DANIELLE WHICHER, MAHNOOR AHMED, SAMEER SIDDIQI, INEZ ADAMS, CLAUDIA GROSSMANN, AND KRISTIN CARMAN,

EDITORS

HEALTH DATA SHARING TO SUPPORT BETTER OUTCOMES

BUILDING A FOUNDATION OF STAKEHOLDER TRUST

NATIONAL ACADEMY OF MEDICINE

HEALTH DATA SHARING TO SUPPORT BETTER OUTCOMES

BUILDING A FOUNDATION OF STAKEHOLDER TRUST

DANIELLE WHICHER, MAHNOOR AHMED, SAMEER SIDDIQI, INEZ ADAMS, CLAUDIA GROSSMANN, AND **KRISTIN CARMAN,**

EDITORS

NATIONAL ACADEMY *of* MEDICINE

PREPUBLICATION COPY—Uncorrected Proofs

Suggested citation: Whicher, D., M. Ahmed, S. Siddiqi, I. Adams, C. Grossmann, and K. Carman, Editors. 2020. *Health Data Sharing to Support Better Outcomes: Building a Foundation of Stakeholder Trust*. NAM Special Publication. Washington, DC: National Academy of Medicine.

"Knowing is not enough; we must apply.
Willing is not enough; we must do"
—GOETHE

LEADERSHIP
INNOVATION
IMPACT

for a healthier future

NATIONAL
ACADEMY
of MEDICINE

ABOUT THE NATIONAL ACADEMY OF MEDICINE

The **National Academy of Medicine** is one of three Academies constituting the National Academies of Sciences, Engineering, and Medicine (the National Academies). The National Academies provide independent, objective analysis and advice to the nation and conduct other activities to solve complex problems and inform public policy decisions. The National Academies also encourage education and research, recognize outstanding contributions to knowledge, and increase public understanding in matters of science, engineering, and medicine.

The **National Academy of Sciences** was established in 1863 by an Act of Congress, signed by President Lincoln, as a private, nongovernmental institution to advise the nation on issues related to science and technology. Members are elected by their peers for outstanding contributions to research. Dr. Marcia McNutt is president.

The **National Academy of Engineering** was established in 1964 under the charter of the National Academy of Sciences to bring the practices of engineering to advising the nation. Members are elected by their peers for extraordinary contributions to engineering. Dr. John L. Anderson is president.

The **National Academy of Medicine** (formerly the Institute of Medicine) was established in 1970 under the charter of the National Academy of Sciences to advise the nation on issues of health, health care, and biomedical science and technology. Members are elected by their peers for distinguished contributions to medicine and health. Dr. Victor J. Dzau is president.

Learn more about the National Academy of Medicine at NAM.edu.

STEERING COMMITTEE AND WORKING GROUP PARTICIPANTS

Steering Committee

ERIN MACKAY (*Co-Chair*), National Partnership for Women & Families

PETER MARGOLIS (*Co-Chair*), Cincinnati Children's Hospital Medical Center

HELEN BURSTIN, Council of Medical Specialty Societies

HUGO CAMPOS, California Precision Medicine Consortium

KRISTIN CARMAN, Patient-Centered Outcomes Research Institute

CHRISTINE GRADY, National Institutes of Health

ADRIAN HERNANDEZ, Duke University Medical Center and Duke Clinical Research Institute

KATHY HUDSON, Hudson Works LLC

RAINU KAUSHAL, New York–Presbyterian Hospital/Weill Cornell Medical Center

BRADLEY MALIN, Vanderbilt University

DEVEN McGRAW, Ciitizen Corporation

C. DANIEL MULLINS, University of Maryland School of Pharmacy

ADNAN MUNKARAH, Henry Ford Health System

HAROLD PAZ, Aetna Inc.

RICHARD PLATT, Harvard University and Harvard Pilgrim Health Care Institute

MICHELLE SCHREIBER, Centers for Medicare & Medicaid Services

JOE SELBY, Patient-Centered Outcomes Research Institute (*until December 2019*)

RACHEL SHERMAN, Food and Drug Administration

MONA SIDDIQUI, Department of Health and Human Services (*until February 2020*)

FRANGISCOS SIFAKIS, AstraZeneca

PAUL WALLACE, AcademyHealth

Patient and Family Leaders Working Group

STACEY LIHN (*Co-Chair*), National Pediatric Cardiology Quality Improvement Collaborative

SUSAN WOODS (*Co-Chair*), Society for Participatory Medicine
CHRISTINE BECHTEL, X4 Health
JANET FREEMAN–DAILY, Patient Advocate and Gray Connections
KAMERON MATTHEWS, Veterans Health Administration
SALLY OKUN, PatientsLikeMe (*until December 2019*)
CASEY QUINLAN, Mighty Casey Media
JOHN SANTA, OpenNotes
ANDREW SPERLING, National Alliance on Mental Illness
SHARON TERRY, Genetic Alliance
VERONICA TODARO, Parkinson's Foundation
DANNY VAN LEEUWEN, Health Hats

Research and Research Oversight Leaders Working Group

SARAH GREENE (*Co-Chair*), Health Care Systems Research Network (*until May 2020*)
RUSSEL ROTHMAN (*Co-Chair*), Vanderbilt University
TANISHA CARINO, Alexion Pharmaceuticals, Inc.
JODI DANIEL, Crowell & Moring LLP
BOB HARRINGTON, Stanford University
JOHN LANTOS, Children's Mercy Kansas City
EMILY LARGENT, University of Pennsylvania Perelman School of Medicine
MICHELLE MEYER, Geisinger's Center for Translational Bioethics and Health Care Policy
PEARL O'ROURKE, Partners HealthCare International
MARK SCHREINER, Children's Hospital of Philadelphia
JEREMY SUGARMAN, Berman Institute of Bioethics, Johns Hopkins University

Health Care Executives Working Group

RAINU KAUSHAL (*Co-Chair*), NewYork–Presbyterian Hospital/Weill Cornell Medical Center
GREGG S. MEYER (*Co-Chair*), Partners HealthCare International
KEVIN BAN, athenahealth, Inc.
RICKY BLOOMFIELD, Apple Inc.

ADRIENNE BOISSY, Cleveland Clinic
JOHN BULGER, Geisinger
RAJ DAVDA, Cigna
ROBERT EMERSON, BlueCross BlueShield of North Carolina
JULIE GERBERDING, Merck & Co., Inc.
JOHN HALAMKA, Mayo Clinic
LEWIS SANDY, UnitedHealth Group
DARSHAK SANGHAVI, OptumLabs
MARIANN YEAGER, The Sequoia Project

NAM Staff

Development of this publication was facilitated by contributions of the following NAM staff, under the guidance of J. Michael McGinnis, Leonard D. Schaeffer Executive Officer and Executive Director of the NAM Leadership Consortium: Collaboration for a Value & Science-Driven Health System:

DANIELLE WHICHER, Senior Program Officer (*until September 2019*)
MAHNOOR AHMED, Associate Program Officer
SAMEER SIDDIQI, Technical Consultant (*temporary*)
INEZ ADAMS, Senior Program Officer (*temporary*)
JENNA OGILVIE, Deputy Director of Communications

Patient-Centered Outcomes Research Institute Staff

NAKELA COOK, Executive Director
CLAUDIA GROSSMANN, Senior Program Officer
MARYAN ZIRKLE, Associate Director (*until December 2019*)
KRISTIN CARMAN, Director
JOE SELBY, Executive Director (*until December 2019*)

Consultant

STEVE OLSON, Science Writer

REVIEWERS

This Special Publication was reviewed in draft form by individuals chosen for their diverse perspectives and technical expertise, in accordance with review procedures established by the National Academy of Medicine (NAM).

We wish to thank the following individuals for their contributions:

ANEESH CHOPRA, CareJourney
PATRICK O. GEE, SR., Health Care Consultant and Consumer Advocate
WILLIAM (BILL) GREGG, HCA Healthcare
SUSAN KIRSH, Department of Veterans Affairs
ARTI K. RAI, Duke University School of Law
TERESA ZAYAS-CABÁN, Office of the National Coordinator for Health Information Technology

The reviewers listed above provided many constructive comments and suggestions, but they were not asked to endorse the content of the publication, and did not see the final draft before it was published. Review of this publication was overseen by **MAHNOOR AHMED,** Associate Program Officer, and **J. MICHAEL McGINNIS,** Leonard D. Schaeffer Executive Officer. Responsibility for the final content of this publication rests entirely with the editors and the NAM.

FOREWORD

The effective use of data is foundational to the concept of a learning health system—one that leverages and shares data to learn from every patient experience, and feeds the results back to clinicians, patients and families, and health care executives to transform health, health care, and health equity. More than ever, the American health care system is in a position to harness new technologies and new data sources to improve individual and population health. Wisely stewarded, data can inform decision making about prevention and care for a wide variety of health conditions and result in health care services tailored to the needs of individuals, populations, and communities. The range of data sources relevant to this task is vast and continuously growing. Achieving this potential depends on overcoming substantial friction and inertia that exist today between this ideal state and current reality.

Learning health systems are driven by multiple stakeholders—patients, clinicians and clinical teams, health care organizations, academic institutions, government, industry, and payers. Each stakeholder group has its own sources of data, its own priorities, and its own goals and needs with respect to sharing that data. However, in America's current health system, these stakeholders operate in silos without a clear understanding of the motivations and priorities of other groups. To foster dialogue, the National Academy of Medicine and Patient-Centered Outcomes Research Institute convened a multi-stakeholder steering committee of patients and families, health system executives, representatives from biopharmaceutical and technology companies, clinicians, and research and research oversight leaders with the goal of generating wider awareness and discussion about the barriers to effective, efficient, and ethical data sharing. The committee's charge was to bring together these groups to identify actions that could stimulate more demand for this ideal state of data sharing.

The three stakeholder working groups that served as the authors of this Special Publication identified many cultural, ethical, regulatory, and financial barriers to greater data sharing, linkage, and use. What emerged was the foundational role of trust in achieving the full vision of a learning health system. Numerous examples detailed in this Special Publication reflect the broader environment of health care, in which factors like market competition, the potential to treat data as a monetized commodity, and reluctance to share override the moral and ethical imperatives of exchanging and using data to improve the health of patients and populations. Historic and current misuses of data have only further diminished public trust in institutions that rely on data for advancing progress.

Understanding and addressing the challenges of data sharing and trust are especially noteworthy at the time of publication. The COVID-19 pandemic exemplifies the need for data sharing to drive rapid learning and meaningful actions. The U.S. response to the COVID-19 pandemic is characterized by a patchwork of data sources barriers to sharing data across health care, public health, and other sectors; antiquated methods of data capture, including a reliance on manual data entry and faxed surveillance reports; inadequate use of electronic health records; and gaps and variation in public reporting of data related to race and ethnicity. Together, these factors have thwarted a unified response by public health and policy makers, business leaders, health care practitioners, and the general public. Moreover, the absence of a connected system for exchanging data has reduced the ability of communities to understand and respond to local context and has compromised real-time learning. The COVID-19 pandemic also highlights the structural inequities that have resulted in worse outcomes for communities of color and underscores the need to improve data sharing and use in ways that advance health equity.

This Special Publication outlines a number of potentially valuable policy changes and actions that will help drive toward effective, efficient, and ethical data sharing, including more compelling and widespread communication efforts to improve awareness, understanding, and participation in data sharing. However, there is tension between the role of national policy organizations' top-down recommendations and the bottom-up actions and relationships required to facilitate and build participation and trust among the individuals who will be sharing their personal data. For example, some health data are produced out of relationships between patients and clinicians as part of health care services and in the pursuit of better health. In any relationship, trust grows as a result of thoughtful, respectful, and transparent interactions. Thus, decision makers should prioritize collaborations and activities that are likely to generate trust among stakeholder groups. One of the action steps this Special Publication proposes is the

establishment of a consortium of organizations committed to progress by testing new approaches to data sharing. The authors of this publication believe that this is an important action-oriented proposal that could build the knowledge and momentum to realize this ideal state of data sharing. The proposed consortium of organizations committed to progress by testing new approaches to data sharing is an important action-oriented approach that could build the knowledge, expertise, and momentum to realize the goals of the report.

Continued involvement of patients and communities is essential to achieving this ideal state of data sharing. If patients are to take on a more robust and informed role in guiding decision making about the collection, use, and sharing of their data, substantial commitment and openness on the part of all stakeholders is integral. This includes a commitment to authentic engagement and participation of patients and families; extensive education about the use of data; changes in technology to make data sharing easier; necessary privacy and civil rights protections; and novel governance models that recognize, define, and support the rights and responsibilities of a wide variety of patients as data contributors and users. Only then will all patients and other stakeholders feel empowered to exert a stronger voice in governing shared data resources.

Achieving the vision of a learning health system will require eliminating the artificial boundaries that exist today among patient care, health system improvement, and research. Breaking down these barriers will require an unrelenting commitment across multiple stakeholders toward a shared goal of better, more equitable health. We can improve together by sharing and using data in ways that produce trust and respect. Patients and families deserve nothing less.

Erin Mackay, M.P.H.
Peter Margolis, M.D., Ph.D.
Co-Chairs of the Special Publication Steering Committee

PREFACE

This Special Publication was first conceived out of the firm belief that health data sharing is a moral imperative. It is an obligation that requires the equal engagement of all health care stakeholders—patients, consumers, providers, researchers, health system leaders, technology and pharmaceutical partners—to facilitate greater data sharing for advancing health, health care, and health equity.

Throughout this Special Publication, the authors cite the numerous benefits of data sharing and present compelling reasons from a variety of viewpoints that underscore the importance of this mission. However, nothing has made a more urgent case for data sharing than the coronavirus disease 2019 (COVID-19) pandemic.

Due to COVID-19, health data sharing is no longer just a moral imperative but a vital component in overcoming this crisis. The novelty of severe acute respiratory syndrome coronavirus 2 (SARS-CoV-2) and the variable and mysterious manner in which the ensuing disease manifests in different people highlights the need for rapid, timely, and accurate data exchange from a myriad of sources. COVID-19 has demonstrated the value of and raised our reliance on patient- and consumer-reported data in tracking transmissions and understanding risk factors for the disease. The pandemic necessitates the sharing of results, broadening the potential for new insights and accelerating the pace of developing a cure.

The authors of this Special Publication have seen an encouraging coming together of stakeholders across borders and sectors of the health care system to share new discoveries and experiences with COVID-19. Several public initiatives such as the National Institutes of Health's National COVID Cohort Collaborative, the Food and Drug Administration's Evidence Accelerator, and the National Patient-Centered Clinical Research Network's COVID-19 Common Data Model have emerged to coordinate data resources across groups. Private entities and academic institutions have put aside competition to form new data partnerships for surveillance, predictive modeling, comparative effectiveness,

addressing health disparities, quality improvement, and innovation. Additionally, waivers and modifications of the Health Insurance Portability and Accountability Act (HIPAA) privacy rules have eased the sharing of patient medical data across hospitals, vendors, and public health authorities.

The data collaborations and policy adjustments promoted by COVID-19 are a testament to the rapid dismantling of decades-old barriers—many of them mentioned in this Special Publication—to solve a public health crisis. These rapid pivots reveal a remarkable commitment among stakeholder groups to sideline concerns over market competition, the burden of managing data, and data control and ownership in pursuit of a common cause. Above all, it reflects the ability of stakeholders to develop trust in each other for the sake of progress.

This Special Publication repeatedly identifies trust as the cornerstone of building successful data sharing partnerships. It is no different under the current circumstances. Trust must remain a priority in all efforts to address the pandemic. Trust begins with health care leaders being transparent about their intentions and plans for health data and using clear, understandable language to communicate data-sharing plans with patients and caregivers. Particular attention must be given to engaging underrepresented minorities, who have disproportionately borne the burden of COVID-19 and, yet, are underrepresented in demographic and social data.

The research community can instill trust by ensuring that data and information used in COVID-19 studies are credible, verified, and sourced appropriately. While scientific integrity is sometimes compromised by the urgency to publish, it behooves researchers and research oversight leaders to develop and adhere to agreed-upon standards in the use of electronic data and data analysis transparency. Without these standards, public trust in institutions that rely on data, as fragile as it is, will erode further.

An area in which trust plays a crucial role is the protection of privacy. As shown in this Special Publication, privacy is an enduring concern of health care stakeholders, further accentuated by COVID-19. Understandably, in times of crisis, the relaxation of privacy regulations may be warranted in service to public health and safety. However, in doing so, trust and transparency must maintain a central presence. It is here that the opportunity presents itself once again for implementing many of the approaches proposed in this Special Publication—a sweeping educational campaign for consumers on the implications of changing policies, the use of anonymized and de-identified datasets, and the development of novel data governance and stewardship models to ensure that data shared for the purposes of COVID-19 are used responsibly and according to the preferences of their providers during and well after the pandemic.

Although COVID-19 has been a horrific and unwelcome disruption in our lives, it serves as a much needed catalyst for change. The pandemic has provided a window of opportunity to reassess and re-design interactions in health care for the better and shown that barriers long-assumed immovable can be overcome, including many of the barriers identified in this Special Publication. However, sustaining progress requires upholding the central tenet of trust. Without trust, not only will health care and data sharing struggle to move forward, but the gains achieved during this pandemic may be reversed.

Stacey Lihn
Susan Woods
Co-Chairs, Patient and Family Leaders Working Group

Sarah M. Greene
Russell Rothman
Co-Chairs, Research and Research Oversight Leaders Working Group

Rainu Kaushal
Gregg S. Meyer
Co-Chairs, Health Care Executives Working Group

CONTENTS

PREPUBLICATION COPY—Uncorrected Proofs

BOXES AND FIGURES

BOXES

FIGURES

ACRONYMS AND ABBREVIATIONS

AAN	American Academy of Neurology
API	application programming interface
CDC	Centers for Disease Control and Prevention
CHIP	Children's Health Insurance Program
CMS	Centers for Medicare & Medicaid Services
EHR	electronic health record
HHS	Department of Health and Human Services
HIPAA	Health Insurance Portability and Accountability Act
HL7	Health Level Seven International
IRB	institutional review board
IT	information technology
MACRA	Medicare Access and CHIP (Children's Health Insurance Program) Reauthorization Act of 2015
NAM	National Academy of Medicine
NGA	National Governors Association
NIH	National Institutes of Health
OCR	Office for Civil Rights
OHRP	Office for Human Research Protections
ONC	The Office of the National Coordinator for Health Information Technology
OSTP	Office of Science and Technology Policy

PCORI   Patient-Centered Outcomes Research Institute
PCORnet   National Patient–Centered Clinical Research Network

ResDAC   Research Data Assistance Center (CMS)

TEFCA   Trusted Exchange Framework and Common Agreement

VHA   Veterans Health Administration

EXECUTIVE SUMMARY

Advances in the collection and use of health data offer tremendous opportunities to improve patient health outcomes, improve evidence-based decision making, and transform the nation's health care system. While the technological capabilities exist, a number of ethical, regulatory, cultural, financial, and organizational barriers hamper the growth of data sharing. To accelerate progress toward addressing these barriers and to promote data sharing, linkage, and use, the National Academy of Medicine (NAM), in partnership with the Patient-Centered Outcomes Research Institute (PCORI), facilitated conversation within and among three stakeholder workgroups—health care executives, research and research oversight leaders, and patient and family leaders. The aim of this initiative is to transform the development of evidence and application of care innovations by generating stakeholder support and demand for leveraging and sharing data for continuous learning.

At the start of this undertaking, a 21-member multi-stakeholder steering committee, chaired by Erin Mackay of the National Partnership for Women & Families and Peter Margolis of Cincinnati Children's Hospital Medical Center, developed a vision statement that describes an ideal state of data sharing in the U.S. health system.

Vision Statement

A health system that shares and applies routinely generated health data and information to support continuous learning to transform health, health care, and health equity, and does so in a manner that enhances stakeholder trust, experience, and transparency in system performance.

Building on and responding to the vision statement, the aforementioned stakeholder workgroups developed individual statements (see Chapters 3, 4, and 5).

Each statement (1) describes the importance of data sharing, linkage, and use from the perspective of the stakeholder constituency; (2) identifies barriers to routine data sharing and use, and (3) puts forth successful long- and short-term approaches for addressing those barriers and strategies to build support for routine and widespread health data sharing. A key element of this initiative was a February 7, 2019, convening, during which members of the three stakeholder groups prioritized the most pressing barriers, considered common themes across stakeholder groups, and brainstormed action steps that are achievable within the next 2 or 3 years for advancing health data sharing, linkage, and use.

As the stakeholder statements solidified over the course of this initiative, they revealed a remarkable amount of overlap among the cultural, ethical, regulatory, and financial barriers to greater data sharing, linkage, and use (see Figure ES-1):

- The groups representing health care executives and patient and family leaders identified a misalignment of financial and other incentives as common barriers.
- The groups representing patient and family leaders and research and research oversight leaders identified a lack of agreed-upon practices and principles regarding patient data access, data control, and data ownership.
- The groups representing research and research oversight leaders and health care executives identified concerns regarding controversial uses of data, differing beliefs about whether data should be freely shared, and costs associated with data procurement.

A concern shared by all three stakeholder groups was a lack of trust in the intentions and actions of other groups. The patient and family community lacks trust that health care systems and researchers will make data and the conclusions based on those data available to them and will not misuse data they provide by rationing care and sharing it with unauthorized third parties. Researchers share a similar mistrust in the intentions of third-party users. Health systems are hesitant that patients and families will misinterpret data or use data inappropriately, such as allowing it to be combined with other elements so as to identify individuals.

The overlapping and unique barriers of each stakeholder statement, along with the accompanying short- and long-term solutions, were presented at an NAM meeting on August 23, 2019, to a broad array of outside experts, along with members of the working groups and steering committee. The purpose of the meeting was to invite outside experts to offer reactions to the vision statement and stakeholder statements and, together with the steering committee and working group members, identify several priorities for the nation to address the barriers to data sharing, linkage, and use.

CULTURAL, ETHICAL, REGULATORY, AND FINANCIAL BARRIERS TO DATA SHARING, LINKAGE, AND USE

Concern regarding controversial uses of data such as achieving competitive advantage or rationing care, etc.

Differing stakeholder beliefs about whether data should be freely shared

Costs associated with data procurement

HEALTH CARE EXECUTIVES

Concern regarding the financial costs associated with sharing data when the ability for individual actors to appropriate value (achieve an ROI) from the pooled data is underdeveloped.

Misalignment of financial and other incentives (fear of penalties associated with data breaches, reputational risk, etc.)

PATIENT AND FAMILY LEADERS

Low recognition of patients and family members as data users and data providers

Lack of understanding of the value of patient-generated data

Lack of trust

RESEARCH AND RESEARCH OVERSIGHT LEADERS

Organizational variability in interpretations of regulations and responsibilities

Operational challenges (uneven data quality, lag time between data collection and data availability, etc.)

