An Information-Rich Health Care Ecosystem

Response to the Office of the National Coordinator's Request for Information Regarding the PCAST Report on Realizing the Full Potential of Health Information Technology to Improve Health Care for Americans

This comment represents a collective view informed by the many and diverse collaborators of Markle Connecting for Health.

Executive Summary

Markle Connecting for Health, a public-private collaborative, supports the President's Council of Advisors on Science and Technology (PCAST) vision for an information-rich health ecosystem to improve health outcomes, increase the cost-effectiveness of care, encourage innovation, and protect privacy. We share PCAST's sense of urgency to catalyze broad-scale implementation of health information technology to transform health care.

Our comments emphasize the importance of clear goals and a policy framework, and consider the implications of implementing novel technology approaches in a heterogeneous environment such as the US health care system. Lastly, we provide a set of forward-looking recommendations.

We support the PCAST vision for the following:

- A nationwide capability of secure health information exchange using the Internet, not a new network.
- A distributed network for information-sharing, and not a national database.
- A model for linking patient information across sites of care using *existing* identifiers, and not a single national health identifier.
- An approach to technology that emphasizes innovation and a diversity of solutions to support broad participation and new entrants.
- A comprehensive set of privacy and security practices to support trust in information sharing.
- A universal exchange language for exchanging health information securely over the Internet.
- Population health improvement and analysis using distributed networks.

However, we also identify areas for further development and analysis based on our experience with three foundational principles. These principles, which have guided our work for nearly a decade, most notably the Markle Connecting for Health Common Framework, offer grounding for our comments on the PCAST report. These principles with related key findings and commentary are summarized below.

A. Adopt a trust framework based on Fair Information Practices (FIPs).

- Any information-sharing effort should adopt a trust framework that includes a full complement of protections, including clear and transparent policies and practices, limitations on data collections and uses, individual consent and controls, oversight, accountability, remedies, and enforcement, in addition to technical and security protections.

- Trust cannot be achieved with technology alone. We recommend that the approach taken develop information policies alongside the technical system requirements. The challenge is to find the right mix of policies, practices, technologies, and standards that can protect health information while allowing it to be shared with authorized parties, who will inherently be at different stages of technology adoption and sophistication.

- Consent, if used as the sole mechanism to protect privacy, can unintentionally result in weak protections for consumers. Consent is an important element of a full complement of both policy and technology protections, but it must be balanced and applied together with others. It may not be possible for individuals to make informed consent decisions about all of the granular data elements in an environment as complex as health care; therefore, the buttress created by a full array of protections is vital.

B. Protect privacy while enabling greater information sharing through simple, progressive steps using well-tested standards and technology.

- We believe the path toward this goal starts with the imperfect data of today, and takes into account the varying capabilities of a wide array of health care settings, ranging from sophisticated environments in large integrated delivery systems to small office practices.

- In order to move in this direction, the Office of the National Coordinator for Health Information Technology (ONC) should focus on deploying well-tested and widely used standards and technology that can be implemented within a comprehensive privacy and security framework of policies and practices.

- Because trust is primarily an attribute of entities or participants, rather than of software or data, progress will be made primarily through an expanding network of trusted participants, rather than being driven through novel networks or infrastructures.

- ONC should consider the following observations while evaluating the report's recommendations for using granular metadata and granular permissions controls, catalogued and moderated by a few national Data Element Access Services (DEAS):

- Experience has shown that large IT upgrades or novel national infrastructures have a high risk of implementation failure.

- Improving the reasons to share data, namely achieving quality and safety goals, creates an incentive to improve data quality and adopt more standardization— something the mere specification of standards can never achieve on its own.

- Experience with digital rights management (DRM) and the Platform for Privacy Preferences (P3P) also offer important insights whose implications must be further understood in efforts to tether privacy permissions to data in health care or to entirely rely on novel technology to solve a complex policy problem. The successful use of technologies that tether rules to data remains elusive, particularly in instances in which the technology was used to enforce a set of rights and obligations.

- The PCAST proposal requires services that can locate patient records. These services take information from patient records and store metadata about them in a small number of encrypted indices, queriable at the national level. While encryption is one key part of an approach to protect this metadata, it is not sufficient against some forms of breach, such as attacks by authorized actors, a common source in health care as well as other sectors (e.g. Equifax and SIPRnet). Restricting clinical information from indices can mitigate the risks posed by other vulnerabilities and wide-scale implementation challenges in the current environment.

C. Focus on rapid learning and better decision making by many.

- Our goal is an information-driven health care ecosystem, where analysis can be accomplished in a timely way to show what works, to alert decision makers about emerging trends, and to help clinicians make the best decisions possible to improve care while protecting privacy.

- One of the greatest strengths of the PCAST report is its vision for robust distributed population-level analysis and quality measurement that leverages digitized and networked health information.

- ONC is in a good position to take steps toward this vision today by encouraging the adoption of research methods and tools that enable distributed analysis of aggregate clinical data where data are cleaned and analyzed in a common way at the source before being sent in a standardized summary format. Stage 1 Meaningful Use is a good example, and we applaud its reporting requirements utilizing only de-identified aggregate summary results.

