INTRODUCTION

Health information technology (HIT) has an unparalleled potential to improve the quality, safety, and efficiency of patient care. It is particularly fitting that the Institute of Medicine (IOM), which alerted the nation to the need for increased attention to healthcare safety through a series of dramatic reports begun more than a decade ago, should undertake a study of the safety risks posed by this exciting and rapidly expanding new technology. The Agency for Healthcare Research and Quality (AHRQ) is pleased to have the opportunity to address this distinguished Committee on this important topic.

We also very much appreciate the leadership that the Office of the National Coordinator for HIT (ONC) has demonstrated in implementing the Health Information Technology Economic and Clinical Health Act of 2009 (HITECH), and, in particular, along with the Centers for Medicare and Medicaid Services (CMS) and the Office for Civil Rights (OCR), promulgating regulations to support providers in their adoption and meaningful use of electronic health records (EHRs).

We support the broad interpretation of “HIT-assisted care” and related technology as defined by the IOM. A broad interpretation is particularly important in view of: 1) the continuously changing nature and expansion of technology (beyond the EHR); and 2) the fact that the cause of a patient injury may not be initially discernable and may be attributable to one or more devices/technologies, their interaction, and/or other factors.

I. IDENTIFY CHALLENGES TO IMPROVED REPORTING OF PATIENT SAFETY EVENTS.

Accurate and complete reporting of patient safety events is essential to identify threats to patient safety, their causes, and whether corrective changes have been effective. Yet there is not widespread, uniform reporting of patient safety events, whether HIT-related or other types of events. The Department of Health and Human Services Office of the Inspector General, in its March 2010 report, Adverse Events in Hospitals: Methods for Identifying Events, found that “hospitals participating in the case study apparently did not have any internal incident reports for 112 of the 120 events (93 percent), including some of the most serious events involving death or permanent disability to the patients.”

Reporter’s viewpoint. There are many challenges to accurate and complete reporting of patient safety events, and one way to categorize them is from the viewpoint of the reporter – the person who becomes aware of an event and either does or does not report it. There are four (implicit) questions that confront the reporter, all of which influence the likelihood of complete and accurate reporting of data that are useable locally and nationally:

1. Do I want to report?
2. What do I report?
3. Is there a system to support my report?
4. How much time does it take to complete my report?
Do I want to report? Reporting adverse events is facilitated by a “culture of safety” where individuals understand the value of reporting and feel safe doing it (i.e., they will not get disciplined or sued as a result of reporting). With ever increasing pressure for accountability and public reporting, however, the individual provider can feel conflicted about reporting. The appetite for reporting will follow from how well institutions walk the line between establishing a “no blame” culture while maintaining the necessary accountability. Leadership, starting with the CEO, is necessary to establish a value system that reinforces reporting all patient safety events. As suggested by the OIG report, this area is one where substantial progress needs to be made if reporting is to become an effective tool in supporting safe care. Development of Patient Safety Organizations, or PSOs, which began in 2008, should have a major impact by providing legal privilege and confidentiality to reporting of quality and safety concerns.

What do I report? There is considerable frustration on the part of hospital providers about the growing number of reporting requirements and the many different approaches, definitions, and systems involved. Currently, there is enormous variability in what events get reported and how they are defined, sometimes even within a single institution. This variability prevents aggregation of data across institutions and over time and slows both initial learning and dissemination of the results of learning – information about threats to patient safety and effective approaches to address those threats.

AHRQ is authorized, under the Patient Safety and Quality Improvement Act of 2005 (Act), to define common definitions and reporting formats (Common Formats) for healthcare quality and safety. This authority supports uniform, voluntary reporting by Patient Safety Organizations (PSOs) established under the Act, which otherwise would not have a way of collecting comparable information for benchmarking and trending by PSOs and nationally. Common Formats can, however, be used by anyone choosing to employ them. As an evidence base for the Common Formats, AHRQ has compiled an inventory of 69 event reporting systems from Federal, state, private, and international institutions. The finding most pertinent to this Committee is that there is virtually no commonality among systems in how events – of any type – are defined and reported. Resolving the question of “what do I report” in a consistent manner is a central issue in improving the value of reporting of adverse events.