Lack of agreed upon practices and principles regarding patient data access, data control, and data ownership
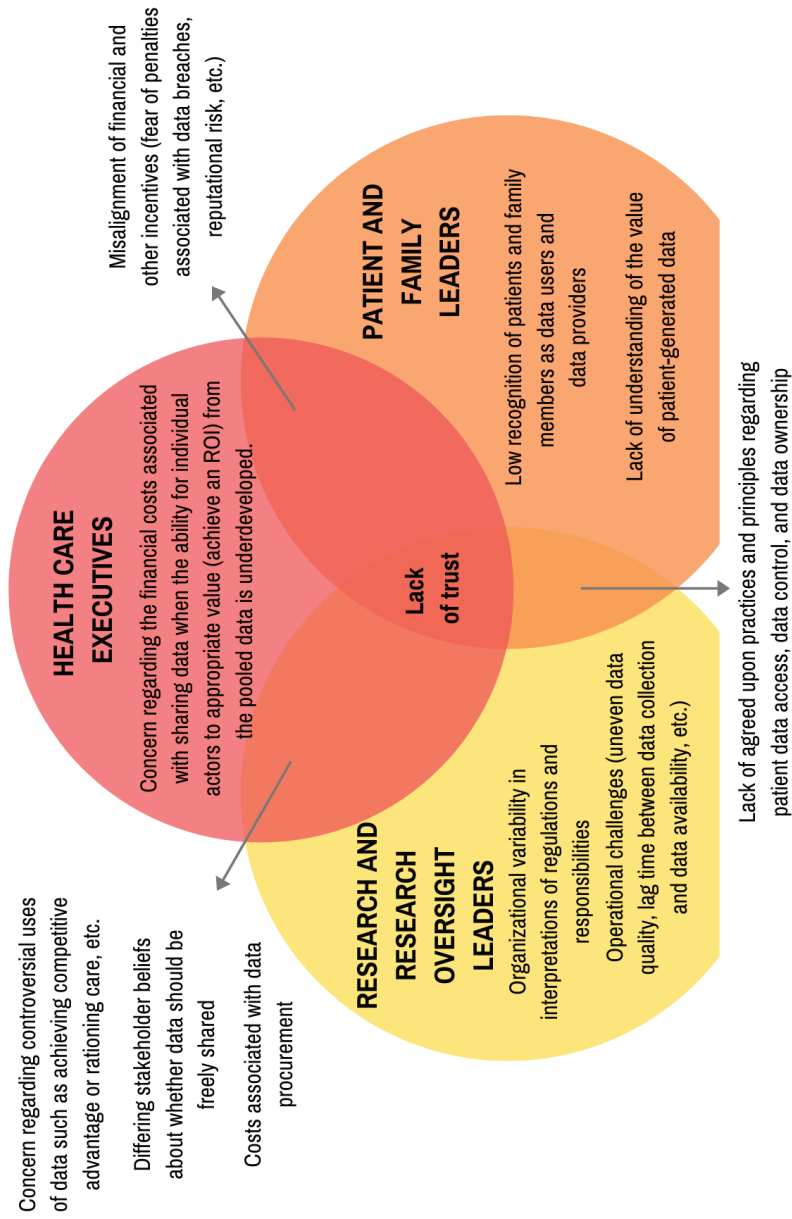
FIGURE ES-1 | Cultural, ethical, regulatory, and financial barriers to data sharing, linkage, and use.

Recognizing that greater knowledge is essential to move data sharing forward, it was suggested that a widely disseminated public information campaign could help change attitudes and behaviors by showing consumers how the use of health data could improve their rights to data sharing. Foundational to devising a national educational campaign, the development of use cases that promote various reasons for sharing and linking health data could help build demand for data sharing, and demonstrate how to overcome the barriers identified by the stakeholder groups and achieve the vision described in Chapter 2. Each stakeholder in the health care system will need to see the advantages of moving toward greater data sharing. Particularly in the private sector, this will require the development of compelling business cases that clearly demonstrate these advantages and return on investment. A business case can demonstrate how data sharing is useful and brings benefits to multiple parties, including the consumers of health care.

On a macro scale, new payment models that incentivize paying for value and outcomes, rather than paying for volume of care that is delivered, could have concurrent benefits to the imperative for more seamless data sharing. Another proposed solution is institution-supportive government policies. Policies such as the Centers for Medicare & Medicaid Services Interoperability and Patients Access rules can establish ground rules and standards for data exchange across networks, as well as support the development of technologies and systems that promote, rather than impede, data sharing. In addition, all funders of research, not just government entities, can require researchers to make their data available to other researchers and to research participants.

Overall, greater trust and transparency among stakeholder groups can both foster and support data sharing. Standards of conduct can build trust, because people know what to expect. Collaborative efforts built on trust can convert zero-sum relationships into positive-sum relationships, where data sharing serves everyone's interests.

However, trust has to be built and sustained thoughtfully and intentionally, given that it is a fragile commodity and can easily be lost. This includes making consumers of health care come first through business plans and actions of those in the organization need to reflect that mission.

To implement these actions, participants of the August 23 meeting also discussed a wide array of resources that are both needed and available to achieve the goal of greater data sharing. Though the stakeholder groups were directed not to address the technical barriers to greater data sharing, computational technologies are a major part of the resources needed to achieve the priorities the groups identified. These technologies can provide solutions, such as enabling audit trails, to enforce compliance with regulations or balancing access with security and privacy. One

example is third-party applications that enable consumers to access clinical data and as a result interact much more directly with their health data.

Some data-sharing initiatives can begin with small groups, such as patients with particular diseases, and then spread more widely, as exemplified by the creation of many of PCORI's Patient-Powered Research Networks. Others may start with particular institutions and then be adopted or adapted in other settings. A consortium of organizations rallied around a shared framework and commitment to stewarding progress on data linkage, sharing, and use could produce greater collaboration and faster progress.

These strategies could unlock data sharing at a critical time, when the U.S. health care system faces the momentous challenge of rising costs and subpar health outcomes, as well as an unprecedented opportunity given the wealth of digital technologies. With enhanced health data sharing, a vision of a continuously learning health system, in which science, informatics, incentives, and culture are aligned to yield continuous improvement, innovation, and equity, is attainable. Doing so requires addressing the existing cultural, ethical, regulatory, and financial barriers to data sharing, and building support and demand for data-sharing efforts across and among key stakeholders, including patients and caregivers, clinicians, health care executives, and researchers. Effective action on the potential of data sharing requires the strong commitment of all of these stakeholders to create a vision of how to overcome these barriers.

1

INTRODUCTION

OVERVIEW

Against the backdrop of increasing costs and unacceptable shortcomings in the nation's health and health care system, sharply demonstrated by the coronavirus disease 2019 (COVID-19) pandemic, and unprecedented opportunity exists to improve health care by effectively applying new tools and technologies to accelerate learning and evidence development. Advances in the generation and use of health-related data offer new capabilities to leverage information to address pressing questions and improve clinical decision making. These data are now routinely generated from a variety of sources, including electronic health record systems; health insurance claims; clinical and health services research; and genomic, proteomic, and immunomic studies. They range in type from social and environmental determinants of health to data collected during clinical encounters or outside of the health care system through community, state, and federal organizations, and from patients, their family members, or caregivers (ONC, 2018; Sharfstein et al., 2017).

While the technical capacity to speed progress toward better health outcomes exists due to computational research and developments in data science, most health-related data remain siloed and data sharing, linkage, and use have not been adequately or cooperatively marshaled for care improvement. A number of ethical, regulatory, cultural, and organizational barriers hamper the growth of data sharing. These challenges include concerns from health systems, hospitals, and health insurers about the sensitivity of health data and liabilities associated with potential data breaches. Researchers and research oversight leaders have raised questions about appropriate frameworks for data ownership, governance, and control; approaches to adequately protecting individual privacy; and concerns related to electronic health data quality. Above all, there is a lack of understanding and lack

of incentives as to how to effectively and efficiently provide patients and their families or caregivers with access to their electronic health data and enable the use of the data in care encounters without overwhelming clinicians. While the perspectives of different stakeholder groups vary, all share the common goal of improving health care and health outcomes. However, these stakeholders have rarely had the opportunity to interact with each other to develop common solutions. A coordinated effort is needed to rally the involvement of these key stakeholder groups to address their unique challenges and capture the possibilities of better sharing, linking, and using clinical data.

To accelerate progress toward addressing outstanding barriers and to promote data sharing, linkage, and use for the purpose of improving health care and health outcomes, the National Academy of Medicine (NAM) in partnership with the Patient-Centered Outcomes Research Institute facilitated conversation within and among three stakeholder communities, which consisted of leaders from provider organizations, health care delivery systems, and health plans; researchers and research oversight leaders; and patient and family leaders.[1] This publication summarizes these discussions with three goals: (1) to describe an overall vision for a health system that shares electronic health data to improve health outcomes and health care; (2) to outline the barriers and short- and long-term approaches to address those barriers from the perspective of the three stakeholder communities; and (3) to describe the overlapping themes and critical next steps for improving data sharing, linkage, and use over the next several years. The following sections explain the purpose and process of developing each of these elements.

STEERING COMMITTEE AND VISION STATEMENT

A multi-stakeholder steering committee led by Erin Mackay of the National Partnership for Women & Families and Peter Margolis of Cincinnati Children's Hospital was convened to guide and oversee the execution of project activities according to their intended outcomes (see Box 1-1 and Figure 1-1).

The first task of the steering committee was to create a unified vision of data sharing, linkage, and use to facilitate continuous learning and care improvement, which it accomplished through a series of conference calls and an in-person meeting on June 11, 2018 (see Appendix A). The vision statement describes the ideal state for a health care system: one that leverages and shares data to learn from every patient experience and feeds the results back to clinicians, patients, and health care executives to improve care outcomes (see Chapter 2).

---

[1] Several working group members represented dual perspectives as practicing clinicians and members of their stakeholder group.

BOX 1-1

List of Steering Committee Members

Erin Mackay (*Co-Chair*), National Partnership for Women & Families

Peter Margolis (*Co-Chair*), Cincinnati Children's Hospital Medical Center

Helen Burstin, Council of Medical Specialty Societies

Hugo Campos, California Precision Medicine Consortium

Kristin Carman, Patient-Centered Outcomes Research Institute

Christine Grady, National Institutes of Health

Adrian Hernandez, Duke University Medical Center and Duke Clinical Research Institute

Kathy Hudson, Hudson Works LLC

Rainu Kaushal, Weill Cornell Medicine and NewYork-Presbyterian Hospital/ Weill Cornell Medical Center

Bradley Malin, Vanderbilt University

Deven McGraw, Ciitizen Corporation

C. Daniel Mullins, University of Maryland School of Pharmacy

Adnan Munkarah, Henry Ford Health System

Harold Paz, Aetna Inc.

Richard Platt, Harvard University and Harvard Pilgrim Health Care Institute

Michelle Schreiber, Centers for Medicare & Medicaid Services

Joe Selby, Patient-Centered Outcomes Research Institute (*until December 2019*)

Mona Siddiqui, Department of Health and Human Services (*until February 2020*)

Frangiscos Sifakis, AstraZeneca

Paul Wallace, AcademyHealth

STAKEHOLDER WORKING GROUP STATEMENTS

Building on and responding to the vision statement are three stakeholder statements, each written from the perspective of one of the three stakeholder communities—patient and family leaders, researchers and research oversight leaders, and health care executives (see Chapters 3, 4, and 5). Developed through a consensus-driven process, the statements describe the importance of data sharing, linkage, and use for facilitating continuous learning and improvement; the key cultural, political, and ethical barriers for each community in realizing the vision of data sharing; and successful approaches and principles for addressing those barriers. Technical barriers and solutions to data sharing and linkage were outside of the scope of this initiative.
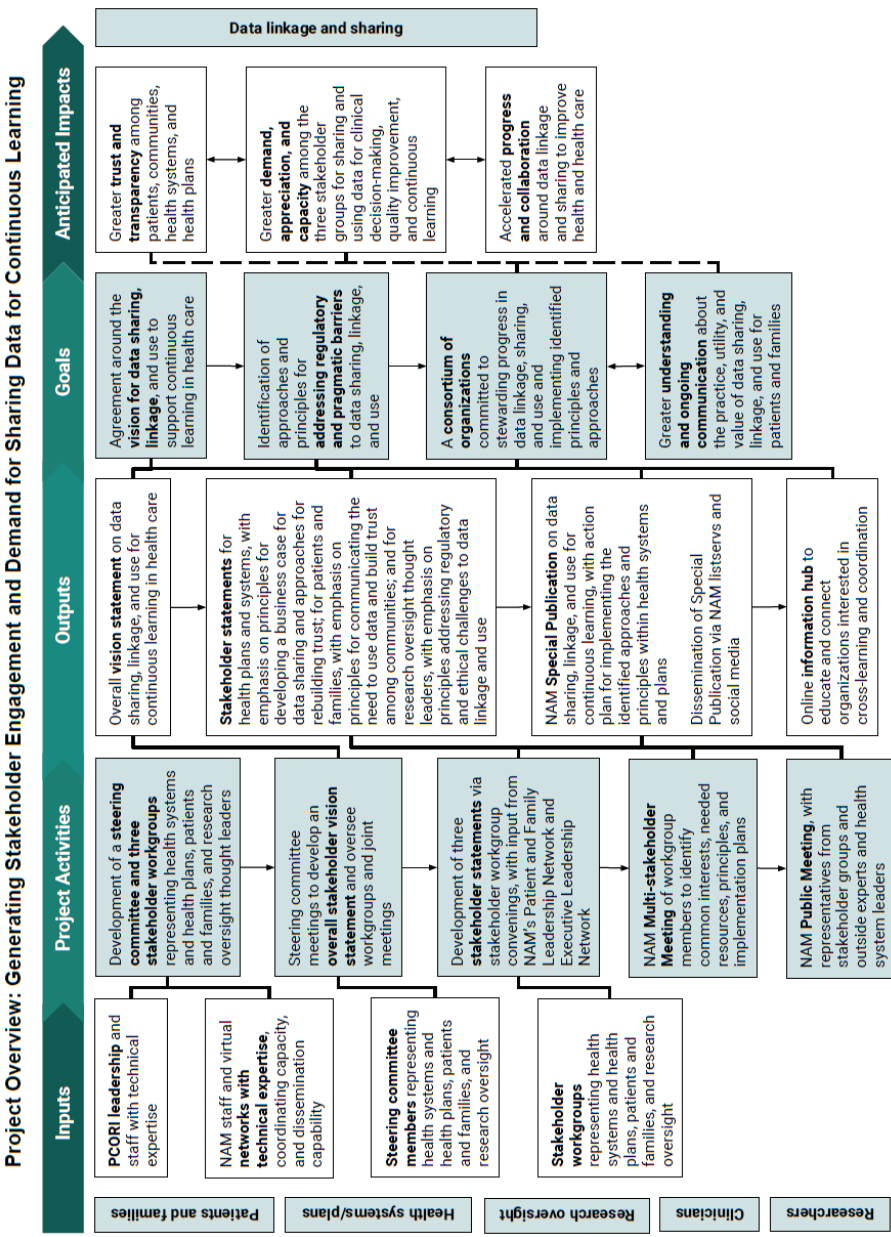
Project Overview: Generating Stakeholder Engagement and Demand for Sharing Data for Continuous Learning

Inputs	Project Activities	Outputs	Goals	Anticipated Impacts

Data linkage and sharing

Inputs

PCORI leadership and staff with technical expertise

NAM staff and virtual networks with technical expertise, coordinating capacity, and dissemination capability

Steering committee members representing health plans, patients and families, and research oversight

Stakeholder workgroups representing health systems and health plans, patients and families, and research oversight

Project Activities

Development of a steering committee and three stakeholder workgroups representing health systems and health plans, patients and families, and research oversight thought leaders

Steering committee meetings to develop an overall stakeholder vision statement and oversee workgroups and joint meetings

Development of three stakeholder statements via stakeholder workgroup convenings, with input from NAM's Patient and Family Leadership Network and Executive Leadership Network

NAM Multi-stakeholder Meeting of workgroup members to identify common interests, needed resources, principles, and implementation plans

NAM Public Meeting, with representatives from stakeholder groups and outside experts and health system leaders

Outputs

Overall vision statement on data sharing, linkage, and use for continuous learning in health care

Stakeholder statements for health plans and systems, with emphasis on principles for developing a business case for data sharing and approaches for rebuilding trust; for patients and families, with emphasis on principles for communicating the need to use data and build trust among communities; and for research oversight thought leaders, with emphasis on principles addressing regulatory and ethical challenges to data linkage and use

NAM Special Publication on data sharing, linkage, and use for continuous learning, with action plan for implementing the identified approaches and principles within health systems and plans

Dissemination of Special Publication via NAM listservs and social media

Online information hub to educate and connect organizations interested in cross-learning and coordination

Goals

Agreement around the vision for data sharing, linkage, and use to support continuous learning in health care

Identification of approaches and principles for addressing regulatory and pragmatic barriers to data sharing, linkage, and use

A consortium of organizations committed to stewarding progress in data linkage, sharing, and use and implementing identified principles and approaches

Greater understanding and ongoing communication about the practice, utility, and value of data sharing, linkage, and use for patients and families

Anticipated Impacts

Greater trust and transparency among patients, communities, health systems, and health plans

Greater demand, appreciation, and capacity among the three stakeholder groups for sharing and using data for clinical decision-making, quality improvement, and continuous learning

Accelerated progress and collaboration around data linkage and sharing to improve health and health care

Patients and families | Health systems/plans | Research oversight | Clinicians | Researchers

FIGURE 1-1 | Generating stakeholder engagement and demand for sharing data for continuous learning.

After identifying a list of barriers, members of the three working groups converged in February 7, 2019, for an in-person meeting in Washington, DC. The purpose of the meeting was to prioritize the most important barriers, discuss areas of overlapping interest, and identify the opportunities and steps achievable within the next 2 or 3 years to overcome those barriers. In addition, meeting participants considered a wide range of organizations that should be involved in implementing the necessary changes (see Chapters 3, 4, and 5 and Appendix B).

OVERLAPPING THEMES

To share and collect reactions to the barriers and solutions identified by the three working groups and discuss overlapping themes as well as next steps, the NAM hosted a meeting in August 2019, that brought together working group and steering committee members with outside experts who have the authority to implement some of the solutions identified in the stakeholder statements (see Appendix C). The goal of the meeting was to begin to build a network of organizations committed to facilitating the change necessary for widespread data sharing, linkage, and use.

The strategies discussed during the meeting and in this document aim to promote progress toward addressing the nontechnical barriers to data sharing, linkage, and use to improve health care and health outcomes across the United States. Efforts most crucial to this undertaking require improving communication among stakeholder groups regarding how data can be used to shape progress; developing a business case for data sharing tailored to address the priorities of each stakeholder community; and securing the strong commitment of health system and health plan leaders, research oversight thought leaders, and patients and families to create a vision of how to overcome these barriers.

2

VISION AND STRATEGY BACKGROUND

A VISION FOR A LEARNING HEALTH SYSTEM SHARING DATA FOR CONTINUOUS IMPROVEMENT

As a defining starting point, the steering committee developed a vision statement to describe the ideal state for data sharing, linkage, and use to facilitate continuous learning and care improvement.

Vision Statement

A health system that shares and applies routinely generated health data and information to support continuous learning to transform health, health care, and health equity, and does so in a manner that enhances stakeholder trust, experience, and transparency in system performance.

STRATEGIC APPROACH

THE POTENTIAL OF ELECTRONIC HEALTH DATA

In recent decades, the amount of electronic health data generated by health systems and health plans, biopharmaceutical organizations, health care consumers, and a variety of organizations outside health care has rapidly expanded (IDC, 2014; Stanford Medicine, 2017). Many advances have enabled this electronic health data revolution, including the introduction of electronic health records in health systems and hospitals; systems interoperability and uniform reporting; federal investments

and incentives; the availability of transactional health care data; new biometric and genomic data; and the development of technologies and applications that allow individuals to assess their own health and well-being, upload health data to electronic repositories, and access their online medical records (Adler-Milstein et al., 2015; IOM, 2013; Raghupathi and Raghupathi, 2014; Sim, 2019). The data resulting from these advances have the potential to dramatically improve health, health care, and health equity among Americans. They make it possible to provide important information to patients, caregivers, clinicians, and health care organizations, resulting in improved decision making and outcomes.

The routine use of health data1 is a central component of a continuously learning health care system in which, as the National Academy of Medicine has stated, "science, informatics, incentives, and culture are aligned for continuous improvement and innovation, with best practices seamlessly embedded in the care process, patients and families active participants in all elements, and new knowledge captured as an integral by-product of the delivery experience" (NAM, 2015). Another critical feature of a continuously learning health care system is that it is driven by its stakeholders. Patients and families, health care executives, researchers, clinicians, community members, and other stakeholders should be actively engaged in identifying deficiencies and opportunities in the system, prioritizing and designing efforts to address those deficiencies and opportunities, and ensuring that the information generated from those efforts is translated into meaningful system improvements.

EXISTING BARRIERS TO DATA SHARING, LINKAGE, AND USE

Despite recent efforts to improve the engagement of stakeholders in decision making about the appropriate use of electronic health data, many health care consumers are still unaware of how data are being used and how these data could be used more effectively to improve health care and outcomes (Kim and Helfand, 2018). They are more aware of news stories about major security breaches than they are of the potential for health data to improve health (Blumenthal, 2017).

---

[1] Health data refer to all of the information that accumulates about a person or population that may affect health outcomes. This includes, but is not limited to, health data generated during clinical encounters and stored in electronic health records or other data systems; health insurance claims data; data gathered from clinical and health services research; genomic, proteomic, and immunomic data; data related to the social and environmental determinants of health collected during clinical encounters or outside of the health care system through community, state, and federal organizations; and patient-generated health data, which has been defined as health-related data created, recorded, or gathered by or from patients (or family members or other caregivers). As an understanding of health continues to evolve and the types of data that are routinely collected continue to expand, this list will continue to expand and evolve as well.

Some organizations have begun to leverage health data to improve outcomes and health system performance. However, these data have generally remained siloed, have so far had only marginal effects on health, and have had limited reliability. Generating robust information to support continuous improvement requires sharing and combining data so that differences in outcomes resulting from alternate health care interventions or approaches to delivering care can be efficiently detected and measured. Additionally, linking data from different sources can provide more complete information and allow for a greater number of questions to be addressed. Achieving the vision for a health system that shares data for continuous improvement requires breaking down silos, linking data among data holders, and using those data to maximum advantage in improving health.

Today, major ethical, regulatory, cultural, financial, and operational challenges limit the routine sharing and linking of data among data holders. Efforts are under way to address the technological challenges, which include a lack of interoperability and poor data quality, but resolving the technological challenges alone is not sufficient (Holmgren et al., 2017). The ethical, regulatory, financial, operational, and cultural challenges also need to be addressed. These include the absence of business models to support sharing data across organizations; barriers related to informed consent and privacy protections; the need for better ways of educating and engaging consumers about data transactions; and the creation of more widespread awareness about how electronic health data can improve individual, population, and systems outcomes.

GENERATING STAKEHOLDER SUPPORT AND DEMAND

Addressing these barriers requires the commitment and support of many important stakeholder groups, including patients and their families, clinicians, the research oversight community, and health care executives. Each of these groups has unique interests and concerns related to the sharing, linkage, and use of electronic health care data:

- Patients and families want more access to their health information, including the ability to seamlessly share information with others. Patients and families also want more transparency and control over how their electronic health data are used by others.
- Health systems, clinicians, health plans, public health agencies, and biopharmaceutical companies are well positioned to leverage data sharing for improved patient outcomes, clinician satisfaction, discovery, and overall system performance. However, to the extent that health data are seen as tools of

competitive advantage, creative thinking about how to incentivize data sharing will be necessary.

- The research oversight community is concerned with ensuring that electronic health data are shared and used in ways that appropriately balance population-level interests in generating new knowledge for current and future patients with the need to protect individuals and groups from risks, such as those that might arise from privacy intrusions and data misuse.

Reflecting the distinct interests and concerns of stakeholder groups, conversations among these groups have been limited, as have efforts to facilitate conversations among these groups to foster a shared understanding of opportunities, approaches, and common principles. Improving communication and engagement both within and across stakeholders is critical to building support and demand for responsible sharing, linkage, and use of electronic health data.

KEY POLICY AND CULTURAL LEVERS TO FACILITATE PROGRESS

Several crosscutting policy and cultural levers could facilitate progress toward achieving the vision of a health system that employs data to support continuous improvement, including the following:

- **Routinely and systematically engaging stakeholders across the health care system in conversations about how electronic health data may be used to support health and health care improvements.** Health care consumers, clinicians, health care leaders, and policy makers need to be engaged in conversations about the practical uses and benefits of electronic health data as well as the risks of harm and how those have been mitigated. Such data may be used to support informed decision making when patients are considering different treatment options. This engagement should consider each stakeholder's relationship to the broader health care ecosystem as well as the cost–benefit considerations relevant to that stakeholder in achieving the stated vision. Effective approaches to engagement must involve clear guidelines to resolve conflicts when disagreements arise regarding policies or approaches to support data sharing. While some engagement efforts are under way, particularly in clinical research, discussions about electronic data sharing need to be much more extensive.
- **Implementing systematic approaches for demonstrating value that results from the use of electronic health data.** Engendering support for

data sharing will require greater awareness of how the use of electronic health care data has led to improved outcomes for patients, higher levels of patient and clinician satisfaction, reduced health care costs, better access to necessary services, and other benefits. Achieving this goal requires that patients, caregivers, and providers have access to information generated from data-sharing efforts at the point of care and in formats that allow them to use that information to support health-related decision making. These approaches should also create incentives for innovation and competition within and across the organizations that comprise the U.S. health care system.

