Questions for Panelists

Current Law

1. What legal issues do you see as being the most pressing when you consider the landscape of health big data?
2. Which laws (federal and state) pose challenges to or may advance the use (including aggregation, analysis, dissemination, sharing) of big data in healthcare?
   a. For those doing big data analyses, what are the points of confusion or challenges related to HIPAA? What are options for resolving these?
3. What are the current gaps in rules structures (laws, regulations, self-governance regimes, best practices) across sectors, or with respect to privacy and security compliance? How do those gaps impact our ability to maximize health big data while also protecting privacy and security?
   a. From the standpoint of enforcement, are HIPAA, FTC, and other rules adequate to protect patient information in the era of big data, regardless of the source of the data and the entity that is involved with the data?
   b. With respect to governance of a health big data ecosystem, is it possible to establish a structure or mechanism for filling the gaps in a more rapid cycle (for instance, rather than relying on a long statutory or regulatory approval/implementation cycle) to stay abreast of technological innovation? What roles should the government and the private sector play in a more rapid cycle environment? Is formal guidance in the form of regulations preferable?   Or put another way, what should be put in place to maintain good "guardrails" over time? What is the cost of not addressing the need for more guidance more quickly?
4. What recommendations would you make to help keep policy at pace with or ahead of technology?

Health Big Data Opportunities

1. What current uses of big data are likely to provide the greatest benefit and impact to the healthcare community? What direction for big data in healthcare do you believe holds the most potential? What barriers do you see for realizing this potential?
   a. What are common use cases, data flows, types of data needed and purposes of big data analyses to improve healthcare?
   b. What promising opportunities are likely to emerge in the future (both short and long term)?
   c. What do you believe is necessary or desirable that would enable the realization of these potential future uses?
2. What is the state of the art in bringing together clinical, genomics and other data (for example, sensors and patient reported outcomes) for big data analyses? What's on the horizon?
3. What about patients who want to contribute to research, such as by setting research agendas, accessing their own data and contributing to research, and/or performing their own analyses – are there options available for them? What are the obstacles/challenges to patient-directed models and how do we resolve them?

4. Marketers have used big data to influence consumer behavior. How can health big data be used to create a culture of health in American communities and encourage healthy behaviors?
5. What privacy and security-enhancing technologies exist?
6. What recommendations would you make to help keep policy at pace with or ahead of technology?

Learning Health System (LHS)[1]

1. What would you say are the most pressing privacy, data security, and ethical issues regarding the learning health system?
2. What big data uses will have the greatest impact for making the learning health system successful?
3. How should policies to protect privacy and security, and honor ethical obligations, be adjusted for different aspects of the learning health system; specifically, for (1) general data analytics in which an individual's identity is not required, and for (2) precision medicine, in which patient identity is necessary?
4. What challenges to researchers face when they try to aggregate and analyze diverse types of data, some covered and some not by HIPAA? What are potential solutions to these challenges?
5. How do systems let patients know that their data might be re-used for learning purposes and that it is a part of a learning health system?
6. What recommendations would you make to help keep policy at pace with or ahead of technology?

Health Big Data Concerns for Individuals

1. What are the top privacy and security concerns with regard to the use of big data in the healthcare space, and what are options for resolving them?
   a. What is the foreseeable impact on longstanding fair information practice principles (FIPPs), such as (1) transparency, (2) purpose specification, (3) data minimization, (4) use limitation, (5) data quality and integrity, and (6) accountability and auditing?
   b. Do certain use cases raise greater concerns than others?
   c. Do certain types of data that the LHS might want to take advantage raise more concerns than others? If so, which types of data and which types of concerns?
2. Could disparate access to data analysis resulting from big data by some patients but not all (e.g., socioeconomic issues) raise trust or other issues?
3. Please discuss the extent to which big data poses risks of negative impacts to personal privacy, security, or negative impact on particular groups (e.g., race, ethnicity, religion, disabled status, language access, LGBTQ, socioeconomic status, etc.).
   a. Do you have ideas about how these risks could be mitigated?

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[1] See A Ten Year Vision to Achieve Interoperable Health IT Infrastructure, pp. 2, 8, available at: http://healthit.gov/sites/default/files/ONC10yearInteroperabilityConceptPaper.pdf. See Also, The Learning Health Care System in America, Institute of Medicine of the National Academies, available at: http://www.iom.edu/Activities/Quality/LearningHealthCare.aspx.

b. Please provide specific examples of disparate treatment, discrimination or civil rights harms that have or may result from the use of big data in healthcare

c. Are there examples of discrimination or harm from other industry use of big data that apply? What are the lessons learned?

4. What are some potential economic or reputational harms that may result from using big data in healthcare?

5. Could the exploitation of big data negatively impact the trust relationship between patients and providers? Between institutions and communities? Please provide specific examples of potential harms.

6. Where would health big data be stored and used? Does this pose any new, unique, previously unidentified risks? Or does it significantly increase already applicable risks?

7. What recommendations would you make to help keep policy at pace with or ahead of technology?

Protection for Patients and Consumers

1. What are the top consumer protection issues that must be addressed to protecting privacy and security while simultaneously taking advantage of the opportunities presented by big data?

2. What current protections and rights of redress are available to patients/customers for privacy and security violations?
   a. What rules currently exist or should be promulgated for ethical violations?

3. What changes to policy or guidance (or ultimately, law) must be made to ensure that patients/customers have adequate protections to address big data harms in the healthcare space?

4. The White House and PCAST reports on big data both express significant concerns about the use of de-identification or anonymization techniques to protect privacy in health big data analytics. Are the current HIPAA anonymization / de-identification standards sufficient to address the future use of big data in healthcare?
   a. What might be modified or updated? What innovations should be considered?
   b. How can the healthcare community combine and use data from various sources (and siloed regulatory schemes) for better information awareness ? Should such pooled data remain "anonymized" (and can it remain "anonymized")? If not, why not/in what circumstances should re-identification be permitted?
   c. Would it be possible to remove certain identifiers and still use other data sets that retain those data elements without causing re-identification?

5. In your opinion, what are the most successful ways to protect patients'/consumers' personal information and gain the public's trust? What role does value to the patient of the data analytics/big data play in public trust?

6. What is the role of consent in protecting privacy and assuring ethical uses of health big data?
   a. If consent is required, can we expect that sufficient individuals will provide it to support the needs of a learning health system?
   b. Do we have the technical capabilities today to register a consent to use data in the health care system, adjudicate and then revise that adjudication as the person's wishes change? If not, what is missing?

7. What should be the role that fair information practice principles (FIPPs) play in protecting privacy and security, and how do we assure accountability for implementing FIPPs, even if individuals take no action to register their privacy choices?
8. What are existing privacy-enhancing technical architectures that could enable and support big data analyses to improve healthcare (for example, data enclaves; pseudonymization; distributed analytics)? How frequently are these approaches used and what is the impact on both the analytics and on privacy, security and/or trust? What use cases could or should not be pursued using these different approaches?
9. What recommendations would you make to help keep policy at pace with or ahead of technology?