Is there a system to support my report? Tallying of events, no matter how seemingly simple, is only feasible when supported by an automated system. In a 2009 study commissioned by AHRQ and completed by the RAND Corporation (pending publication), only 23.1% of hospitals had computer-only reporting systems, 61.1% had computer and paper, and 15.8% had paper only. As discussed above, it is safe to say that the events reported by these systems were defined in myriad ways. This survey referenced internal reporting systems; there has also been significant recent growth of external reporting systems by organizations dedicated to improving patient safety. Increasingly, hospitals are being asked to report to different external organizations using Web-based reporting systems, such as those of The Joint Commission, CDC’s NHSN system, various mandatory state reporting systems, and others. Providers are, then, responding to a growing number of reporting requirements using different internal and external reporting systems that lack a common conceptual framework (e.g., consistent way of reporting where an event occurred, the level of harm, definition of clinical event, etc.) and often do not provide the ability to report results locally or easily benchmark with national experience.

How much time does it take to complete my report? Ideally, there should be an appropriate balance between the time taken to report adverse event data and the value of the output of the reporting system in supporting improvements in quality and safety in the institution. There is a temptation for experts to create checklists comprising a large number of phenomena in the interest of being thorough, without adequate appreciation for the impact on data collection burden. Dr. Robert Wachter, in a presentation to the 2nd Annual Meeting of PSOs on May 7, 2010, observed that poorly designed reporting systems created
a “huge opportunity to waste time, money, and squander caregiver good will. [The] admonition to ‘report everything’ was silly and naïve (and a mis-analogy from aviation).”

There is a perhaps subtle distinction here in that we are suggesting that providers report all significant events (including incidents, near misses, and unsafe conditions) but be presented with (by the system employed) only a reasonable number of structured questions about each event type. The structured data that are collected should have proven value – in terms of quality improvement, that is greater than their cost – in terms of time to collect, report, and analyze. Free text is efficient and effective as an adjunct to support local sleuthing regarding individual events, although it is not useful in aggregation of event data for further study at local, regional, or national levels.

In summary, and from the vantage point of the individual upon whom we are relying on to report adverse events, there is much room for improvement in:

1. The culture of safety that supports a reporting and learning environment
2. Standardized definitions and reports (common formats)
3. One-time, automated data collection that supports provision to multiple systems/organizations
4. Intelligent balancing of data collection burden with demonstrated value in quality improvement.

Institutional viewpoint. Many of the same concerns that affect reporters are relevant at the institutional level, such as developing a culture of safety. The following additional concerns pertain to institutional management:

1. Cost of a reporting system
2. Frontline reporter resources
3. Feedback
4. Educational awareness of human factors and ergonomics

Cost of a reporting system. The cost of creating a new system, or modifying an existing system, and training staff can be significant. In today’s hospital IT departments, resources are scarce. More immediately profitable projects, as well as projects required by regulation, understandably can come before investments in patient safety event reporting systems.

Frontline reporter resources. Entering patient safety event data can be burdensome, especially in environments with significant mandatory reporting requirements. In addition to issues summarized above dealing with “time to complete my report,” factors that affect collection time include sophistication of software design (e.g., expert system with ‘smart’ skip-logic), ease of reporting access, proximity of reporting tool to direct patient care areas, and adequacy of training regarding tools.

Feedback. Timely feedback regarding information entered into event-reporting systems is critical, not only for identification of an institution’s important patient safety concerns and what needs to be done to correct them, but also to provide meaning to the never-ending task of data entry by frontline reporters. Many systems, whether local or national, produce few reports – or reports that are difficult to understand. In addition, many systems require entry of data that are never used in reports at all. (One solution: design systems so no data are ever collected for which a report has not been designed that includes their use.)

