



Health IT Policy Committee

A Public Advisory Body on Health Information Technology to the National Coordinator for Health IT

October 31, 2011

Farzad Mostashari, MD, ScM
National Coordinator for Health Information Technology
U.S. Department of Health and Human Services
200 Independence Avenue, SW
Washington, DC 20201

Dear Dr. Mostashari:

The HIT Policy Committee (Committee), established by Congress in the Health Information Technology for Economic and Clinical Health Act (HITECH) provisions of the American Recovery and Reinvestment Act of 2009 (ARRA), gave the following broad charge to its privacy and security policy working group (known as the Privacy & Security Tiger Team or “Tiger Team”):

Broad Charge for the Privacy & Security Tiger Team:

The Tiger Team is charged with making short-term and long-term recommendations to the Health Information Technology Policy Committee (HITPC) on privacy and security policies and practices that will help build public trust in health information technology and electronic HIE, and enable their appropriate use to improve healthcare quality and efficiency, particularly as related to ARRA and the Affordable Care Act (ACA) which mandates a number of duties to the ONC relative to privacy and security.

This letter provides recommendations on the initial set of policies developed by the HHS Office of the National Coordinator for Health IT (ONC) to govern its Query Health pilot project. These recommendations were reported by the Tiger Team and approved by the Policy Committee on October 12, 2011.

Introduction

Richard Elmore of ONC first described the Query Health project to the Policy Committee at its meeting on September 14, 2011. The vision of Query Health is “to enable a learning health system to understand population measures of health, performance, disease and quality, while respecting patient privacy, to improve patient and population health and reduce costs.”¹ This letter will not repeat the details of that initial Query Health presentation, but of critical importance to the Tiger Team’s consideration of initial policies for the pilot of Query Health were the following points:

- The model for Query Health is to bring questions to the data, not collect data centrally to answer the question. The data holder retains control of the raw data and performs the analysis, reporting back aggregate or de-identified results.

¹ See presentation to HIT Policy Committee by Privacy & Security Tiger Team October 12, 2011 [http://healthit.hhs.gov/portal/server.pt/community/healthit_hhs_gov__health_it_policy_committee/1269].

- The initial set of queries for the pilot will be developed by the Query Health Clinical Workgroup, but data holders will decide whether or not they want to participate in a particular query.

Recommendations

The Policy Committee addressed the initial set of policies developed by ONC for Query Health and adopted the following recommendations with respect to those policies:

ONC Policy #1:

•**Disclosing Entity (data holder):** Whether or not to run a particular query, and to release any results, will be under the control of the disclosing entity/data holder.

Policy Committee Recommendation:

The Policy Committee endorses this policy. It is consistent with the core value that patients trust their providers with respect to the privacy and security of health information; it is also consistent with our most recent recommendations on secondary uses of EHR data, which called for provider entities to be accountable for all access, use and disclosure of health information from their EHRs, including for secondary purposes.

ONC Policy #2

Data Exchange: Data being exchanged by a disclosing entity/data holder will be either (1) mock or test data; (2) aggregate de-identified data sets or aggregated limited data sets, each with data use agreements (even in circumstances where they are not required by law), or (3) a public health permitted use under state or federal law (which may be identifiable information where permitted by law).

Policy Committee Recommendations:

- a. The Tiger Team agrees that the data being exchanged should either be de-identified or aggregated limited data set, with a data use agreement in place even for de-identified data. The data use agreement should prohibit the recipient from re-identifying the data.
- b. During the initial pilot phase of Query Health, there should be some limits on how recipients of Query Health results are permitted to subsequently use and disclose those results. Permissible uses for classes or categories of Query Health questions should be established, and the data use agreement should limit subsequent use and disclosure to those permissible uses. Such permissible uses should be commensurate with the potential privacy risk posed by the data (for example, a more limited set of permissible uses for “line level” data vs. data that is provided in summarized form). Of note, recipients of Query Health data should be permitted to use results received from Query Health to develop follow-up queries or questions.
- c. As noted above, the permitted uses of Query Health results and prohibitions against re-identification should be set forth in the data use agreement, but as Query Health scales beyond the pilot phase, ONC should consider the need for a governance structure that can enforce compliance with data use agreements and other policies. ONC should also use the experience of the pilots to help inform the type of governance that may be needed for oversight of Query Health in the future.
- d. Although HIPAA and public health statutes allow identifiable data to be disclosed for public health purposes. At the same time, not all public health activities require identifiable data.

Query Health policy should be that when identifiable data are needed to address a particular public health query, identifiable data should be disclosed in a manner consistent with applicable law. However, if identifiable data are not needed—and a limited data set, aggregate summary data or de-identified data would adequately address the question and are feasible to generate—such data should be disclosed in less identifiable form. This policy of Query Health should not be interpreted to impede public health reporting requirements.

ONC Policy #3

•**Small cells:** For other than regulated/permitted use purposes, cells with less than 5 observations in a cell shall be blurred by methods that reduce the accuracy of the information provided. (The CDC-CSTE Intergovernmental Data Release Guidelines Working Group has recommended limiting cell size to three counts presuming a sufficiently large population; this is also reflected in guidelines used by several states.)

Policy Committee Recommendation:

Policy Committee endorses this policy as a method of reducing the risk of identifiability of the data.

Conclusion

We appreciate the opportunity to provide these recommendations on policies governing the Query Health pilot project and look forward to discussing next steps.

Sincerely yours,

/s/

Paul Tang
Vice Chair, HIT Policy Committee