- **Developing and maintaining a trustworthy data-sharing environment.** A trustworthy data-sharing environment must ensure ethical uses of health data. It must demonstrate respect for individual data sharing and linkage preferences through the adoption of appropriate oversight, disclosure, and consent practices; maintain a commitment to data security; and ensure privacy at every step of the data management life cycle, from data collection, to their use in a primary care setting, to their analysis and sharing in secondary settings. Policies for electronic health data sharing must explicitly prohibit the use of those data for discriminatory purposes as well as the re-identification of anonymized data. Developing and maintaining trust also will require informing health care consumers of federal, state, and other system-specific policies related to data collection, sharing, and use so that consumers understand when and how their data are protected. Finally, the health care system should work to engender trust by preventing the use of electronic health care data to gain competitive advantage.

- **Addressing structural incentives that discourage electronic data sharing.** The dominant fee-for-service payment model in the U.S. health care system provides little incentive to share information. To facilitate change, outcomes and payments need to be aligned in the delivery of value-based care. In addition, resources need to be available to maintain data integrity, reliability, and access, such as a state-of-the art data security framework and data governance and use policies. Resources are also needed to support the hiring and training of staff with the appropriate expertise to maintain data-sharing efforts and to function on investigative teams within health care organizations.

CONCLUSION

The health care system faces a momentous challenge that is linked to an unprecedented opportunity. The current system has unacceptable shortcomings and unsustainable costs. At the same time, it has an opportunity to apply new tools

and technologies to help solve these problems. Working together, key stakeholders could capture this opportunity by better sharing, linking, and using electronic health data. Transforming the U.S. health care system into one that continuously learns and improves requires addressing ethical, regulatory, operational, financial, and cultural barriers. Technological barriers also exist and have been analyzed in many other locations—this Special Publication focuses on the other barriers. Such a transformation could result in a health care system in which the generation of new knowledge is embedded into and an expected goal of care delivery.

The current initiative aims to engage patients and family members, health care leaders and health plan executives, and the research and research oversight community in a coordinated effort to identify the critical issues, overcome the barriers to resolving those issues, and build demand for the routine sharing and use of data to improve health.

3

STATEMENT OF THE PATIENT
AND FAMILY LEADERS

To improve health care generally and their own health specifically, patients, families, and caregivers want to be able to access, contribute to, and share their health and personal data, particularly with respect to information and outcomes that are important to them (Haug, 2017). They also want transparency in all cases in which their data are aggregated, whether for public health or for commercial purposes (e.g., drug development). This is because the unauthorized access and/or disclosure of health data jeopardizes trust in the health system and could be used to discriminate against patients in insurance access or rates or employment (Kravitz and Allen, 2018; *The New York Times* Editorial Board, 2016). In addition, patients want access to research results that may directly impact their care.

The extent to which patient, family, and caregiver involvement in the sharing, linkage, and use of data can improve health and health care is not widely recognized by stakeholders in the health care system. The resulting underuse of data can hamper disease self-management, clinical decision making, and research involving health data.

This statement describes key barriers and solutions for leveraging and sharing health data from the perspective of the patient and family leaders working group (see Box 3-1).

CONCERNS AND BARRIERS

From the perspective of this stakeholder group, the key concerns and existing barriers to advancing data sharing, linkage, and use can be divided into four categories: (1) cultural barriers, (2) organizational barriers, (3) pragmatic and operational barriers, and (4) regulatory barriers.

BOX 3-1

Members of the Patient and Family Leaders Workgroup

Stacey Lihn (*Co-Chair*), National Pediatric Cardiology Quality Improvement Collaborative

Susan Woods (*Co-Chair*), Society for Participatory Medicine

Christine Bechtel, X4 Health

Janet Freeman–Daily, Patient Advocate and Gray Connections

Danny van Leeuwen, Health Hats

Kameron Matthews, Veterans Health Administration

Sally Okun, PatientsLikeMe (*until December 2019*)

Casey Quinlan, Mighty Casey Media

John Santa, OpenNotes

Andrew Sperling, National Alliance on Mental Illness

Sharon Terry, Genetic Alliance

Veronica Todaro, Parkinson's Foundation

CULTURAL BARRIERS

The organizations and individuals that generate, collect, and store health data ("data holders") tend to lack awareness and understanding of the ways in which the participation of patients, families, and caregivers in health data collection can improve health care, despite growing research that points to the potential benefits of such involvement (Castle-Clarke and Imison, 2016; Toll et al., 2019). Electronic health record (EHR) data are largely encounter-based data, which are filtered and entered by clinicians. Contextual and personal information about patients is often missing; however, patients serve as an important source of data about their home and environment, their social and behavioral information that could be key to treatment (Zulman et al., 2016), and their own patient–reported outcomes (Jim et al., 2020). Providers can underestimate patients' "invisible work" as well as patients' expertise about their own health issues and self-care (Klasnja et al., 2010; Valdez et al., 2015). Without awareness of the myriad types of data patients can supply, stakeholders may not fully appreciate the many ways in which patients and caregivers could support efforts in care delivery and health improvement. This leads to underestimating how patient–generated data can assist with reconciliation of health data, enhance health record completeness and accuracy, and improve population health outcomes (Lavallee et al., 2020).

In addition, there is an imperfect understanding about individuals' rights to their data under the Health Insurance Portability and Accountability Act (HIPAA), the federal law that puts forth national standards for the protection, use, and disclosure of an individual's sensitive health information. Clinicians and health systems are not sufficiently responsive to patient, family, and caregiver requests for health data. They have been reluctant to support full clinical data transparency with patients or promote data-sharing systems, in part owing to concerns about additional workload, disrupted workflows, or a lack of understanding regarding legal requirements for sharing medical or mental health data. Clinicians and health systems generally do not seem to recognize and appreciate that patients, families, and caregivers are major users, managers, and contributors of data, even though this is the case in other industries (e.g., travel, banking, fitness, and web-based retail). Banking, retail, and travel have fundamentally altered how consumer data are used to facilitate smooth and easy transactions. Yet, health care, as an industry, has resisted a similar shift. Clinicians and health systems believe that health data are useful for informing clinician decision making but not necessarily for patient decision making and care self-management, despite evidence to the contrary (Cohen et al., 2016; Hixson et al., 2015).

These factors collectively contribute to a less-than-ideal culture of data sharing across the health care system, one that does not embrace patients, families, and caregivers as core members of that system (Topol, 2016). Some health care systems do recognize the value of patient-generated data and are integrating these data into their strategies and operations. Yet, barriers continue to exist, preventing the evolution of such initiatives and limiting their scale and dissemination. Some patients mistrust the health systems and other firms that collect data, and other patients often have difficulty accessing their own health data, which can undermine their willingness and ability to provide data.

ORGANIZATIONAL BARRIERS

Health information technology (IT) systems (e.g., EHRs) tend to focus on business processes and billing. They generally devote fewer resources to providing patients with convenient access to their data or to patients' ability to directly provide data electronically. Other aspects of health IT systems, such as patient portals, are often not sufficiently designed to work well for patients (Archer et al., 2011; Farber et al., 2015; Irizarry et al., 2015; Ryan et al., 2016; Taha et al., 2013). Despite their name, "patient portals" only provide a fraction of the patient's information that resides in EHRs. Some systems limit the types of data available to patients and families. Data may be available but not conveniently accessible,

which means that the patient often has to navigate several screens before being able to download his or her data. In general, health systems may underestimate the burden and degree of work required by patients to find, access, compile, update, and exchange health data, which negatively impacts patient experience and willingness to engage (Ancker et al., 2015; Gordon et al., 2018).

Clinicians often lack an established and routine workflow with which they can comprehensively capture all patient information, including patient-reported data (Cohen et al., 2016; Genes et al., 2018). Features of EHR systems also can contribute to clinician burnout, which can lead to negative effects for patients (e.g., resistance at the organizational level to implement additional technology solutions for patients) (Kroth et al., 2018).

Health IT vendors are typically incentivized to ensure the efficiency and effectiveness of their systems for the organizations using those systems rather than to consider the applicability of the systems and the data they contain for patients. Those vendors often are not incentivized to effectively enable data sharing with other vendor systems—creating technological silos. This is compounded by issues of data blocking by health systems or data holders, which have not been adequately addressed.

PRAGMATIC AND OPERATIONAL BARRIERS

Patients, families, and caregivers face many obstacles in providing health data. Ready- and easy-to-use web-based and mobile channels that solicit and allow patients to provide data that can directly be accessed by clinicians and integrated into clinical IT systems such as EHRs are lacking. The reconciliation of data represents an additional obstacle. Clear mechanisms that patients can use to suggest corrections to erroneous or outdated data collected about them by health systems, payers, or others are absent. Patients encounter cumbersome processes when requesting to update or correct their health data. Inaccurate information can lead to patient safety hazards and negatively impact a myriad of factors—for example, entities sometimes use patient data to generate risk scores, which dictate the pricing of services (Bell et al., 2017; Bourgeois et al., 2019; Landi, 2019; Ravindranath, 2019). Evidence shows that patients' feedback and input can improve the accuracy of their health record data (Dullabh et al., 2014).

EHRs typically do not allow providers to catalog patients' preferences about with whom they would like to share their information. In addition, patients generally are not able to confirm the accuracy of information in their medical records or provide additional information (Nyrop et al., 2019).

REGULATORY BARRIERS

A variety of regulatory barriers inhibit the sharing, linkage, and use of health data. Furthermore, these barriers are greater for some subpopulations, including adolescents, racial and ethnic minorities, and members of marginalized groups—many of whom struggle with challenges related to accessing and using devices and tools—even though some research suggests that these individuals have the most to gain from access to health data (Walker et al., 2019).

The legal requirements associated with data sharing often lack clarity. For example, regulatory policies and institutional review board decisions are inconsistent about the return of genomic research results to patients when tests are not conducted in a Clinical Laboratory Improvement Amendments–certified laboratory. Hospitals often are not in compliance with federal and state regulations regarding the release of information in medical records (Lye et al., 2018). Patients lack simple methods to complete identity proofing and provide permission for low-barrier, bidirectional data sharing.

The management of rare diseases provides a striking example of how regulatory barriers impede care. Patients with rare diseases are especially eager to contribute to research by donating data and tissue, and patient–partnered research is becoming more common (Kirwan et al., 2017). However, data generated on a specific patient are not easily linked across research studies, even when that patient is willing to consent to such linkage. Current regulatory policies, research practices, and EHR design all hinder patient–partnered research.

PRIORITIES AND ACTION STEPS

From the above description of concerns and barriers, the stakeholder group representing patients and families identified five priority issues that need to be addressed to facilitate widespread data sharing. When prioritizing the barriers, the working group members considered which barriers represented the most significant issues preventing widespread data sharing and linkage to improve patient care and which could be either wholly or partially addressed in the next 2 to 3 years. Some of these priorities combine several of the themes from the previous section.

1. Patients wanting but not being granted access to health data

All stakeholders in the health system should be aware of patients', families', and caregivers' rights and desires to benefit from and be involved in the provision, receipt, management, and use of health data. Though patients have not been seen

as primary users of health data, evidence documents the benefits of supporting patient and family data-sharing preferences (Avram et al., 2018). Patient demand for data sharing is only likely to increase in the coming years because younger patients who have grown up in the digital era are especially likely to demand access to their data and will be propelled by the Centers for Medicare & Medicaid Services (CMS) *Interoperability and Patient Access and Office of National Coordinator 21st Century Cures Act: Interoperability, Information Blocking, and the ONC Health IT Certification Program* rules (Nelson, 2019) (see Chapter 5).

In addition, an action step achievable within 2 to 3 years is the development of a national campaign led by a consortium of advocacy organizations designed to increase awareness among data-holding entities such as health systems and EHR vendors about the benefits of bidirectional data exchange, which will de facto educate patients about the potential uses for data and the rights they have with regard to data sharing and access. This campaign should tie together different disease communities and target crosscutting groups like the National Health Council, PatientsLikeMe, or the National Patient Safety Foundation, along with representatives of health systems, insurers, clinicians, pharmaceutical companies and other data holders.

Another action step is for OpenNotes, CARIN, and FasterCures to champion guidelines for how to engage patients, payers, caregivers, clinicians, hospital administrators, and compliance officers in seeing the value of transforming data into useful information to be used virtually at the point of care.

A longer-term goal is to pursue a "patients first" approach to data access. Such an approach would prioritize data transparency and reciprocity while recognizing that interest in and preferences for data sharing may vary among individual patients and among groups sharing particular conditions (Nelson, 2019). An action step would be to convene patient advocacy groups and networks representing chronic and acute conditions, pediatric and adult conditions, and rare and common conditions to develop statements on patient data access needs and preferences. The questions these statements could address include the following:

- What types of information do patients want to access, and what are the preferred methods of getting that access?
- What does bidirectional data exchange entail?
- What is the appropriate reimbursement structure for covering the costs of exchanging, reviewing, and using data for care delivery?
- How do data link to patient outcomes?

At the national level, the Office for Human Research Protections should develop guidelines that clarify the type of sharing permitted by HIPAA. These guidelines

should be available in patient-friendly language and should be accessible through appropriate media.

In the area of mental health, policy makers and patient advocacy groups should work together to address policy barriers to data sharing. The Veterans Health Administration (VHA) shares mental health notes, and the VHA has created a course to help veterans understand how to access and understand mental health and other sensitive topic notes in their EHRs (Dobscha et al., 2016). This could serve as a model for various health care settings.

2. Insufficient appreciation among stakeholders that patients and families are key providers of patient-generated data

Evidence-based arguments for sharing health-related data, including the potential harms of not sharing data, could demonstrate to all stakeholders the value of data sharing. Case studies demonstrating these benefits should also be made available (Bell et al., 2017; Kreimer, 2015; Nelson, 2019; Schulte and Fry, 2019). Data sharing can be a component of patient safety, self-management, and quality improvement, contributing to a new standard of care. Evidence also shows the benefits to scientific studies of inviting patients to contribute their data for research purposes (CancerBase, 2020; Count Me In, 2020).

A systematic review of research could characterize patient preferences related to data sharing at the point of care as well as the benefits of data sharing for research purposes. Use cases from organizations that have facilitated bidirectional data exchange could include Geisinger, Dartmouth, the VHA, and Kaiser Permanente (Anderson et al., 2017; Bourgeois et al., 2019; Geisinger, 2018; Mafi et al., 2018;VA, 2018). Disseminating research could help address cultural barriers to widespread patient data access, especially if the link is made between data sharing and value-based care results.

Opportunities to contribute data to publicly funded research projects, particularly to projects related to outcomes and preferences such as the All of Us Research Program, should be a core feature of health data management nationally. This would provide a real-life context for patients to understand the power and the value of data aggregation and sharing. Many organizations could provide examples of the value of bidirectional data exchange to both care and research, including the epilepsy and the amyotrophic lateral sclerosis communities, the metastatic breast and prostate cancer communities, the angiosarcoma and gastroesophageal cancer communities, and the hereditary cancer communities (BRCA Exchange, 2020; Broad Institute, 2020; Harvard Medical School, 2020). If commercial entities are provided with access to patient datasets, there should be

a central fund aggregation pool that can put those commercial payments to use in funding public research and in defraying the costs to patients and families of participating in research. Perhaps, a portion of the fees collected from commercial entities by the Centers for Medicare & Medicaid Services (CMS) Research Data Assistance Center could be re-invested into making data useful and eventually lowering the cost to access (ResDAC, 2020a).

3. Lack of understanding among stakeholders of how patient–generated data can improve workforce efficiency, enhance data coverage and accuracy, and yield better population health outcomes

An action step is to present certifying and specialty boards with data about the barriers to data sharing and engage them in developing tools that clinicians can use to determine how to inform patients about data-sharing opportunities. One successful example is the partnership between PatientsLikeMe and the American Academy of Neurology (AAN) to improve quality care guidelines for epilepsy and the training of future neurologists. This work resulted in the addition of two quality measures informed by patients and included in the "Epilepsy Update: Quality Measurement Set" approved by the AAN Quality and Safety subcommittee (Wicks and Fountain, 2012).

4. Financial disincentives to data sharing

Most health care systems and clinicians can only bill for time spent providing information to patients during appointments and not by communicating with patients through online portals, e-mail, text, or other digital media. Providers may be concerned about being overburdened by new workflows and technologies to support bidirectional data sharing, especially if EHRs are poorly designed. A commitment to develop a compensation strategy for asynchronous care and electronic communication could help allay these concerns. In the wake of the coronavirus disease 2019 (COVID-19) pandemic, insurers and federal agencies have relaxed regulations around virtual care. A specific action step is to create reimbursement codes for bidirectional communication among providers, staff overseeing clinical data systems, and patients. A related longer-term opportunity for modifying clinician and patient behavior is to change the reimbursement structure to one that pays for patient-centric value, outcomes, and population health. Considerable work is ongoing in this area, but a majority of reimbursement remains fee-for-service.

Additionally, patient advocacy groups and organizations serving disease-specific

communities could help reframe notions about the risks and benefits of data sharing, changing perceptions so that the risks associated with not sharing data are greater than those associated with sharing data. The most significant risks associated with not sharing data are misdiagnosis, late diagnosis, repeat tests, poor care coordination, and medical errors, with consequent effects on health, care quality, and costs to patients, payers, and the U.S. health care system. Advocates for data sharing could help demonstrate that these risks are greater than those related to the potential harms of data sharing.

Another action step is to develop a communication campaign targeted at health systems and physician professional societies highlighting evidence that data sharing in health settings decreases risks for clinicians and health organizations (Kreimer, 2015; Quinn et al., 2012; Tai–Seale et al., 2019). Organizations to be engaged in developing such a campaign include the Council of Medical Specialty Societies, the Institute for Patient– and Family–Centered Care, the Society to Improve Diagnosis in Medicine, and the Institute for Healthcare Improvement. Among the examples that could be cited are the Virginia Mason health system in Seattle, which has adopted a position of data transparency and full accountability for mistakes involving data, and the national Culture of Safety movement, which called for admitting to errors, figuring out root causes, addressing associated costs, and reducing immediate impacts (Kamo et al., 2019). At the same time, patient advocacy organizations could work with malpractice insurance companies to integrate expert patient participation into their work and to increase organizational knowledge of patients' interest in bidirectional data exchange.

5. Lack of workflows and technologies that make it easy for providers to incorporate patient-generated and patient-held data

Apps, patient portals, and other tools, such as personal health records, could enable patients to easily gather and share their own data. Such tools could also help patients understand and shape the ways data are used; the ability to turn on and off access to different categories of data would increase trust and data accuracy (Kreimer, 2015). However, linkages between some apps and patient portals are such that each time a piece of information is added or changed in the EHR, the patient must manually initiate a new download of data to his or her app. The ability to "set and forget" automated data feeds between EHRs and apps will be critical to making patient workflows easier. For example, a probable solution is one demonstrated by the Health Level Seven International Fast Healthcare Interoperability Resources Argonaut Project technical standard, which includes a provision for "persistent token" access. This provision enables ongoing connectivity without requiring a

manual data request. CMS has implemented a policy of persistent token access for 1 year, unless revoked, in its Blue Button 2.0 application programming interface.

Design challenges in technology need to be addressed using a human-centered approach, especially with regard to transforming data into information that is useful for patients *and* providers. Efforts are under way at the Patient Family-Centered Care Partners—a group consisting of patient family advisors, health care administrators, clinicians, and social workers—to design a patient portal that facilitates increased communication among patients, families, and care providers.

In addition, new technology is needed to make data sharing between patients and providers easier and more beneficial for clinicians in a way that alleviates the burden of data collection for clinicians. For example, technology that would facilitate the comparison, selection, and exchange of data between a patient's device and an EHR, much like exchanges between smartphones, could make it easier and faster for clinicians to integrate patient-held data, whether those data are generated by other clinicians and specialists, pharmacies, laboratories, or the patients themselves. (Genes et al., 2018; Nkoy et al., 2019). This also would facilitate the transfer of medical data when patients see new or multiple providers. CMS's new Data at the Point of Care program enables this very scenario and could serve as a model for other entities (CMS, 2019a).

In partnership with patients, clinicians, health system leaders, HIPAA experts, and others, technology companies should continue to develop solutions that allow patients to access relevant information in EHRs, provide feedback on errors and completeness, and contribute their own health data. An action step would be for The Office of the National Coordinator for Health Information Technology or another entity to issue a challenge in which companies would compete to develop and present the most viable way to instantaneously upload and use patient data in EHRs and for data from the clinical record to be meaningfully visualized for patients' use.

SOLUTIONS IMPACTING MULTIPLE PRIORITY BARRIERS

An action step that would address many of the barriers identified above is to measure and publicly report data on the level of access health care providers give to patients, as well as the level of bidirectional exchange with patients and with other providers. These measures could be process or structural measures and could be reported on Hospital Compare, Physician Compare, and individual ratings sites managed by payers, accrediting bodies, private entities, and others (e.g., Consumer Reports, Checkbook).

The federal government will need to make an initial investment in determining

appropriate measures. Measures should be co-designed with patient advocates.

RESPONSIBLE ORGANIZATIONS

Many groups will be responsible for implementing the action steps described above, including

- providers,
- patient advocates,
- researchers,
- health disparities advocates,
- malpractice lawyers,
- medical ethicists,
- health IT developers,
- payers,
- employers,
- HIPAA compliance officers,
- consumer advocacy organizations,
- informaticists,
- digital inclusion experts,
- data privacy experts,
- app developers, and
- policy makers and regulators.

Specific organizations to involve include the National Patient Safety Foundation, the National Health Council, the Institute for Patient- and Family-Centered Care, the Institute for Healthcare Improvement, PatientsLikeMe, Faster Cures, and disease-specific organizations and communities.

4

STATEMENT OF THE RESEARCH AND RESEARCH OVERSIGHT LEADERS

There is broad recognition that health data are a cornerstone of current and future health research. However, when health data are shared and used, population-level interests in generating new knowledge must be appropriately balanced with the need to protect individuals and groups from risks, such as those that might arise from intrusions of privacy or data misuse.

This statement describes key barriers and solutions for leveraging and sharing health data from the perspective of the research and research oversight leaders working group, including bioethicists, health law experts, and institutional review board (IRB) members (see Box 4-1).

BOX 4-1

Members of the Research and Research Oversight Leaders Workgroup

Sarah Greene (*Co-Chair*), Health Care Systems Research Network (*until May 2020*)

Russell Rothman (*Co-Chair*), Vanderbilt University

Tanisha Carino, Alexion Pharmaceuticals, Inc.

Jodi Daniel, Crowell & Moring LLP

Bob Harrington, Stanford University

John Lantos, Children's Mercy Kansas City

Emily Largent, University of Pennsylvania Perelman School of Medicine

Michelle Meyer, Geisinger's Center for Translational Bioethics and Health Care Policy

Pearl O'Rourke, Partners HealthCare International

Mark Schreiner, Children's Hospital of Philadelphia

Jeremy Sugarman, Berman Institute of Bioethics, Johns Hopkins University

---

CONCERNS AND BARRIERS

From the perspective of this stakeholder group, the key concerns and existing barriers to advancing data sharing, linkage, and use can be divided into five categories: (1) cultural barriers, (2) ethical barriers, (3) regulatory barriers, (4) financial barriers, and (5) operational barriers.