Educational awareness of human factors and ergonomics. Educational awareness of human factors and ergonomics is important for the reporting of all patient concerns but particularly important for the reporting of HIT-related concerns. Staff may not be aware that what seems, at first, to be user preference (and as such potentially not worth reporting) may actually be a human factors engineering issue.
II. WHAT EVENTS SHOULD BE REPORTED THAT CAN BE ROLLED UP TO A NATIONAL LEVEL?
ARE THEY DEFINED AND READY FOR INCLUSION IN THE MEANINGFUL USE CRITERIA?

There are four general considerations that are important in evaluating what events to report nationally and their relationship to meaningful use.

1. **Everything can be rolled up.** All events (including incidents that reach the patient, near misses, and unsafe conditions) that are important enough to be explicitly defined, incorporated into software for reporting, and result in human capital being used to enter data and/or analyze reports can and should be rolled up to a national level. The relevant distinction is not level of reporting but rather the choice of events to report and the quality and precision of definition of those events. Any event that is important enough to be reported and tracked at the local level for quality improvement can be reported, tracked, and benchmarked at the national level.

2. **HIT is part of a greater whole.** HIT-related patient safety events represent only one aspect of broader patient safety event reporting. All events need to be reported according to consistent conceptual and operational frameworks if systems are to be clinically valid, useful, and efficient in operation. AHRQ has modularized its Common Formats for patient safety event reporting into those categories that pertain to virtually all events (e.g., when and where the event occurred, who reported it, the degree of harm sustained by the patient) and those categories specific to a particular event type (e.g., medication, perinatal, HIT-device). The data required to describe specific event types are sometimes fewer than the core data collected about all events, an indication of how important it is to have a consistent approach across all event types. Furthermore, some events have more than one cause or contributing factor, which is particularly true for HIT-related events. (A programming error can result in a drug overdose, the latter being how the event is initially characterized by a frontline reporter.) Hence it is important to report common information across different events in a consistent manner and to report information about different causes or contributing factors about a single (but complex) event in a conceptually congruent way. Purpose-specific systems designed around single event types define uniquely not only the specific domain involved but also the subject matter that is common to all events. Institutions are left with reporting conceptually and electronically incongruent data about similar phenomena to different organizations though different systems. The result is inefficient, expensive collection of data that cannot be related to each other in any meaningful way and, in any case, are maintained in isolated silos in different organizations.

3. **HIT-related events may not present as such.** HIT-related patient safety events often manifest themselves as clinical events, such as wrong medication, wrong dose, etc. An initial reporter may not know if/when HIT is involved or which HIT component is playing a role. HIT may be just one part of a process, steps in a chain of events that result in unintended consequences. Events that are eventually found to be HIT-related often reveal the HIT role as a “contributing factor.” An event reporting system should not require that the initial reporter assign a final classification to the event but rather contemplate further analysis before such designation.

4. **Meaningful use extends beyond the EHR.** Event data are currently organized in three different ways depending on the purpose of the reporting system: 1) patient-centered; 2) event-centered; and 3) device or drug centered. *Patient-centered systems* focus on incidents that reach the patient and for which some data may be found in the medical record. *Event-centered systems* encompass information from #1 and also include two other patient safety concerns – near misses and unsafe conditions. Event-centered systems also collect other event information, such as detailed contributing factors, root cause analyses, and recommended changes to care processes. These
additional types of information are virtually never recorded in the medical record, an important consideration when discussing meaningful use. Drug or device-centered systems, principally those of the FDA, are centered on the drug or device thought to have contributed to an adverse event and will have only some of the information associated with #1 and #2. The relationship of meaningful use to event reporting systems might be thought of as defining both clinically and electronically those aspects of an event that should be found in the medical record, lab, pharmacy, etc., with the objective of exporting them to appropriate event-reporting systems. Such systems could include a hospital’s own event-reporting system, a PSO with which the hospital is working, CDC’s NHSN for healthcare-associated infections, FDA’s MedWatch and MedSun systems for drug and device incidents, and state reporting systems for serious reportable events. In addition, event-reporting systems will always require some information that will not be included in the EHR or any other electronic databases, so while meaningful use can make a huge contribution to the efficiency of event-reporting systems, it will not represent a complete solution that obviates input of additional information by frontline personnel.

