambulatory practices and the many other tools and resources being marketed to them to help them respond, any campaign to promote awareness of these guides runs the risk of becoming lost as “background noise.” To reduce that risk, key stakeholders should develop and use common messages and marketing strategies. Small practices, in particular, need that common, united front. As noted, this congruence should extend to the relationship between the SAFER Guides and various external requirements and regulations facing practices, such as MU requirements and NCQA medical home accreditation standards, with an emphasis on how use of the SAFER Guides can help practices in meeting these external requirements.
- **Emphasize the evidence:** Clinicians are used to dissecting clinical evidence, and hence will be more responsive if they understand that these guides are based on a substantial body of evidence—in this case, operational rather than clinical evidence. As a result, marketing efforts should emphasize the data-gathering process used to support development of the guides, including the extensive site visits and pilot testing.
- **Explain costs of not participating (and benefits of doing so):** Would-be users need to understand clearly the benefits of participating, including any negative ramifications of not doing so. Consequently, marketing and awareness campaigns should emphasize the magnitude of the problem of EHR-related safety risks; the potential to avoid patient safety events, save lives, and reduce liability-related costs by proactively addressing these risks through use of the SAFER Guides; and the potential human and financial consequences of failing to do so. The

goal is to convince practices of the merits of being proactive in this area, rather than having them become motivated only after a major safety event occurs.

- **Emphasize ability to integrate into existing workflows:** Completing the guides and addressing the problems identified in them cannot be viewed as a burdensome, time-consuming process. Rather, these activities must fit within existing work processes and flows, including activities already required by external regulators and stakeholders. The goal is to make regular use of these tools a part of the everyday culture and operations of the practice, embedding it within existing systems and technology.
- **Create communities of practices based on common needs:** People naturally want to find and share information with others in similar situations. Consequently, consideration should be given to using social media and other vehicles to promote development of various “communities” made up of practices dealing with similar challenges.
- **Avoid unrealistic recommendations:** The leaders of small practices will likely ignore recommendations viewed as unrealistic, such as insisting that they invest substantial sums of money in expensive IT systems, or that they shut down their practice completely during a system outage. Instead, these leaders need realistic options, along with guidance on how to identify their most pressing problems and realistic, affordable actions to address them.

Promoting Dissemination and Use in Large Health Systems

Karen P. Zimmer, MD, MPH, FAAP, Medical Director of the Patient Safety, Quality, and Risk Group at ECRI Institute, led a discussion of how best to promote dissemination and use of the SAFER Guides in large health systems, including drivers and/or leverage points that could encourage such dissemination and use. The discussion surfaced many of the same strategies and activities highlighted in the previous section for ambulatory practices. Additional thoughts on these strategies and activities, along with other issues and needs specific to large health systems, are outlined below:

- **Need for testing and adaptation to integrate into existing structures and workflows:** Large healthcare systems likely need to test and refine the guides to make them fit within existing organizational structures and workflows. For example, the VA is considering testing the guides to see which parts apply. Some reconfiguring will likely be necessary to make the guides fit into the VA’s functional structure, which includes separate departments focused on the care environment, facilities management, and other functional areas. It is not yet clear where specific guides or sections of guides fit into these areas.
- **Need for clear articulation of the value of guides, including anecdotes and return on investment (ROI) data:** The leaders of most large systems are focused on putting in place new care delivery models that promote value and financial sustainability, while simultaneously meeting MU and other requirements. Consequently, c-suite executives are unlikely to pay

attention to these guides without some evidence that demonstrates the value of doing so. To that end, it would be useful to share anecdotes of systems that have benefited or could have benefited from the guides; for example, the VA had a configuration problem several years ago that likely could have been avoided through use of the guides, particularly those parts targeting people and process issues. (PSOs might serve as a potential source for other anecdotes.) In addition, information on the potential ROI from completing the guides and addressing problem areas would be useful in attracting c-suite support.