CULTURAL BARRIERS

Different groups—including researchers, clinicians, patients, health care executives, and other stakeholders in the health care system—and members of these groups have different beliefs about whether data should be freely shared and different working definitions of what constitutes "health data." For example, no standard approach exists regarding how best to involve patients in decision making about the sharing of data—even de-identified data.

These different beliefs arise in part from the shared culture—the set of beliefs, behaviors, and values—of each group. For example, one reason why researchers have been reluctant to share data is that the culture of research rewards scientific productivity and keeping data proprietary rather than making data available as a public good (Kuntz et al., 2019). Even when researchers do engage in initiatives that aim to increase transparency about the ways that health care data are being used, they may encounter resistance from health care executives, patients, clinicians, and other stakeholder groups with differing beliefs.

ETHICAL BARRIERS

In the United States there is not a shared vision or an agreed-upon set of ethical principles regarding data ownership, control, and access requirements, in part because of differing ethical convictions about how data should be gathered, maintained, and used for individual or collective good (Haug, 2017). Differences encompass such issues as who should have control over certain types of data, including when and how data are shared as well as the degree of transparency about data sharing and about the linkages among the organizations and individuals responsible for collecting and storing health data. Additional considerations include what rights patients and clinicians have regarding control over data and any financial gain resulting from the sharing and use of data. These issues are especially important with highly sensitive data and with data involving vulnerable populations or communities.

While many data-sharing efforts that aim to improve health and health care will not meet the federal definition of research involving human participants (U.S. Government, 2017), policies and practices regarding data ownership, access, and control have important implications for health care research that leverages electronic health data as well as for human subjects research and privacy protections.

In addition, researchers can encounter concerns among patients and communities regarding potential unintended consequences of data sharing: for example, whether inappropriate use of shared data could lead to care rationing, discrimination, profiteering, or other adverse effects.

REGULATORY BARRIERS

While regulations focus on minimizing risk, institutions and states vary in their interpretation of regulations and responsibilities related to health data sharing and use. This has led to variability in data-sharing practices, IRB requirements, privacy offices and privacy officer practices, institutional approaches to disclosing information about data sharing to patients, and the structure of data use agreements, among other things. This variability can create significant impediments to multi-institutional research, which is now more common than when the research regulations were introduced. In addition, the absence of clarity about data ownership leads to variation in legal interpretations about data as intellectual property.

To minimize risk, efforts are made to render data non-identifiable (Emam et al., 2015). However, given the maturation of tools and algorithms to compile, match, and re-identify previously non-identifiable data, it is essential to develop more robust anonymization procedures and create effective and enforceable measures that ensure proper stewardship, access, and use (Na et al., 2018; Rocher et al., 2019). Future uses of data will continue to evolve and will be affected by technological advances, especially as personal data are increasingly generated and shared through new social platforms, online patient communities, mobile and wearable devices, and other means. Data from these platforms could be "cross-walked" with other data sources, imperiling privacy and creating unanticipated discoveries (Parasidis et al., 2019). In addition, the uncertainty about the future uses of data has made it difficult to evaluate potential risks beyond re-identification and to determine what should be disclosed to individuals when informed consent is required (Dove, 2015).

Data have value and can be used for financial gain. For example, technology companies and biopharmaceutical companies are increasingly seeking access to electronic health data for commercial development (Cassel and Bindman, 2019) and are not typically bound by the same covenants as health care professionals to keep data confidential, which increases the risk of data misuse (Parasidis et al., 2019). In general, many kinds of companies see commercial potential in health data, particularly when blended with social media and geolocation data.

Another financial consideration is that the cost of purchasing data for research can be prohibitive. This cost can vary by data holder. For example, the Centers for Medicare & Medicaid Services (CMS) has created a tiered pricing schema based on the size of the dataset (ResDAC, 2018), whereas other privately held data vendors deploy different pricing strategies. Completeness and quality of the data may vary by source. Newer companies are creating a consumer-driven model for individuals to determine the value of their data and make them available to industry or other purchasers. Underlying all of this is the fact that the value of data is relative based on the intended use, and no simple formula exists to help data creators or data purchasers navigate this arena.

OPERATIONAL BARRIERS

As data sharing becomes more widespread, challenges related to data governance, provenance, and quality will intensify. For example, the tremendous variability in the quality of electronic health data creates onerous burdens for validating the data prior to research use (Platt and Lieu, 2018).

The time required to prepare and validate data for research often creates a lag from data generation to availability for research that can diminish the utility of the data for some research. An additional barrier is that in the absence of a national systematic catalog of available electronic health data, individual researchers are obligated to conduct a search each time they seek a given data resource.

PRIORITIES AND ACTION STEPS

From the above description of concerns and barriers, the research and research oversight group prioritized five high-priority issues that are critical to address to facilitate appropriate and widespread data sharing and use for improving health and well-being. When prioritizing the barriers, the working group members considered which barriers represented the most significant issues preventing

widespread data sharing and linkage to improve patient care and which could be either wholly or partially addressed in the next 2 to 3 years. Some of these priority barriers combine several of the themes from the previous section.

1. Heterogeneity in beliefs among patients, clinicians, and researchers about whether data should be freely shared

The differing beliefs among stakeholders about how health data should be used has slowed progress. The greatest need, which could be met within 2 to 3 years, is to understand more about what these beliefs are and where they coincide and conflict. A literature review and national survey could identify the beliefs of different stakeholders and knowledge gaps. It would also be useful to understand the heterogeneity that exists within specific patient populations. A research organization could conduct such a study, with funding from the National Institutes of Health (NIH) or the Patient-Centered Outcomes Research Institute (PCORI).

Consistency in policies and clearer understanding of the range of beliefs and attitudes would motivate health systems, health insurers, and researchers to share data. A commentary in a high-profile, peer-reviewed journal could describe a model policy to establish common ground that incorporates a commitment to openness and sharing. Existing policies could then be compared with the model policy to improve consistency.

Funders have made major steps in embracing open science and data-sharing policies, which require that researchers make their results openly available (Hrynaszkiewicz and Altman, 2009). However, they have struggled with implementing new standards and with monitoring and enforcing requirements for data sharing. Promising approaches to promoting data sharing include demonstrating and implementing best practices to incentivize desired behaviors and building infrastructure that makes it easier to conduct and track open science (Bierer et al., 2016).

Health systems and health insurers are significant generators and holders of health data, and these data hold tremendous value in the research context. However, apart from a few vanguard health systems and health plans, the motivation to provide these data for use in scientific research is lacking. In particular, open science is conceptually incompatible with the business model for health care providers, who benefit from internalizing benefits gleaned from their patients' information rather than sharing it.

An important first step would be to create incentives to share data and to learn more about how to encourage stakeholders to take advantage of these incentives.

To lay the groundwork for the development of a set of open science standards, existing policies should be assessed to determine and improve their provisions for openness. Key organizations to engage in this effort include the Department of Health and Human Services (HHS)—in particular, NIH, CMS, and The Office of the National Coordinator for Health Information Technology (ONC)—as well as relevant trade organizations. One useful approach would be to work with the communities and organizations that have made considerable progress on data sharing, such as the pediatric hospital community, the cardiology community, and the Center for Open Science (2020).

Promotion and tenure policies that recognize and reward open science and collaboration would increase the impetus for data sharing (Kuntz et al., 2019; Pierce et al., 2019). In addition, the articulation of ethical principles for data sharing by a multi-stakeholder convening could advance this cause. Organizations to involve in this effort include PCORI, the Office of Science and Technology Policy (OSTP), NIH's Office of Science Policy, and bioethics groups. This would also need significant buy-in from academia and journal publishers. Once such ethical principles are established, training could be developed and provided through professional channels, such as NIH or the Collaborative Institutional Training Initiative.

2. Lack of shared principles regarding data ownership, stewardship, governance, rights, and responsibilities

Without shared principles, organizations and stakeholders work at cross-purposes and collaboration is difficult. Addressing the lack of shared principles will influence many of the other barriers and action steps identified below.

A critical first step would be the convening of a task force to create a consensus statement—with signatories—that would publicly affirm a set of principles and commitments on the collective benefits of data as a public good. A neutral organization such as the National Academy of Medicine could convene such a group. Stakeholders that should participate in the convening include patients and patient advocacy groups, IRB members, users of health data, medical societies, federal agencies (including NIH and its National Library of Medicine [NLM]), health information technology developers, other technology companies that both produce and use data, and health journalists. As part of this work, current perspectives on data ownership should be identified and compared.

A related action step would be to establish a multi-stakeholder commission to craft a code of conduct for data holders (Sim, 2019) and an accompanying "patient health data bill of rights" to ensure that both the generators and the

users of data have clear understandings and expectations of how data will be held and shared (see, for example, Knoppers et al., 2011). This code of conduct should (1) describe appropriate data stewardship models; (2) establish a fiduciary role for data holders and identify criteria for data sharing and use for those data holders; and (3) define the scope of what needs governance (e.g., the permitted uses of data or the review of data use), who should govern, and the pros and cons of different data governance models. The major standard-setting bodies, such as Health Level Seven International, will need to be engaged to identify optimal governance approaches. The governance system for the All of Us Research Program may be a valuable model. Lessons learned from the implementation of the General Data Protection Regulation in the European Union, which governs data protection, privacy, and portability and applies to all companies processing the personal data of people residing in the European Union, could provide additional guidance (European Union, 2020).

A complementary action step is to establish a federal commission that could seek agreement on issues of data control and data protections. Federal organizations that should be involved in this effort include HHS, ONC, OSTP, the Food and Drug Administration, the Office for Human Research Protections (OHRP), the Office for Civil Rights (OCR), and the Centers for Disease Control and Prevention (CDC). It may also be worth including the Federal Trade Commission and the Federal Communications Commission. These two Commissions should be clear about the link between clinical and claims data and other data types/systems. This is a bipartisan issue on which rapid progress could be made, especially with leadership from the White House.

Federal agencies should create clearer guidance concerning data policies, including any legal restrictions. The newly finalized ONC and CMS regulations on data blocking and interoperability will shape this effort. (See Chapter 5 for a description of these rules.)

These action steps could be part of a broader effort to develop a statement or identify existing statements that articulate reasons to share data, such as altruism, community-mindedness, future benefit, and solidarity. As a longer-term opportunity, stakeholders in the health care system could collaborate to establish a national honest broker akin to Medicare to house and share data, to allow merging of data, and to establish uniform coding that would allow data to be anonymized (Boyd et al., 2007; Dhir et al., 2008). As an initial step, it would be useful to speak with CMS's Virtual Research Data Center and Research Data Assistance Center to assess the time and resources required to establish these capabilities (ResDAC, 2020b).

3. Uncertainty about potential uses of data and accompanying concerns about consequences arising from inappropriate or unauthorized use

Many uncertainties surround potential future uses of data and the ramifications of those uses. Controversial cases include the use of data for competitive advantage or commercial gain, rationing care, and discrimination as more data become available (e.g., genomic data) (Parasidis et al., 2019). A recent example of a controversy involves the transmission of data from machines that people use to treat sleep apnea to insurance companies and to the companies that manufacture and distribute the devices (Marshall, 2018).

The potential value of health data is drawing considerable commercial interest—these data are useful in, for instance, research, product development, and advertising, the latter of which raises concerns (Thielman, 2017). Research on the valuation of health data, on the effects of uncertainty on this value, and on other commercial issues associated with health data will help resolve questions that arise. This research should be informed by discussions about data ownership, stewardship, governance, rights, and responsibilities, as described under the first priority barrier above. Specific questions include the following:

- Should data be monetized? If so, how should data be monetized (for short-term use, for long-term use, in each instance)?
- Who should be compensated for the use of health data (patients, organizations that collect and store the data, no one)?
- What can be learned from other industries about the value of data, given that health data are characterized by high volume, inherent dynamism, and innumerable permutations for use in a research context?

This work likely will require different sources of funding for different questions. For example, the Robert Wood Johnson Foundation, The Donaghue Foundation, or The Greenwall Foundation might support work addressing the question of compensation described above. Improving approaches for communicating with patients in plain language about how their data are collected and used is also essential. Potential approaches include

- developing improved approaches to patient privacy notifications and consent for data sharing that embrace principles of health literacy and use plain language (Ridpath et al., 2009; Stableford and Mettger, 2007; Vernon et al., 2007);
- empirically testing such language for salience, comprehension, and so on; and
- clarifying the range of data that may be collected, used, and linked, including future uses and commercialization potential.

Disclosures about data use require a substantial amount of context (Paasche-Orlow et al., 2005); CDC has done work on clear communications that could be leveraged (CDC, 2019).

The regulations and associated penalties for unauthorized data sharing and re-identification need to be clarified, as do protections for organizations that experience data breaches despite following existing regulations. In addition, the challenge of reconciling federal laws with state or other laws sometimes results in a no-win situation for organizations that abide by some laws but violate others because there are direct conflicts among them. Further analysis could identify where additional guidance or regulations are needed.

Other countries and industries could provide valuable lessons in how to address data-sharing issues. Examples include social media companies, the aviation industry, the banking industry, and the European Union's experience with the General Data Protection Regulation.

As a specific proposal, lawmakers could pass a law like the Genetic Information Nondiscrimination Act to enhance governance of the sharing and use of health data, prohibit discrimination and other harms, and increase transparency about the regulations that exist to protect patients and others (Equal Employment Opportunity Commission, 2008). As a first step, several philosophically aligned advocacy organizations, such as Research!America, FasterCures, AcademyHealth, the Electronic Frontier Foundation, and Genetic Alliance, could work with legislators and advise on a course of action. A longer-term opportunity will be to require transparency about the commercial uses of health data.

4. Variability across institutions and states in their interpretation of regulations and responsibilities

Variability in the interpretation of regulations and responsibilities aligns with the first priority barrier, in that shared principles must be developed and used to interpret regulations and responsibilities in a consistent way.

As action steps achievable within 2 to 3 years, the National Governors Association (NGA), along with other organizations, could request clearer guidance from the federal government (e.g., OCR and OHRP) about data policies similar to recommendations put forth in NGA's report *Getting the Right Information to the Right Health Care Providers at the Right Time* (NGA, 2018). In addition, HHS—especially ONC—could develop use cases with associated legal and regulatory considerations akin to ONC's resources for PCORI data (HealthIT.gov, 2018).

A "help line" to federal agencies (e.g., HHS, OCR, OHRP) or a real-time appeals process could clarify different interpretations to federal policies. Alternatively, the identification of an honest broker (e.g., the CMS Virtual

Research Data Center [ResDAC, 2020b]) could help clarify different interpretations of federal oversight.

Another potential way to address this barrier, building on previous efforts by the Association of American Medical Colleges to reduce variability in the interpretation of regulations (NIH, 2006), could be to convene IRB chairs, privacy officers, regulatory officials, and thought leaders to draft guidance for IRBs and compliance offices.

5. Operational challenges, including uneven data quality, the cost to procure data, and the lag time between when data are collected and when they are available for use by researchers

Even with shared principles in place, operational challenges will need to be overcome. Further work on data ownership, access, and control will inform future efforts regarding this barrier—for example, by pointing toward incentives for institutions to share data.

In the meantime, and as a starting point, academic institutions and health systems should identify and implement incentives that encourage data sharing by researchers and other data holders.

In addition, ONC could take the lead in developing data standards in partnership with clinicians and patients. Specific approaches include

- exploring, perhaps with NLM, the creation of a repository (building on experiences with previous repositories), with a curated list of datasets and metadata about each dataset to encourage reuse and reduce lag times;
- requesting support from ONC and others for data standardization across electronic health records (EHRs) and expansion of the U.S. Core Data for Interoperability development; and
- creating a model data quality framework that defines what should go into a minimally acceptable note about a clinical encounter.

Technical experts could provide possible solutions to data capture issues in ways that improve quality overall.

Continued demonstrations of poor or incomplete EHR data will help convince health care executives of the need to improve EHR quality. New policies and funding could allow federal data holders to provide data more cost-effectively and more quickly. Finally, an enhanced technical infrastructure could enable patients to collect and report health data as well as help to educate them about why it is important to provide those data (Califf et al., 2016).

RESPONSIBLE ORGANIZATIONS

In addition to the major stakeholder groups of clinicians, patients, and researchers, many other groups will be involved in implementing the action steps described above, including

- research administrators,
- IRBs,
- health delivery organizations,
- insurance companies,
- pharmaceutical companies,
- technology companies and EHR vendors,
- federal and state regulators,
- data repositories,
- medical societies and trade associations,
- standard-setting bodies,
- medical journal editors,
- health journalists,
- federal agencies,
- research funders, and
- privacy officers.

5

STATEMENT OF THE
HEALTH CARE EXECUTIVES

Health systems, health plans, public health agencies, and biopharmaceutical companies are all driven by the desire to improve health outcomes for patients. These organizations are also well positioned to leverage data sharing for improved patient outcomes and safety, clinician satisfaction, and overall system performance. However, a variety of concerns impede the sharing of health data by health delivery organizations and pharmaceutical and insurance companies.

This statement describes key barriers and solutions for leveraging and sharing health data from the perspective of the health care executives working group (see Box 5-1).

CONCERNS AND BARRIERS

From the perspective of the stakeholder group representing health care executives, the key concerns and existing barriers to advancing data sharing, linkage, and use can be divided into four categories: (1) financial/operational barriers, (2) cultural barriers, (3) regulatory barriers, and (4) barriers related to policies and procedures.

FINANCIAL/OPERATIONAL BARRIERS

Many health delivery organizations and pharmaceutical and insurance companies believe that data sharing could be detrimental to the interests of organizations that share data. Even if sharing data is favorable to those who receive the data and to the community as a whole, organizations have concerns that data sharing will result in the loss of competitive position and that others will use shared data to achieve competitive advantage or other financial gains.

BOX 5-1

Members of the Health Care Executives Workgroup

Rainu Kaushal (*Co-Chair*), New York-Presbyterian Hospital/Weill Cornell Medical Center

Gregg S. Meyer (*Co-Chair*), Partners HealthCare International

Kevin Ban, athenahealth, Inc.

Ricky Bloomfield, Apple Inc.

Adrienne Boissy, Cleveland Clinic

John Bulger, Geisinger

Raj Davda, Cigna

Julie Gerberding, Merck & Co., Inc.

Robert Emerson, BlueCross BlueShield of North Carolina

John Halamka, Mayo Clinic

Lewis Sandy, UnitedHealth Group

Darshak Sanghavi, OptumLabs

Mariann Yeager, The Sequoia Project

Limited information on the expected return on investment of data sharing exacerbates these concerns (Deloitte, 2018). In addition, the costs of implementing systems that allow for seamless, secure, and reliable data management and sharing are high (Sittig and Singh, 2011), and the U.S. health care system's fee-for-service paradigm offers little incentive for data sharing. However, the value of data sharing is evident in the billion-dollar valuation of several health analytics companies.

CULTURAL BARRIERS

Physicians and physician organizations can be skeptical of efforts to publicly report data on physician performance and develop interventions for improving performance based on those data (Stone and Sullivan, 2007), even though sharing performance data can lead to effective and improved care processes (Glasgow et al., 2018). Even while patients have always had the legal right to access their data, health care executives may also be reluctant to institute web-based portals that share health data with patients because they are concerned that patients will be overwhelmed with trying to manage and understand their own health data. However, experiences with the OpenNotes project have dispelled such fears, and the service has been strongly endorsed as a safety measure. Additionally, health

systems may withhold free-text clinical notes from patients due to concerns about releasing sensitive information or receiving numerous questions from patients about or requests to amend their health records.

Health care executives may also fear reputational loss resulting from a data breach. More generally, data sharing is a coordination problem in which no one wants to bear the risk and burden of going first without others also embracing data-sharing policies and practices.

REGULATORY BARRIERS

Data governance lacks a centralized structure and agreement on a data stewardship model, which acts as a disincentive for organizations that are interested in data sharing.

POLICIES/PROCEDURES BARRIERS

Confusion surrounds the issue of who bears responsibility for collecting consent and what consent forms should cover (Goldstein and Rein, 2010). In addition, general consent for treatment at most health systems does not clearly and simply convey to patients how their data may be used or sold, even if the data are de-identified.

More generally, patchwork policies result in a lack of understanding of what types of data can and cannot be shared. While the Health Insurance Portability and Accountability Act (HIPAA) protects clinically generated data, consumer-generated data lack protection (Bailin, 2019). With the rise of health care data breaches and the lack of comprehensive data protections in the United States, hospitals and health care executives are leery of the risks of data sharing, including the financial and criminal penalties associated with data breaches.

PRIORITIES AND ACTION STEPS

From the above description of concerns and barriers, the stakeholder group representing health care executives has prioritized three major barriers that need to be addressed to facilitate widespread data sharing. When prioritizing the barriers, the workgroup members considered which barriers represented the most significant issues preventing widespread data sharing and linkage to improve patient care and which could be either wholly or partially addressed in the next 2 to 3 years. Some of these priority barriers combine several of the themes from the previous section.

1. Misaligned incentives, including financial and security risks

The risk equation for data sharing needs to be rebalanced. So long as companies see the risks of data sharing as outweighing the potential gains, they will resist taking action. Today, insufficient data exist to demonstrate that data sharing results in savings to individual consumers of health care, yet a continued lack of data sharing will forego a wide array of insights into how better care can be provided for population health management.

An action step achievable within 2 to 3 years to begin to address this issue would be to specify and quantify the actual risks and value of sharing data while also clearly specifying the risks of not sharing data. For example, the criminal and financial penalties associated with data breaches are a significant impediment to data sharing (Palabindala et al., 2016). A possible solution would be to institute policies absolving companies that follow the rules from responsibility for data breaches. The state of Massachusetts is currently considering proposed regulations that would accomplish this. In some states, malpractice judgments can depend on whether an organization has violated community standards, which would require specifying community standards to ameliorate potential risks.

Identifying incentives to sharing data among different stakeholder groups would allow resources to be pooled to tackle the problem. Much can be learned from successful examples of data sharing in the research community, such as the work of PCORnet, the Health Care Cost Institute, and several pharmaceutical companies (Curtis et al., 2014; Ross et al., 2018). An action step would be to learn from other industries that have adopted data standardization and sharing practices, such as the airline industry's e-ticketing processes. Another solution could be to build on successful efforts and increase provider and payer participation in health information networks to promote broader interoperable exchange.

As payment models move from volume to value, there are increased incentives for health systems to share rather than only retain data. Several large integrated health systems such as Geisinger, Intermountain Healthcare, and Kaiser Permanente have taken steps in this direction. However, smaller health systems may lack the resources to make such changes without significant reforms to the current payment model. An action step toward this goal would be to establish a forward-thinking pilot group among payers and health systems to facilitate trust between parties and develop a case for data sharing. This is already under way with BlueCross BlueShield of North Carolina partnering with five regional health systems to offer a value-based model of care called Blue Premier (BlueCross BlueShield of North Carolina, 2019).

Another approach to ameliorate risks to companies would be to give patients control of how their data will be shared and the ability to audit data rights over time and as data move through the system. In this regard, companies that act as intermediaries to obtain and share patient data have already been established. Paying patients to share data or establishing patient-mediated data exchanges are additional options. An immediate action step would be to improve the consent process so that patients are better informed about how their data will be used and what the expected outcomes of that use are. One way to protect patient data may be to use blockchain as a mechanism to capture consent preferences at a national level (de Sousa and Pinto, 2019).

2. The financial costs associated with sharing data

Although data sharing is beneficial to the community, health systems are reluctant to invest the large amounts of capital and time required for building and maintaining the infrastructure for data sharing when the return on investment for such sharing is largely unknown.

An overall goal is to change perceptions about the selling and purchasing of data by emphasizing their value to society and by making it a standard practice and priority to share curated data with trustworthy organizations. A specific action step is to reframe the business case for data sharing by not only qualifying and quantifying the value of sharing data but also enumerating the financial, human, and organizational integrity costs of not sharing data. The National Academy of Medicine, with support from the Patient-Centered Outcomes Research Institute, the Agency for Healthcare Research and Quality, or the National Library of Medicine, would be in a good position to conduct such research, though the analytical methods for such a study would need to be developed carefully.