Because HIT-related events can manifest in so many ways, including seemingly unrelated clinical presentations, and involve complex relationships between IT and devices, more than one HIT device, etc., it is a challenge to provide a list of the events that need to be reported. AHRQ, in its Common Formats, has defined such events and designed a logical sequence of questions that ensure that the initial reporter(s) addresses many variables, including clinical presentation, type of error, type of HIT device involved, and contributing factors. AHRQ will be pleased to make the relevant Common Formats available to this committee; all of the Formats may be accessed at: https://www.psoppc.org/web/patientsafety. AHRQ’s operational definition of HIT-related patient safety event is best appreciated by reviewing both the “Event Description” and the “Aggregate Report” for “Device or Medical/Surgical Supply, Including Health Information Technology (HIT) Device.” Note that the “generic” Formats, as well as the one addressing HIT-related events, should be reviewed, as the latter must be used in conjunction with the former.

The following is suggested as a way of categorizing the many types of hazards that HIT may present from initial development through clinical use:

1. **Broad spectrum for HIT definition**
   a. EHR
   b. Myriad other HIT devices, as included in IOM definition

2. **Broad spectrum of types of HIT-related concerns to be reported**
   a. Clinical (incidents, near misses, unsafe conditions)
   b. Development and pre-implementation hazards – local perspective*
   c. Development, deployment, operational hazards – manufacturing perspective*

3. **Broad spectrum of contributing factors and causality for clinical events**
   a. Device failure/software bug
   b. Use error
      i. Human factors – visual and keyboard interfaces; ergonomics, etc.
      ii. Training issues/knowledge deficits
      iii. Override of alerts, decision support – appropriate and inappropriate
   c. Systems issues
      i. Network failures
      ii. Interfaces between multiple HIT systems
   d. Combination of device and use error.
These categories, while important, are outside the typical domain of providers of clinical care.

III. WHAT MEASURES ARE NEEDED TO ASSESS SAFETY OF HEALTH IT SYSTEMS?

General considerations. The measures needed to assess safety of health IT systems flow largely from definition of the HIT-related patient safety events that should be reported. (See section II.) The only exception would be concerns from the manufacturing and pre-implementation perspectives, which AHRQ leaves for others to address. With respect to measures for clinical events, most patient safety event reporting today is spontaneous and voluntary, which means that the completeness of reporting is unknown, and denominators are virtually impossible to establish. As EHRs become more widespread, and definitions of patient safety incidents become incorporated into meaningful use specifications, reporting of incidents from the entire population of patients in a given setting will become possible – surveillance – enabling the establishment of denominators and hence rates of occurrence of incidents. Near misses and unsafe conditions seem destined to remain indefinitely “voluntary” in actuality, if not in official requirements. (The issue of voluntary versus mandatory reporting is discussed in section IV.) Definition of events of interest, and specification of precise measures to capture them, need not await surveillance systems implemented through meaningful use or chart-abstracting, however. Current measures can be, at the very least, precise numerators that allow: 1) local institutions to learn about the nature of their own patient safety hazards, and 2) regional and national organizations to learn more quickly about hazards that are occurring on a widespread basis.

The journey from definition of events to measures. We believe that the first step, after determining the area of inquiry of a reporting system, is to construct clear, precise, English-language definitions of the events to be reported. From those definitions, desired reports can be constructed, followed by specification of data elements (questions) that need to be answered to operationalize the reports. This process results in only those data being collected that are absolutely required to develop reports that contain information on incidents, near misses, and unsafe conditions that conform to precise definitions agreed on before construction of the reporting system. Such a system can be continuously updated based on feedback from those using it on how it can be improved.

