

STATEMENT

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Health information technology (HIT) has been shown decisively to be capable of improving the quality and safety of patient care. HIT combines the patient's own information with the spectrum of medical knowledge, putting information at the fingertips of the clinician and the patient in a useful and actionable way that is not possible with paper-based care.

The Institute of Medicine has been a leader in bringing attention to these potentials. In its landmark reports, *To Err Is Human* and *Crossing the Quality Chasm*, the Institute has helped create broad consensus regarding the need to move rapidly in adopting and making meaningful use of electronic health records (EHR).

Our national determination to achieve HIT-assisted care is expressed in the Health Information Technology Economic and Clinical Health Act of 2009 (HITECH), part of the broader American Recovery and Reinvestment Act (ARRA). In HITECH, Congress and the President have made an unprecedented commitment, both in terms of incentive payments to providers who adopt and make meaningful use of EHRs, and in the creation of new programs to support that transition.

As America makes the broad and rapid transition envisioned by HITECH, we are determined to realize the full benefits that HIT promises, as well as anticipating and avoiding potential problems. While we know the potential benefits of HIT-assisted care, we also know that rapid transition of any kind on a broad scale entails significant learning curves, risks of various kinds, and unanticipated problems and challenges. This may be especially true for technology-related changes. It is unlikely to be different with HIT, and we do not downplay the importance of those factors and their potential consequences for patient safety.

ONC has asked the Institute of Medicine to bring together a committee of experienced experts to help identify likely areas of vulnerability as well as recommend the most effective means for preventing and addressing problems and protecting patient safety, especially during these transitional years. This includes potential actions and best practices by public sector agencies as well as private sector entities.

Studies supported by HHS' Agency for Healthcare Research and Quality (AHRQ) and others have already shown how EHR-related errors can occur. In particular, adverse events related to EHRs appear to have arisen from user interface problems. These may involve clinician error as new systems are being learned, errors related to changes in workflow, or errors that may arise from suboptimal design or usability of EHR products. Some other

errors may be related to faults in EHR systems themselves, whether these involve misplacement of information during the transition process or even the presence of error-causing factors in EHR software. An important first charge to the IOM committee is to summarize existing knowledge of the effects of HIT on patient safety.

A second key charge to the committee is to make recommendations to HHS regarding action that federal agencies should take to maximize the safety of HIT-assisted care. Specifically, we ask the committee to consider the roles of the Food and Drug Administration (FDA), AHRQ, Centers for Medicare & Medicaid Services, and the ONC itself.

Of course, a number of steps have already been taken, and mechanisms already exist, to support safe delivery of EHR-based care. For example, both government and the private sector have put in place technical assistance and training resources that will help ensure safety as providers transition to EHRs:

- ONC has created a nationwide system of 62 Regional Extension Centers (RECs) to provide on-the-ground assistance and training, especially for smaller-practice primary care providers as well as small and rural hospitals.
- ONC has also contracted with Westat (assisted by the nation's medical informatics society, AMIA) to develop practical tools to assist providers in making the transition, and especially to avoid unintended consequences.
- Professional societies like the American Medical Association, the American Academy of Family Physicians, and others are also providing services to their members to assist in the transition to EHRs, to minimize disruptions that might result in safety problems.
- And of course, EHR vendors themselves provide transitioning service. To my mind, the service and follow-up element will be one of the most important factors that will mark successful EHR vendors.

Likewise, a number of systems already exist for surveillance of adverse events, including EHR-related events:

- The FDA has multiple reporting systems, including voluntary systems that are already compiling some information pertaining to EHRs that are medical devices and to related events.
- A nationwide system of Patient Safety Organizations listed by AHRQ help bring about confidential reporting that can lead to effective corrective action on a system-wide basis.

- The Joint Commission, which provides oversight and guidance for hospitals, issued a Sentinel Event Alert in December 2008 to encourage reports concerning serious adverse events involving HIT.
- A private sector-supported online reporting system, EHRevent.org, has also been created by the iHealth Alliance, a not-for-profit organization composed of medical society and professional liability carrier executives in collaboration with the PDR Network as well as FDA and AHRQ. EHRevent.org enables reporting by physicians and other providers concerning issues related to the implementation and use of EHRs.

These surveillance and safety improvement mechanisms are already in place. We are asking the committee to review the existing reporting system and make recommendations.

We are also asking the committee, in particular, to make recommendations concerning the best use of FDA authorities with regard to EHRs and HIT-assisted care going forward. Throughout its oversight of the drug and device sectors, FDA seeks to fulfill its statutory obligation to ensure patient safety while maintaining an environment that is open to innovation and continual improvement of health care products. We believe the committee can employ its public process to bring balanced and fact-grounded advice as we seek these twin goals for HIT-assisted care.

Finally, we ask the committee to make recommendations regarding the potential roles and activities of key players in the private sector, including accreditation organizations, certifying bodies for HIT and other functions, patient safety organizations, professional and trade associations, individual clinicians and health care provider organizations, standards development organizations, and measurement development organizations.

We are asking the committee for an accelerated process, with a report to HHS next September. This reflects a dual need and opportunity: On the one hand, we want to adjust rapidly to build our capacity, where needed, to protect patient safety; and on the other hand, we will enter a period next month when adoption and use of EHRs will accelerate rapidly, making more experience-based information available as well as heightening our need to acquire and understand that information.

It was the Institute of Medicine that alerted Americans to the serious problems of safety in medical care. It was the Institute that created a consensus-based, forward-looking agenda toward a health care system that would achieve the quality it should be capable of. Once again, we are asking this committee to bring the resources of the Institute to bear – to help America successfully bring about the transition to HIT-assisted care that the Institute envisioned 11 years ago.

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