- **Shorter summary pieces:** The leaders of large systems do not have time to pay attention to lengthy documents. Consequently, shorter pieces should be developed that concisely capture the rationale for the guides, and that help system staff use them efficiently and effectively within existing workflows. Ms. Kenyon noted that it is impossible to determine the appropriate length for the guides, and that some audiences may want more details than what is currently available. However, she believes there may also be a need for a “mini” version of the guides oriented for senior-level executives.
- **Guidance on hand-held devices:** As noted earlier, many clinicians use hand-held devices when caring for patients, collecting data that will then be input into the EHR system. Use of these devices is particularly common among physicians practicing in hospitals and large systems. At one system, for example, roughly half of doctors already use such devices, a figure that is expected to reach 80 or 90 percent by 2015. In many cases, hospital and health system leaders encourage use of such devices. Consequently, there is a need to develop guidance on use of these devices and how they interface with EHRs. Dr. Sittig noted that some guidance on this issue does exist, but it is not part of the SAFER Guides.
- **Potential for students, residents, and fellows to be involved:** In collaboration with the Association of American Medical Colleges (AAMC), the VA National Center for Patient Safety is getting medical students, trainees, and fellows involved in using the SAFER Guides to assess EHR-related safety issues. This work will allow these students to meet their requirement to participate in quality and safety projects as part of their training. Other large systems with medical schools could consider a similar approach, allowing them to use trainees as a source of manpower to work through the self-assessment tools in the guides.
- **Potential role for provider associations:** Like the medical professional societies, provider associations such as the American Hospital Association (AHA) can play a key role in disseminating and promoting use of the guides through website postings, regional and national meetings, webinars, and other vehicles. For example, the annual meeting of AHA’s National Patient Safety Fellow Program might be a natural place to disseminate and discuss the guides.
- **Need for comprehensive plan with common message, tied to culture of safety:** Given that the guides will be available in a few months, the timeline is short to put together a

comprehensive, coordinated marketing plan involving all key stakeholders. As discussed earlier, the many stakeholders working to disseminate and promote these materials need to speak with a common voice that emphasizes use of the guides as consistent with the overall safety of culture that exists within large systems and hospitals. The message should be positive, emphasizing the role of the guides in promoting the best (and safest) care possible.

- **Need to tie to existing mandates and requirements:** As discussed earlier in the context of ambulatory practices, large health systems will be more likely to pay attention to the guides if they understand their tie to existing requirements and mandates from CMS, the Joint Commission, MU, and other external accreditation and recognition programs (e.g., NCQA’s medical home recognition program, the American Nurses Credentialing Center’s magnet hospital program). The willingness of leaders of hospitals and health systems to use the guides will be greater if they understand how doing so can help them respond to these external demands and/or earn external recognition and positive publicity. Similar to the discussion during the earlier panel on ambulatory practices, some attendees felt that large systems will not use the guides to focus on EHR-related safety issues unless forced to do so. At the same time, other attendees cautioned against mandating use of the guides, preferring instead that external organizations allow them to be used as a way to demonstrate compliance with existing regulations and requirements. For example, completing the guides could help organizations to meet various conditions of participation, such as existing requirements to demonstrate the existence of safe systems or to comply with national patient safety goals related to reducing patient identification errors. The SAFER Guides could also be a valuable resource for Joint Commission surveyors as they assess the safety of IT systems (an area where most surveyors lack in-depth knowledge).
- **Need to tap into informatics community:** Organizations focused on informatics, including the American Medical Informatics Association, the American Nursing Informatics Association, and the Healthcare Information and Management Systems Society, represent critical partners in any effort to promote dissemination and use of the guides to hospitals and health systems.
- **Potential for vendors to promote use of guides:** Vendors often face challenges in partnering with hospitals and health systems in the area of patient safety. The SAFER Guides, however, might represent an opportunity for vendors to “compete” on safety by creating systems that are “SAFER-compliant” and by working more closely with hospitals to end the traditional just-in-time implementations of EHR systems that often result in failure. Instead, vendors and hospitals could move to a new type of arrangement where, as a prerequisite to partnering, vendors offer SAFER-compliant systems and hospitals meet people and process recommendations within the guides.
- **Need for ongoing measurement and monitoring:** Once the guides have been released, a system will be needed to determine if anyone is using them and to track the impact for those that do. While the self-assessment tools are meant to be used internally, there may be opportunities

for some benchmarking across institutions so that individual users can determine where they are performing well or not well versus groups of peers. (Data from other organizations would be blinded to protect confidentiality.) ACP's Practice Advisor product might be able to integrate this type of benchmarking.