Another goal is to decrease the costs associated with data sharing by creating a widely available infrastructure and robust government stimulus for the development and adoption of technology. One step toward this goal would be to decrease costs by specifying an operating model that would distribute the expense for a shared infrastructure and standardize the data models used for data aggregation. Another action step would be to weigh the impacts of data sharing against the costs—for example, how could data sharing improve medical device safety or inform payer risk assessments? Prior to taking these steps, however, efforts need to be undertaken to create an inventory of prioritized use cases for data sharing by clarifying what kinds of data different groups are trying to access and for what purpose and to learn from case examples of successful health information exchanges.

Implementing national and federal registries could mitigate costs while providing organizations with a safe harbor for data sharing. An action step is to highlight existing safe harbor or "safe lane" constructs and to develop new safe harbor frameworks that would mitigate risks.

Adopting a common data model could optimize the transfer, importation, and utility of data. An action step is to build on the work of the U.S. Core Data for Interoperability Task Force in developing a standardized set of health data classes and constituent data elements for a nationwide, interoperable health information exchange (ONC, 2020a). By and large, utilizing the momentum of existing efforts solves the aforementioned coordination problem and obviates the need to generate buy-in from key stakeholders.

3. Potential harms associated with the loss of competitive advantage and with the sensitivity of information

A significant barrier to data sharing is the perception that data transparency risks revealing information on comparative performance, cost structures, utilization, or contractual arrangements among hospitals, payers, and suppliers. Organizations also fear that data sharing will have harmful unintended consequences. For example, while patient-directed sharing is important, health systems worry about bearing liability for the misuse that might happen when patients share data with third-party entities. Unlike health systems, which have to abide by HIPAA, third-party app companies are not covered by HIPAA. However, health systems to some extent share operational data for benchmarking, and pioneering organizations such as Cleveland Clinic have seen gains in patient satisfaction and throughput by publicly posting physicians' respective quality performance data (Lee and Cosgrove, 2014).

Toward the longer-term goal of establishing trust between data providers and data users, an action step is to create a common foundation of policies and practices—a "code of conduct" for data sharing and use. Such a code should contemplate a broad range of use cases independent of technology—examples are the Trusted Exchange Framework and Common Agreement (TEFCA), the New York eHealth Collaborative Statewide Health Information Network policies, Carequality Trust Framework, and CARIN Alliance code of conduct (Carequality, 2019; CARIN Alliance, 2019; NYeC, 2019; ONC, 2019). Depending on the type of data and use case, different parties could serve as a coordinating entity for such a code.

The research community has also been active in this space, particularly as it relates to genetic result sharing. The All of Us Research Program adopted a detailed

data security framework as well as a set of privacy and trust principles developed by the Precision Medicine Initiative that could also serve as models (NIH, 2019). The Clinical Sequencing Evidence-Generating Research consortium is another entity that has best practices around return of results (CSER, 2020). Carequality, a private-sector initiative, supports a nationwide trust framework that enables providers who participate in different health information networks to access and share health information (Carequality, 2019). Another action step is to forge national collaborations among health systems, clinical registries, and researchers to determine how data will be used. Existing networks could be used to leverage such collaborations, such as the Food and Drug Administration's Sentinel Network, the eHealth Exchange, or PCORnet (FDA, 2018; ONC, 2015; PCORnet, 2013). A related action step is to delineate the rights and responsibilities of different actors for thoughtful stewardship of health data.

A longer-term goal is to make data available through enclaves that allow for distributed analysis of data without taking possession of those data (this approach is also a solution to Priority Barrier 2: The financial costs associated with sharing data) (Platt and Lieu, 2018). An action step toward this goal is to define what is meant by data enclaves and what the role of the federal government should be in establishing data safe harbors.

As a variation on data enclaves, where data are allowed for use while being walled off and protected, Massachusetts shares mimic datasets containing de-identified intensive care unit data with organizations that want to do research. Competing organizations are able to access each other's data as long as they have institutional HIPAA training and common institutional review board approval.

COMMON ISSUES

Several potential solutions could affect all three prioritized barriers. A longer-term goal is to convert private data into a public good so that these data can have widespread benefit. One possibility is anonymizing data so that, paradoxically, information belongs to everyone and to no one, which is an approach that Finland is taking. A related longer-term goal is to implement the federal mandate for data sharing, instituted by the 21st Century Cures Act.

To that end, a shorter-term action step that will certainly make a difference is the implementation of the Centers for Medicare & Medicaid Services' (CMS's) *Medicare and Medicaid Programs*; *Patient Protection and Affordable Care Act*; *Interoperability and Patient Access for Medicare Advantage Organization and Medicaid Managed Care Plans, State Medicaid Agencies, CHIP Agencies and CHIP Managed Care Entities, Issuers of Qualified Health Plans in the Federally-Facilitated Exchanges and Health Care Providers*

and The Office of the National Coordinator for Health Information Technology (IT) (ONC's) *21st Century Cures Act: Interoperability, Information Blocking, and the ONC Health IT Certification Program* released in March 2020. These two final rules provide much needed guidance on interoperability and data blocking. In their proposed state, they have been endorsed by all of the past National Coordinators for Health Information Technology, patient advocates, and relevant entities such as the American Academy of Family Physicians, American Medical Informatics Association, Apple, IBM, Microsoft, National Association of Accountable Care Organizations, and Rock Health for the innumerable patient benefits they offer. These benefits include (1) enabling seamless data exchange between patients and clinicians, (2) consolidating a person's health information ideally in one place, and (3) potentially giving patients the opportunity for enhanced decision making through application programming interfaces (APIs), which could obtain patient preferences on medication and treatment plans (Blumenthal et al., 2019; Gleason and Dave, 2020; The Pew Charitable Trusts, 2020).

The CMS final rule expands health plans' participation in the MyHealthEData initiative by requiring payers in CMS programs such as Medicaid, the Children's Health Insurance Program, Medicare Advantage Plans, and Qualified Health Plans in the federally facilitated exchanges to do the following (CMS, 2020):

- Provide enrollees access to medical claims and other health information electronically through the implementation of open data–sharing technologies, and
- Participate in trust networks to improve interoperability.

To improve care coordination, the rule requires Medicaid- and Medicare-participating health care facilities to electronically inform hospitals and practitioners in a patient's care network if and when that person has been admitted, discharged, or transferred. The CMS rules also set up a framework of accountability by proposing to publicly report providers or hospitals that intentionally partake in information blocking.

Extending the efforts of CMS, ONC's final rules call for health systems to adopt standardized APIs based on Fast Healthcare Interoperability Resources standards and for health IT developers to stand up APIs that allow for the access and exchange of health information without any additional effort (ACEP, 2019; ONC, 2020a). ONC also provides clarity on the information blocking provisions in the 21st Century Cures Act by enumerating the eight conditions under which an organization can withhold data (ONC, 2020b):

1. Preventing harm,
2. Promoting the privacy of electronic health information,
3. Promoting the security of electronic health information,
4. Recovering costs reasonably incurred,
5. Responding to requests that are infeasible,
6. Licensing of interoperability elements on reasonable and nondiscriminatory terms,
7. Maintaining and improving health IT performance, and
8. Limiting the content and manner of responses.

ONC also puts forward a proposed, voluntary model for a nationwide trusted exchange framework through TEFCA; however, it is unclear what incentives will be available for health information networks to adopt it.

The impact of the rules remains uncertain, especially as enforcement has been delayed due to the COVID-19 pandemic (Miliard, 2020). When the ONC and CMS rules were released in their proposed state, a number of potential consequences were raised that could impede data sharing:

- The rules will force standardization of claims models integrated with clinical data models that are well vetted with Health Level Seven International (HL7).
- Data sharing could be hampered by organizations misapplying or exploiting the information-blocking exemptions. For example, according to a subcomponent of the "promoting the privacy of EHI [electronic health information]" exception, organizations could be allowed to limit information flow if they are abiding by "certain practices not regulated by HIPAA but which implement documented and transparent privacy policies" of the organization (Savage, 2019).
- For-profit organizations not covered by HIPAA could commercialize data being obtained through an API not tethered to a portal.
- Greater accessibility to claims data might increase people's ability to submit fraudulent claims for services not provided or rendered.
- Given the ambiguity in the proposed rule and lack of definitive examples, there are also concerns that there will be a large number of unfounded complaints and resulting litigation.

These proposed rules have received significant comments from the private sector, as well as recommendations from the Federal Trade Commission regarding important adjustments "to ensure the final rule does not inadvertently distort competition or impede innovation, to the detriment of consumer welfare" (FTC, 2019).

RESPONSIBLE ORGANIZATIONS

Many groups, both within and outside the stakeholder communities, will be responsible for implementing the action steps described above, including

- chief financial officers and chief medical officers contemplating the overall risks and benefits of data sharing;
- federal agencies, including the Office for Civil Rights;
- electronic health record vendors;
- Carequality;
- institutions doing research on data enclaves, such as The University of Texas and the University of California, San Diego;
- CARIN Alliance;
- DaVinci Project, HL7;
- institutions experimenting with using synthetic datasets, such as Intermountain Healthcare, Washington University, and MDClone;
- companies that monetize data, such as Harvard Stem Cell Institute;
- health information networks; and
- data aggregators and cloud providers, such as Verily, Microsoft, Health Catalyst, and Optum.

6

CONCLUSION

To share and receive feedback on the vision statement (see Chapter 2), the definition of health data, and the stakeholder statements (see Chapters 3, 4, and 5), and to begin building support for implementing the short-term action steps identified, the National Academy of Medicine Leadership Consortium: Collaboration for a Value & Science-Driven Health System hosted a meeting on August 23, 2019, in Washington, DC, which brought together representatives of the steering committee and stakeholder groups that prepared the statements in Chapters 3–5 along with a broad array of other experts and health system leaders. The goal of the meeting was building partnerships and implementing principles and priorities to overcome the cultural, regulatory, financial, and ethical barriers identified by the stakeholder groups and achieve the vision described in Chapter 2 (see Appendix C). Drawing on that discussion, this chapter describes the overlapping barriers and solutions from the stakeholder statements and a number of priorities for the nation that are critical to addressing the outstanding barriers to health data sharing, linkage, and use.

OVERLAPPING BARRIERS AND SOLUTIONS

As was observed at the meeting, the statements produced by each of the stakeholder groups revealed a remarkable amount of overlap among the cultural, ethical, regulatory, and financial barriers to greater data sharing, linkage, and use (see Figure 6-1).

- The groups representing health care executives and patient and family leaders identified a misalignment of financial and other incentives as common barriers.
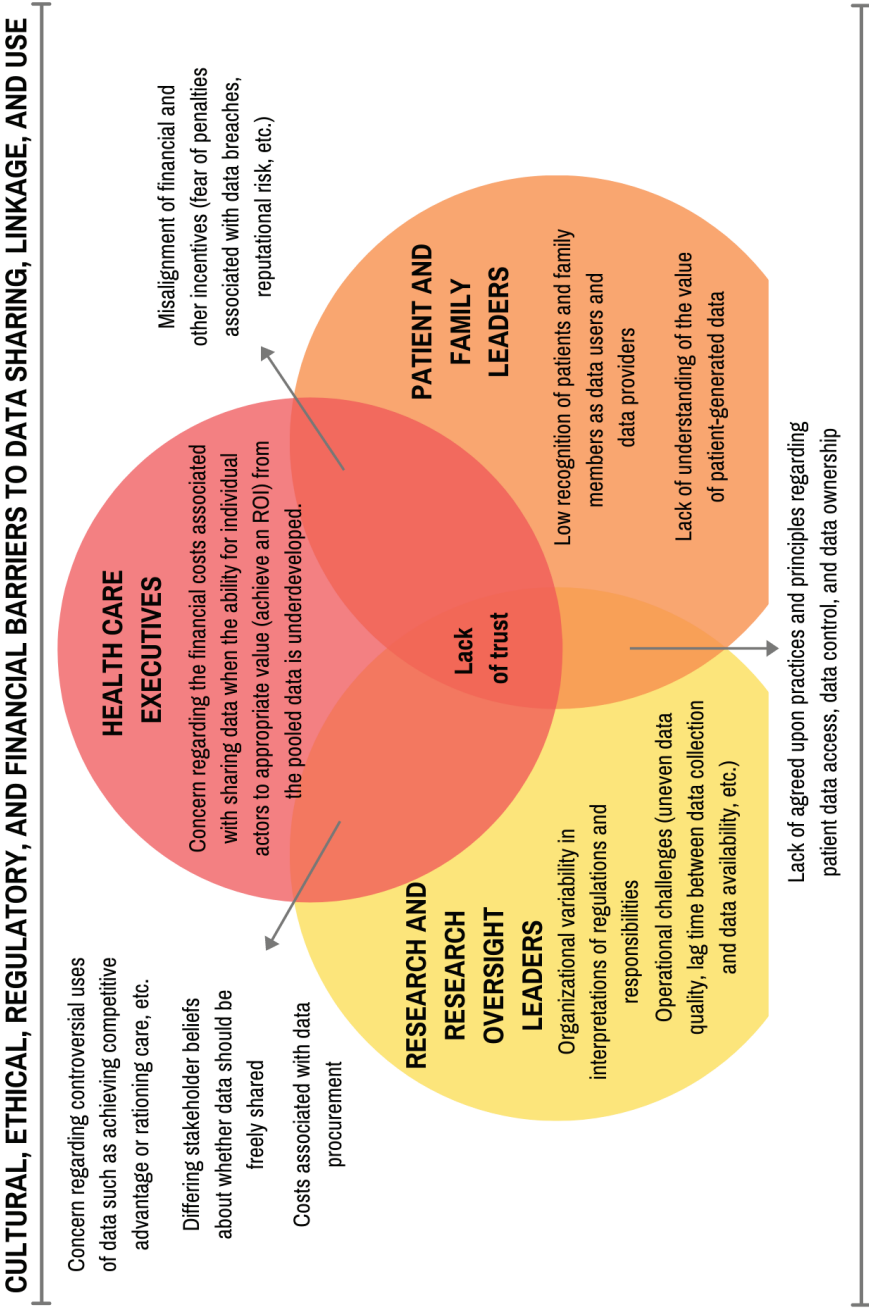
CULTURAL, ETHICAL, REGULATORY, AND FINANCIAL BARRIERS TO DATA SHARING, LINKAGE, AND USE

HEALTH CARE EXECUTIVES

Concern regarding controversial uses of data such as achieving competitive advantage or rationing care, etc.

Differing stakeholder beliefs about whether data should be freely shared

Costs associated with data procurement

Concern regarding the financial costs associated with sharing data when the ability for individual actors to appropriate value (achieve an ROI) from the pooled data is underdeveloped.

PATIENT AND FAMILY LEADERS

Misalignment of financial and other incentives (fear of penalties associated with data breaches, reputational risk, etc.)

Low recognition of patients and family members as data users and data providers

Lack of understanding of the value of patient-generated data

Lack of trust

RESEARCH AND RESEARCH OVERSIGHT LEADERS

Organizational variability in interpretations of regulations and responsibilities

Operational challenges (uneven data quality, lag time between data collection and data availability, etc.)

Lack of agreed upon practices and principles regarding patient data access, data control, and data ownership

FIGURE 6–1 | Cultural, ethical, regulatory, and financial barriers to data sharing, linkage, and use.

- The groups representing patient and family leaders and researchers and research oversight leaders identified a lack of agreed-upon practices and principles regarding patient data access, data control, and data ownership.
- The groups representing research and research oversight leaders and health care executives identified concerns regarding controversial uses of data, differing beliefs about whether data should be freely shared, and costs associated with data procurement.

A concern shared by all three stakeholder groups was a lack of trust in the intentions and actions of other groups. The members of the patient and family community lack trust that health care systems and researchers will make data and the conclusions based on those data available to them and will not misuse data they provide by rationing care and sharing those data with unauthorized third parties. Researchers share a similar mistrust in the intentions of third-party users. Health systems are concerned that patients will misinterpret data or use data inappropriately, such as allowing them to be combined with other elements so as to identify individuals. Specific examples of these problems were mentioned at the meeting, such as the dialysis clinic that refused to share a patient's data that he wanted to share with researchers, or the lack of cooperation between two health systems that refused to even refer to each other by name because of the competition between them. Ultimately, such lack of trust stems from the diverging interests of each group and the lack of common cause for data sharing among the three groups.

The stakeholder statements reveal several imperatives for addressing data-sharing challenges that are common to one or more stakeholder groups, including

- developing a set of principles and commitments on data ownership, accessibility, and control;
- reframing the risk discussion or business case related to data sharing to highlight patient safety and evidence-based arguments about the risks of not sharing data;
- devising a national educational campaign tailored to specific stakeholder groups that highlights the benefits of bidirectional data exchange and prepares these stakeholder groups for using and contributing to shared data;
- conducting and disseminating research on stakeholder preferences and beliefs regarding whether and how data should be shared;
- standardizing data collections and use over the long term by identifying and implementing common data models and data standards, establishing data enclaves or safe harbors, and clarifying what kinds of data various groups are trying to access; and

• continuing efforts to address the misalignment of financial incentives by implementing payment models that reward value-based care and population health.

These common solutions formed the basis for much of the discussion at the August 23 meeting.

PRIORITIES FOR THE FIELD

Over the course of the meeting, several priorities emerged as the most important to addressing the barriers identified by the stakeholder groups. Many of these priorities reinforced ideas generated in prior discussions of the stakeholder working groups.

ENGAGING IN A PUBLIC INFORMATION CAMPAIGN

Greater knowledge is essential to move data sharing forward. In particular, a widely disseminated public information campaign could help change attitudes and behaviors by showing people how the use of health data could improve their health and the health of people they know. Such a campaign could target not only the general public but also care providers, policy makers, health care administrators, and others in a position to influence data issues as described in the Statement of Patient and Family Leaders in Chapter 3. Given the importance of this issue to the future of health care, reaching out to school-aged children and building data literacy early in life will be important.

An educational campaign could entail commercials, social media campaigns, public service announcements, webinars, newsletters, and many other forms of communication. Information from the campaign also could be extracted into PowerPoint presentations, infographics, narratives of personal experiences, accounts by early adopters of new approaches, and other flexible and usable forms. Such stories could emphasize that past instances of data sharing have not only created benefits but also not resulted in problems. An article in *Science* or another high-profile journal could address data sharing. Even movies and television shows could help make the case.

Several wedge issues could prove important in such a campaign. One is that the lack of data access is an issue of patient safety. Health care executives and organizations, insurers, clinicians, patients, families, and others all resonate with this issue. Another is the intersection of data sharing with privacy and security as subsets of health data are governed differently. In the absence of an

overarching privacy law in the United States, the Health Insurance Portability and Accountability Act (HIPAA) protects health data that flow among health systems, payers, and other covered entities but not consumer-generated data that originate from mHealth apps or wearable devices or data that are shared with third-party technology companies.. Therefore, guides to privacy and security could be disseminated as part of the campaign to educate consumers of health care about the issue.

Change will occur when there is sufficiently high demand by all of health care's stakeholders, from the public to the clinical and research communities. Today, however, the public does not fully understand the benefits and value of data sharing, and the demand is not commensurate with the need for change.

CREATING AND PRIORITIZING USE CASES

Foundational to devising a national educational campaign, the development of use cases that promote various reasons for sharing and linking health data could help build demand for data sharing, demonstrate how to overcome the barriers identified by the stakeholder groups, and achieve the vision described in Chapter 2. These use cases should highlight the benefits of sharing data and information not only with patients or for research but also for artificial intelligence applications, machine learning, performance improvement, best practice guidelines, and many other uses.

Use cases could highlight potential cost savings and analytics that drive value. They could reveal the interdependencies of complex systems and show how to build on success by extending successful innovations into new areas.

A matrix of all of the providers and users of data and their interconnections would reveal many potential use cases. This matrix could describe who provides data, who consumes data, what data elements need to be shared, and the benefits and risks of sharing data. Such a matrix could also identify gaps, both in the private and public sectors, and demonstrate the returns on investment of specific actions.

Use cases can focus on short-, medium-, and long-term objectives and on the critical levers for each. Within each use case category, it would also be helpful to identify exemplar organizations that have shared or linked data to positively impact health outcomes. By demonstrating how greater sharing and use of data can improve health, use cases and exemplars can drive the adoption of a variety of initiatives. For example, a use case that embodies value-based care or personalized medicine could be structured around the exchange and broader use of data. Use cases also could spur greater involvement by organizations and groups that are

not yet heavily involved in data sharing, such as small health care systems or communities that have been disenfranchised.

Use cases can range widely across sectors and incorporate many types of data, including clinical, claims, social determinants, and consumer-generated data. To take just one example, standardized patient-reported outcomes could provide the basis for a use case, enabling robust comparison of these outcomes across health systems and care settings.

MAKING THE BUSINESS CASE

Each stakeholder in the health care system will need to see the advantages of moving toward greater data sharing. Particularly in the private sector, this will require the development of compelling business cases that clearly demonstrate these advantages and return on investment.

Developing a business case will require the involvement of different people and stakeholder groups. It also will require estimates of the costs and potential benefits of sharing data and of not sharing data. The business case should lay out not only the financial impact but also the other potential gains and losses (e.g., cost of patient harm, reputation/brand, market share). The existing market for health data, where organizations already attach value to curated databases, could help in understanding and deriving these costs.

A business case can demonstrate how data sharing is useful and brings benefits to multiple parties, including consumers, in preventing medical error and enhancing the care delivery experience. It can show how data sharing has the potential to produce competitive advantages rather than disadvantages. In these and other ways, a strong business case can inspire organizations to be early adopters of new procedures rather than waiting for others to go first. Discussions or partnerships with business groups on health or similar state-based alliances of employers and purchasers could help inform the development of the business case.

BASING PAYMENT ON VALUE

New payment models that incentivize paying for value and outcomes, rather than paying for the volume of care that is delivered, could have concurrent benefits to the imperative for more seamless data sharing. Population health management depends on shared knowledge of patients' experiences of care across time and across setting. For example, value-based arrangements with care providers and health systems can result in tools that consumers can use to better navigate

health care. Value-based health care also can support data exchange, infrastructure development, technology support, and research (Kent, 2018).

There are already a number of initiatives under way to incentivize value-based payments. For example, the Centers for Medicare & Medicaid Services (CMS), an early adopter of value-based care delivery, has identified several alternative payment models that incentivize value over volume. The Medicare Access and CHIP (Children's Health Insurance Program) Reauthorization Act of 2015 (MACRA) creates a new framework for rewarding Medicare patients' physicians for providing higher quality care. One of the performance tracks in MACRA, Merit-Based Incentive Payments Systems, emphasizes promoting interoperability through focusing on patient engagement and the electronic exchange of health data (Quality Payment Program, 2020). Additionally, new payment models, such as the CMS Primary Care First Model—which offers an innovative payment structure to support primary care delivery for patients with complex chronic needs and high need, seriously ill patients—are being developed (CMS, 2019b). Private payers are also testing alternative payment approaches and are using approaches such as Shared Savings and Shared Losses Models, Bundled Payment Models, and Alternative Quality Contract to control spending growth and increase care quality (Chernew et al., 2011).

A complication of basing payments on value is that the United States does not have a single health care system. Rather, it is comprised of multiple health care systems that sometimes cooperate and sometimes compete. Business priorities drive some of this competition, as do cultural factors. Nevertheless, increased adoption of value-based care can lead to potential returns on investment and engage communities in exploring and identifying related principles and actions that improve health.

INSTITUTING SUPPORTIVE GOVERNMENT POLICIES

Government policies can support data sharing in a variety of ways, as elaborated in the health care executives' statement. Such policies can establish ground rules and standards for data exchange across networks, as well as support the development of technologies and systems that promote rather than impede data sharing. They can send clear signals about how existing technologies should be used and what new technologies are needed. One example is the CMS Interoperability and Patient Access final rule, which mandates Medicare participants to share data via open, secure, and standardized application programming interfaces (CMS, 2019b; see Chapter 5). Another example is the 21st Century Cures Act, which includes provisions requiring data sharing and management plans among recipients of federal research funds (ONC, 2020c).

