Digital Health and Evidence Mobilization Action Collaboratives Joint Webinar

Developing a nationwide coordinated system of shared health data with insight from COVID-19

April 22, 2021 | 9:30 AM – 12:30 PM EST

Share your thoughts!

@theNAMedicine

NATIONAL ACADEMY OF MEDICINE
Welcome & Introduction

Michael McGinnis
Leonard D. Schaeffer Executive Officer
Evidence Mobilization
Action Collaborative Chairs

Richard Kuntz
Medtronic

Richard Platt
Harvard University
Digital Health Action Collaborative Chairs

Reed Tuckson
Tuckson Health Connections

Jonathan Perlin
HCA Healthcare
Stakeholder leaders in private, public, and independent organizations from key health sectors, collaborating under the auspices of the National Academy of Medicine for action on their common interests in advancing effectiveness, efficiency, equity, and continuous learning in health, medical care, and biomedical science.
Advancing the Learning Health System

A learning health system is one in which science, informatics, incentives, and culture are aligned for continuous improvement, innovation, and equity—with best practices and discovery seamlessly embedded in the delivery process, individuals and families active participants in all elements, and new knowledge generated as an integral by-product of the delivery experience.

Leadership Consortium Charter 2006
focus:

COLLABORATIVE ACTION
COLLABORATIVE ACTION

SCIENCE: Evidence Mobilization Action Collaborative
FOCUS: *continuous learning through real-world evidence*

INFORMATICS: Digital Health Action Collaborative
FOCUS: *digital infrastructure & data as a core utility*

INCENTIVES: Value Incentives & Systems Action Collaborative
FOCUS: *payment based on health outcomes for people and populations*

CULTURE: Culture, Inclusion & Equity Action Collaborative
FOCUS: *full and equitable health engagement for people and communities*
CORE ELEMENTS FOR EACH COLLABORATIVE

ORGANIZATIONAL NETWORKS

ANCHOR PRINCIPLES

KEY PROGRESS INDICATORS

COLLABORATIVE PROJECTS
## Agenda

<table>
<thead>
<tr>
<th>Time</th>
<th>Session</th>
<th>Facilitators/Participants</th>
</tr>
</thead>
<tbody>
<tr>
<td>9:30 – 9:45 AM</td>
<td><strong>Welcome</strong></td>
<td><strong>Michael McGinnis</strong>, National Academy of Medicine&lt;br&gt;<strong>Richard Platt</strong>, Harvard University</td>
</tr>
<tr>
<td>10:50 – 12:05 PM</td>
<td><strong>Nation-wide Data Governance: Progress and Promise</strong></td>
<td>Facilitator: <strong>Reed Tuckson</strong>, Tuckson Health Connections&lt;br&gt;<strong>Micky Tripathi</strong>, ONC&lt;br&gt;<strong>Peter Margolis</strong>, Cincinnati Children’s Hospital Medical Center; ImproveCareNow&lt;br&gt;<strong>Amy Abernethy</strong>, FDA</td>
</tr>
<tr>
<td>12:25 – 12:30 PM</td>
<td><strong>Closing Remarks &amp; Adjourn</strong></td>
<td><strong>Michael McGinnis</strong>, National Academy of Medicine</td>
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</tbody>
</table>
Zoom Instructions

Panelists
• Always keep your line muted unless you are called on to speak
• If possible, turn on video while speaking to the group. To enable video click the ‘start video’ option at the bottom left of your screen

Attendees - Q & A
• Please type in questions into the Q&A located at the bottom of the screen on your zoom interface
• Question format:
  • Your name and organization
  • To whom
  • Question

@theNAMedicine
Strategic Framing
## COVID-19 Sector Impact Assessments Lead Authors

