



November 23, 2010

Department of Health and Human Services  
Agency for Healthcare Research and Quality  
National Quality Forum (NQF)

**Re: Comments on Device or Medical/Surgical Supply Including HIT Device Common Format, Version 1.1**

On behalf of AMIA, I am pleased to submit these comments in response to the above-referenced request for comments to inform important considerations regarding patient-safety issues related to the use of electronic health records. AMIA is the professional home for biomedical and health informatics and is dedicated to the development and application of informatics in support of patient care, public health, teaching, research, administration, and related policy. AMIA seeks to enhance health and healthcare delivery through the transformative use of information and communications technology.

AMIA's 4,000 members advance the use of health information and communications technology in clinical care and clinical research, personal health management, public and population health, and translational science with the ultimate objective of improving health. Our members work throughout the health system in various clinical care, research, academic, government, and commercial organizations.

AMIA thanks the Agency for Health Care Quality and Research (AHRQ) and the National Quality Forum (NQF) for issuing this request for comments. In these comments, we offer our thoughts regarding the proposed process, in general, as well as the proposed data elements specific to health information technology (HIT).

**General Comments**

AMIA supports the development of common reporting formats to address patient safety data collection and event reporting, and we applaud AHRQ/HHS for conceptualizing a framework to track patient safety issues related to HIT use. However, the types of failures and modes of failures with HIT devices are sufficiently different from those associated with other devices to warrant a distinct form and classification for reporting HIT device failures.

AMIA suggests that data collection be limited in the initial implementations to description of the events surrounding the failure of the system while the current proposed framework is further developed and enhanced to better clarify the types of events to be reported, provide unambiguous and concise definitions of terms, and expand reporting to allow inclusion of device interoperability and device/HIT functionality issues.

The use of health information technologies and informatics principles, tools, and practices will, ultimately, enable clinicians to make healthcare safer, more effective, efficient, patient-centered, timely, and equitable. But this goal can be achieved only if such concepts and technologies are fully integrated into clinical practice and education of health care providers. In addition to the substantial investment in capital, technology, and

resources, the successful implementation of a safe electronic platform to improve healthcare delivery and quality will require a significant investment in human resources across a broad range of expertise levels—to build an informatics-aware healthcare workforce.

### **Comments Regarding Proposed Data Collection and Reporting Processes**

AMIA is dedicated to the development and application of informatics in support of patient care. We believe that the idea of developing a common format related to HIT devices is an essential first step in building an evidence base for tracking patient safety issues related to HIT use. We agree that a standardized format and process is imperative for identifying and reconciling errors related to medical/surgical devices, supplies, and electronic health records. Specific comments are noted below:

- To further improve the proposed data collection and reporting process, AMIA suggests that a mechanism be established to describe and clarify the types of events that users should report. Additionally, we believe that the final selection of reportable items should be informed by existing literature on the classes of known errors and their relative frequencies. The proposed data collection scheme seems far too broad to allow collection of much comparable and useful data.
- We also encourage the development of clearer definitions of terms. As an example of term confusion, current Federal Register documents provide contradictory definitions of “device” and “HIT device”.
- AMIA supports a reporting process that will ensure that individual event information is shielded from malpractice litigation discovery, similar to local peer review processes.
- AMIA recommends clear and explicit language on the form itself that speaks to the processes that govern confidentiality of users and the reported data.
- Significant questions also arise related to event definition. Are users expected to report every event of system downtime as a “near miss”? When an individual computer goes down, is that event reportable as a “near miss”? If a PC’s operating system (e.g., Windows) or another application freezes, how is that event to be reported?
- The form is designed to collect a lot of information, yet that information may not be available to the individual filling it out. Is it intended that one individual in an organization complete the form? It is similarly not clear when (in relation to the event) the form is to be submitted?
- In the face of these problems with the reporting forms, limiting initial data collection to qualitative descriptions of the events surrounding the system failure is a preferable first step to the use of an inadequately specified reporting classification system. Use of an inadequately specified classification system may result in conclusions about the safety of HIT devices that are erroneous and that deprive patients of the benefits of functional systems.
- It is critical that the classification system developed for failure modes recognizes that HIT devices are an integral part of networks of integrated systems linked by humans. A systems approach to error detection and management is needed.

## Comments Regarding Proposed Format Elements and Language

AMIA believes that there is a critical need for a broad-based, comprehensive effort to develop a complete taxonomy of HIT-related events. However, the proposed process is not sufficient to identify and classify all of the needed terms. AMIA is concerned that the proposed format requests a complex set of information that may not be available to or understood by the individual filling out the form and, by consequence, will lead to the collection of data that cannot be effectively interpreted.

- We recommend that the format include explicit directions for completion and submission, considering that occasional users of the format may have difficulty navigating the form(s) and understanding the definition(s) and intent of the terms without guidance. Further, we suggest that AHRQ/NQF undertake a comprehensive educational campaign to disseminate information about the (final) reporting process and forms.
- Event definitions are also under specified. To think that all failures are a result of either device failure, user failure, or a combination of both is overly simplistic. We encourage AHRQ to consider situations when both the device and the user are operating as intended, but in combination manage to produce an unexpected error. It is not clear how these situations are to be categorized or reported.
- Additionally, types of care-process errors are not adequately captured in the proposed format. AHRQ should also consider capturing data, separately, about system design flaws, their effects on user actions, and the ultimate impact of those actions on care processes. These interactions are also dimensions of HIT errors.
- AMIA views the report format as “device” centric and recommends further review and expansion of reporting elements on interoperability and human-computer interaction events. This should be achieved by creating a separate data collection for details of modes of failure of HIT systems. We recognize that while errors may come from interactions between devices, the form captures very little information related to device interoperability.
- Reporting forms and processes ultimately need to be able to express the relationship between modes of failure and health system business and care delivery processes.
- Additionally, the existing proposed categories of device failure and use error do not capture errors in the functional application of devices or HIT. For example, the HIT may not appear to have any problem, yet clinical workflows and communications may not be operationalized appropriately in relationship to the device or HIT.

## Summary

As a source of informed, unbiased opinions on policy issues relating to the national health information infrastructure, uses and protection of clinical and personal health information, and public health considerations, AMIA appreciates the opportunity to submit these comments. We

believe work in this area should go forward with collection of qualitative descriptions of models of failure of HIT devices while a more refined classification structure for reporting failure modes is developed, one that is specific to HIT devices and also to the relationships between organizations, their care delivery processes and HIT implementations.

AMIA and its members are active in developing policy proposals and commentaries to inform the Federal government, regional/state governments, and provider organizations in a wide variety of matters related to HIT and its effective and safe use. Many of these are relevant to your activities and deliberations. We mention a few of them here:

- Anticipating and Addressing the Unintended Consequences of Health IT and Policy: A Report from the AMIA 2009 Health Policy Meeting. Meryl Bloomrosen, Justin Starren, Nancy M. Lorenzi, Joan S. Ash, Vimla L. Patel, and Edward H. Shortliffe. JAMIA January 2011
- The informatics opportunities at the intersection of patient safety and clinical informatics. Kilbridge PM, Classen DC. **J Am Med Inform Assoc.** 2008; Jul–Aug; 15(4):397-407.
- Edward H. Shortliffe, MD, PhD. TESTIMONY TO HIT Policy Committee, Adoption/Certification Workgroup, Office of the National Coordinator for Health Information Technology, Department of Health and Human Services, Thursday, February 25, 2010

Again, we thank AHRQ and NQF for issuing this request for comments, which we anticipate will be revised as necessary going forward. Please feel free to contact AMIA at any time for further discussion of the issues raised here.

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