AHRQ’s Common Formats. AHRQ has used the above-described process in constructing its Common Formats for reporting patient safety concerns. The Formats have been designed to be maximally useful to those at the “front lines” – to support reporting and quality improvement at the institutional level. There are two important concepts behind this design choice: 1) care must be improved at the level where it is delivered, and feedback of local results from the reporting system is key to identifying and supporting needed improvement; and 2) the opportunity to specify precisely the data that are needed for an accurate reporting system only has relevance where the data are going to be initially collected. Hence AHRQ’s Common Formats are designed to provide an individual case summary of a single adverse event as well as aggregate reports pertaining to a local institution. Data are designed to be exported to a PSO (or other institution, such as FDA or a state reporting system), and then on to the national “Network of Patient Safety Databases” that aggregates data for: 1) publication in AHRQ’s National Healthcare Quality Report, 2) use by researchers, and 3) other public dissemination.

In response to the growing interest in HIT safety, AHRQ recently released a Format specifically designed to capture HIT-related concerns. That Format is currently being reviewed by the National Quality Forum (NQF) and will be incorporated into AHRQ’s next version of the Common Formats. We await the report of this IOM Committee and plan to incorporate appropriate findings as soon as possible in a subsequent version of the Formats. As suggested above, we consider the relevant Common Formats as the most complete answer we can give about the measures we believe most suitable for assessing HIT-related
patient safety events. Review of these formats will reveal that, while we provide structured protocols for commonly-occurring events (including HIT-related events), the AHRQ Common Formats provide for collection of some structured data even for the very rare, “one-time” adverse event through the generic modules, supplemented by free text for local use. Hence the Formats allow collection and aggregation of data about all adverse events, not just relatively common events (or selectively-chosen rare events).

We have also addressed in Section V below how we see our role in “reporting and regulating health IT,” an optional question suggested to us by the IOM.

IV. HOW CAN HEALTH IT HELP MAKE REPORTING MORE EFFECTIVE? IS MANDATORY OR VOLUNTARY REPORTING NEEDED? AT WHAT LEVEL?

HIT can make reporting more effective. Health IT can make reporting more effective primarily by lessening the burden on human reporters through electronic transfer of clinical fields and some administrative data. Once information on patient safety events is specified for reporting, its sources can be delineated. Information in medical records, laboratory, pharmacy, and a hospital’s administrative system – when specified properly to support event reporting – can automatically populate designated systems. As noted above under Section II, *Meaningful use extends beyond the EHR*, all of the necessary information to support event reporting systems will not be found in these sources, so human data entry will be needed to supplement automated data entry indefinitely. But health IT can make the process substantially more efficient, reliable, and accurate, and, as noted above, it can support surveillance of patient safety *incidents*, a very substantial improvement over today’s spontaneous, voluntary reporting.

**Mandatory vs. voluntary reporting.** In its 1999 report, *To Err Is Human*, the Institute of Medicine suggested that both mandatory and voluntary reporting should play a future role in reporting of patient safety events. The development of reporting systems over the past decade has largely reflected that recommendation, with a majority of states mandating the reporting of serious events, and private organizations and hospitals instituting voluntary reporting systems that attempt to collect all incidents and, in many cases, near misses and unsafe conditions, as suggested by the IOM. Some have observed that all systems are really voluntary, in that many events go unreported, and there is little way to enforce a mandatory system. “No blame” cultures, where reporting is encouraged in an environment that stresses learning, are thought to result in the highest level of reporting, although data are difficult to collect and evaluate on these issues. The role of public versus confidential reporting seems to have potentially an even greater significance in terms of what gets reported. A number of states with mandatory reporting systems for serious events make the information public, and the number of reports to those states is relatively small. By contrast, the state of Pennsylvania has established a mandatory reporting system where individually- or institutionally-identifiable results are confidential, and they are receiving reports on incidents and near misses that total over 200,000 annually. The Patient Safety Organization program, which confers both privilege and confidentiality on those providers with whom it works, has not yet begun to submit data nationally, so it is too early to know what the effect of those protections will be. While the PSO program is relatively new, there has been a very substantial interest in it; there are currently 80 PSOs in 30 states and the District of Columbia.