<table>
<thead>
<tr>
<th>Sector Assessment</th>
<th>Lead Authors</th>
</tr>
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<tbody>
<tr>
<td>Patients, families, &amp; consumers</td>
<td>CEO, Families USA&lt;br&gt;Director, Center for Health Transitions&lt;br&gt;CEO, AAMC</td>
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<tr>
<td>Clinicians &amp; professional societies</td>
<td>CEO, American Medical Association&lt;br&gt;CEO, American Academy of Nursing</td>
</tr>
<tr>
<td>Care delivery organizations</td>
<td>CEO, Vanderbilt University Medical Center&lt;br&gt;CEO, Geisinger</td>
</tr>
<tr>
<td>Digital health</td>
<td>Principal Deputy Commissioner, FDA&lt;br&gt;Research Director, Microsoft</td>
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<tr>
<td>State &amp; local public health</td>
<td>Chief Health Officer, Google&lt;br&gt;President, Missouri Health Foundation</td>
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<td>Health payers</td>
<td>Former Administrator, CMS&lt;br&gt;COO, Optum Care Solutions</td>
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<tr>
<td>Health product manufacturers &amp; innovators</td>
<td>Global R&amp;D Head, J&amp;J/Janssen&lt;br&gt;CEO, Novartis</td>
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<tr>
<td>Health &amp; biomedical research</td>
<td>Executive Director, PCORI&lt;br&gt;Deputy Director, NIH</td>
</tr>
<tr>
<td>Quality, safety, &amp; standards</td>
<td>Deputy Under Secretary, VA&lt;br&gt;SVP, Humana</td>
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</table>
Public Health COVID-19 Impact Assessment: Lessons Learned and Compelling Needs

Karen DeSalvo, MD, MPH, MSc, Dell Medical School at The University of Texas at Austin; Bob Hughes, PhD, Missouri Foundation for Health; Mary Bassett, MD, MPH, Harvard University; Georges Benjamin, MD, American Public Health Association; Michael Fraser, PhD, CAE, Association of State and Territorial Health Officials; Sandra Galoia, MD, MPH, DrPH, Boston University School of Public Health; J. Nadine Gracias, MD, MSc, Trust for America’s Health; and Jeffrey Howard, MD, MBA, MPH, former Public Health Commissioner, Kentucky

April 7, 2021

About the NAM series on Emerging Stronger After COVID-19: Priorities for Health System Transformation
This discussion paper is part of the National Academy of Medicine’s Emerging Stronger After COVID-19: Priorities for Health System Transformation initiative, which commissioned papers from experts on how 9 key sectors of the health, health care, and biomedical science fields responded to and can be transformed in the wake of the COVID-19 pandemic. The views presented in this discussion paper and others in the series are those of the authors, and do not represent formal consensus positions of the NAM, the National Academies of Sciences, Engineering, and Medicine, or the authors’ organizations.
Scan: namic.edu/TransformingHealth

Introduction
Farms in life expectancy and quality of life over the course of American history can be attributed to forward-looking investments in public health infrastructure (1). For example, the creation of a national public health infrastructure in the 18th century supported improvements in sanitation and, reduced the mortality burden from infectious diseases such as typhoid and cholera. Likewise, strategies to protect health environments and improve access to clinical services have improved the prevention and management of chronic diseases such as cardiovascular disease and cancer. In addressing each population health challenge, the public health sector has played a multifaceted role, from surveilling the incidence and outcome of disease (e.g., the National Notifiable Diseases Surveillance System), to convening stakeholders across sectors to develop coordinated solutions (e.g., historical collaborations with housing authorities to inform policymakers and the public about best practices on how to reduce the risk of promote indoor air pollution) (2,3). These multidisciplinary actions are more important than ever due to the complexity and scope of challenges that demand a multi-sectoral approach.

These multidisciplinary actions are more important than ever due to the complexity and scope of challenges that demand a multi-sectoral approach.
Nakela Cook, MD, MPH  
Executive Director,  
Patient-Centered Outcomes Research Institute (PCORI)

Peter Lee, PhD  
Corporate Vice President,  
Research and Incubations,  
Microsoft

Sarah Greene, MPH  
Strategic Advisor,  
National Academy of Medicine
Data Sharing During the COVID-19 Pandemic

Insights from the COVID-19 Biomedical Research Sector Assessment

Nakela L. Cook, MD, MPH
Executive Director, PCORI
A Stress Test and Learning Opportunity
Research Sector’s Experience with Data Sharing During COVID-19

Advancing Data Sharing in Research

Embracing Opportunities in a Crisis for Short and Long-term Learning and Impact
COVID-19 Use Case for Data Sharing
Lessons Learned

Trust
- Imbue and communicate trust
- Data sharing governance to reinforce

Incentives
- Data sharing is feasible and not prohibited by technical issues
- Alignment of incentives to advance

Methods & Technology
- Standards, harmonization, interoperability critical to path forward
- Infrastructure investment to support sharing

Health Data Sharing Governance Framework: Do we regress to the mean when the urgency is gone or capitalize on the progress made?
Impact Assessment:
Digital Health and COVID-19