The Role of EHR Developers in Promoting Dissemination and Use

Zach Hettinger, MD, MS, Director of Informatics Research at the National Center for Human Factors Engineering in Healthcare at the MedStar Institute for Innovation, led an interactive discussion on the role of EHR developers in integrating SAFER Guide recommendations into their systems and in promoting dissemination and use of the guides among clients. Key points are outlined below:

- **Near-term opportunity to integrate SAFER recommendations into systems:** With the impending roll-out of the second round of MU requirements, developers must refine and upgrade their systems and software in 2014. This requirement gives them an opportunity to incorporate SAFER Guide recommendations and then talk to their clients about these enhancements. Going forward, each upgrade cycle can be viewed as an opportunity to engage in this same process.
- **Need to articulate how recommendations are integrated:** Vendors should consider developing educational materials that explain to provider organizations how and where their systems incorporate various SAFER Guide recommendations.
- **Need for standardization:** As upgrades occur, vendors have an opportunity to push for greater standardization of products on the front end. The goal is to strive for consistency across platforms, even if users then engage in adaptation and customization at the local site level. To succeed in standardization efforts, vendors need to come together and agree on common approaches to various issues, such as patient identification, system interfaces, and the like.
- **Request for greater clarification:** While some SAFER Guide recommendations are quite clear and specific, others remain open for interpretation.
- **Need to work through professional associations:** Providers may not react well to directives from vendors telling them to behave in a certain manner with respect to implementation and use of EHR systems. However, the same message may be better received if it comes from a respected professional association, such as ACP or AAFP.
- **Need for ongoing monitoring and feedback by users to vendors:** Developers need regular feedback from users on the pros and cons of various features, such as how well the alert systems are working, including the degree to which users pay attention to or ignore such alerts.

- **Need for reliable resources, including best practices:** Vendors can support providers by helping them run reports to identify major EHR-related safety issues (e.g., how often outages occur) and/or by hosting links to reliable resources to help manage these issues, such as best practices related to medication safety and configuring and handling alerts.

Conclusion and Next Steps

Ms. Kenyon closed the meeting by expressing appreciation to attendees for their valuable input and by thanking everyone on the project team for their hard work and dedication throughout the process, including the Westat team, Dr. Sittig, Dr. Singh, Dr. Ash, and everyone else who worked diligently to develop, test, and refine the guides. She asked representatives of organizations planning to pilot test and/or prototype the guides to keep ONC and Westat informed of their plans, and to report on their experiences in using them. She also called on developers to report on their efforts to disseminate the guides to clients, and to incorporate SAFER Guide recommendations into their systems. Feedback can be funneled through Lois Olinger, MA, Project Director at Westat.

Given the clear message from this meeting that the guides are useful and will be used, Ms. Kenyon plans to work with her colleagues at ONC and AHRQ to determine appropriate next steps, including coordination of a marketing plan to accompany the roll-out. One issue that remains unclear is the appropriate tradeoff between pushing for standardization and allowing experimentation. The goal is not to push for new regulations or mandates, but rather to strike the appropriate balance between developing best practices and common approaches while still “letting a thousand flowers bloom.”

Appendix A: List of Attendees

EHRA Representatives

Allscripts

- Tobias C. Samo, MD, FACP, Chief Medical Officer

NextGen

- Sarah T. Corley, MD, FACP, Chief Medical Officer

QuadraMed

- Richard W. Landen, MBA, MPH, Director of Regulatory Affairs

Siemens Medical Solutions

- Marilyn S. Waxberg, MS, MBA, Director Quality and Regulatory Affairs

Liability Representatives

AHSRM

- Susan Boisvert, BSN, MHSA, CPHRM, Clinical Risk Management Consultant

CRICO

- Carol Keohane, BSN, RN, Assistant Vice President,

PIAA

- P. Divya Parikh, MPH, Director, Research and Risk Management

Quality Oversight/Patient Safety Organizations

CHPSO

- Rory Jaffe, MD, MBA, Executive Director

ECRI

- Ronni P. Solomon, JD, Executive Vice President and General Counsel*
- Karen P. Zimmer, MD, MPH, FAAP, Medical Director, Patient Safety, Quality, and Risk Group

ISMP

- Christina Michalek, PharmD, FASHP, Medication Safety Specialist

Joint Commission

- Gerard M. Castro, MPH, Project Director, Patient Safety Initiatives

NPSF

- Tejal Gandhi, MD MPH, President

Pascal Metrics

- David Classen, MD, Chief Medical Officer
- Drew Ladner, MBA, MA
- Sarah Pratt, MHA

