TESTIMONY TO
HIT Policy Committee, Adoption/Certification Workgroup
Office of the National Coordinator for Health Information Technology
Department of Health and Human Services
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Introduction

On behalf of the American Medical Informatics Association (AMIA), I am pleased to submit these comments to inform your important deliberations regarding patient-safety issues related to the use of electronic health records. As you requested, I would like to address both risks and potential approaches to mitigating those risks.

The questions you are considering are of great interest to AMIA, which 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. Our organization seeks to enhance health and healthcare delivery through the transformative use of information technology. Our 4,000 multidisciplinary members advance the use of health information technology (HIT) in clinical care and research, personal health management, public health, and translational science, working throughout the health system in various clinical care, research, academic, government, and commercial organizations. Several of the panelists who are testifying before you today are senior leaders within AMIA, contribute to our policy-related activities, and are national thought leaders in the general area of health information technology, its application, and the challenges and opportunities that we face in deploying systems on behalf of our patients, providers, and society as a whole.

Workforce and Education

Since the health sector is on the brink of wide-scale implementation of robust health information technology, there is a pressing need to increase and broaden the pool of workers who can help healthcare organizations and practitioners to maximize the effectiveness of their investments in such technology. Strengthening the breadth and depth of the biomedical and health informatics workforce is a critical component of the transformation of the American healthcare system through the deployment and use of HIT, and AMIA commends ONC for its current efforts to enhance the HIT workforce through a variety of novel stimulus programs. We believe that additional types of training opportunities are needed, however, to help address the important issues of safe design, implementation, and error monitoring that have come before your working group today.

We at AMIA are committed to the education and training of a new generation of informaticians to lead the needed transformation and view this activity as a fundamental component of any effort to enhance the safety and efficacy of HIT systems. Biomedical and health informaticians

are experts in the use of information that is derived from basic biomedical research (biomedical informatics); they also apply their skills to the clinical care of patients (clinical informatics) and help to protect the public through a wide range of public health activities (population and public health informatics). Informaticians' knowledge base and sensitivities span a wide range of disciplines including biomedical and health sciences, organizational behavior, and cognitive science, as well as computer and communications technology. A key goal of biomedical informaticians is to integrate multidisciplinary knowledge in the design, construction, and implementation of systems that can assure safe, timely, efficient, equitable, patient-centered, and effective care for individuals and populations. This includes knowledge and skills relating to monitoring and evaluating HIT, with a commitment to pursue open exchange of information about systems coupled with interventions to correct or mitigate problems as they are identified.

Formal training helps to prepare individuals for careers that emphasize the application of information technology to healthcare, as well as research and scholarly careers that focus on the application of information technology to health systems. Biomedical and health informaticians may be health professionals with training in informational and computational methods, or other professionals whose work involves biomedical applications of informatics and its component sciences. Demand is high and growing for individuals with training and skills in biomedical and health informatics who can become independent investigators working on faculties in informatics, health services management, medicine, nursing, and other health professions, and in commercial and public research organizations. Because the demand for such expertise exceeds the availability of individuals with advanced training in biomedical informatics (graduate degrees or fellowship programs), *we urge you to consider ways in which ONC can help to stimulate the creation of more such advanced training opportunities, both through increased numbers of positions in existing programs and the creation of new academic units and degree programs in universities and health science schools*.

The use of informatics principles, tools and practices also enables clinicians to make healthcare safer, more effective, efficient, patient-centered, timely and equitable. This goal can be achieved only if such concepts and technologies are fully integrated into clinical practice and education. 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 an investment in people across a broad range of expertise levels—to build an informatics–aware healthcare workforce. This has accelerated the need to ensure that healthcare providers obtain competencies required to work with electronic records, including basic computer skills, information literacy, and an understanding of informatics and information management capabilities. W*orkforce education must accordingly be adapted to keep up with the rapidly changing technology environment, and this includes efforts to devise and disseminate curricula for adoption by the health professions in preparing students and graduates for careers in a world with increasingly intense dependence on information technology*. Safe use of EHRs depends on a professional clinical workforce (physicians, nurses, pharmacists, dentists, etc.) that is increasingly attuned to the challenges, pitfalls, and potential of HIT in clinical care, health promotion, and public health monitoring.

