NATIONAL ACADEMY OF MEDICINE

DIGITAL LEARNING COLLABORATIVE (DLC) MEETING

JUNE 28, 2018 Meeting Highlights

MEETING FOCUS: Patient ownership of health data – implications for a learning health system

Motivating Questions:

1. *Potential:* Countless health data points are generated and collected daily – in routine care and treatment, through research studies, by personal assessment and monitoring activities – yet only a tiny fraction are applied for care improvement or treatment discover. If all health data could be available in a protected fashion for new insights, what might be the benefits for health care and health progress?
2. *Barriers:* To what extent are uncertainties about data ownership and control presenting a rate-limiting problem? How much do institutional competitive forces present an issue? Is the interpretation of institutional privacy regulations a barrier?
3. *Ownership implications:* If it is clear that individuals own their personal data, what access, control, and use protocols are necessary to facilitate data application for care improvement and discovery? How can the necessary infrastructure be supported?
4. *Strategies:* What issues and strategies take priority to catalyze transformative change? What are the stakeholders responsibilities, how can they be mobilized, and is there a constructive role for the National Academy of Medicine.

Expected outcome: Establishment of a time-limited NAM Working Group to elaborate on issues, implications, and approaches for fostering patient data ownership and control of health data as a strategy for health progress.

REPRESENTATIVE OBSERVATIONS

- There are various conceptualizations of patient data ownership ranging from strict ownership, to data stewardship/custodial models, to co-ownership where patients possess a copy of the data and have the ability to do whatever with their copy, to remunerative models where patients are compensated for the use of their data. The most appropriate model depends on the goal the system is trying to achieve. (JD)
- Most current paradigms operate by giving patients access and control of their data rather than full ownership. Efforts include the CARIN Alliance, OpenNotes, and MyHealth*e*Vet. The Argonaut project accelerates the development of FHIR- based application programming interfaces to give patients digital access to their data. (RH, CD, NE, MT)
- With 25+ million patients using OpenNotes and 1.39 million Blue Button downloads in a single quarter through the MyHealth*e*Vet program, there is a demonstrable desire among patients for data access. (CD, NE)
- However, health data needs to be curated carefully and presented in a meaningful, computable, and actionable way in order to have utility. Education at the patient, provider, and researcher level is necessary to empower people to be knowledgeable consumers of information. (MT, DF)
- In giving patients access to their data, it is important to bridge the digital divide and not alienate patients who do not have access to the internet. (DF)
- Concomitant to the issue of access is privacy. Unlike the European Union, the US lacks a comprehensive federal law regulating the collection and use of personal data. The Health Insurance Portability and Accountability Act (HIPPA) applies to medical information exchange between covered entities and does not protect health relevant data derived from mobile and wearable devices, data outside of the health care system, copies of health data in the hands of individual patients, and data stored by FDA-regulated medical devices. The HIPAA preamble states that data is owned by providers. (JD, BE)
- About half of the states have enacted privacy laws supplemental to HIPPA. New Hampshire is the only state that acknowledges patients right to ownership of their data, although this acknowledgement does not appear to have a meaningful impact for health care consumers. (JD, BE, RH, MT)
- The concept of data ownership invokes property rights which would not ensure privacy and security protections, an enduring right to access, or exclusive control. Data ownership would also require an expensive administrative infrastructure. HIPPA is a civil rights model. (BE)
- There is growing concern that patient control of data will limit sharing and stifle innovation. Genetic Alliance helps patients set individual data sharing and privacy preferences to promote responsible research and inform better care. (JO)
- Data trust/custodial models, where an organization makes data sharing decisions on behalf of individuals, could rightfully balance data access and openness with security and privacy.
    - The Johns Hopkins Medical Data Trust is a rules-based, purposeful data repository. A council, which includes patients, informaticists, providers, and administrators, makes decisions on the appropriate use and disclosure of various types of data collected from patients. (SR)
    - United Healthgroup has an individual health record custodianship initiative that has shown 4-5% year-over- year cost reductions. (RK)
- While some entities view greater transparency and access to data as a threat to their competitive advantage, organizations should only be able to profit from the algorithms and methods developed through the use of the data, not from harboring the data itself. (BW)
- Although HIPPA limits organizations from selling data for anything more than the cost of preparation, patients can sell their data for any price. Therefore, remunerative ownership models might incentivize patients to sell their data to companies that might abuse or improperly store it. (BW)

ISSUES FOR COLLABORATIVE CONSIDERATION Issues that could be addressed through a NAM Collaborative Working Group include:

- *Health data definition and use case identification*: Define what constitutes health data and create an inventory the different types of health-related data. Identify and prioritize uses cases. Determine the data access needs for different stakeholders.
- *Exploration of data ownership and sharing models:* Develop a neutral incubator to develop and test various data ownership models, considering approaches from other industries. Identify the governance and technical framework for each one.
- *Principles for data stewardship:* Define data stewardship and develop principles for data stewards especially operating in the private sector.
- *Enhancing patient health literacy*: Promote educational programs to help patients/consumers navigate and interpret their health data.
- *Understanding patient preferences*: Understand what factors drive patient preferences for different ownership, access, and control models.
- *Oversight and regulation:* Specify the particular protections for the different kinds of data.

Participants

Jonathan Perlin (Hospital Corporation of America), Reed Tuckson (Tuckson Health Connections), Orly Avitzur (Brain & Life), Michael S Barr (NCQA), Paul Bleicher (OptumLabs), Janet Campbell (Epic), Kevin Chaney (ONC), Apryl Clark (NQF), Elaine Collier (NCATS), Jodi Daniel (Crowell & Moring LLP), Amar Das (IBM). Catherine DesRoche (OpenNotes), Christine Dymek (AHRQ), Barbara Evans (University of Houston Law Center), Neil Evans (VHA), Anna Fine (FDA), Doug Fridsma (AMIA), Sarah Greene (Health Care Systems Research Network), Ryan Howells (Leavitt Partners), Javier Jimenez (Sanofi), Ralph Korpman (UHG), Lisa Lee (Walter Reed Army Institute of Research), Daniel Van Leeuwen (HealthHats), Peter Long (Blue Shield of California Foundation), Jennifer MacDonalds (VA), Lara Mangravite (Sage Bionetworks), Kristin Martin Anderson (Booz Allen Hamilton), David McCallie (Cerner), Laurie McGraw (AMA), Katherine Mikk (MITRE), Joey Nichols (MITRE), Sally Okun (PatientsLikeMe), James O'Leary (Genetic Alliance), David Price (American Board of Medical Specialties), Stephanie Reel (John Hopkins Medicine), Chesley Richards (CDC), Erin Richardson (FAH), Tania Simoncelli (Chan Zuckerberg Initiative), Harry Sleeper (MITRE), Sonoo Thadaney (Stanford Presence Center, School of Medicine), Micky Tripathi (Massachusetts eHealth Collaborative), Benjamin Wanamaker (Aetna), Jim Weinstein (Microsoft), Jutta Williams (Google), Steve Wretling (HIMSS), Niam Yaraghi (UConn & Brookings Institution), Maryan Zirkle (PCORI)

DIGITAL LEARNING COLLABORATIVE

Participating Organizations

AAMC
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ABMS
ACMG
AstraZeneca
AHIP
AHA
AMA
Baylor Scott & White
Blue Cross and Blue Shield
Brigham and Women's
Bristol-Myers Squibb
Brookings Institution
Cedars-Sinai Medical Center
CMTP
Christiana Care
Duke University
Epic Systems
Fairfax Family Practice
Georgetown University
Harvard University
ICER
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Intermountain Healthcare
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Mayo Clinic
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