Provider Representatives

AAFP

- Jason M. Mitchell, MD, Director, Center for Health Information Technology

ACP

- Michael S. Barr, MD, MBA, FACP, Senior Vice President, Division of Medical Practice

AHA

- Chantal Worzala, PhD, Director of Policy

AMA

- Matt Reid, MS, CHC, CPHIMS, Senior Health Information Technology Consultant

ANA

- Darryl W. Roberts, PhD, MS, RN, Senior Policy Fellow

ANIA

- Patricia P. Sengstack, DNP, RN-BC, CPHIMS, President

MGMA

- Robert Tennant, MA, Senior Policy Advisor, Health Informatics
- David N. Gans, MSHA, FACMPE, Senior Fellow Industry Affairs*

Informatics Organizations

AHIMA

- Meryl Bloomrosen, MBA, RHIA, FAHIMA, Vice President, Public Policy

AMIA

- Ross Martin, MD, MHA, Vice President, Corporate Relations and Business Development

CHIME

- Russell P. Branzell, FCHIME, CHCIO, President and Chief Executive Officer Large Health Systems

HCA

- Carl Vartian, MD, MS, Chief Medical Information Officer, Gulf Coast Division

MedStar

- Rollin J. (Terry) Fairbanks, MD, MS, FACEP, Director, National Center for Human Factors Engineering in Healthcare
- Zach Hettinger, MD, MS, Director of Informatics Research

Weill Cornell Medical College

- Rainu Kaushal, MD, MPH, Director, Center for Healthcare Informatics and Policy

Wellspan

- R. Hal Baker, MD, Senior Vice President, Clinical Improvement, Chief Information Officer

Federal Representatives:

ONC

- Kathy Kenyon, JD, MA, Project Officer and Senior Policy Analyst, Office of Policy and Planning
- Amy Helwig, MD, Medical Officer, Office of the Chief Medical Officer
- David Hunt, MD, FACS, Medical Officer, Office of the Chief Medical Officer
- Karson Mahler, JD, Policy Analyst, Office of Policy and Planning
- LaVerne Perlie, RN, MSN, Nurse Consultant, Office of the Chief Medical Officer
- Sandra Rausch, MS, RN, Nurse Consultant, Office of the Chief Medical Officer
- Steven Posnack, MHS, MS, Director, Federal Policy Division, Office of Policy and Planning

AHRQ

- Jon White, MD, Director, Health Information Technology Portfolio

VA

- Dani Hoover, MD, MPH, Patient Safety Physician, VA National Center for Patient Safety
- Jeanie Scott, CPHIMS, Director, Informatics Patient Safety, VHA Office of Informatics and Analytics/Health Informatics

CMS

- Paula DiStabile, RN, MSN, JD, Nurse Consultant
- Captain Lisa Marunycz, RN, MBA, Senior Health Insurance Specialist

SAFER Project Staff:

- Joan Ash, PhD, MLS, MS, MBA, Professor and Vice Chair, Department of Medical Informatics and Clinical Epidemiology, School of Medicine, Oregon Health & Science University
- Hardeep Singh, MD, MPH, Associate Professor of Medicine, Michael E. DeBakey Veterans Affairs Medical Center and Baylor College of Medicine and Director of the Houston VA Patient Safety Center of Inquiry
- Dean F. Sittig, PhD, Professor of Biomedical Informatics, The University of Texas Health Science Center at Houston
- Lois Olinger, MA, Project Director, Westat
- Scott, Finley, MD MPH, Senior Physician Informaticist, Westat
- Cynthia K. Russell, MSN, RN, Nurse Informatics Specialist, Westat
- Eric Gebhardt, MBI, Oregon Health & Science University*

*indicates attended the meeting via WebEx

¹ Contingency Planning for EHR-based Care Continuity: A Survey of Recommended Practices. J Am Med Inform Assoc. 2013 (in preparation) .

² EHR-Related Safety Concerns: A Cross-Sectional Survey. J Healthc Risk Manag. 2014 (in press).

³ ECRI Institute PSO Deep Dive: Health Information Technology. Plymouth Meeting, PA (2012).

⁴ The SAFER Guides: Empowering Organizations to Improve the Safety and Effectiveness of Electronic Health Records. J Am Med Inform Assoc. 2013 (under review)