Amy Abernethy, Peter Lee, David Shaywitz
Murali Doraiswamy, Adi Gundlapalli, Subha Madhavan, Kevin Shulman, Jim Weinstein
Digital Health: Observations Across All Sectors

• Telehealth became real, practical, and essential during COVID-19 response.
• Data proved critical for coordination, forecasting, and quality, but also a time-consuming, and sometimes chaotic, burden on clinicians and administrators.
• Data interoperability and scaling proved to be more theory than reality in health and public health.
• Effective public-private partnerships proved essential in crisis response.
• The digital divide was occasionally bridged but more frequently contributed to and often exacerbated health inequities.
• Digital and AI tools became key to advancing knowledge and coping with information
# Digital Health Across All Sectors

<table>
<thead>
<tr>
<th>Sectors</th>
<th>Digital Health Challenges and Opportunities</th>
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<tbody>
<tr>
<td></td>
<td><strong>Telehealth became real</strong></td>
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<tr>
<td>1. Health product manufacturers</td>
<td>X</td>
</tr>
<tr>
<td>2. Clinicians &amp; Professional Societies</td>
<td>X</td>
</tr>
<tr>
<td>3. Payers</td>
<td>X</td>
</tr>
<tr>
<td>4. Care delivery organizations</td>
<td>X</td>
</tr>
<tr>
<td>5. Quality &amp; Safety</td>
<td>X</td>
</tr>
<tr>
<td>6. Patients/Families/Communities</td>
<td>X</td>
</tr>
<tr>
<td>7. Public Health</td>
<td>X</td>
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<tr>
<td>8. Research</td>
<td>X</td>
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</tbody>
</table>
Digital Health in COVID-19 Response

The U.S. health care community looked to the interconnected system of devices, digital platforms, and data to help address questions [critical for COVID-19 response], since surely the answers lurked within the petabytes of digital data being generated daily by the health care system. The notion was that it only needed to be extracted, integrated, and disseminated in useful form – actions that are commonplace in many other industries with the use of a wide range of digital tools.

Instead, during the first nine plus months of the pandemic in the U.S., decision-makers were essentially “flying blind...” Legions of technologists rushed to address these crises in access, connectivity, and interoperability. Hundreds, and perhaps thousands, of new data systems were created and deployed with incredible speed... But these valiant efforts, while locally impactful, also resulted in the creation of yet more data silos that not only struggled to interoperate with the rest of the health care ecosystem, but contributed even more to its staggering, ineluctable complexity.
Health Data: Water, Water, Everywhere...

• Data without architecture leads to data silos

One is reminded of the poem, *The Rime of the Ancient Mariner*, which contains the verse, “Water, water, everywhere, nor any drop to drink.” Despite nearly complete digitization, and so many tools at our disposal for data analysis, machine learning, AI, and visualization, the health care community remained thirsting for the high-quality, actionable data upon which these technologies, patients, and caregivers foundationally depended, including data not only from health systems, but from all other relevant sources -- personal, social, infrastructural, biological, population-wide, and more. Thus, the tremendous advances in computer science that today powers global supply chains, massive retail markets, internet search, social media, and more, remained and still remains a stark contrast to the ongoing creation of yet more inaccessible data silos in health care. The ongoing challenges encountered in vaccine distribution and monitoring are only the most current and urgent example of the existing limitations of data visibility, fluidity, transparency, and access.
Advancing Progress toward Health Data Sharing

Sarah M. Greene, MPH
April 22, 2021
DHAC/EMAC Joint Meeting
(Biggest) Barriers to Sharing Health Data

- Cultural
- Ethical
- Regulatory
- Financial
- Operational
HEALTH DATA SHARING TO SUPPORT BETTER OUTCOMES
BUILDING A FOUNDATION OF STAKEHOLDER TRUST
Key Findings from the Report

Proposed Action Steps

1. Develop business case for data sharing
2. Create and prioritize use cases
3. Engage in a public information campaign
4. Incentivize data sharing via new payment models
5. Institute legislation and policy levers
6. Forge consensus on data stewardship, accessibility, and control principles
7. Build trust & transparency
11 Data Sharing Exemplars across the health/care ecosystem

• **Aim**: Develop an accessible reference, based on real-world examples, to show how organizations can collaborate to share and link data while safeguarding consumer interests around data protection and privacy

• **Anchor**: Map case studies to common barriers identified in the report

• **Case Study Summaries**: value proposition, success factors, barriers they addressed, data governance and organizational governance, advice for others, and “magic wand request”

• **Timeline**: In progress, anticipated completion Nov 2021
Prevalent Themes from the Case Studies – Value Proposition

Data get better with use--
Sharing data will enable discovery, lead to better care, and enhance reputation

“Every single touchpoint provides information about our patients and populations.