Direct financial incentives can also drive change—for example, by encouraging hospitals and clinicians to share data through interoperable systems. Negative incentives can have an effect as well, such as public identification or the levying of financial penalties on systems that are blocking or not doing enough to share data. The aforementioned 21st Century Cures Act sets limits for data blocking (CMS, 2019a; ONC, 2019).

All funders of research, not just government, can require researchers to make their data available to other researchers and to research participants. However, as acknowledged by the National Institutes of Health's request for public comments on the Draft Policy for Data Management and Sharing, the complexity and cost of preparing, curating, and sharing research data for secondary analyses could complicate the ability of research entities to comply with this. Funders also can support data–gathering efforts among other groups and organizations to generate datasets and make them publicly available.

BUILDING TRUST

Greater trust and transparency among stakeholder groups can both foster and support data sharing. Standards of conduct can build trust, because people know what to expect. For example, making the return of research results to participants the norm rather than the exception could inform people about the value of research and help build trust. Collaborative efforts built on trust can convert zero-sum relationships into positive-sum relationships, where data sharing serves everyone's interests.

Trust has to be built and sustained thoughtfully and intentionally, given that it is a fragile commodity and can easily be lost. Even if an organization's mission statement says that the consumers of health care come first, business plans and actions of those in the organization need to reflect that mission. Patients and consumers are often unaware that HIPAA protections do not extend to third-party health data companies, and a well-publicized breach in this area could undermine public confidence and set back the move toward data sharing. Ensuring that non-HIPAA-covered entities are protected by robust and enforced laws for data privacy will be critical in maintaining public trust. Hoping for trust when the customers' interests are not being served will not work, especially given that contextual factors can influence trust in an entire sector. Additionally, trust can be maintained even when things go wrong. For example, a compensation plan funded by the users of data would be one way to make amends for data breaches.

ALLOCATING RESOURCES FOR ACHIEVING PRIORITIES

At the August 23 meeting, participants discussed a wide array of resources that are both needed and available to achieve the goal of both improved and more frequent data sharing.

One point made repeatedly at the meeting is that health data extend far beyond the data most directly related to health care and health outcomes. Health data include such widely varied data sources as geospatial data; census data; consumer data from groceries, media companies, and smartphone applications; and fitness- and wellness-related data. Many of these forms of data, alone or in combination, can be used to infer health status or inform health care.

Though the stakeholder groups were directed not to address the technical barriers to greater data sharing, computational technologies are a major part of the resources needed to achieve the priorities the groups identified. These technologies are advancing rapidly, highlighting the need for flexibility in responding to new capabilities and circumstances. Technologies can provide solutions to some barriers to data sharing, such as enabling audit trails to enforce compliance with regulations or balancing access with security and privacy. Technology development also can involve innovators and entrepreneurs in the health care system, further speeding progress.

As an example of a technological advance, many health care providers and hospitals are on the verge of meeting requirements for meaningful use by enabling consumers to use third-party applications to access clinical data. By enabling the consumers of health care to interact much more directly with their health data, this advance could mark the beginning of a transformation in health care. For example, given that not enough providers are available to manage the chronic diseases of an aging population, the use of such applications could greatly increase the number and agency of people who are taking an active role in co-managing their health care.

Some data-sharing initiatives can begin with small groups, such as patients with particular diseases, and then spread more widely as exemplified by the creation of many of the Patient-Centered Outcomes Research Institute's Patient-Powered Research Networks. Others may start with particular institutions and then be adopted or adapted in other settings. Other industries offer examples of data sharing that the health care system could adopt. For example, the August 23 meeting featured a presentation about the spread of data sharing within the airline industry. Convening information technology experts who work outside of the health care industry with health care experts could help to drive innovative solutions to addressing the barriers to health data sharing.

A consortium of organizations committed to stewarding progress on data linkage, sharing, and use could produce greater collaboration and faster progress. Lessons can be derived from the Clinical and Translational Science Awards' Connecting Data to Health program (NCATS, 2020). Similarly, a shared framework and commitment to data sharing could rally all stakeholders around the idea, and a website that compiles ongoing data-sharing initiatives and resources could be a source of information and momentum.

TOWARD A CONTINUOUS LEARNING HEALTH SYSTEM

Health data are the foundation for a continuously learning health system in which science, informatics, incentives, and culture are aligned to yield continuous improvement, innovation, and equity. In such a system, new knowledge is seamlessly embedded in the delivery of health care, individuals and families are active participants in all elements of care, and new knowledge is generated as an integral product of the delivery of care. Addressing the cultural, ethical, regulatory, and financial barriers to data sharing that currently exist, and building support and demand for data-sharing efforts among key stakeholders including patients and caregivers, clinicians, health care executives, and researchers is paramount to achieving the vision of a continuously learning health system and improving health and health care outcomes.

REFERENCES

ACEP (American College of Emergency Physicians). 2019. *Summary of the CMS and ONC Interoperability and Patient Access Proposed Rules.* https://www.acep.org/globalassets/new–pdfs/advocacy/acep-summary-of-cms-and-onc-health-it-proposed-rules.pdf (accessed January 17, 2020).

Adler–Milstein, J., C. M. DesRoches, P. Kralovec, G. Foster, C. Worzala, D. Charles, T. Searcy, and A. K. Jha. 2015. Electronic health record adoption in US hospitals: Progress continues, but challenges persist. *Health Affairs* 34(12):2174–2180. https://doi.org/10.1377/hlthaff.2015.0992.

Ancker, J. S., H. O. Witteman, B. Hafeez, T. Provencher, M. Van de Graaf, and E. Wei. 2015. The invisible work of personal health information management among people with multiple chronic conditions: Qualitative interview study among patients and providers. *Journal of Medical Internet Research* 17(6):e137. https://doi.org/10.2196/jmir.4381.

Anderson, M. O., S. L. Jackson, N. V. Oster, S. Peacock, J. D. Walker, G. Y. Chen, and J. G. Elmore. 2017. Patients typing their own visit agendas into an electronic medical record: Pilot in a safety-net clinic. *The Annals of Family Medicine* 15(2):158–161. https://doi.org/10.1370/afm.2036.

Archer, N., U. Fevrier-Thomas, C. Lokker, K. A. McKibbon, and S. E. Straus. 2011. Personal health records: A scoping review. *Journal of the American Medical Informatics Association* 18(4):515–522. https://doi.org/10.1136/amiajnl–2011-000105.

Avram, R., G. Marquis-Gravel, F. Simard, C. Pacheco, É. Couture, M. Tremblay-Gravel, O. Desplantie, I. Malhamé, L. Bibas, S. Mansour, M. C. Parent, P. Farand, L. Harvey, M. G. Lessard, H. Ly, G. Liu, A. E. Hay, and E. Marc Jolicoeur. 2018. Understanding the patient perspective on research access to national health records databases for conduct of randomized registry trials. *International Journal of Cardiology* 262:110–116. https://doi.org/10.1016/j.ijcard.2017.12.074.

Bailin, P. 2019. Executive summary: Evolution of health data regulation. *Medium*. https://medium.com/datavant/executive-summary-evolution-of-health-data-regulation-faa5fbb4dc3c (accessed January 17, 2020).

Bell, S. K., M. Gerard, A. Fossa, T. Delbanco, P. H. Folcarelli, K. E. Sands, B. S. Lee, and J. Walker. 2017. A patient feedback reporting tool for OpenNotes: Implications for patient-clinician safety and quality partnerships. *BMJ Quality and Safety* 26(4):312–322. https://doi.org/10.1136/bmjqs-2016-006020.

Bierer, B. E., R. Li, M. Barnes, and I. Sim. 2016. A global, neutral platform for sharing trial data. *New England Journal of Medicine* 374(25):2411–2413. https://doi.org/10.1056/NEJMp1605348.

BlueCross BlueShield of North Carolina. 2019. *Blue Cross NC and Five Major Health Systems Announce Unprecedented Move to Value-Based Care.* http://mediacenter.bcbsnc.com/news/blue-cross-nc-and-five-major-health-systems-announce-unprecedented-move-to-value-based-care (accessed January 17, 2020).

Blumenthal, D. 2017. Data withholding in the age of digital health. *The Milbank Quarterly* 95(1):15–18. https://www.ncbi.nlm.nih.gov/pmc/articles/PMC5339379 (accessed January 14, 2020).

Blumenthal, D., D. Brailer, K. DeSalvo, R. Kolodner, F. Mostashari, and V. Washington. 2019. Former national health IT coordinators respond to proposed ONC, CMS interoperability rules. *HealthAffairs Blog.* https://www.healthaffairs.org/do/10.1377/hblog20190604.428654/full (accessed January 17, 2020).

Bourgeois, F. C., A. Fossa, M. Gerard, M. E. Davis, Y. J. Taylor, C. D. Connor, T. Vaden, A. McWilliams, M. D. Spencer, P. Folcarelli, and S. K. Bell. 2019. A patient and family reporting system for perceived ambulatory note mistakes: Experience at 3 US healthcare centers. *Journal of the American Medical Informatics Association* 26(12):1566–1573. https://doi.org/10.1093/jamia/ocz142.

Boyd, A. D., C. Hosner, D. A. Hunscher, B. D. Athey, D. J. Clauw, and L. A. Green. 2007. An "Honest Broker" mechanism to maintain privacy for patient care and academic medical research. *International Journal of Medical Informatics* 76(5–6):407–411. https://doi.org/10.1016/j.ijmedinf.2006.09.004.

BRCA Exchange. 2020. *BRCA Exchange: Facts & Stats.* https://brcaexchange.org/factsheet (accessed January 14, 2020).

Broad Institute. 2020. *Count Me In.* https://www.broadinstitute.org/count-me-in (accessed January 14, 2020).

Califf, R. M., M. A. Robb, A. B. Bindman, J. P. Briggs, F. S. Collins, P. H. Conway, T. S. Coster, F. E. Cunningham, N. De Lew, K. B. DeSalvo, C. Dymek, V. J. Dzau, R. L. Fleurence, R. G. Frank, M. Gaziano, P. Kaufmann, M. Lauer, P. W. Marks, J. M. McGinnis, C. Richards, J. V. Selby, D. J. Shulkin, J. Shuren, A. M.

Slavitt, S. R. Smith, B. V. Washington, P. J. White, J. Woodcock, J. Woodson, and R. E. Sherman. 2016. Transforming evidence generation to support health and health care decisions. *New England Journal of Medicine* 375:2395–2400. https://doi.org/10.1056/NEJMsb1610128.

CancerBase. 2020. *CancerBase: Share, Discover & Change.* https://cancerbase.org (accessed January 14, 2020).

Carequality. 2019. *What is Carequality?* https://carequality.org/what–we–do (accessed January 17, 2020).

CARIN Alliance. 2019. *The CARIN Alliance Code of Conduct.* https://www.carinalliance.com/our-work/trust-framework-and-code-of-conduct (accessed April 30, 2020).

Cassel, C., and A. Bindman. 2019. Risk, benefit, and fairness in a big data world. *JAMA* 322(2):105–106. https://doi.org/10.1001/jama.2019.9523.

Castle-Clarke, S., and C. Imison. 2016. *The digital patient: Transforming primary care.* London: Nuffield Trust.

CDC (Centers for Disease Control and Prevention). 2019. *Health Communication Basics.* https://www.cdc.gov/healthcommunication/healthbasics/index.html (accessed October 7, 2020).

Center for Open Science. 2020. *Homepage.* https://cos.io (accessed January 14, 2020).

Chernew, M. E., R. E. Mechanic, B. E. Landon, and D. G. Safran. 2011. Private-payer innovation in Massachusetts: The "alternative quality contract." *Health Affairs* 30(1):51–61. https://doi.org/10.1377/hlthaff.2010.0980.

CMS (Centers for Medicare & Medicaid Services). 2019a. Speech: Remarks by Administrator Seema Verma at the Blue Button Developer Conference. https://www.cms.gov/newsroom/press-releases/speech-remarks-administrator-seema-verma-blue-button-developer-conference (accessed April 30, 2020).

CMS. 2019b. *Primary Care First Model Options.* https://innovation.cms.gov/innovation-models/primary-care-first-model-options (accessed April 30, 2020).

CMS. 2020. *Medicare and Medicaid programs; Patient Protection and Affordable Care Act; Interoperability and Patient Access for Medicare Advantage organization and Medicaid managed care plans, state Medicaid agencies, CHIP agencies and CHIP managed care entities, issuers of qualified health plans on the federally-facilitated exchanges, and health care providers.* https://www.cms.gov/files/document/cms-9115-f.pdf (accessed July 8, 2020).

Cohen, D. J., S. R. Keller, G. R. Hayes, D. A. Dorr, J. S. Ash, and D. F. Sittig. 2016. Integrating patient-generated health data into clinical care settings or clinical decision-making: Lessons learned from Project HealthDesign. *JMIR Human Factors* 3(2):e26. https://doi.org/10.2196/humanfactors.5919.

Count Me In. 2020. *Count Me In Homepage.* https://joincountmein.org/projects (accessed January 14, 2020).

CSER (Clinical Sequencing Evidence-Generating Research) Consortium. 2020. *Clinical Sequencing Evidence-Generating Research.* https://cser-consortium.org (accessed January 17, 2020).

Curtis, L. H., J. Brown, and R. Platt. 2014. Four health data networks illustrate the potential for a shared national multipurpose big-data network. *Health Affairs* 33(7):1178–1186. https://doi.org/10.1377/hlthaff.2014.0121.

de Sousa, H. R., and A. Pinto. 2019. Blockchain based informed consent with reputation support. In *Blockchain and Applications*, edited by J. Prieto, A. K. Das, S. Ferretti, A. Pinto, and J. M. Corchado. Basel, Switzerland: Springer Nature Switzerland. Pp. 54–61.

Deloitte. 2018. *EHR convergence and interoperability: A key strategic question for health care providers.* https://www2.deloitte.com/content/dam/Deloitte/us/Documents/life-sciences-health-care/us-lshc-ehr-convergence-and-interoperability.pdf (accessed January 17, 2020).

Dhir, R., A. A. Patel, S. Winters, M. Bisceglia, D. Swanson, R. Aamodt, and M. J. Becich. 2008. A multidisciplinary approach to honest broker services for tissue banks and clinical data: A pragmatic and practical model. *Cancer* 13(7):1705–1715. https://www.ncbi.nlm.nih.gov/pmc/articles/PMC2745185 (accessed January 14, 2020).

Dobscha, S. K., L. M. Denneson, L. E. Jacobson, H. B. Williams, R. Cromer, and S. Woods. 2016. VA mental health clinician experiences and attitudes toward OpenNotes. *General Hospital Psychiatry* 38:89–93. https://doi.org/10.1016/j.genhosppsych.2015.08.001.

Dove, E. S. 2015. Biobanks, data sharing, and the drive for a global privacy governance framework. *Journal of Law, Medicine, and Ethics* 43(4):675–689. https://doi.org/10.1111/jlme.12311.

Dullabh, P. M., N. K. Sondheimer, E. Katsh, and M. A. Evans. 2014. How patients can improve the accuracy of their medical records. *Egems* 2(3):10. https://doi.org/10.13063/2327-9214.1080.

Emam, K. E., S. Rodgers, and B. Malin. 2015. Anonymising and sharing individual patient data. *British Medical Journal* 350:h1139. https://doi.org/10.1136/bmj.h1139.

Equal Employment Opportunity Commission. 2008. *The Genetic Information Nondiscrimination Act of 2008.* https://www.eeoc.gov/laws/statutes/gina.cfm (accessed January 16, 2020).

EU (European Union). 2020. *Data protection in the EU.* https://ec.europa.eu/info/law/law-topic/data-protection/data-protection-eu_en (accessed September 16, 2020).

Farber, N. J., L. Liu, Y. Chen, A. Calvitti, R. L. Street, Jr., D. Zuest, K. Bell, M. Gabuzda, B. Gray, S. Ashfaq, and A. Agha. 2015. EHR use and patient satisfaction: What we learned. *Journal of Family Practice* 64(11):687–696. https://mdedge-files-live.s3.us-east-2.amazonaws.com/files/s3fs-public/issues/articles/JFP_06411_Article3.pdf (accessed July 8, 2020).

FDA (Food and Drug Administration). 2018. *FDA's Sentinel Initiative.* https://www.fda.gov/safety/fdas-sentinel-initiative (accessed January 17, 2020).

FTC (Federal Trade Commission). 2019. *FTC Submits Comment on Proposed Information Blocking Rule to the Department of Health & Human Services Office of the National Coordinator for Health Information Technology (ONC).* https://www.ftc.gov/news-events/press-releases/2019/06/ftc-submits-comment-proposed-information-blocking-rule-department (accessed January 17, 2020).

Geisinger. 2018. Geisinger and Merck unveil new applications developed to help improve patient communication and care delivery. *Geisinger News Releases.* https://www.geisinger.org/about-geisinger/news-and-media/news-releases/2018/08/16/21/10/geisinger-merck-unveil-new-applications-to-help-improve-patient-communication-and (accessed April 30, 2020).

Genes, N., S. Violante, C. Centrangol, L. Rogers, E. E. Schadt, and Y. Y. Chan. 2018. From smartphone to EHR: A case report on integrating patient-generated health data. *NPJ Digital Medicine* 1:23. https://doi.org/10.1038/s41746-018-0030-8.

Glasgow, R. E., S. Finlayson, and D. M. Ray. 2018. To enlist physicians in reducing costs, show them the costs. *Harvard Business Review,* May 3. https://hbr.org/2018/05/to-enlist-physicians-in-reducing-costs-show-them-the-costs (accessed January 17, 2020).

Gleason, M., and E. Dave. 2020. Patient/caregiver letter supporting proposed HHS rules on improving flow of our data. *Society for Participatory Medicine,* January 26. https://participatorymedicine.org/epatients/2020/01/patient-caregiver-letter-supporting-proposed-onc-rule-on-improving-flow-of-our-data.html (accessed June 10, 2020).

Goldstein, M. M., and A. L. Rein. 2010. *Data segmentation in electronic health information exchange: Policy considerations and analysis.* https://www.healthit.gov/sites/default/files/privacy-security/gwu-data-segmentation-final-cover-letter.pdf (accessed January 17, 2020).

Gordon, W., A. Chopra, and A. Landman. 2018. Patient-led data sharing—A new paradigm for electronic health data. *NEJM Catalyst*. https://catalyst.nejm.org/patient-led-health-data-paradigm (accessed August 6, 2019).

Harvard Medical School. 2020. *Harvard Personal Genome Project*. https://pgp.med.harvard.edu (accessed January 14, 2020).

Haug, C. J. 2017. Whose data are they anyway? Can a patient perspective advance the data–sharing debate? *New England Journal of Medicine* 376(23):2203–2205. https://doi.org/10.1056/NEJMp1704485.

HealthIT.gov. 2018. *Legal and Ethical Architecture for Patient-Centered Outcomes Research (PCOR) Data ("Architecture")*. https://www.healthit.gov/topic/scientific–initiatives/pcor/legal-and-ethical-architecture-patient-centered-outcomes-research-pcor-data-architecture (accessed July 7, 2020).

Hixson, J. D., D. Barnes, K. Parko, T. Durgin, S. Van Bebber, A. Graham, and P. Wicks. 2015. Patients optimizing epilepsy management via an online community: The POEM Study. *Neurology* 85(2):129–136. https://www.ncbi.nlm.nih.gov/pmc/articles/PMC4515038 (accessed January 14, 2020).

Holmgren, A. J., V. Patel, and J. Adler-Milstein. 2017. Progress in interoperability: Measuring US hospitals' engagement in sharing patient data. *Health Affairs* 36(10):1820–1827. https://doi.org/10.1377/hlthaff.2017.0546.

Hrynaszkiewicz, I., and D. G. Altman. 2009. Towards agreement on best practice for publishing raw clinical trial data. *Trials* 10:17. https://doi.org/10.1186/1745-6215-10-17.

IDC (International Data Corporation). 2014. *The Digital Universe of Opportunities: Rich Data and the Increasing Value of the Internet of Things.* https://www.emc.com/leadership/digital-universe/2014iview/digital-universe-of-opportunities-vernon-turner.htm (accessed January 14, 2020).

IOM (Institute of Medicine). 2013. *Digital data improvement priorities for continuous learning in health and health care: Workshop summary.* Washington, DC: The National Academies Press. https://doi.org/10.17226/13424.

Irizarry, T., A. DeVito Dabbs, and C. R. Curran. 2015. Patient portals and patient engagement: A state of the science review. *Journal of Medical Internet Research* 17(6):e148. https://www.ncbi.nlm.nih.gov/pmc/articles/PMC4526960 (accessed January 14, 2020).

Jim, H. S., A. I. Hoogland, N. C. Brownstein, A. Barata, A. P. Dicker, H. Knoop, B. D. Gonzalez, R. Perkins, D. Rollison, S. M. Gilbert, and R. Nanda. 2020. Innovations in research and clinical care using patient generated health data. *CA: A Cancer Journal for Clinicians*. https://doi.org/10.3322/caac.21608.

Kamo, N., B. L. Williams, and C. C. Blackmore. 2019. Evaluation of the association of public reporting of patient ratings of US primary care providers with

inappropriate care. *Journal of General Internal Medicine* 34(3):336–337. https://doi.org/10.1007/s11606-018-4706-1.

Kent, J. 2018. 74% of execs say interoperability is critical for value-based care. *Health IT Analytics.* https://healthitanalytics.com/news/74-of-execs-say-interoperability-is-critical-for-value-based-care (accessed April 30, 2020).

Kim, K. K., and M. Helfand. 2018. Engagement in PCORnet research networks. *Medical Care* 56:S1–S3. https://doi.org/10.1097/MLR.0000000000000958.

Kirwan, J. R., M. de Wit, L. Frank, K. L. Haywood, S. Salek, S. Brace-McDonnell, A. Lyddiatt, S. P. Barbic, J. Alonso, F. Guillemin, and S. J. Bartlett. 2017. Emerging guidelines for patient engagement in research. *Value Health* 20(3):481–486. https://doi.org/10.1016/j.jval.2016.10.003.

Klasnja, P., A. Civan Hartzler, K. T. Unruh, and W. Pratt. 2010. Blowing in the wind: Unanchored patient information work during cancer care. In *Proceedings of the SIGCHI Conference on Human Factors in Computing Systems*. https://doi.org/10.1145/1753326.1753355.

Knoppers, B. M., J. R. Harris, A. M. Tasse, I. Budin-Ljosne, J. Kaye, M. Deschenes, and M. H. Zawati. 2011. Towards a data sharing code of conduct for international genomic research. *Genomic Medicine* 3(7):46. https://doi.org/10.1186/gm262.

Kravitz, D., and M. Allen. 2018. Your medical devices are not keeping your health data to themselves. *Pro Publica.* https://www.propublica.org/article/your-medical-devices-are-not-keeping-your-health-data-to-themselves (accessed January 14, 2020).

Kreimer, S. 2015. Avoiding an EHR-related malpractice suit. *Medical Economics* 92(20):66–69. https://pubmed.ncbi.nlm.nih.gov/26619632 (accessed July 8, 2020).

Kroth, P. J., N. Morioka-Douglas, S. Veres, K. Pollock, S. Babbott, S. Poplau, K. Corrigan, and M. Linzer. 2018. The electronic elephant in the room: Physicians and the electronic health record. *JAMIA Open* 1(1):49–56. https://doi.org/10.1093/jamiaopen/ooy016.

Kuntz, R. E., E. M. Antman, R. M. Califf, J. R. Ingelfinger, H. M. Krumholz, A. Ommaya, E. D. Peterson, J. S. Ross, J. Waldstreicher, S. V. Wang, D. A. Zarin, D. M. Whicher, S. M. Siddiqi, and M. H. Lopez. 2019. Individual patient-level data sharing for continuous learning: A strategy for trial data sharing. *NAM Perspectives.* Discussion Paper, National Academy of Medicine. Washington, DC. https://doi.org/10.31478/201906b.