**Level of reporting.** A likely trend will be continued expansion of:

- State-level mandatory, and in many cases public, reporting of serious events, including healthcare-associated infections
- Local-level voluntary, confidential reporting of “all” incidents and some near misses and unsafe conditions.
The most dramatic improvements in patient safety event reporting could potentially come from:

1. Improved reporting systems that have:
   a. More precise definitions of events of interest
   b. Expert systems to speed data collection
   c. One-time data collection with provision to multiple reporting systems
   d. Enhanced local reporting to support local improvement
   e. Routine access to regional and national norms

2. Agreement on what to report at national, regional, and local levels:
   a. Common formats for common conditions (regardless of whose formats)
   b. Agreement on common formats by major stakeholders
      i. AHRQ/CDC/CMS/FDA/IHS/ONC/DOD/VA
      ii. The Joint Commission
      iii. NCQA
      iv. AABB
      v. PSOs
      vi. States
      vii. Others

IT systems are beginning to blur the boundaries of what is local, regional, or national. Large providers sponsor IT reporting systems that serve numerous other hospitals and health systems. Software vendors serve individual hospitals as well as supporting data systems for PSOs, and in some cases they sponsor PSOs as well. Regional systems have emerged that aggregate health information from their geographic area – or from disparate areas across the US, if institutions from those areas join their regional system. Standardization of definitions of patient safety events – HIT-related and others – will accelerate this trend and enhance the opportunity for learning on the part of increasing numbers of providers.

V. WHAT IS AHRQ’S POTENTIAL ROLE IN REPORTING AND REGULATING HEALTH IT? WHAT IS AHRQ’S AUTHORITY IN THIS AREA?

AHRQ does not have a regulatory role with respect to health IT. AHRQ has supported and will continue to support research on health IT reporting as well as in the general area of patient safety reporting.

AHRQ does have a defined, specific role with respect to promulgating common definitions and reporting formats (Common Formats) for reporting quality and safety issues to Federally-listed PSOs and nationally to the “Network of Patient Safety Databases.” This role, also mentioned briefly above, was authorized by the Patient Safety and Quality Improvement Act of 2005 and clarified in the Notice of Proposed Rulemaking and Final Rule related to the Act. The authority applies to the subject matter of any deliberations regarding quality and safety by licensed practitioners in the United States. For reasons of practicality, AHRQ has chosen to begin by defining Common Formats that pertain to patient safety event reporting (including HIT-related events) in the hospital setting. While AHRQ is authorized to promulgate the Formats for use by PSOs and providers working with PSOs, they are available for use by any organization. There has been considerable interest in the Formats at Federal, state, and local levels as an organizing focus for the common objective of reporting patient safety events in a consistent manner. The World Health Organization is integrating the Common Formats into its International Classification for Patient Safety (ICPS).

Process for developing and maintaining Common Formats. AHRQ created a process for developing and maintaining Common Formats that was published in the PSO Notice of Proposed Rulemaking in
2008 and received public comment that was supportive. This process is formal (approved by the Office of Management and Budget in 2008) and efficient. It has allowed AHRQ to solicit public feedback on three occasions and to publish three versions of the Formats since August of 2008. The next version, including the Format addressing HIT-related events, is currently in development.

Briefly summarized, the Common Formats development and maintenance process is as follows:

1. Review evidence from AHRQ’s inventory of reporting systems, now numbering 69
2. Develop/revise Formats with Federal interagency workgroup comprising all major health agencies in the Department of Health and Human Services (i.e., AHRQ, CDC, CMS, FDA, HRSA, IHS, NIH, ONC, and SAMHSA) as well as the Department of Defense and the Department of Veterans Affairs
3. Pilot test draft Formats in Federal facilities, as appropriate
4. Publish availability of new/revised Formats in the Federal Register
5. Solicit private sector and public comment, including from PSOs, other users, and software developers, through the NQF
6. Receive advice on both the proposed Formats and comments received from an expert NQF panel
7. Review feedback from NQF and, with the Federal workgroup, finalize the version of Formats.

This process is an iterative, continuous one. AHRQ’s first expansion of the Common Formats will be for skilled nursing facilities, currently under development, with an anticipated release as a beta version in 2011.