If we just let it sit there, we are not fulfilling part of our responsibility as a health system.”
Several groups are publishing their experiences, and promulgating transparency and engagement.

“We need to learn from past incidents in which patient trust was damaged as a result of data breaches or intentional data sharing without patient consent…

We want to contribute to the evidence base on engagement and data sharing and simultaneously use that evidence to shape our policies and procedures, and create a roadmap for others.”
The Imperative: Cultivating Trust

"We can improve together by sharing and using data in ways that produce trust and respect. Patients and families deserve nothing less."

Thank you to Case Study Project Collaborators Noor Ahmed & Peak Sen-Chua!
Insights driven by the burning platform of COVID-19
David Meyers, MD
Acting Director,
Agency for Healthcare Research and Quality (AHRQ)

Ken Sands, MD, MPH
Chief Epidemiologist and Chief Patient Safety Officer,
HCA Healthcare

Ken Gersing, MD
Director of Informatics,
National Institutes of Health
The COVID-19 Consortium of HCA Healthcare and Academia for Research GEneration (CHARGE)

David Meyers
Acting Director

April 22, 2021
AHRQ’s Role

• Making evidence-based, patient-centered care a reality for all Americans

• While science and research to discover cures is needed, science, research, and implementation to improve care is imperative.
AHRQ’s Vision, Aim and Core Competencies: Why, What and How

**Our Goal**

Improve the lives of patients

**Our Aim**

To help healthcare systems and professionals deliver care that is

- High Quality
- Safe
- Equitable
- High Value

**Our Competencies**

- Health Systems Research
- Practice Improvement
- Data & Analytics
Innovation in a Time of Crisis

- The urgency of the COVID-19 pandemic provided motivation to overcome conventional barriers in healthcare delivery, healthcare evidence generation, and healthcare data sharing.
A Few Words About HCA Healthcare

- 187 hospitals
- 154 freestanding surgery centers
- > 1,000 physician practices
- > 120 urgent care centers
- 37 million patient episodes annually
- Located in 21 states and UK
- Approximately 5% of major hospital services in U.S. including ~ 2.4 million admissions
- Hospitals range from complex tertiary referral and academic medical centers to urban and suburban community medical centers
  - ~ 287,000 employees, including
    - > 98,000 nurses and 35,000 allied health professionals
  - > 40,000 affiliated physicians, including
    - > 6,000 employed physicians and practitioners
    - > 4,000 housestaff
- > 45,000 licensed beds
HCA Healthcare COVID-19 Registry

Data collected from patients who tested positive for COVID-19 at an HCA Healthcare facility since March 1, 2020.

130K+ inpatients 2020

Encounter types:
- Inpatient (>110K*)
- Outpatient
- ED
- Scheduled surgery
Research Consortium Objectives

1. Accelerate Understanding of COVID-19 and its Treatment
2. Introduce Novel Technology For Collaborative Research That Protects Privacy
3. Create Platform for New Paradigm of Research Partnership (Governance)
4. Create an Engine to Accelerate Quality and Safety
Founding CHARGE Organizations

- HCA Healthcare
- Sarah Cannon/ HCA Research Institute
- Agency for Healthcare Research and Quality (AHRQ)
- Columbia University
- Duke University
- Harvard Pilgrim Healthcare Institute
- Johns Hopkins University
- Meharry Medical College

Hospital Medicine Reengineering Network (HOMERuN):

- Beth Israel Deaconess Medical
- Brigham and Women’s Hospital
- Cleveland Clinic
- Univ. California San Francisco
- UMass Medical School – Baystate
Refining the Data Set

HCA Healthcare Database
(all, identifiable)

HCA Healthcare COVID-19 Registry
(COVID+, identifiable)

Limited Data Set (LDS)

Clinically irrelevant data and identifiers removed
Potential Models for Ensuring Data Privacy

HCA Healthcare / HCA Research Institute

COVID-19

Limited Data Set (LDS)

Privacy Protected Data Set

Noise-injected Result

Query

Differentially Private SQL query

Analysis & Model development

HCA Analyst Ran analysis

Analysis designed from ‘B & C’