Landi, H. 2019. ECRI: Top patient safety risks include inaccurate EHRs, clinician burnout. *FierceHealthcare.* https://www.fiercehealthcare.com/tech/ecri-cites-ehr-use-clinician-burnout-mobile-health-as-top-patient-safety-risks (accessed April 30, 2020).

Lavallee, D. C., J. R. Lee, E. Austin, R. Bloch, S. O. Lawrence, D. McCall, S. A. Munson, M. B. Nery-Hurwit, and D. Amtmann. 2020. mHealth and patient generated data: Stakeholder perspectives on opportunities and barriers for transforming healthcare. *mHealth* 6(8). https://doi.org/10.21037/mhealth.2019.09.17.

Lee, T. H., and T. Cosgrove. 2014. Engaging doctors in the healthcare revolution. *Harvard Business Review.* https://hbr.org/2014/06/engaging-doctors-in-the-health-care-revolution (accessed January 17, 2020).

Lye, C. T., H. P. Forman, R. Gao, J. G. Daniel, A. L. Hsiao, M. K. Mann, D. deBronkart, H. O. Campos, and H. M. Krumholz. 2018. Assessment of US hospital compliance with regulations for patients' requests for medical records. *JAMA Network Open* 1(6):e183014. https://doi.org/10.1001/jamanetworkopen.2018.3014.

Mafi, J. N., M. Gerard, H. Chimowitz, M. Anselmo, T Delbanco, and J. Walker. 2018. Patients contributing to their doctors' notes: Insights from expert interviews. *Annals of Internal Medicine* 168(4):302–305. https://doi.org/10.7326/m17-0583.

Marshall, A. 2018. You snooze, you lose: Insurers make the old adage literally true. *ProPublica.* https://www.propublica.org/article/you-snooze-you-lose-insurers-make-the-old-adage-literally-true (accessed January 14, 2020).

Miliard, M. 2020. ONC, CMS give some breathing room for interop rules during COVID-19. *Healthcare IT News.* https://www.healthcareitnews.com/news/onc-cms-give-some-breathing-room-interop-rules-during-covid-19 (accessed April 30, 2020).

Na, L., C. Yang, C. C. Lo, F. Zhao, Y. Fukuoka, and A. Aswani. 2018. Feasibility of reidentifying individuals in large national physical activity data sets from which protected health information has been removed with the use of machine learning. *Journal of the American Medical Association Network Open* 1(8):e186040. https://doi.org/10.1001/jamanetworkopen.2018.6040.

NAM (National Academy of Medicine). 2015. *The learning health system series.* https://nam.edu/wp-content/uploads/2015/07/LearningHealthSystem_28jul15.pdf (accessed January 27, 2020).

NCATS (National Center for Advancing Translational Sciences). 2020. *Clinical and Translational Science Awards (CTSA) Program.* https://ncats.nih.gov/ctsa (accessed April 30, 2020).

Nelson, B. 2019. Taking the lead: A new breed for patient advocate is reshaping the future of cancer research. *Cancer Health.* https://www.cancerhealth.com/article/taking-lead-patient-advocacy (accessed January 14, 2020).

The New York Times Editorial Board. 2016. Protecting employee's health data. *New York Times*, March 26. https://www.nytimes.com/2016/03/27/opinion/sunday/protecting-employees-health-data.html (accessed January 14, 2020).

NGA (National Governors Association). 2018. *Getting the right information to the right health care providers at the right time: A road map for states to improve health information flow between providers.* http://natlgovassoc.wpengine.com/wp-content/uploads/2018/07/1612HealthCareRightInformation.pdf (accessed July 7, 2020).

NIH (National Institutes of Health). 2006. *National Conference on Alternative IRB Models: Optimizing Human Subject Protection—November 19–21, 2006.* https://osp.od.nih.gov/wp-content/uploads/2013/08/irbconf06rpt.pdf (accessed January 14, 2020).

NIH. 2019. *Precision Medicine Initiative: Privacy and Trust Principles.* https://allofus.nih.gov/about/program-overview/precision-medicine-initiative-privacy-and-trust-principles (accessed January 17, 2020).

Nkoy, F. L., B. A. Fassl, V. L. Wilkins, J. Johnson, E. H. Unsicker, K. J. Koopmeiners, A. Jensen, M. Frazier, J. Gaddis, L. Malmgren, S. Williams, H. Oldroyd, T. Greene, X. Sheng, D. A. Uchida, C. G. Maloney, and B. L. Stone. 2019. Ambulatory management of childhood asthma using a novel self-management application. *Pediatrics* 143(6). https://doi.org/10.1542/peds.2018-1711.

NYeC (New York eHealth Collaborative). 2019. *Policy & Governance.* https://www.nyehealth.org/shin-ny/policy-governance (accessed January 17, 2020).

Nyrop, K. A., A. M. Deal, K. E. Reeder-Hayes, S. S. Shachar, B. B. Reeve, E. Basch, S. K. Choi, J. T. Lee, W. A. Wood, C. K. Anders, L. A. Carey, E. C. Dees, T. A. Jolly, G. G. Kimmick, M. S. Karuturi, R. E. Reinbolt, J. C. Speca, and M. B. Muss. 2019. Patient-reported and clinician-reported chemotherapy-induced peripheral neuropathy in patients with early breast cancer: Current clinical practice. *Cancer* 125(17):2945–2954. https://doi.org/10.1002/cncr.32175.

ONC (The Office of the National Coordinator for Health Information Technology). 2015. *What Is the eHealth Exchange?* https://www.healthit.gov/faq/what-ehealth-exchange (accessed January 17, 2020).

ONC. 2018. *What Are Patient-Generated Health Data?* https://www.healthit.gov/topic/otherhot-topics/what-are-patient-generated-health-data (accessed October 7, 2020).

ONC. 2019. *Trusted Exchange Framework and Common Agreement.* https://www.healthit.gov/topic/interoperability/trusted-exchange-framework-and-common-agreement (accessed January 17, 2020).

ONC. 2020a. *The U.S. Core Data for Interoperability: Laying the foundation for broader data sharing to support patient care.* https://www.healthit.gov/sites/default/files/nprm/ONCCuresNPRMUSCDI.pdf (accessed January 17, 2020).

ONC. 2020b. *Seven exceptions to the information blocking provision.* https://www.healthit.gov/sites/default/files/nprm/ONCCuresNPRMInfoBlocking.pdf (accessed January 17, 2020).

ONC. 2020c. *21st Century Cures Act: Interoperability, Information Blocking, and the ONC Health IT Certification Program.* https://www.federalregister.gov/documents/2020/05/01/2020-07419/21st-century-cures-act-interoperability-information-blocking-and-the-onc-health-it-certification (accessed April 30, 2020).

Paasche-Orlow, M. K., D. M. Jacob, and J. N. Powell. 2005. Notices of privacy practices: A survey of the Health Insurance Portability and Accountability Act of 1996 documents presented to patients at US hospitals. *Medical Care* 43(6):558–564. https://doi.org/10.1097/01.mlr.0000163646.90393.e4.

Palabindala, V., A. Pamarthy, and N. R. Jonnalagadda. 2016. Adoption of electronic health records and barriers. *Journal of Community Hospital Internal Medicine Perspectives* 6(5):32643. https://doi.org/10.3402/jchimp.v6.32643.

Parasidis, E., E. Pike, and D. McGraw. 2019. A Belmont Report for health data. *New England Journal of Medicine* 380(16):1493–1495. https://doi.org/10.1056/NEJMp1816373.

PCORnet (National Patient-Centered Clinical Research Network). 2013. *The National Patient-Centered Clinical Research Network.* https://pcornet.org (accessed July 8, 2020).

The Pew Charitable Trusts. 2020. *Pew Urges HHS Secretary to Implement Health IT Rules to Help in Light of Coronavirus.* https://www.pewtrusts.org/en/research-and-analysis/speeches-and-testimony/2020/04/02/pew-urges-hhs-secretary-to-implement-health-it-rules-to-help-in-light-of-coronavirus (accessed June 10, 2020).

Pierce, H. H., A. Dev, E. Statham, and B. E. Bierer. 2019. Credit data generators for data reuse. *Nature* 570(7759):30–32. https://doi.org/10.1038/d41586-019-01715-4.

Platt, R., and T. Lieu. 2018. Data enclaves for sharing information derived from clinical and administrative data. *Journal of the American Medical Association* 320(8):753–754. https://doi.org/10.1001/jama.2018.9342.

Quality Payment Program. 2020. *MIPS overview.* https://qpp.cms.gov/mips/overview (accessed April 30, 2020).

Quinn, M. A., A. M. Kats, K. Kleinman, D. W. Bates, and S. R. Simon. 2012. The relationship between electronic health records and malpractice claims. *Archives of Internal Medicine* 172(15):1187–1189. https://doi.org/10.1001/archinternmed.2012.2371.

Raghupathi, W., and V. Raghupathi. 2014. Big data analytics in healthcare: Promise and potential. *Health Information Science and Systems* 2:3. https://www.ncbi.nlm.nih.gov/pmc/articles/PMC4341817 (accessed January 14, 2020).

Ravindranath, M. 2019. How your health information is sold and turned into "risk scores." *Politico.* https://www.politico.com/story/2019/02/03/health-risk-scores-opioid-abuse-1139978 (accessed January 14, 2020).

ResDAC (Research Data Assistance Center). 2018. *Fee list for RIFs: Physical research data request.* https://www.resdac.org/sites/resdac.umn.edu/files/CMS%20Fee%20List%20for%20Research%20Files_4.pdf (accessed January 14, 2020).

ResDAC. 2020a. *CMS Fee Information for CMS Research Identifiable Data.* https://www.resdac.org/cms-fee-information-research-identifiable-data (accessed July 8, 2020).

ResDAC. 2020b. *CMS Virtual Research Data Center (VRDC).* https://www.resdac.org/cms-virtual-research-data-center-vrdc (accessed January 14, 2020).

Ridpath, J. R., C. J. Wiese, and S. M. Greene. 2009. Looking at research consent forms through a participant-centered lens: The PRISM Readability Toolkit. *American Journal of Health Promotion 23*(6):371–375. https://doi.org/10.4278/ajhp.080613-CIT-94.

Rocher, L., J. M. Hendrickx, and Y. A. de Montjoye. 2019. Estimating the success of re-identifications in incomplete datasets using generative models. *Nature Communications* 10(1):3069. https://www.ncbi.nlm.nih.gov/pmc/articles/PMC6650473.

Ross, J. S., J. Waldstreicher, S. Bamford, J. A. Berlin, K. Childers, N. R. Desai, G. Gamble, C. P. Gross, R. Kuntz, R. Lehman, P. Lins, S. A. Morris, J. D. Ritchie, and H. M. Krumholz. 2018. Overview and experience of the YODA Project with clinical trial data sharing after 5 years. *Scientific Data* 5:180268. https://doi.org/10.1038/sdata.2018.268.

Ryan, B. L., J. B. Brown, A. Terry, S. Cejic, M. Stewart, and A. Thind. 2016. Implementing and using a patient portal: A qualitative exploration of patient and provider perspectives on engaging patients. *Journal of Innovation in Health Informatics* 23(2):848. https://doi.org/10.14236/jhi.v23i2.848.

Savage, L. C. 2019. ONC's proposed rule on information blocking: The potential to accelerate innovation in health care. *HealthAffairs Blog.* https://www.healthaffairs.org/do/10.1377/hblog20190215.3077/full (accessed January 17, 2020).

Schulte, F., and E. Fry. 2019. Death by 1,000 clicks: Where electronic health records went wrong. *Kaiser Health News.* https://khn.org/news/death-by-a-thousand-clicks (accessed January 14, 2020).

Sharfstein, J. M., D. Chrysler, J. Bernstein, L. Armijos, L. Tolosa-Leiva, H. Taylor, and L. Rutkow. 2017. *Using electronic health data for community health: Example cases and legal analysis.* https://www.debeaumont.org/wp-content/uploads/2019/04/Electronic-Health-Data-Report-1.pdf (accessed January 14, 2020).

Sim, I. 2019. Mobile devices and health. *New England Journal of Medicine* 381(10):956–968. https://doi.org/10.1056/NEJMra1806949.

Sittig, D. F., and H. Singh. 2011. Legal, ethical, and financial dilemmas in electronic health record adoption and use. *Pediatrics* 127(4):e1042–e1047. https://doi.org/10.1542/peds.2010-2184.

Stableford, S., and W. Mettger. 2007. Plain language: A strategic response to the health literacy challenge. *Journal of Public Health Policy* 28(1):71–93. https://doi.org/10.1057/palgrave.jphp.3200102.

Stanford Medicine. 2017. *Stanford Medicine 2017 health trends report: Harnessing the power of data in health.* https://med.stanford.edu/content/dam/sm/sm-news/documents/StanfordMedicineHealthTrendsWhitePaper2017.pdf (accessed January 14, 2020).

Stone, T. J., and D. Sullivan. 2007. Payer trend: "Tiering" physicians and "steering" patients. *Family Practice Management* 14(10):24–26. https://www.aafp.org/fpm/2007/1100/p24.html (accessed October 7, 2020).

Taha, J., S. J. Czaja, J. Sharit, and D. G. Morrow. 2013. Factors affecting usage of a personal health record (PHR) to manage health. *Psychology and Aging* 28(4):1124–1139. https://doi.org/10.1037/a0033911.

Tai-Seale, M., N. L. Downing, V. G. Jones, R. V. Milani, B. Zhao, B. Clay, C. D. Sharp, A. S. Chan, and C. A. Longhurst. 2019. Technology-enabled consumer engagement: Promising practices at four health care delivery organizations. *Health Affairs* 38(3):383–390. https://doi.org/10.1377/hlthaff.2018.05027.

Thielman, S. 2017. Your private medical data is for sale–and it's driving a business worth billions. *The Guardian.* https://www.theguardian.com/technology/2017/jan/10/medical-data-multibillion-dollar-business-report-warns (accessed on July 25, 2019).

Toll, E. T., M. A. Alkureishi, W. W. Lee, S. F. Babbott, P. A. Bain, J. W. Beasley, R. M. Frankel, A. A. Loveys, H. S. Wald, S. S. Woods, and W. R. Hersh. 2019. Protecting healing relationships in the age of electronic health records: Report from an international conference. *JAMIA Open* 2(3):282–290. https://doi.org/10.1093/jamiaopen/ooz012.

Topol, E. 2016. *The patient will see you now: The future of medicine is in your hands.* New York: Basic Books.

U.S. Government. 2017. Federal policy for the protection of human subjects: Final rule. *Federal Register* 82(12):7149–7274. https://www.gpo.gov/fdsys/pkg/FR-2017-01-19/pdf/2017-01058.pdf (accessed July 8, 2020).

VA (Department of Veterans Affairs). 2018. *Blue Button.* https://www.va.gov/bluebutton (accessed April 30, 2020).

Valdez, R. S., R. J. Holden, L. L. Novak, and T. C. Veinot. 2015. Transforming consumer health informatics through a patient work framework: Connecting

patients to context. *Journal of the American Medical Informatics Association* 22(1):2–10. https://doi.org/10.1136/amiajnl-2014-002826.

Vernon, J. A., A. Trujillo, S. Rosenbaum, and B. DeBuono. 2007. Low health literacy: Implications for national health policy. *Health Policy and Management Faculty Publications.* https://publichealth.gwu.edu/departments/healthpolicy/CHPR/downloads/LowHealthLiteracyReport10_4_07.pdf (accessed August 7, 2019).

Walker, J., S. Leveille, S. Bell, H. Chimowitz, Z. Dong, J. G. Elmore, L. Fernandez, A. Fossa, M. Gerard, P. Fitzgerald, K. Harcourt, S. Jackson, T. H. Payne, J. Perez, H. Shucard, R. Stametz, C. DesRoches, and T. Delbanco. 2019. OpenNotes after 7 years: Patient experiences with ongoing access to their clinician's outpatient visit notes. *Journal of Medical Internet Research* 21(5):e13876. https://doi.org/10.2196/13876.

Wicks, P., and N. B. Fountain. 2012. Patient assessment of physician performance of epilepsy quality-of-care measures. *Neurology: Clinical Practice* 2(4):335–342. https://doi.org/10.1212/CPJ.0b013e318278beac.

Zulman, D. M., N. H. Shah, and A. Verghese. 2016. Evolutionary pressures on the electronic health record: Caring for complexity. *JAMA* 316(9):923–924. https://doi.org/10.1001/jama.2016.9538.

Appendix A

Generating Stakeholder Support and Demand for
Leveraging and Sharing Data for Continuous Learning

National Academy of Sciences Building
Lecture Room
2101 Constitution Avenue, NW
Washington, DC 20418

Meeting Focus: *A shared vision for generating stakeholder support and demand for data sharing, linkage, and use for a continuously learning health system*

Motivating Questions:
1. *Vision:* What is our shared vision for a health system that leverages and shares data to learn from patients, clinicians, and payers and feeds the results back to end users to continuously improve care and outcomes? What are the essential elements needed to achieve this vision? What is the role of stakeholder support and demand in achieving this vision?
2. *Stakeholders:* What are the concerns of relevant stakeholder groups, specifically, health system and health plan executives, patient and family leaders, and the research oversight community, in advancing data sharing, linkage, and use? What are the barriers and challenges facing each group and what opportunities and strategies can each group leverage to achieve progress?
3. *Case examples:* For each stakeholder community, what case examples demonstrate the barriers or potential strategies to leveraging and linking health data to support continuous learning?

Outcomes Intended: Develop a shared vision, common to all stakeholder groups, for leveraging and linking health data to support continuous learning; and identify case studies that demonstrate practical opportunities for progress.

8:30 a.m.   Coffee and Light Breakfast Available

9:00 a.m.   Welcome, Introductions, and Meeting Overview

Welcome from the National Academy of Medicine and the Patient-Centered Outcomes Research Institute
> *J. Michael McGinnis,* National Academy of Medicine
> *Joe Selby,* Patient-Centered Outcomes Research Institute

Opening Remarks and Meeting Overview by the Clinical Effectiveness Research Innovation Collaborative Co-Chairs
> *Richard Platt,* Harvard Medical School
> *Richard Kuntz,* Medtronic

9:15 a.m.   Overview and Discussion of Steering Committee Aims and Objectives

Review of the aims of the steering committee followed by a discussion of the initiative logic model, the inputs and outputs of a continuously learning health system, with specific examples, and the strategic and operational elements that facilitate data sharing to support continuous learning.

> *Erin Mackay,* National Partnership for Women & Families
> *Danielle Whicher,* National Academy of Medicine

Open Discussion

10:15 a.m.   Break

10:30 a.m.   Building Support and Demand Among Patients and Families

Identification of key considerations and elements necessary, from the patient and family perspective, to build support and demand for leveraging and linking data and information to support continuous learning.

Moderators:
> *Kiely Law,* Kennedy Krieger Institute
> *Kristin Carman,* Patient-Centered Outcomes Research Institute

Open Discussion

11:15 a.m.   Building Support and Demand Among the Research Oversight Community

Identification of key considerations and elements necessary, from the perspective of the research oversight community, to build support and demand for leveraging and linking data to support continuous learning.

Moderators:
> *Richard Platt,* Harvard Medical School
> *Laura Rodriguez,* National Human Genome Research Institute

Open Discussion

12:00 p.m.   Lunch

12:30 p.m.   Building Support and Demand Among Health Plans and Health Systems

Identification of key considerations and elements necessary, from the health plan and health system perspective, to build support and demand for leveraging and linking data to support continuous learning.

Moderators:
> *Andrew Baskin,* Aetna Inc.
> *Michelle Schreiber,* Henry Ford Health System

Open Discussion

1:15 p.m.   Break

1:30 p.m.   A Vision for a Continuously Learning Health System That Leverages Data to Support Health and Health Care Improvement

Building on earlier discussions, the steering committee will develop a vision for a continuously learning health system that leverages data to support continuous learning, discuss the significance and strategy for building demand, and identify common challenges and opportunities spanning stakeholder groups.

Moderator:
Paul Wallace, AcademyHealth

Open Discussion

2:30 p.m.   Vision Statement: Writing Assignments and Timeline

The steering committee will discuss writing assignments and the timeline for the development of the vision statement.

Moderator:
Erin Mackay, National Partnership for Women & Families

Open Discussion

3:00 p.m.   Summary of Next Steps Regarding the Vision Statement and Stakeholder Groups

Comments from the Chairs
Richard Platt, Harvard Medical School
Richard Kuntz, Medtronic

Thanks from the National Academy of Medicine and the Patient-Centered Outcomes Research Institute
J. Michael McGinnis, National Academy of Medicine
Joe Selby, Patient-Centered Outcomes Research Institute

3:15 p.m.   Adjourn

MEETING PARTICIPANTS

(all affiliations were accurate as of June 11, 2018)

Andrew E. Baskin, M.D.
Vice President, National Medical Director for Quality and Provider Performance
    Measurement
Aetna Inc.

Helen Burstin, M.D., M.P.H.
Executive Vice President and Chief Executive Officer
Council of Medical Specialty Societies

Kristin L. Carman, M.A., Ph.D.
Director of Public and Patient Engagement
Patient-Centered Outcomes Research Institute

Jeff Hurd, M.S., Ph.D., M.S.
Regional Clinical Account Director
AstraZeneca

Richard E. Kuntz, M.D., M.S.
Senior Vice President, Chief Medical and Scientific Officer
Medtronic

Kiely Law, M.D., M.P.H.
Research Director, Interactive Autism Network
Kennedy Krieger Institute

Erin Mackay, M.P.H.
Associate Director, Health Information Technology Programs
National Partnership for Women & Families

Bradley Malin, Ph.D.
Director, Heath Information Privacy Laboratory
Vanderbilt University

C. Daniel Mullins, Ph.D.
Professor, Pharmaceutical Health Services Research Department
University of Maryland School of Pharmacy

Richard Platt, M.D., M.Sc.
Professor and Chair of the Department of Population Medicine and Executive
  Director of the Harvard Pilgrim Health Care Institute
Harvard Medical School

Laura Rodriguez, Ph.D.
Director, Division of Policy, Communications, and Education
National Human Genome Research Institute

Michelle B. Schreiber, M.D.
Senior Vice President and Chief Quality Officer
Henry Ford Health System

Joe Selby, M.D., M.P.H.
Executive Director
Patient-Centered Outcomes Research Institute

Rachel Sherman, M.D., M.P.H.
Principal Deputy Commissioner
Food and Drug Administration

Mona Siddiqui, M.D., M.P.H.
Chief Data Officer, Office of the Chief Technology Officer
Department of Health and Human Services

Paul Wallace, M.D.
Senior Scholar
AcademyHealth

National Academies Staff

Mahnoor Ahmed, M.Eng.
Research Associate

Hannah Hirasuna
Intern

Gwen Hughes
Research Coordinator

Erin Jones
Intern

Henrietta Osei–Anto, M.A., M.P.P.
Senior Program Officer

Ioana Petricel
Senior Program Assistant

Sameer Siddiqi, Ph.D. Candidate
Technical Consultant

Danielle Whicher, Ph.D., M.H.S.
Senior Program Officer

J. Michael McGinnis, M.D., M.P.P.
Executive Director, Leadership Consortium for a Value & Science-Driven Health
   System
Leonard D. Schaeffer Executive Officer

PCORI Staff

Shayna Barbash
Program Associate

Claudia Grossmann, Ph.D.
Senior Program Officer

Kimberly Marschhauser, Ph.D.
Program Officer

Maryan Zirkle, M.D., M.S., M.A.
Senior Program Officer

Web Participants

Adrian Hernandez, M.D., M.H.S.
Director, Health Services and Outcomes Research
Duke University Medical Center and Duke Clinical Research Institute

Michelle Johnston–Fleece, M.P.H.
Senior Program Officer

Appendix B

FEBRUARY 7, 2019—NAM MEETING AGENDA AND PARTICIPANT LIST

Generating Support and Demand for Health Data Sharing, Linkage, and Use

National Academy of Sciences Building
Lecture Hall
2101 Constitution Avenue, NW
Washington, DC 20418

Meeting Focus: *Stakeholder convening for the National Academy of Medicine (NAM) Generating Support and Demand for Health Data Sharing, Linkage, and Use initiative to review the progress and develop principles, approaches, and strategies for addressing barriers to data sharing, linkage, and use*

Motivating Questions: Each stakeholder workgroup in developing their stakeholder statement will consider the following:
1. *Key Issues:* Does the stakeholder statement adequately capture the ethical, regulatory, cultural, and financial barriers to data sharing from the perspective of their constituent group?
2. *Strategies:* What are the opportunities and key policy and cultural levers for facilitating progress?
3. *Practices:* What are concrete next steps for advancing electronic health data sharing, linkage, and use, and who should steward implementation of these action steps?

