NAM LEADERSHIP CONSORTIUM: Collaboration for a Value & Science-Driven Learning Health System
EVIDENCE MOBILIZATION ACTION COLLABORATIVE
January 23, 2020 Meeting Highlights

MEETING FOCUS: *An exploration of the evolution of data privacy and the implications for secondary use of health data in support of a learning health system.*

REPRESENTATIVE OBSERVATIONS

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

- The meeting opened with a list of the initial dashboard indicators for measuring nation's progress in moving toward enhanced evidence generation and evidence mobilization.
- There are two issues of latency: 1.) Latency between the development of clinical trials and establishment of national guidelines based on new evidence and 2.) Latency between validating the accuracy of guidelines and the translation to a quality metric. These issues beg the following questions: How to make the system more efficient to reduce this gap? Are there other sources of evidence from specific structure clinical trials that might be incorporated into developing guidelines? (Michael Barnett; Rick Kuntz; Anand Parekh)
- Guidelines lack standardization. A need to create a national guidelines clearing house database that would create mechanism for judging whether evidence is accurately being translated into a guideline. (Eric Schneider)
- How do you convert guidelines into rule sets that can be useful in a digital world? (Charles Aunger)
- Value based purchasing metrics may not be consistent with guidelines. As we shorten the time between evidence and practice, we need to consider how we are incentivizing providers to deliver the right care. (Elaine Fontaine)
- Development of an indicator that addresses reimbursement. The latency between evidence and practice is downstream from reimbursement. Measuring the evidence behind what is reimbursed or things that do have evidence and are not reimburse as an important issue. (Dan O'Neill; Michael Barnett)
- In instances where coverage determinations are made with lacking evidence, it is imperative for payers to be able to fund evidence generation research. (Zubin Eapen)
- Regarding how evidence is consumed, it is important to define good evidence by the largest scale impact and focus on empowering individuals to consume the literature by providing it an easy to understand, accessible way. This can build public support both people's willingness to share data and funding for evidence development.
- Applying Donabedian's Quality Framework (structure, process, outcomes, and experience) as a framework to develop the indicators. (Eric Schneider)
- Proposed indicators: Percentage of patients who report that their care follows guidelines that they have been shown. How many times is one of those agreements used, the data has been accessed and how relevant is the quality of the data? (Sally Okun; Charles Aunger)

Rethinking Patient Data Privacy in the Era of Digital Health

- Due to the availability of data and expanded patient involvement in their care, traditional healthcare providers are starting to partner and share data in more public and larger scale ways with non-traditional actors who are not covered entities. These groups are collecting data from consumers and are attempting to build businesses around these electronic health records which are typically governed as business associates under HIPAA.
- Recommended changes to HIPAA to create a more robust and comprehensive set of health data privacy protections: 1. Define individually-identifiable health information (IIHI) as an inherently protected class of data, 2. Create new definitions of IIHI "custodians" and "processors" 3. Establish individuals' right to access, amend and delete IIHI, and to consent to or decline participation in aggregated data sets. 4. Codify permitted uses of IIHI, rooted in fiduciary principle, 5. Specific parameters for consumer-friendly and revocable consent (Dan O'Neill)
- Entities dealing with consumer data have to abide by FTC policies also. The FTC examines cases from the consumer perspective and considers whether deceptive acts or practices were employed by an entity. (Elisa Jillson)

Vision • Research • Evidence • Effectiveness • Trials • IT Platform • Data Quality & Use • Health Costs • Value • Complexity • Best Care • Patients • Systems • Measures • Leadership

THE LEARNING HEALTH SYSTEM SERIES

- There is concern that data governed by opt in consent would be a non-representative, homogenous group.
- Under HIPAA, patients have the right to add or correct information in the medical record by providing written notice to the health care providers in order to remove information from their record.
- PatientsLikeMe self-imposed HIPAA and GDPR requirements in addition to focusing on informed and understood consent by implementing a cohort of reviewers that provide the patient's perspective in their understanding of the consent rules. (Sally Okun)
- Health data research no longer falls into discrete categories. There is overlap between the Common Rule, HIPAA and the commercial sector which are all regulated differently. There is also ambiguity as to what is considered health data. (Bonnie Kaplan)

Luncheon Discussion: Consumer Behaviors in Other Sectors

- State laws are trying to fill the gap of protecting health information. California Consumer Privacy Act provides financial incentive for the first time for the personal information of California residents. (Linn Freedman)
- Patient-consumers can grant healthcare providers and organizations as well as research organizations access to their personal health information and get paid for it or obtain other benefit. In return, entities can obtain data specific to a patient to better treat that patient or get anonymized data that they can use for population health. (Linn Freedman)
- Use consent as a service model. We should extract medical information from users who consent privacy and begin using multi-factor authentication to identify our patients transparently and securely. (Linn Freedman)
- Consider movable consent and the patients having the right to move the consent, along with the type of data that is being moved and how that might relate to the data that is shared in the tech and health care world. (Linn Freedman)
- Described as the privacy paradox, there is an inconsistency between the concerns of people regarding privacy and their actual behavior. What is important to people is contextually based. (Bonnie Kaplan)
- People should not be forced to be legal privacy experts to understand implications of sharing data. The lack of public understanding puts an added burden on healthcare providers and researchers. (Bonnie Kaplan)