Relevant Policy Work

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 today's deliberations, and we mention a few of them here. For example, AMIA completed a series of policy related papers for AHRQ under the Health Information Technology Resource Center, of which two are particularly relevant:

- 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.
  The authors outline a series of critical safety-related healthcare informatics issues, and then provide specific recommendations to address them. Based on their experience and their review of the literature, the authors present their recommendations and viewpoints about pressing opportunities to advance patient safety at its intersection with health care informatics.
- How to successfully select and implement electronic health records (EHR) in small ambulatory practice settings. Lorenzi NM, Kouroubali A, Detmer DE, Bloomrosen M. **BMC Med Inform Decis Mak.** 2009;Feb 23;9:15.
  The authors conclude that the EHR implementation experience depends on a variety of factors including the technology, training, leadership, the change management process, and the individual character of each ambulatory practice environment. Sound processes must support both technical and personnel-related organizational components. Additional research is needed to further refine recommendations for the small physician practice and the nuances of specific medical specialties.

Selected other papers that include AMIA members as authors provide useful perspectives for today's discussion:

- Eight rights of safe electronic health record use. Sittig DF, Singh H. **JAMA.** 2009;302(10):1111-1113.
- EHR safety: The way forward to safe and effective systems. Walker JM, Carayon P, Leveson N, Paulus RA, Tooker J, Chin H, Bothe A, Steward WF. **J Am Med Inform Assoc.** 2008;15:272-277.
- Role of computerized physician order entry systems in facilitating medication errors. Koppel R, Metlay JP, Cohen A, et al. **JAMA.** 2005;293:1197-1203.
- Health care information technology vendors' "hold harmless" clause: Implications for patients and clinicians. Koppel R, Kreda D. **JAMA.** 2009;301;1276-1278.
- Safe electronic health record use requires a comprehensive monitoring and evaluation framework. Sittig DF, Classen DC. **JAMA.** 2010;303:450-451.

AMIA's 2009 Health Policy Meeting

In September 2009, AMIA convened its Annual Health Policy Meeting in Reston, VA. During the meeting, multiple, diverse stakeholders discussed potential unintended consequences of health information technology and HIT policy, as well as effective options for addressing them. We sought to develop approaches to anticipate and avoid as many unintended negative consequences as possible before the implementation of HIT systems. The attendees also sought to develop strategies to rapidly identify unintended consequences that could not be anticipated, so that they might be promptly addressed before significant harm could occur.

Although the summary report from this meeting is still in preparation[1], several recommendations arose that relate to today's discussion, since many of our greatest safety concerns with EHRs involve unintended consequences of their implementation. We include here a few that are particularly pertinent to today's safety discussion:

- **Create a taxonomy to improve understanding of and develop consensus around terminology related to unintended consequences of HIT implementations.** A taxonomy that documents a comprehensive (albeit not exhaustive) array of these consequences would assist implementers and users of HIT as well as policymakers to view the range of potential unexpected, negative effects related to HIT implementations.
- **Conduct research to improve the ability to identify, anticipate, and avoid/mitigate unintended consequences.** Research is needed to support ongoing identification of unintended consequences of HIT design and implementation efforts and the situations in which they are most likely to occur.
- **Create best practices for HIT design and implementation.** Efforts are needed to synthesize the results of existing and future studies on unintended consequences in order to capture, compile, and disseminate best practices and guidelines for designing and implementing HIT systems; these should include usability guidelines, as well as proven technical and organizational safeguards.
- **Acknowledge the role and limitations of HIT**. The Federal government should take a leadership role in assuring that HIT is seen as a strategic driver of health system strengthening, but not the entire solution. Federal efforts should avoid fostering "technology for technology's sake," but rather encourage system designers and implementers to focus on the use of HIT to contribute to the ultimate goal of improvement in outcomes.
- **Sponsor comparative effectiveness studies of HIT systems and implementations**. Resources should be allocated to develop and implement the critical evaluative efforts noted above for systems purchased with ARRA-designated funds. For example, the federal government could fund the development and dissemination of a validated toolkit that could be used to measure implementation impact and help identify needed changes.

