

NAM LEADERSHIP CONSORTIUM: Collaboration for a Value & Science-Driven Learning Health System

DIGITAL HEALTH ACTION COLLABORATIVE

February 20, 2020 Meeting Highlights

MEETING FOCUS: *An exploration of individual agency over health data as well as models for data sharing and principles for responsible data stewardship.*

REPRESENTATIVE OBSERVATIONS

Strategic Framing: Overview of the Leadership Consortium Operating Model and Principles

- The meeting opened with a draft list of dashboard indicators that reflect the status of the field for measuring the nation's progress toward advancing population health.
- The group suggested a move to process measures such as patient experience, and to consider how outcomes change as a result of better interoperability and information access. (Lina Walker, Mark Savage)
- This issue comes down to whether that data is complete, usable, and accessible. Three key areas to help focus these indicators: 1. Is the data available? 2. Is the data accessed and used? 3. What was the impact of the outcomes?
- Current indicators are EHR- centric, and there is a need to change indicators to reflect that technology is changing and available data is beyond traditional clinical encounters. (Jon Perlin, Reed Tuckson, Dale Sanders, Lina Walker)
- How to develop a framework that incentivizes the collection, aggregation, and use of data from disparate sources when the current framework poses barriers in how rules of consent are applied. (Jane Hyatt Thorpe)
- Consider addressing centralization of consent models (Reed Tuckson)

Rethinking Patient Data Ownership in the Era of Digital Health

- Data ownership, privacy, exchange, contracts, ethics, risks and the specific role of health systems need to be reexamined under alternative models as health data increasingly transfers outside private institutions and mobile devices act as data aggregators. ([Amalio Telenti](#))
- Risks of alternative models include spread of genetic information via social media and hacking. (Amalio Telenti)
- Solutions: 1. Homomorphic encryption – encrypt data and complete calculations with the secure data. 2. Sandbagging - Instead of the data going away for analysis, the algorithm comes to the institution. 3. Edge AI - moving part of the AI workflow to a device. (Amalio Telenti)
- Dilemma: We are pushing for having data from multiple sources but protections and rules are not apace with the rate of data creation and new business models.
- There is a need to figure out how to protect individuals without stifling free flow of information. This includes setting best practices for informing consumers of necessary disclosures and educating them on data protection laws and regulations. (Reed Tuckson, Lygeia Ricciardi, Lina Walker)
- Health data is dynamic and different from other property. Rights and responsibilities depend upon who holds the information, what it's used for, and its access. Consider dynamic state of ownership and recognize the other stakeholders who hold and are using data pulled from a variety of sources. (Jane Hyatt Thorpe)
- Importance of transparency and meaningful choice for consumers in health care. Empowering individuals and institutions to understand what is being collected, tracked, and aggregated. (Dorothy Siemon)
- Analogy of credit card transactions in granting access to data. Who do we trust with our healthcare data and how are we notified when it's used? How to roll economic value of data back to patients? (Dale Sanders)
- Focus on the primary outcomes and sidestep privacy issues by embedding the analytics at the point of care. (Robert Emerson)
- Need to be cognizant of the potential burden put on consumers having to constantly give consent. (Lina Walker)

Luncheon Discussion: Consumer Behavior

- In the new view of individual agency via health data and data access, consumers should be able to know where the data is, understand implications of use/sharing of data, choose or deny access to and use of it, and leverage it for personal agency. ([Lygeia Ricciardi](#))
- NAM should: 1. Support existing policy changes & enforcement (CMS/ONC rules, OCR "right of access"), 2. Call for new comprehensive privacy policy legislation that minimize harm. 3. Spearhead private-sector led activities: develop tools and guidelines for consumer literacy, health quality and cost, privacy/data use. (Lygeia Ricciardi)
- We need broader protections of privacy for all data use. (Lygeia Ricciardi)
- GDPR actions have limited access to sensitive data leading to hurdles in clinical workflows. We need better consideration of practical side and patient safety. (Charlotte Moser)

- There is a need for an industry standard of sufficiency in terms of privacy protecting risk, etc. Then consumers need only to figure out the best tools to using data to meet their objectives. (Lina Walker)
- The adverse consequences of endorsing a general privacy role as opposed to a specific health privacy rule is that health data is not homogenous. General law needs to be adaptive or overlook nuances of health data. (Jon Perlin, Gregg Moore, Reed Tuckson)
- Need to balance the social good versus the danger that comes out of exposure of identities from data sharing, and need to require specific legal protections for vulnerable subgroups. (Ben Hamlin)