Outcomes Anticipated: Development of three stakeholder statements that, in addition to articulating the importance of data sharing from their constituent's perspective, describe the cultural, regulatory, financial, and ethical barriers, and identify long- and short-term solutions for accelerating progress.

8:30 a.m.　　　**Coffee and Light Breakfast Available**

9:00 a.m.　　　**Welcome, Introductions, and Meeting Overview**

Welcome from the National Academy of Medicine
　　　J. Michael McGinnis, National Academy of Medicine
　　　Joe Selby, Patient-Centered Outcomes Research Institute

Opening Remarks and Meeting Overview by Collaborative and Steering Committee Chairs
　　　Rich Platt, Harvard Medical School and Harvard Pilgrim Health Care Institute
　　　Erin Mackay, National Partnership for Women & Families
　　　Peter Margolis, Cincinnati Children's Hospital Medical Center

9:30 a.m.　　　**Update from the Stakeholder Workgroup Co-Chairs**

During this session, participants will hear from each set of co-chairs on the status of their stakeholder statement and highlight the barriers to data sharing their groups have identified and any outstanding issues for group consideration.

Patient and Family Engagement Leaders (10 minutes)
　　　Stacey Lihn, National Pediatric Cardiology Quality Improvement Collaborative
　　　Susan Woods, Society for Participatory Medicine

Research Community Oversight Leaders (10 minutes)
　　　Sarah Greene, Health Care Systems Research Network
　　　Russell Rothman, Vanderbilt University

Health Care Executives Workgroup (10 minutes)
　　　Rainu Kaushal, Weill Cornell Medical College and New York-Presbyterian Hospital

Q&A and Open Discussion

10:30 a.m.　　　**Break**

10:45 a.m.   Breakout Sessions: Refinement of Stakeholder Statements

Participants will divide into their workgroups to address the outstanding issues and to develop strategies for overcoming barriers and specific action steps that can be accomplished in the near future to make progress.

12:00 p.m.   Lunch

Pick up lunch and continue with breakout activities.

1:15 p.m.   Break

1:30 p.m.   Summary of Workgroup Discussions

Participants will reconvene to be briefed by the workgroup chairs on the breakout session discussions.

Patient and Family Engagement Leaders (10 minutes)
>   *Stacey Lihn,* National Pediatric Cardiology Quality Improvement
>   Collaborative
>   *Susan Woods,* Society for Participatory Medicine

Research Community Oversight Leaders (10 minutes)
>   *Sarah Greene,* Health Care Systems Research Network
>   *Russell Rothman,* Vanderbilt University

Health Care Executives Workgroup (10 minutes)
>   *Rainu Kaushal,* Weill Cornell Medical College and New York–Presbyterian
>   Hospital

Q&A and Open Discussion

**2:15 p.m.   Potential Synergistic Effects of Workgroup
                Recommendations**

Participants will discuss ways in which recommendations of one group can bolster or impede recommendations of another group.

Moderators:

> *Erin Mackay,* National Partnership for Women & Families
> *Peter Margolis,* Cincinnati Children's Hospital Medical Center

3:15 p.m.   Summary and Next Steps

Comments and Thanks from the Collaborative Chair and the NAM

> *Rich Platt,* Harvard Medical School and Harvard Pilgrim Health Care
> Institute
> *J. Michael McGinnis,* National Academy of Medicine

3:30 p.m.   Adjourn

MEETING PARTICIPANTS

(all affiliations were accurate as of February 7, 2019)

Innovation Collaborative Chair

Richard Platt, M.D., M.S.
Professor, Harvard Medical School
Harvard Pilgrim Health Care Institute

Patient and Family Engagement Leaders
Co-Chairs

Stacey Lihn, B.A.
Parent Lead
National Pediatric Cardiology Quality Improvement Collaborative

Susan Woods, M.D., M.P.H.
President
Society for Participatory Medicine

Health Care Executives Workgroup Chair

Rainu Kaushal, M.D., M.P.H.
Chief of Healthcare Policy and Research
Weill Cornell Medical College and New York–Presbyterian Hospital/
   Weill Cornell Medical Center

Research Community Oversight Leaders Co-Chairs

Sarah Greene, M.P.H.
Executive Director
Health Care Systems Research Network

Russell Rothman, M.D., M.P.P.
Vice President for Population Health Research
Vanderbilt University

Participants

Kevin Ban, M.D.
Chief Medical Officer
athenahealth, Inc.

Shayna Barbash
Senior Program Associate
Patient-Centered Outcomes Research Institute

Ricky Bloomfield, M.D.
Clinical and Health Informatics Lead
Apple Inc.

Helen Burstin, M.D., M.P.H., MACP
Executive Vice President and Chief Executive Officer
Council of Medical Specialty Societies

Tanisha Carino, Ph.D.
Executive Director
FasterCures

Kristin Carman, M.A., Ph.D.
Director of Public and Patient Engagement
Patient–Centered Outcomes Research Institute

Jodi Daniel, J.D., M.P.H.
Partner
Crowell & Moring LLC

Janet Freeman–Daily, M.S.
Stage IV Lung Cancer Survivor
Patient Advocate
Gray Connections

Patrick Getzen, FSA, MAAA
Senior Vice President, Chief Data and Analytics Officer
BlueCross BlueShield of North Carolina

Claudia Grossmann, Ph.D.
Program Officer
Patient–Centered Outcomes Research Institute

John Halamka, M.D.
Chief Information Officer
Beth Israel Deaconess Medical Center

John Keats, M.D.
National Medical Director
Cigna

John Lantos, M.D.
Director, Center for Bioethics
Children's Mercy Kansas City

Emily Largent, J.D., Ph.D., RN
Assistant Professor, Medical Ethics and Health Policy
University of Pennsylvania Perelman School of Medicine

Erin Mackay, M.P.H.
Associate Director, Health Information Technology Policy and Programs
National Partnership for Women & Families

Bradley Malin, Ph.D.
Director, Heath Information Privacy Laboratory; Professor of Biomedical
  Informatics
Vanderbilt University

Peter Margolis, M.D., Ph.D.
Co-Director, James M. Anderson Center for Health Systems Excellence
Cincinnati Children's Hospital Medical Center

Kameron Matthews, M.D., J.D., FAAFP
Deputy Undersecretary of Health for Community Care
Veterans Health Administration

Michelle Meyer, Ph.D., J.D.
Assistant Professor and Associate Director
Geisinger's Center for Translational Bioethics and Health Care Policy

Sally Okun, RN, MMHS
Vice President of Advocacy, Policy & Patient Care
PatientsLikeMe

Pearl O'Rourke, M.D.
Director of Human Research Affairs
Partners HealthCare International

Casey Quinlan
Chief Messaging Officer
Mighty Casey Media

Lewis Sandy, M.D., FACP
Executive Vice President, Clinical Advancement
UnitedHealth Group

John Santa, M.D., M.P.H.
Director of Dissemination
OpenNotes

Michelle Schreiber, M.D.
Director, Quality Measurement and Value-Based Incentives Group
Centers for Medicare & Medicaid Services

Mark Schreiner, M.D.
Vice Chair, Committees for the Protection of Human Subjects
Children's Hospital of Philadelphia

Joe Selby, M.D., M.P.H.
Executive Director
Patient-Centered Outcomes Research Institute

Andrew Sperling, M.A., J.D.
Director, Legislative and Policy Advocacy
National Alliance on Mental Illness

Jeremy Sugarman, M.D., M.P.H., M.A.
Harvey M. Meyerhoff Professor of Bioethics and Medicine
Johns Hopkins Berman Institute of Bioethics

Veronica (Ronnie) Todaro, M.P.H.
Senior Vice President, Chief Operating Officer
Parkinson's Foundation

Danny van Leeuwen, M.P.H., RN, CPHQ
Principal
Health Hats

Paul Wallace, M.D.
Senior Scholar
AcademyHealth

Maryan Zirkle, M.D., M.S., M.A.
Senior Program Officer
Patient-Centered Outcomes Research Institute

Web Participants

Christine Bechtel, M.A.
President and Chief Strategist
X4 Health

Adrienne Boissy, M.D., M.A.
Chief Experience Officer
Cleveland Clinic

Hugo Campos
Chair of the Community Advisory Board
California Precision Medicine Consortium

C. Daniel Mullins, Ph.D.
Professor and Chair, Pharmaceutical Health Services Research Department
University of Maryland School of Pharmacy

Harold Paz, M.D., M.S.
Executive Vice President and Chief Medical Officer
Aetna Inc.

National Academies Staff

Inez Adams, Ph.D., M.A.
Senior Program Officer (Temporary)

Mahnoor Ahmed, M.Eng.
Research Associate

Jessica Brown
Executive Assistant to the Executive Officer

Anna Cupito, M.P.H.
Research Associate

Jeff Fishman
Senior Program Assistant (Temporary)

Fasika Gebru
Senior Program Assistant

Steve Olson
Science Writer

Sameer Siddiqi, Ph.D. Candidate
Technical Consultant

Danielle Whicher, Ph.D., M.H.S.
Senior Program Officer

J. Michael McGinnis, M.D., M.A., M.P.P.
Executive Director, Leadership Consortium for a Value & Science–Driven Health System
Leonard D. Schaeffer Executive Officer

Appendix C

AUGUST 23, 2019—NAM MEETING AGENDA AND PARTICIPANT LIST

Generating Support and Demand for Health Data Sharing, Linkage, and Use

National Academy of Sciences Building
Lecture Room
2101 Constitution Avenue, NW
Washington, DC 20418

Meeting Focus: *Building partnerships and implementing principles and priorities to achieve the vision of a health system that shares data for continuous learning and improvement*

Motivating Questions:
1. *Vision:* Does the vision statement for a health system that shares data for continuous improvement clearly articulate the benefits of widespread data sharing and make a convincing case for addressing the outstanding cultural, regulatory, financial, and ethical barriers?
2. *Barriers and priorities:* Do the stakeholder statements identify the most pressing cultural, regulatory, financial, and ethical barriers preventing widespread data sharing in the United States as well as feasible priorities for beginning to address those barriers in the near term?
3. *Resources:* What resources are required to support the implementation of the key priorities and which organizations should be engaged in implementing those priorities?
4. *Affecting change:* How can participants work to actualize the priorities identified following the meeting discussion?

Outcomes Anticipated: Commitments from key stakeholders to implement the principles and priorities for addressing cultural, regulatory, financial, and ethical barriers to widespread data sharing to support continuous learning and improvement in the U.S. health care system.

8:30 a.m.   Coffee and Light Breakfast Available

9:00 a.m.   Welcome, Introductions, and Meeting Overview

Welcome from the National Academy of Medicine and the Patient-Centered Outcomes Research Institute
        J. Michael McGinnis, National Academy of Medicine
        Joe Selby, Patient-Centered Outcomes Research Institute

9:30 a.m.   A Vision for a Health System That Shares Data for Continuous Improvement

During this session, the steering committee co-chairs will provide an overview of the initiative and the vision statement for a health system that shares data for continuous improvement.

        Erin Mackay, National Partnership for Women & Families
        Peter Margolis, Cincinnati Children's Hospital Medical Center

Q&A and Open Discussion

10:00 a.m.   Break

10:15 a.m.   Data Sharing for Continuous Learning: Barriers, Opportunities, and Priorities

Participants will hear from representatives of three stakeholder communities regarding the barriers to widespread data sharing to support continuous learning and improvement, as well as opportunities and key priorities for addressing those barriers.

Patient and Family Engagement
        Susan Woods, Society for Participatory Medicine
        Christine Bechtel, X4 Health

Research Oversight
> *Sarah Greene,* Health Care Systems Research Network
> *Russell Rothman,* Vanderbilt University

Health Care Executives
> *Rainu Kaushal,* Weill Cornell Medical College and New York-Presbyterian Hospital
> *Gregg Meyer,* Partners Healthcare International

Q&A and Open Discussion

11:15 a.m.   Building Support: Stakeholder Reactions

Stakeholders representing key organizations for affecting change will comment on the feasibility of implementing the key priorities and the resources needed to support those efforts.

> *Patrick Gee,* PFA Network, and *Libby Hoy,* Patient & Family-Centered Care Partners (Remote)
> *Michael Hodgkins,* American Medical Association
> *Michael Lauer,* National Institutes of Health
> *Steve Gravely,* Gravely Group

Q&A and Open Discussion

12:15 p.m.   Lunch Keynote

Participants will pick up lunch outside of the meeting room and return for a lunch keynote.

> *Jeremy Wertheimer,* Biological Engineering Ventures and the Broad Institute

1:15 p.m.   Identifying Resources for Implementing Key Priorities

Representatives from organizations with access to resources needed to implement the key priorities identified will comment on the feasibility of committing those resources to support change efforts over the next couple of years**.**

     Teresa Zayas-Cabán, The Office of the National Coordinator for Health Information Technology
     Kate Goodrich, Centers for Medicare & Medicaid Services
     Hilary Heishman, Robert Wood Johnson Foundation
     Margo Edmunds, AcademyHealth

Q&A and Open Discussion

2:15 p.m.   **Break**

2:30 p.m.   **Achieving the Vision: Building Support and Actualizing Change**

Participants will engage in a moderated discussion around next steps for actualizing change. The goal of the session is to reach consensus about critical next steps and achieve buy-in from key organizations and stakeholder representatives.

Moderators:
     Erin Mackay, National Partnership for Women & Families
     Peter Margolis, Cincinnati Children's Hospital Medical Center

3:30 p.m.   **Closing Remarks**

Final Thoughts and Thanks from the Patient-Centered Outcomes Research Institute and the National Academy of Medicine
     Joe Selby, Patient-Centered Outcomes Research Institute
     J. Michael McGinnis, National Academy of Medicine

MEETING PARTICIPANTS

(affiliations were accurate as of August 23, 2019)

PCORI Partners

Kristin L. Carman, M.A., Ph.D.
Director of Public and Patient Engagement
Patient-Centered Outcomes Research Institute

Joe V. Selby, M.D., M.P.H.
Executive Director
Patient-Centered Outcomes Research Institute

Steering Committee Co-Chairs/Presenters

Erin Mackay, M.P.H.
Associate Director, Health Information Technology Policy and Programs
National Partnership for Women & Families

Peter A. Margolis, M.D., Ph.D.
Co-Director, James M. Anderson Center for Health Systems Excellence
Cincinnati Children's Hospital Medical Center

Patient and Family Engagement Leaders
Co-Chairs/Presenters

Christine Bechtel
President and Chief Strategist
X4 Health

Susan Woods, M.D., M.P.H.
Past President
Society for Participatory Medicine

Health Care Executives Workgroup
Co-Chairs/Presenters

Rainu Kaushal, M.D., M.P.H.
Chief of Healthcare Policy and Research
Weill Cornell Medical College and New York–Presbyterian Hospital/Weill
    Cornell Medical Center

Gregg S. Meyer, M.D., M.Sc.
Chief Clinical Officer
Partners Healthcare International

Research Community Oversight Leaders
Co-Chairs/Presenters

Sarah Greene, M.P.H.
Executive Director
Health Care Systems Research Network

Russell Rothman, M.D., M.P.P.
Vice President for Population Health Research
Vanderbilt University

Speakers

Margo Edmunds, Ph.D.
Vice President for Evidence Generation and Translation
AcademyHealth

Kate Goodrich, M.D., M.H.S.
Director and Chief Medical Officer
Centers for Medicare & Medicaid Services

Steve Gravely, J.D.
Founder and Chief Executive Officer
Gravely Group

Hilary Heishman, M.P.H.
Senior Program Officer
Robert Wood Johnson Foundation

Michael Hodgkins, M.D., M.P.H.
Chief Medical Information Officer
American Medical Association

Michael Lauer, M.D.
Deputy Director for Extramural Research
National Institutes of Health

Jeremy Wertheimer
Chief Executive Officer
Biological Engineering Ventures and the Broad Institute

Teresa Zayas-Cabán, Ph.D.
Chief Scientist
Office of the National Coordinator for Health Information Technology

Participants

Laura Adams, M.S.
Catalyst
X4 Health

Kevin Ban, M.D.
Chief Medical Officer
athenahealth, Inc.

Meryl Bloomrosen, M.B.A., M.B.I.
Senior Director, Federal Affairs
Premier

Christopher P. Boone, Ph.D.
Vice President, Global Medical Epidemiology & Big Data Analysis
Pfizer Inc.

Helen Burstin, M.D., M.P.H., MACP
Executive Vice President and Chief Executive Officer
Council of Medical Specialty Societies

Milton Corn, M.D., FACP, FACMI
Deputy Director for Research and Education
National Library of Medicine

Donna R. Cryer, J.D.
Interim Executive Director
People-Centered Research Foundation

Robert Emerson, Ph.D.
Vice President and Head of Strategic Data Management
BlueCross BlueShield of North Carolina

Patrick O. Gee, Sr., Ph.D., JLC
Healthcare Consultant/Consumer Advocate
PFA Network

Rachel Goldberg, Ph.D.
Director, Health and Long-Term Services and Support Issues, Office of Policy
   Development and Integration
American Association of Retired Persons

Ben Green, M.D.
Strategic Initiatives
Amazon

William Gregg, M.D., M.S., M.P.H.
Chief Clinical Transformation Officer, Vice President, Clinical Informatics
HCA Healthcare

Claudia Grossmann, Ph.D.
Program Officer
Patient-Centered Outcomes Research Institute

Kevin Haynes, Pharm.D., MSCE
Principal Scientist
HealthCore Inc.

Mary C. Hennessey, J.D.
General Counsel
Patient-Centered Outcomes Research Institute

Adrian Hernandez, M.D., M.H.S.
Vice Dean for Clinical Research
Duke Clinical Research Institute

Kristen Honey, Ph.D., PMP
Innovator in Residence
Department of Health and Human Services

Barbara J. Howard, M.D.
Assistant Professor of Pediatrics, Johns Hopkins University School of Medicine
Total Child Health, Inc.

Matthew Hurford, M.D.
Chief Medical Officer
University of Pittsburgh Medical Center

Javier Jimenez, M.D., M.P.H.
Vice President, Real-World Evidence
Sanofi

Burcu Kilic, Ph.D.
Director, Digital Rights Program and Research Director, Access to Medicines
Public Citizen

Susan R. Kirsh, M.D., M.P.H.
Acting Assistant Deputy Under Secretary for Health for Access to Care
Department of Veterans Affairs

Gloria Kupferman, M.B.A.
Chief Data Strategy Officer
American Hospital Association

John Lantos, M.D.
Director, Center for Bioethics
Children's Mercy Kansas City

Emily Largent, J.D., Ph.D., RN
Assistant Professor, Medical Ethics and Health Policy
University of Pennsylvania Perelman School of Medicine

Tracie Lattimore, B.S.N., M.S.N., Dr.P.H.
Senior Policy Advisor, Executive Office of the President
Office of Science and Technology Policy

Jenny Luray, M.P.A.
Senior Advisor
Research!America

Bradley Malin, Ph.D.
Director, Heath Information Privacy Laboratory; Professor of Biomedical
    Informatics
Vanderbilt University

David Maron, M.A., M.H.S.
Statistician
Veterans Health Administration

Kameron Matthews, M.D., J.D., FAAFP
Deputy Undersecretary of Health for Community Care
Veterans Health Administration

John Mattison, M.D.
Chief Medical Information Officer
Kaiser Permanente

Ross McKinney, Jr., M.D.
Chief Scientific Officer
Association of American Medical Colleges

Jerry Menikoff, M.D., J.D.
Director
Office for Human Research Protections

Michelle Meyer, Ph.D., J.D.
Assistant Professor and Associate Director
Geisinger's Center for Translational Bioethics and Health Care Policy

C. Daniel Mullins, Ph.D.
Professor and Chair, Pharmaceutical Health Services Research Department
University of Maryland School of Pharmacy

Adnan Munkarah, M.D.
Executive Vice President and Chief Clinical Officer
Henry Ford Health System

Sally Okun, RN, M.M.H.S.
Vice President of Advocacy, Policy & Patient Care
PatientsLikeMe

Stacy Palmer, CPXP
Senior Vice President and Chief Operating Officer
The Beryl Institute

Elizabeth Pike, J.D., LLM
Associate General Counsel
Patient-Centered Outcomes Research Institute

Casey Quinlan
Chief Messaging Officer
Mighty Casey Media

Michael Radtke, M.D.
Clinical Informatics Physician
Epic

Brooke Rockwern, M.P.H.
Associate, Health IT Policy
American College of Physicians

Sally Rodriguez, M.P.H.
Chief of Staff
Health Care Cost Institute

Carla Rodriguez-Watson, Ph.D., M.P.H.
Scientific Director, Innovation in Medical Evidence Development and Surveillance
Reagan–Udall Foundation for the Food and Drug Administration

Susannah L. Rose, Ph.D.
Associate Chief Experience Officer
Cleveland Clinic

Lewis Sandy, M.D.
Executive Vice President, Clinical Advancement
UnitedHealth Group

Sophie Shen, Dr.P.H., PCMH, CCE
Director of Value-Based Care, Oncology
Johnson & Johnson

Mona Siddiqui, M.D., M.P.H., M.S.E.
Chief Data Officer, Office of the Chief Technology Officer
Department of Health and Human Services

Walter G. Suarez, M.D., M.P.H.
Executive Director, Health Information Technology Strategy and Policy
Kaiser Permanente
Chair-Elect, Health Level Seven International Board of Directors

Bharat Sutariya, M.D., FACEP
Vice President and Chief Medical Officer, Population Health
Cerner Corporation

Sharon Terry, M.A.
President and Chief Executive Officer
Genetic Alliance

Danny van Leeuwen, M.P.H., RN, CPHQ
Principal
Health Hats

Ryan Vega, M.D.
Diffusion of Excellence Lead
Veterans Health Administration

James Weinstein, D.O., M.S.
Senior Vice President, Microsoft Healthcare, Head of Innovation and Health
    Equity
Microsoft

John Wilbanks
Chief Commons Officer
Sage Bionetworks

Mariann Yeager, M.B.A.
Chief Executive Officer
The Sequoia Project

Maryan Zirkle, M.D., M.S., M.A.
Senior Program Officer
Patient-Centered Outcomes Research Institute

Web Participants

Richard Conroy, Ph.D., M.B.A.
Program Leader
National Institutes of Health

John Halamka, M.D., M.S.
Chief Information Officer
Beth Israel Deaconess Medical Center

Libby Hoy
Patient Family Advisor
Patient & Family-Centered Care Partners

Paul Wallace, M.D.
Senior Scholar
AcademyHealth

National Academies Staff

Mahnoor Ahmed, M.Eng.
Research Associate

Ayodola Anise, M.H.S.
Director, Value & Culture

Jessica Brown
Executive Assistant to the Executive Officer

Anna Cupito, M.P.H.
Research Associate

Fasika Gebru
Senior Program Assistant

Angana Roy, M.P.H.
Program Strategy Officer

Danielle Whicher, Ph.D., M.H.S.
Director, Science & Technology

J. Michael McGinnis, M.D., M.A., M.P.P.
Executive Director, Leadership Consortium for a Value & Science-Driven
    Health System
Leonard D. Schaeffer Executive Officer