[1] Anticipating and Addressing the Unintended Consequences of Health IT and Policy: A Report from the AMIA 2009 Health Policy Meeting. Manuscript in Process. AMIA February 2010.

- **Identify and analyze effects of HIT-related policies**. Analysis of intended and unintended consequences of ARRA/HITECH-related policies should be an integral component of the DHHS/ONC efforts to promote HIT deployment in the U.S.
- **Create a framework and designate official groups to help ensure the safety and effectiveness of HIT systems.** The federal government, building on existing models and working with organizations active in the patient safety field, should lead in the development of procedures, systems and entities to ensure the safe and effective use of HIT. For example, Sittig and Classen argue (see 2010 reference above) that it will be necessary to develop a comprehensive monitoring and evaluation framework and the infrastructure to oversee EHR use and implementation. This framework would include a system to report adverse events or potential safety hazards and a national investigative board, created by the ONC to look into them and make findings public; a self-assessment tool for EHR users and implementing organizations; and enhanced EHR certification and onsite accreditation of EHRs via periodic inspections.
- **Continue to identify, study, and address ethical issues and best practices, including governance and regulation.** We have learned that HIT poses deep and interesting challenges for clinicians and researchers related to decision-support systems, secondary uses of health information, privacy and confidentiality, public health and emergency preparedness and response, pharmacogenomics and bioinformatics, and many others.
- **Promote additional information dissemination.** Enhanced communication among stakeholders in different sectors and disciplines will strengthen our collective ability to identify and address unintended consequences of HIT. The Federal government should lead efforts to develop, vet and disseminate widely-accepted methods to identify system design features and organizational attributes that can lead to failure or success of HIT implementations as well as ways to avoid or minimize unintended consequences. Federal leadership is required to create incentives so that organizations will be more willing and able to share information about technical and organizational safeguards that address unintended consequences. Further, mechanisms are needed to facilitate sharing of the findings of HIT system implementers so that data captured by individual organizations can have broader impact.

AMIA's Task Force

Not yet mentioned, but very much on the minds of AMIA's policy groups, is the question of what kind of regulatory or oversight interventions might be warranted in order to help to assure the safety of EHR systems. This topic was discussed at the September 2009 policy meeting and further stimulated by the publication of the article by Koppel and Kreda (cited above), which appeared earlier in 2009.

AMIA has been tracking these issues for many years. In 1987, the FDA Commissioner published an article summarizing the agency's philosophy and approach to software regulation,

with an emphasis on clinical decision-support programs.[2] Software was viewed as similar to a textbook or other knowledge source, as long as there was no direct computer control of a patient's care (closed-loop system). Thus the FDA stated that the presence of a "learned intermediary" (generally a physician) who interpreted the output from the computer before applying results to a patient meant that the software did not require regulatory oversight. As computing technology advanced in health care, this issue was revisited from time to time. AMIA published a summary article with recommendations in 1997.[3] [4]

Subsequently we have seen the increasing complexity of EHR and other HIT systems, with roles in patient care decision making that have demonstrated potential risks to patients and to optimal care, even when the system is not explicitly offering decision support. As a result, issues of software regulation, including the definition and enforcement of best practices, have arisen again in recent years. Some of the articles cited earlier in these comments have further illustrated the concerns and raised the issue of interventions to help assure or promote the safety of clinical IT systems.

Recognizing that the issues are complex, AMIA appointed a task force in late 2009 to study ethical and safety issues as they relate to clinical products and the role of vendor-supplied systems. The AMIA Task Force, whose work is nearing completion, is chaired by the head of our ethics committee and includes representatives from industry as well as our clinical systems and patient safety working groups. AMIA has devoted nearly two decades of attention to ethical issues raised by the use of health information technology. The specific charge is to address questions related to ethical issues in clinical software contracting while considering regulatory and oversight options that might help to assure that EHR systems and other clinical software is suitably overseen, assessed, and monitored for affronts to patient safety. The question of reconsidering an FDA regulatory role for HIT systems, or safety-motivated requirements administered through other mechanisms, is a central question in the ongoing deliberations.