Best Practices from the Field

- CoverUS app works to figure out how to give patients more agency over their data by connecting patients of chronic disease with the healthcare companies who pay to engage patients. Key factors: user experience, value, and trust. On this platform patients provide anonymized profiles and share data to earn real financial benefits. ([Christopher Sealey](#))
- Biospecimens and health data are governed by method of procurement: Although biospecimens and health data are procured differently, they are used similarly. ([Kayte Spector-Bagdady](#))
- Revolving door of data and specimens between academia and industry: academia commercializes specimens and data and academia is also using commercialized specimens and data from private industry. (Kayte Spector-Bagdady)
- Having too much regulation in the academic federally funded space and lack of regulations in the industry space leading to a self-fulfilling loop: industry can collect data easier and we continue to invest in self-reported data which encourages data privatization. (Kayte Spector-Bagdady)
- Privatization of data leads to issue of access: 1. Gives industry a gatekeeping function over what research is enabled, 2. Limits ability to validate work or build derivative discoveries, 3. Decreased future access (e.g., price increases or change in leadership) (Kayte Spector-Bagdady)
- Industry is able to utilize a short and understandable consent form, academia is legally mandated to use forms that are difficult for patients to grasp. (Kayte Spector-Bagdady)

Opportunities for Collaborative Action

- There are variety of rules that govern the data, depending on where it comes from, who's holding it, and what it's used for. Identify a set of data or attributes that should be protected regardless of who holds the data. (Jane Hyatt Thorpe)
- The academy could highlight the societal value of data to the public in order to mitigate the overblown risks of privacy. And address the issues caused by over application of HIPAA from an internal privacy perspective. (Dale Sanders)
- Include patients and people with risk factors as stakeholders. (Charlotte Moser, Christopher Sealey, Dorothy Siemon)
- Three suggested indicators: 1. Are patients using their access to their health information? 2. Are doctors taking their quality measures and stratified them by disparity variables from existing medical records? 3. Are patients accessing and using shared care plans for their shared care? (Mark Savage)
- Need to move away from individual informed consent in secondary research because: risks are much lower for secondary research, we should not to attempt to reconcile individual risk against community benefit, and most people don't read or understand informed consent forms. Need to refocus on baseline standards for industry to simplify consent and create better alignment with academia. (Kayte Spector-Bagdady)
- When designing systems consider the: 1. Inclusion of patients and people with risk factors, 2. Engagement from a systems- level to understand context outside an individual or disease. 3. Importance of design thinking.
- A burden analysis or measure for everything that's put on to the consumer. Importance of transparency in what is collected, aggregated, and used. (Dorothy Siemon)
- Stop setting our targets on what we could do today, but focus on tomorrow's priorities. The dashboard architecture should be governed with a social responsibility approach, centered on individual societal benefits. (Ben Hamlin)
- Importance of informing new comers and industry leaders of health data ethics: Digital Hippocratic Oath - first do no harm with digital data. (Ben Hamlin, Gregory Moore, Reed Tuckson)
- The National Academies could make a statement highlighting the societal impact of growing health data and stating healthcare runs on trust: 'Data and Privacy in The Age of Intelligent Health'. (Greggory Moore)
- The National Academy could call for Congress or state lawmakers to create legislation in areas that are lacking a viable policy framework, such as privacy and discrimination. In industry based policy, create best practices and templates related to privacy, consent, value, and risk. (Lygeia Ricciardi)

COLLABORATIVE ACTIVITIES FOR CONSIDERATION

- Revise the dashboard indicators to be more person/patient centric: 1. Degree to which consumers or people have access to and are using data pertinent to their health, both within and beyond personal health system data. 2. The

extent to which consumers understand and exercise their agency with regard to use of their health data for diverse purposes.

- Catalog the changes in play with respect to digital health and health data and the fragmentation and constraints of the regulatory landscape.
- Develop a consensus on consent and create template that is easy to understand and can be use by academia and industry alike.
- Develop a trustworthy framework that can be applied to healthcare organizations about ways they collect and use data to build a trust environment.

MEETING PARTICIPANTS

Jon Perlin (Hospital Corporation of America), Reed Tuckson (Tuckson Health Connections), Lygeia Ricciardi (Carium), Christopher Sealey (CoverUS), Kayte Spector-Bagdady (University of Michigan), Amalio Telenti (Vir Biotechnology), Glenn Cohen (Harvard Law School), Robert Emerson (Blue Cross Blue Shield of North Carolina), Andrew Gettinger (ONC), Valerie Grey (New York eHealth Collaborative), Carlos Rodarte (Volar Health, LLC), Benjamin Hamlin (National Committee for Quality Assurance), David Kendrick (University of Oklahoma), Gregory Moore (Microsoft Healthcare), Charlotte Moser (Galera Therapeutics), Dale Sanders (Health Catalyst), Mark Savage (UC San Francisco's Center for Digital Health Innovation), Pamela Tenaerts (Clinical Trials Transformation Initiative), Jane Hyatt Thorpe (George Washington University), Sheryl Turney (Anthem, Inc), Dorothy Siemon (AARP), Lina Walker (AARP)

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