Collaboration Output

Publishable Results

Partnered Research Institution
• CHARGE governance established by formal signed memorandum between each partner and HCA Healthcare/HCA Research Institute
• HCA maintains full control of its registry data sets and their use
• MOU establishes a Consortium Steering Committee (CSC)
• Common IRB framework established through HCA
• CSC reviews all study proposals
  ▶ All organizations may provide feedback to improve methodology and relevance.
  ▶ CSC members provide initial rating of enthusiasm for each proposal
  ▶ HCA makes final determination of study approval
• Consortium MOU protects academic freedom for approved studies
• CSC meets regularly and addresses additional issues such as guidance for grant applications using CHARGE infrastructure
Consortium Steering Committee

Academic Institution 1
Academic Institution 2
Academic Institution 3
Academic Institution 4
Academic Institution “n”

HCA Operational Support

Working Groups

Project 1
Project 2
Project 3
Project 4
Project 5
Project “n”
1. Research Institution(s) submits research proposal to Consortium
2. Experienced HCA Investigator(s) assigned to work with Project Team
3. Proposal submitted to Consortium Steering Committee (CSC) for review
4. CSC provides feedback and approval (confirmed by HCA)
5. Project Team develops analytic plan and conducts preliminary analysis using a privacy protected pathway
6. If needed, HCA analyst repeats analysis on full LDS and shares outputs
7. Team prepares manuscript
8. Internal peer review by CSC prior to submission for publication and pre-publication posting
<table>
<thead>
<tr>
<th>Institution</th>
<th>Title</th>
<th>Study Focus</th>
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<tbody>
<tr>
<td>Johns Hopkins</td>
<td>Comparative effectiveness of therapeutics for hospitalized patients with COVID-19</td>
<td>COVID-19 Clinical Care</td>
</tr>
<tr>
<td>BWH &amp; UCSF</td>
<td>Analysis of Clinical Criteria to Determine Stability for Discharge among Patients Hospitalized with COVID-19</td>
<td>COVDI-19 Clinical Care</td>
</tr>
<tr>
<td>UMMS Bay State</td>
<td>Trends in ventilation and effects on outcomes</td>
<td>COVID-19 Clinical Care</td>
</tr>
<tr>
<td>UCSF</td>
<td>Risk Stratification Scores and Prediction of Clinical Outcomes among COVID-19 Patients</td>
<td>COVID-19 Clinical Care</td>
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<tr>
<td>Duke University</td>
<td>Causal inference machine learning to estimate heterogeneous treatment effects for COVID-19 therapies</td>
<td>Analytic Methodology</td>
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<tr>
<td>Cleveland Clinic</td>
<td>Effect of antibiotic classes on risk of Clostridioides difficile</td>
<td>Other Clinical Care</td>
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<tr>
<td>Meharry Medical College</td>
<td>Developing Phenotype Adjustment Models for COVID-19 Disease Study</td>
<td>Preparatory for Research Grant Application</td>
</tr>
</tbody>
</table>
• The pandemic provided motivation to overcome some of the barriers to data sharing
• This effort is possible because the health system was willing to invest substantial funds to make it possible.
  ► This also allowed the health system to keep control of their data and its uses
  ► Data governance is simplified by HCA maintaining full control
• At this moment, research teams are interested in partnering with health systems (including working without funding)
• This effort has significant potential to advance methodologies for ensuring data privacy in research
• A major potential next step would be if CHARGE can evolve to welcome other health systems to contribute additional data
• Sustainability of this data sharing infrastructure needs to be determined
Potential Models for Ensuring Data Privacy

**HCA Healthcare / HCA Research Institute**

**Limited Data Set (LDS)**

- **A**: Noise-injected Privacy Protected Data Set
- **B**: Query
- **C**: Analysis & Model development
- **D**: HCA Analyst Ran analysis

**Collaboration Output**

**Publishable Results**

**Partnered Research Institution**

COVID-19
National COVID Cohort Collaborative (N3C)

Ken Gersing, MD
04/22/2021
Step 4. Federated Analytics with HPC

CTSA Plus IDeA States
Up-to-date phenotype description will always be here.