The report of the Task Force will be available soon and should be directly relevant to the questions we are addressing today. The group's approach has been to acknowledge that the history of the health sciences demonstrates the utility–indeed, the necessity–of rigorous scientific inquiry. The Task Force is approaching the problem by noting that hypothesis-driven science is as important for health information technology as it is for clinical practice; epidemiology and public health; and pharmaceutical product and medical device development. Such research can identify risks and benefits, as well as ways to minimize or mitigate risks and ways to maximize or optimize benefits.

Such research also depends on data that are unbiased. The proper study of electronic health records, and the identification of safety problems and solutions, will accordingly depend on data from vendors, institutions, health professionals, patients and others. The Task Force has already

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[2] Young, FE. Validation of medical software: Present policy of the Food and Drug Administration. **Ann Intern Med**. 1987;Apr;106(4):628-9

[3] Miller RA, Gardner RM. Summary recommendations for responsible monitoring and regulation of clinical software systems. **Ann Intern Med**. 1997;127:842

[4] Miller Randolph A., Gardner Reed M., Recommendations for Responsible Monitoring and Regulation of Clinical Software Systems **J Am Med Inform Assoc.** 1997 Nov–Dec; 4(6): 442–457

made the following observations, and posed the associated questions, which are guiding their further deliberations:

- Data to drive HIT adoption and certification must be comprehensive and unbiased. The literature has suggested that some EHR vendor contracts impede or prevent the comprehensive disclosure of error or bug reports. What ethical issues are raised, and how should the HIT community respond?
- If proprietary or public relations factors induce vendors or institutions to resist accurate data reporting, what can be done to establish higher standards?
- What kinds of non-punitive mechanisms can be established or expanded to incentivize the comprehensive reporting of useful safety data? Does recent progress in error disclosure and patient safety analysis apply to EHR adoption and certification? How and to what extent?

As the Task Force completes its work, we await their responses to the following questions (which will guide crucial next steps):

- To what size institutions and practices should comprehensive and robust HIT data reporting policies apply?
- Should the EHR/HIT community develop general guidance or more prescriptive requirements? What kinds of governance mechanisms are called for?
- How should safety responsibilities be shared by vendors and institutions? Who should identify or develop these standards?
- What kinds of processes are most likely to help stakeholders meet the ethical standards of transparency and accountability without stifling innovation? Put differently: Can we make innovation and transparency compatible?
- Does ubiquitous EHR data collection constitute human subjects research? If so, is it more akin to public health research or medical device research? What processes are adequate to govern secondary or aggregate use of HIT data for patient safety and public health?
- The Joint Commission requires that healthcare organizations have ethics processes. What can be done to integrate HIT into ethics committees' competencies?

Thus, although we have a study of these issues well underway, the results, and hence a formal AMIA policy statement on the subject, are still pending. Based on discussions to date, the Task Force is very likely to call for policies that promote:

- *Scientific transparency*: Patient safety thrives on openness.
- *Accountability*: Health care improves when stakeholder successes are rewarded – and failures are acknowledged and corrected.
- *Veracity*: Vendors, governments, clinicians and patients all share the same duty to communicate sincerely and truthfully.

We will forward the results to the HIT Policy Committee and your working group as soon as they are ready for AMIA endorsement and distribution.

Summary

AMIA thanks the Office of the National Coordinator and the HIT Policy Committee for your attention to an important public policy issue. As a source of informed, unbiased opinions on policy issues relating to the national health information infrastructure, the uses and protection of clinical and personal health information, and a variety of public health considerations, AMIA appreciates the opportunity to contribute to your deliberations.

Finally, AMIA again wishes to thank you for convening this meeting and for inviting public comments and testimony. Please feel free to contact us at any time for further discussion of the issues we have raised.

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