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HIT Policy Committee Adoption/Certification Workgroup Meeting February 25, 2010

Written Testimony Submitted by the HIMSS Electronic Health Records Association

Presenter: Michael Stearns, MD, President and CEO of e-MDs, Inc.

Dear Adoption/Certification Workgroup Member:

I want to thank the ONC, the HIT Policy Committee and this Workgroup for the opportunity to present information on HIT in the context of patient safety. I am the president and CEO of e-MDs, Inc., an EHR vendor. I am presenting this statement today on behalf of the HIMSS Electronic Health Records Association (EHR Association). During our panel discussion I will also be prepared to share some of my personal experience and observations along with the collective experiences and work in progress shared with me by other members of the EHR Association.

There is a great deal of evidence that EHRs have the potential to improve patient care and reduce medical errors. Experience from around the world, in particular countries with high levels of EHR adoption, has demonstrated these benefits. However less attention has been focused on potential patient safety risks that could be introduced by the use of EHRs. The EHR software provider organizations have a long history of addressing patient safety issues and have drawn from our collective experiences to provide you with feedback and recommendations for moving forward.

At the outset, I would like to emphasize that the EHR Association and its member companies are committed to the highest levels of product quality and patient safety. We take very seriously the concerns that have recently been raised by policymakers and others in this area that that have, in part, occasioned this hearing. We are committed to working cooperatively with key stakeholders to address and resolve questions and issues associated with safe use of EHRs and other healthcare IT. We have initiated a workgroup and process to develop such recommendations and will be expanding on its work as we consider such inputs as the discussions at the HIT Policy Committee hearing being held this week.

Identifying the Issues

The medical literature contains a number of articles that address patient safety issues that could have been potentially introduced by HIT implementations. In general the themes that emerge are related to poor implementation, inadequate training, lack of attention to workflow, and in some cases factors related to human/machine interactions. One challenge with using the literature to identify potential patient safety issues is the delay inherent in the publication process. Software modifications, improved training, and workflow optimization are dynamic processes that EHR developers and users accelerate when potential safety issues are discovered.

As a general classification, several categories of patient safety related areas of focus have emerged identified in the literature, and can be roughly organized into: computerized provider order entry (CPOE), results management, communication, documentation/information display and data integrity. This list is not intended to be inclusive.

Computerized Provider Order Entry (CPOE)

Dramatic reductions in prescribing and other errors with the introduction of a computerized physician order entry (CPOE) system have been reported.¹ More recent studies and reviews have reported a reduction in medical errors and better adherence to medical guidelines, although a direct impact on preventing harm to inpatients has not been firmly established.² Another article³ reported findings from a literature review that suggested that more research is needed to determine the role of clinical decision support (CDS) in preventing severe inpatient prescribing errors. A recent study⁴ found that the frequency of medication errors in a large multispecialty ambulatory practice declined from 18.2% to 8.2% with the introduction of electronic prescribing. In particular errors associated with illegibility, inappropriate use of abbreviations, and missing information were reduced with the use of CPOE. While further study is needed, there is general consensus that CPOE used within an EHR and combined with clinical decision support has the potential to prevent patient harm and *reduce* errors.

Published reports that have analyzed patient safety issue related to CPOE have identified the importance of proper implementation, workflow design, training and iterative feedback to reduce the risk of errors that could present a risk to patient safety. The critical importance of proper workflow design, preparation and training in intensive care CPOE implementations has been well documented.^{5,6} The authors' lessons learned include the need to allow systems to place orders before the patient is registered, the need for order set preparation prior to go-live, human factors analysis, proximity of staff to patients during computer use, utilization of the most current version of the EHR, and adequate training of staff.

Another study⁷ identified and categorized a number of design issues in an older CPOE system that was subsequently replaced.⁸ This analysis illustrates one of the challenges with using the literature to evaluate the status of current HIT related patient safety issues. The relatively rapid rate of software updates does not necessarily map well to the speed at which medical studies are published.

An additional study⁹ noted that important drug safety alerts were being overridden frequently by clinicians due to “alert fatigue” and other factors. The authors concluded that in order to maximize the ability of CPOE to reduce drug safety issues, users should invest a significant amount of time customizing alerts. They also noted that additional human factor studies are needed to gain a better understanding of how best to use CPOE alerts in clinical care.

In summary the literature on patient safety errors related to CPOE illustrates the importance of user preparation, implementation, and ongoing workflow analysis to minimize any potential patient safety risks. Ongoing research is also needed to determine best practices that will optimize human factors related to CPOE usage.