- We agree with PCAST that there is enormous potential for innovation in this area to help drive toward a more nimble and effective quality improvement ecosystem. To accelerate population health analysis, further investments in methodologies and best practices should be made.

Recommendations

1. ## Set clear health objectives to guide health IT investments.

    -   Government leadership is needed to focus the health sector on encouraging the effective use of information to reach specific health objectives. ONC and the Centers for Medicare & Medicaid Services (CMS) have laid a promising foundation with the Meaningful Use Rule.

    -   Government has the opportunity to add crucial visibility to key health objectives for the nation. For example, a declaration of specific targets—such as preventing one million heart attacks and strokes, cutting medication errors, and reducing administrative burdens by half—could add visibility and focus to future stages of Meaningful Use.

    -   The deliberate and strategic alignment of current Health Information Technology for Economic and Clinical Health Act (HITECH) and health reform opportunities is critical to create a more optimal environment for doctors and patients to share and use the best available information for high-quality and cost-effective health decisions. The Department of Health and Human Services' (HHS) emerging national strategy for quality improvement offers an opportunity to align health IT efforts with the nation's health priorities.

2. ## Implement a trust framework that addresses a full complement of protections based on FIPs and that is implemented through both policy and technology.

    -   The starting place is a broad framework of privacy principles based on FIPs and adopted by ONC. It must be used holistically to develop more detailed policies, practices, and technical approaches to achieve the PCAST vision for an information-rich health ecosystem.

3. ## Accelerate standards adoption through bottom-up and top-down approaches.

    -   Most health care is local, and many multi-institution systems that serve particular localities already exist. However, to ensure interoperability among those regional systems as they grow, some national standards must be adopted in the market. We agree with PCAST's desire to accelerate the nation's use of common exchange standards.

    -   The path toward this goal starts with the imperfect data of today, and takes into account the varying capabilities of a wide array of health care settings, ranging from sophisticated environments in large integrated delivery systems to small office practices. The challenge is to build from the simplest and most widely adopted solutions that can work in the real world.

    -   The question is not whether to work from top up or bottom down; both are necessary. The question is which problems are most amenable to which type of solution.

- As the Direct Project has correctly prioritized, a critical starting point is to identify and specify common and implementable standards for secure transport.

- The government's initiative to provide a blue button has provided an example of how giving patients access to downloads of their information available now in the most basic but readable form as a text file, is a building block for individual participation and private-sector innovation.

- Necessary accelerants for greater standardization and adoption will benefit from coordinated efforts to promote and incentivize the sharing of data in its existing forms to improve a patient's care. The standards chosen under Stage 1 Meaningful Use provide a solid foundation.

4. Create pilot projects and prototypes to test some of the innovative elements of the PCAST report and to facilitate rapid standards adoption.

- ONC can support progress by developing pilot projects and prototypes with existing grantees, particularly the Beacon communities and State HIE efforts, and in coordination with other government partners, such as the Center for Medicare and Medicaid Innovation. Promising areas for exploration include the following:

  - Evaluating the potential opportunities and criteria for using metadata in direct communications for sharing information about permissions or other categories of information.

  - Exploring how distributed models for quality reporting and quality improvement that enable the sharing of aggregate data could be used to make progress towards specific health objectives.

5. Commit to further evaluation of the PCAST proposal in the context of the lessons we have learned from past efforts.

- Based on past lessons learned and the vast heterogeneity and asymmetry of US health care, we believe that an optimal approach will include the following:

  - Ensure that policy goals shape technology choices, including standards and architecture, and not vice versa.

  - Work in a series of simple, progressive steps that create value for participants.

  - Design for the simplest sites of care.

  - Always default to sharing what information is available, in the form it is available if it can improve the care of a patient, with a preference, but not a requirement, for improved structure in exchange.

  - Adopt well-tested standards and mechanisms.

  - Keep data as close as possible to where it is captured, and share only as needed.

- Assume that information need not be centralized in order to be shared.

- In addition, many past experiences offer important lessons learned, which should be addressed by ONC in evaluating the report's recommendations for granular metadata, and permissions controls catalogued and moderated by a few national DEAS. Questions to consider in this analysis include the following:

  - To what extent has a DEAS-like model been implemented in other heterogeneous industries?

  - How can consumers be given the tools and insight necessary to make granular privacy decisions beyond the default settings without potentially unleashing unwanted disclosure? How would this be implemented in provider care settings?

  - What approaches could be used to audit the implementation of granular privacy settings in a manner that is scalable?

  - What guidelines should be in place to inform efforts to implement granular controls so that they provide individuals with greater control over their information? How can these controls be implemented by providers in a wide variety of care settings?

  - Who is in the best position to manage consumer expectations and understanding of their rights and responsibilities with regard to managing privacy settings?

  - What are the risks of establishing a limited number of access points for national health information? Are these risks different than those for a limited number of repositories of health information?

  - Would a DEAS-like model require a single authority to monitor the attributes of all users?

  - Who would maintain the infrastructure needed to support the DEAS? How would the rules of the road be determined and who would determine them?

  - What are the privacy and security risks of the DEAS model and how can they be minimized?

  - How would requirements for tethering permissions directly to data elements impact innovation?

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