Scripts for sites to extract data, customized for each data model, are here.
# N3C Enclave Data: Current Stats

(4/09/21)

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<tr>
<th>Metric</th>
<th>Value</th>
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<tr>
<td>COVID-19 Positive Patients</td>
<td>1,222,296</td>
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<tr>
<td>Total Patients</td>
<td>4,960,128</td>
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<td>Sites</td>
<td>50</td>
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<td>Rows of Data</td>
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<td>Projected Participants</td>
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<tbody>
<tr>
<td>Procedures</td>
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<tr>
<td>Lab Results</td>
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<td>Drug Exposures</td>
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<tr>
<td>Visits</td>
<td>257.8m</td>
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<tr>
<td>Observations</td>
<td>721.4m</td>
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<tr>
<th>Age Group</th>
<th>COVID (N=1,222,296)</th>
<th>NON-COVID (N=3,377,832)</th>
<th>OVERALL (N=4,599,128)</th>
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<tbody>
<tr>
<td>0 - 17</td>
<td>114,360</td>
<td>595,058</td>
<td>623,418</td>
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<td>18 - 29</td>
<td>226,827</td>
<td>594,326</td>
<td>700,863</td>
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<td>30 - 49</td>
<td>317,783</td>
<td>1,015,853</td>
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<th>NON-COVID (N=3,377,832)</th>
<th>OVERALL (N=4,599,128)</th>
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<tbody>
<tr>
<td>White</td>
<td>741,252</td>
<td>2,530,030</td>
<td>3,261,272</td>
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<tr>
<td>Other</td>
<td>10,472</td>
<td>34,422</td>
<td>44,894</td>
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<td>Black or African American</td>
<td>185,122</td>
<td>565,573</td>
<td>750,695</td>
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<td>Asian</td>
<td>33,339</td>
<td>109,420</td>
<td>142,774</td>
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<tr>
<td>Pacific Islander</td>
<td>2,983</td>
<td>6,633</td>
<td>9,616</td>
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<td>Unknown</td>
<td>228,809</td>
<td>406,503</td>
<td>639,322</td>
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<th>NON-COVID (N=3,377,832)</th>
<th>OVERALL (N=4,599,128)</th>
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<td>Not Hispanic or Latino</td>
<td>831,135</td>
<td>2,996,243</td>
<td>3,827,378</td>
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<tr>
<td>Hispanic or Latino</td>
<td>211,820</td>
<td>403,031</td>
<td>614,051</td>
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<tr>
<td>Unknown</td>
<td>178,872</td>
<td>423,829</td>
<td>502,713</td>
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</tbody>
</table>

1231 participants
N3C: Governance and Access

Institutions contributing Data:
- IRBs
- DTAs

Original LDS Data Set

Synthetic (Level 1)

De-Identified
17 HIPAA direct identifiers
(Level 2)

Limited Data Set
16 HIPAA direct identifiers
(Level 3)

Data Access Committee Approval

User projects specific IRB

Data Users
- Registration
  Community Guiding Principles
- Data User Request (DUR)
  Code of Conduct
  Data User Attestation (HSP & IT Sec.)

Accessing Institutions
- DUA
- NIH IRB

NIH/NCATS Data Stewards
- NIH IRB

Harmonized Data

Institutional Data Use Agreement
Getting Access to the Data

**First Time Users**
- Register at N3C
- HSP / Security Training
- Sign DUA

**Returning Users**
- Submit DUR
- Data Access Committee
- Research !!!
Goal of the Data Use Agreement is Privacy Protection to Promote broad access:

- COVID-Related research only
- No re-identification of individuals or data source
- No download or capture of raw data
- Open platform to all researchers
- Security: Activities in the N3C Data Enclave are recorded and can be audited
- Disclosure of research results to the N3C Data Enclave for the public good
- Analytics provenance
- Contributor Attribution tracking
Random Forest Top 10 Predictors

- Age
- AST
- BUN
- Cr
- Glucose
- pH
- RR
- SBP
- SpO2
- WBC

✓ High confidence.
✓ Repeatable.
✓ Clinically relevant.
✓ Readily deployable.
✓ Easily refined.

RF Mar-May AUROC: 0.864
RF Jun-Oct AUROC: 0.865
Over time, severity has decreased and use patterns of antimicrobials and immunomodulation have shifted.
Users can view the list of external datasets that have been imported into the Enclave, as well as the datasets requested and their current status in the review process by viewing the External Dataset Registry.

Data Contributors

Jon/John Smith
03/27/1945
Male

John Smith was admitted to IU Health (N3C Site) from his senior living facility due to shortness of breath.

Honest Broker

**Honest Broker has NO PHI**

Patient 123
Patient 456
Patient 789

007

N3C Sites
PseudoID
Patient 123

Omics Data
PseudoID
Patient 456

Imaging Date
PseudoID
Patient 789

Shared PPRL on different types of data
Step 4: Federated Analytics HPC

- NCATS: EHR Data
- NHLBI: Omics Data

NIBIB: Imaging Data

HPC

Federated Analytics
The Honest Data Broker fulfills linkage requests, ensuring privacy & compliance.