Result Management

A fairly common clinical issue that has been identified in the United States is the failure to track tests that have been ordered. This problem can be nearly eliminated by EHRs, which have the ability to track each order and alert the clinician as to when a test result is overdue. Although there is the potential to reduce result management errors through the use of EHRs, implementation of results management must occur through a carefully controlled process. To prevent errors related to the introduction of HIT, adjustments must be made that accommodate nuances associated with workflow, routing logic, and system settings, as noted by Yackel.¹⁰

Documentation, Display, and Data Integrity

Some users have commented on the challenge of being fully expressive with EHRs and how, in theory, this issue could lead to incomplete documentation and create a patient care issue. In contrast, other users have commented on the value of drop down lists that remind them to ask specific questions, consider additional diagnoses, or provide the most appropriate treatments. In general, problems with expressivity are dealt with through various modalities that allow for the entry of additional information as free text.

The reuse of information from prior visits (“copy and paste”) is a common practice in many EHR systems. For patients whose visits and corresponding progress notes are fairly similar and repetitive in nature (e.g., well controlled migraine headaches) this can improve the efficiency of documentation. It also allows the user to focus more closely on granular information that was obtained on the last visit (e.g., cough in the review of systems). However, users must take care to carefully review information such as lab values and findings that may not be current for that day’s visit.

In summary there are a number of articles in the literature that address potential patient safety issues related to HIT. As noted previously, the problems that arise are typically multifactorial and are often related to implementation and training issues. Given the rapidly changing nature of software interfaces, it is difficult to assess the state of current systems via the literature.

Experiences with EHR-Associated Patient Safety Risks

EHR Association member organizations have policies and procedures in place that escalate potential patient safety concerns reported by users or staff members. At the company where I am employed (e-MDs, an ambulatory EHR vendor) it has been extremely rare to see errors that could create patient safety risks that are not intercepted and remedied during the design, quality control, and beta testing processes. Our staff members have been instructed to make even hypothetical patient safety risks the highest priority and for each item to be escalated for immediate review by physician and other members of our senior management team. However, we are unaware of any instances where an adverse healthcare event was related to an EHR related error.

EHR Association Activities

The EHR Association and its member companies are committed to the highest levels of product quality and patient safety. We take very seriously the concerns that have been raised by policymakers and others in this area. We are committed to working cooperatively with key stakeholders to address and resolve questions and issues associated with safe use of EHRs and other healthcare IT.

We have already initiated work within the Association to begin to address these issues across the broad set of vendors who serve this market. We recognize that our industry requires that a comprehensive set of principles that will help ensure patient safety and manage risks before and after our solutions go to the market. Our members have long had quality management processes in place, and we will be sharing those best-practices within our membership to ensure we are aligned on a strong baseline process. As an association, we plan to use the knowledge gained from the HIT Policy Committee meeting this week to continue forward and finalize our recommended principles.

Conclusions

Our member companies have developed a variety of approaches to prevent, identify, and respond to potential patient safety issues. As indicated, we also believe that there is value in reviewing and harmonizing such approaches, to identify a set of potential best practices for the industry to draw upon. We are convinced that appropriate quality management processes adopted by our members will ensure patient safety, facilitate innovation, not impede the timing of getting products to market, and allow for development and testing costs to remain at levels that will encourage the increased adoption of HIT. Such approaches, including consideration of appropriate means of bi-directional communications, can give users additional confidence in EHR safety.

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Approved by the HIMSS EHR Association Executive Committee February 22, 2010.



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About HIMSS EHR Association

HIMSS EHR Association is a trade association of Electronic Health Record (EHR) companies that join together to lead the health information technology industry in the accelerated adoption of EHRs in hospital and ambulatory care settings in the US. Representing a substantial portion of the installed EHR systems in the US, the association provides a forum for the EHR community to speak with a

unified voice relative to standards development, the EHR certification process, interoperability, performance and quality measures, and other EHR issues as they become subject to increasing government, insurance and provider driven initiatives and requests. Membership is open to HIMSS corporate members with legally formed companies designing, developing and marketing their own commercially available EHRs with installations in the US. The association, comprised of more than 40 member companies, is a partner of the Healthcare Information and Management Systems Society (HIMSS) and operates as an organizational unit within HIMSS. For more information, visit <http://www.himssehra.org>.