Emerging Technologies

- The Mayo Clinic- Google partnership allows for sharing of data to advance cure discovery and clinical research. Google acts as a private cloud storage tool while Mayo Clinic maintains control over all the data in the container.
- Secondary use: Bringing the de-identification algorithms to the data instead of bringing data to algorithms so that the only thing that leaves the secure Google Container are answers to clinical questions.
- Hashing names, birth dates, other data in a comparable system that allows for sharing data without sharing identity.
- Data segmentation and granular consent are difficult to implement because of evolving patient preferences, current EHR workflows, and the breadth of data types.
- APIs and blockchain are tools that can make it easier for patients to determine what types of data they would like to share. Using blockchain, an entity that wants to exchange data reads a person's privacy preferences from the block chain and adheres to those principles as it exchanges data.
- Data sharing has to be done in accordance with HIPAA, GDPR, and state laws which may have certain stipulations around the aggregation of data for secondary uses.
- Need to figure out how to optimize the information content taking into account the patient's concerns about not being identified so we can develop algorithms that work in real time that are continuously tested and updated. (Rob Califf)
- Federated learning which leaves the data where it is under the protection of each owner but brings together the data without centralizing it and utilizing federated distributed queries and reference architecture for algorithm sharing. (John Halamka)

COLLABORATIVE ACTIVITIES FOR CONSIDERATION

- Developing an approachable summary of the challenges in data privacy and security and educates patients about the uses of data.
- Establishing public trust by developing an accessible list of key concepts creating a list of questions that people can review when considering data sharing and its implications.
- Formation of a sub working group to identify and refine the dashboard measures
- Collation of case studies and best practices for data sharing and obtaining consent

MEETING PARTICIPANTS

Rick Kuntz (Medtronic), Rich Platt (Harvard Medical School), Linn Freedman (Robinson+Cole), John Halamka (Mayo Clinic), Dan O'Neill (RWJF), Charles Aunger (Health2047 -AMA), Michael Barnett (Harvard), Katherine Blizinsky (NIH All of Us), Robert Califf (Verily), Donna Cryer (The People Centered Research Foundation), Kathleen Davies (FDA), Zubin Eapen (HealthCore), Margo Edmunds (AcademyHealth), Claudia Grossman (PCORI), Sam Halabi (Georgetown University), William Hersh (OHSU), Benson Hsu (University of South Dakota), Elisa Jillson (FTC), Bonnie Kaplan (Yale University), Sachin Kheterpal (University of Michigan), Yvonne Lau (OHRP), Russell Leftwich (InterSystems Corp), Peter Leibold (Ascension), Subha Madhavan (Georgetown University Medical Center), Catherine Meyers (NIH), Aaron Miri (Dell Medical School & UT Health Austin), Allison Oelschlaeger (CMS), Sally Okun (UHG), Norma Padron (Health Research and Educational Trust), Ananad Parekh (BPC), Eric Schneider (The Commonwealth Fund), Janine Schwedes (Flatiron Health), Jane Hyatt Thorpe (George Washington University), Jennifer Wong (Sanofi), Kathryn Marchesini (ONC)

NAM LEADERSHIP CONSORTIUM MEMBERS

Mark B. McClellan, Duke University (Chair)
Jeffrey Balser, Vanderbilt University Medical Center
Georges Benjamin, American Public Health Association
David Blumenthal, The Commonwealth Fund
Troyen Brennan, CVS Health
Josephine Briggs, PCORI
Susan DeVore, Premier, Inc.
Judith Faulkner, Epic Systems
Joseph Fifer, Healthcare Financial Management Association
Stephen Friedhoff, Anthem, Inc.
Julie L. Gerberding, Merck & Co, Inc.
Sandra Hernandez, California Health Care Foundation
Diane Holder, UPMC Health Plan
Robert Hughes, Missouri Foundation for Health
Jeff Hurd, AstraZeneca
Frederick Isasi, Families USA
Gary Kaplan, Virginia Mason Health System
Richard E. Kuntz, Medtronic
Peter Long, Blue Shield of California Foundation
James L. Madara, American Medical Association
Mark Miller, Laura and John Arnold Foundation
Mary D. Naylor, University of Pennsylvania
William D. Novelli, Georgetown University
Sally Okun, UnitedHealth Group
Jonathan B. Perlin, HCA, Inc.
Gerald Petkau, Blue Cross Blue Shield of North Carolina

Richard Platt, Harvard Medical School
Richard J. Pollack, American Hospital Association
John W. Rowe, Columbia University
Jaewon Ryu, Geisinger
Lewis G. Sandy, UnitedHealth Group
Leonard D. Schaeffer, University of Southern California
David Skorton, AAMC
Jennifer Taubert, Johnson & Johnson
Reed V. Tuckson, Tuckson Health
Debra B. Whitman, AARP

EX-OFFICIO

Gopal Khanna, Agency for Healthcare Research and Quality
Robert Redfield, Centers for Disease Control and Prevention
Deputy: Chelsey Richards
Seema Verma, Centers for Medicare & Medicaid Services
Thomas McCaffery, Department of Defense
Deputy: Michael Dinneen
ADM Brett Giroir, Department of Health and Human Services
Richard Stone, Department of Veterans Affairs
Norman E. Sharpless, Food and Drug Administration
Thomas J. Engels, Health Resources & Services Administration
Francis Collins, National Institutes of Health
Deputy: Michael Lauer
Don Rucker, Office of the National Coordinator for Health