Health System A

De-id Pseudo IDs

Pseudo IDs & Data Payload

NCATS N3C Enclave

Ingestion

Honest Data Broker (HDB)

Match Pseudo-IDs & Tokens

Linkage Management:
Respond to requests by producing linkage and de-duplication maps

Health System B

De-id Pseudo IDs

Pseudo IDs & Data Payload

I would like to perform multimodal analytics across institutions
Multi-model Data
EHR and Imaging

Hospital Course

Chest Xray’s with serial
Lab Correlation of SpO2
and Creatinine
### Data Sharing Initiative: Synthetic Data

*Computer Derived Synthetic Data: Public / Private Partnership*
- Gates Foundation
- Microsoft
- MDClone
- Syntegra
- FDA
- NCATS
- Wash U
- U of Washington
- Northwestern

#### ML model performance (random forest)

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<th>10-fold cross-validation</th>
<th>Test</th>
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<td></td>
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</table>

*Wash. U. Philip Payne*
Nation-wide data governance: Progress and Promise
Micky Tripathi, PhD, MPP
National Coordinator for Health Information Technology, ONC
Data Governance in a National Pediatric Learning Health Network

Peter Margolis, MD, PhD
April 22, 2021
A scenario.....
ImproveCareNow Network Mission

Transform the health, care and costs for all children and adolescents with Crohn’s disease and ulcerative colitis by building a sustainable collaborative chronic care network that enables patients, families, clinicians and researchers to work together in a Learning Health System to accelerate innovation, discovery and the application of new knowledge.
Network Organizing

1. Unrelenting focus on outcomes - exceptional, equitable health and well being

2. Engage all stakeholders in co-design and unleash inherent motivation, insight and expertise

3. Shared platform/infrastructure of technology, policies, and processes

4. Rapid learning system
Percent of Patients in Clinical Remission: 2013 - 2021

11,000 additional children in remission in past 7 years
Sustainable generation of patient-led resources in a learning health system

Jennie David, Catalina Berenblum Tobi, Samantha Kennedy, Alexander Jofriet, Madeleine Huwe, Rosa Kelekian, Melissa Neihart, Michelle Spotts, Michael Seid, Peter Margolis ... See all authors

First published: 12 February 2021  |  https://doi.org/10.1002/lrh2.10260

Funding information: National Institute of Diabetes and Digestive and Kidney Diseases; Patient-Centered Outcomes Research Institute

Network infrastructure fuels a portfolio of activities

- **Technology Infrastructure**
  - Direct upload of 70% of data from EHR
  - Real-time comparative performance data
  - Community knowledge sharing hub

- **Continuous Improvement Pathway**
  - Registry implementation and QI training
  - Chronic care management to achieve clinical remission
  - Advanced chronic care management to achieve sustained remission

- **Innovation communities** ("Trailblazers")
  - Therapeutic Drug Monitoring
  - Auto-immune Liver Disease
  - Adherence
  - COVID Response
  - Clinical Research Optimization
  - Health Disparities
  - Payment models
  - Engagement Campaign

- **Research**
  - 30 investigator initiated projects
  - Network-wide Federal, Foundation and Industry-sponsored observational and intervention research
Community Values

Inclusivity
Honesty
Transparency
Community
Empowerment
Learning
Continuous Improvement

community values
improvecarenow.org
Data Sharing in Learning Health Networks Should be Easy

Communities of Practice

Values of Open Science

Trust
What could accelerate progress?

Network Facts

Values

Standards

Risks

Decision Support Tools

Certification Framework
Impact Assessment: Digital Health and COVID-19

Amy Abernethy, Peter Lee, David Shaywitz
Murali Doraiswamy, Adi Gundlapalli, Subha Madhavan, Kevin Shulman, Jim Weinstein
Health Data: Water, Water, Everywhere...

• Data without architecture leads to data silos

One is reminded of the poem, *The Rime of the Ancient Mariner*, which contains the verse, “Water, water, everywhere, nor any drop to drink.” Despite nearly complete digitization, and so many tools at our disposal for data analysis, machine learning, AI, and visualization, the health care community remained thirsting for the high-quality, actionable data upon which these technologies, patients, and caregivers foundationally depended, including data not only from health systems, but from all other relevant sources -- personal, social, infrastructural, biological, population-wide, and more. Thus, the tremendous advances in computer science that today powers global supply chains, massive retail markets, internet search, social media, and more, remained and still remains a stark contrast to the ongoing creation of yet more inaccessible data silos in health care. The ongoing challenges encountered in vaccine distribution and monitoring are only the most current and urgent example of the existing limitations of data visibility, fluidity, transparency, and access.
Digital Health
Priority Actions and Actors

• Data architecture, modularity, and data infrastructure

Imagine for a moment that we are setting out to build a house. We would, of course, need good tools and an adequate supply of lumber. And we would need to understand the architecture of the house we are trying to build. But if we lacked the skilled tradespeople, heavy equipment, building inspectors, and other infrastructure that support the process of construction, it would be impossible to connect the tools and lumber to the architecture and realize a completed house. Furthermore, without modularity that is both intentionally designed and agreed upon, for example in industry standards and building codes, orchestrating the construction of components such as electrical systems, plumbing, roofing, heating, doors and windows, appliances and more, would be wildly complex and unwieldy. Even more important, innovators who make technological advances in those component systems would find it hard to survive in the marketplace, because they would not have standard places to “plug in” their new ideas at industrial scale. Instead, home construction would be a low-productivity, artisanal activity, much like, say, early automobile production – or today’s health care data ecosystem.
Data Architecture+
New Solutions are Needed

• Data architecture, modularity, and data infrastructure
• Challenge is on the scale of some of the largest public challenges ever addressed, especially in public health and health care
• Similar to the need for an interstate highway system, a common financial system, or our modern flight control system
  • All of these efforts were well-served by public-private partnerships
  • Fostered ingenuity and innovation, and greatly expanded economic activity for the country at large
  • All were federal investments
  • The Federal Reserve provides a practical architecture into which innovators and the banking industry have been able to “plug in”
    • Infrastructure = secure data architecture, parsimonious common data standards, business incentives, and regulatory enforcement
Data Architecture+
New Solutions are Needed

• Hard things are hard – and worth doing
• There are real reasons to believe that meaningful progress can and will be made
  • Much of the raw material is already at hand:
    • Rapid digitization of health care (98% of clinical health records are digital)
    • Rapid advances in enabling digital technologies outside of health care
  • Recognized need to align around basic governing rules and an approach to modularity so that consistent components can “plug in,” work efficiently, and bring unique elements to the overall design
• A modular approach fosters competition around components, enabling improved quality, reduced costs, and the ability to connect and optimize relevant modules to address distinct challenges in different domains
Data Architecture+
New Solutions are Needed

• What do we need to do?
  • Data governance
  • Focus on public trust
  • APIs and interconnections
  • Right-sized data standards
  • Driver projects & programs
  • PPPs to define and advance business incentives
  • Bring all actors to the table
  • Talent development
Digital Health
Priority Actions and Actors

• Data architecture, modularity, and data infrastructure – proposed Office of Health and Health Care Digital Integration (OHDI)
  • Government’s role in advancing such a modular architecture includes several elements, including:
    • Fostering the regulatory conditions for innovation and establishing the relevant ground rules, while avoiding excessive specification of what the “right” solutions should be
    • Ensuring a commitment to public trust, equity, and health
    • Facilitating vital private-public partnerships
    • Embracing incremental innovation, recognizing that solutions will emerge gradually
Digital Health
Collaborative Initiatives Within and Across Sectors

• Data architecture, modularity, and data infrastructure – **proposed Office of Health and Health Care Digital Integration (OHDI)**
  • Many of the identified priority actions are dependent on this step
    • Incentivize novel clinical evidence generation approaches
    • Harness AI and other capabilities dependent on a coherent data infrastructure
    • Get individuals the healthcare they need (e.g., reduce bias in AI, match treatments to patients, generalizable clinical research)
    • Realize the potential of a learning health system

• Advancing telehealth by right-sizing healthcare regulation
  • Example actor = Office of Civil Rights

• Business solutions are needed
  • Example actor = public private partnerships

• Cybersecurity

• Digital health training
Open Discussion
Closing Remarks

Thank you for joining!

For more information about the National Academy of Medicine’s initiatives, please visit us at: nam.edu
Digital Health and Evidence Mobilization Action Collaboratives

For more information about the Digital Health and Evidence Mobilization Action Collaboratives or to share opportunities to address and advance this work, please contact:

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