

# DIGITAL HEALTH & EVIDENCE MOBILIZATION ACTION COLLABORATIVES

April 22, 2020 Meeting Highlights

**MEETING FOCUS:** An exploration of the role of a nation-wide framework for health data governance in accelerating evidence generation and mobilization in the aftermath of data and information sharing barriers and associated negative health impacts laid bare by the COVID-19 pandemic.

## Motivating Questions:

1. **Vision:** What conditions are necessary to share and aggregate data generated in the health system, via personal devices and apps and in the public health domain to advance knowledge in support of a learning health system?
2. **Barriers:** What are the current societal/cultural, regulatory, organizational, and technical challenges to coordinating and integrating the historical and ongoing efforts of multiple stakeholders to achieve seamless interoperable data and information sharing to support research, evidence mobilization and improved health outcomes?
3. **Use Cases:** What are best practices in sharing data and information for research?
4. **Assessing progress:** How do we evaluate success of data and information sharing in the context of evidence generation and mobilization.

**Outcomes anticipated:** Identify actions NAM can take to accelerate progress towards a nation-wide framework for health data governance that respects individual agency over health data sharing while ensuring access to data to support the learning health system.

## REPRESENTATIVE OBSERVATIONS

*Strategic Framing Session: Overview of related works from the National Academy of Medicine & Common themes from selected NAM projects*

- This meeting focused on promoting cooperation across the nation to capture, organize, and share data as a core utility to advance new knowledge and better health. Relatedly, the Leadership Consortium has developed papers to capture lessons learned and opportunities that have arisen from the COVID-19 pandemic in nine different sectors. Each paper called out the need for improvement around data sharing and governance.
- **Nakela Cook, PCORI**, presented key insights from the Biomedical Research sector paper. The pandemic shifted the data sharing risk-benefit calculus. Hesitancy was diminished by the urgency for information, and centralized approaches to harmonization were seen as more acceptable. The sector witnessed the seamless merger of studies, the development of rapid data sharing agreements based on policy and legal parameters, and the advancement of data standards and interoperability. The pandemic underscored the importance of governance structures to mitigate the risks related to data use and outline parameters of accountability. Moving forward, it is crucial to not revert to pre-pandemic practices and instead capitalize on the gains achieved.
- **Peter Lee, Microsoft**, described the work of the Digital Health (DH) sector paper and its relevancy to other sectors. Despite the near-complete digitization of health records and advancements in telehealth and AI, the pandemic revealed several shortcomings in the DH sector, such as the lack of standardized elements for tracking patient encounters. There also were challenges in connecting with people who spoke different languages and communities that have been historically underserved. For the path forward, the DH sector paper emphasized the need for a national coherent digital architecture that provides high-quality actionable data wherever, whenever.
- Using the joint work between **PCORI and NAM** as an example for key insights Sarah Greene, **NAM**, discussed crucial elements of a wide-scale data sharing approach. A chief barrier to the sharing of data is the lack of trust that exists among stakeholder groups related to whom health data is shared and how it was used. As a Part II to the Health Data Sharing publication, Sarah presented key insights from 11 case studies under development. A common theme from the 11 examples was that democratizing health data is the way forward. However, to

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perpetuate this notion will require evidence about the value of data sharing and for stakeholders to engender trust through their actions.

*Insights driven by the burning platform of COVID-19 – Session*

- David Meyers, AHRQ, spoke about the HCA Healthcare and Academia for Research GEneration (CHARGE) initiative. AHRQ and HCA Healthcare worked together to create this long-term collaboration to allow external researchers to use HCA's vast patient data registry. This effort would help provide evidence for the best management of COVID-19 and inform projects that would improve understanding of the disease at the national level. An important outcome of this partnership was the development of a data privacy model. Synthetically derived limited datasets become available to the researchers to experiment and develop their analyses once HCA analysts approve researchers' queries. If the query does not provide the necessary protections, HCA runs the query on a full dataset and passes the answers back to the researchers. Data governance is managed through an established IRB framework, a steering committee set up to review research proposals, and a formal memorandum signed between partners that protect academic freedoms and the eventual release of any findings. This process would not be possible without HCA's commitment, leadership, financial resources, and infrastructure. The next step is to invite other health systems to contribute their data. *Kenneth Sands, Chief Epidemiologist at HCA*, added to David's presentation on the initiative between AHRQ and mentioned the [Sentinel project](#), which has also helped create a learning health system by generating new information to improve outcomes and HCA operations.
- Kenneth Gersing, NIH NCATS, discussed the National COVID Cohort Collaborative (N3C) as an example of how data can be aggregated from various sources and made available to investigators. NCATS funds this collaboration between academic institutions, community hospitals, federally qualified health centers, IDeA states, and other stakeholders to collect data across the nation. At the start of the pandemic, they requested medical records from their partners for patients who have COVID-19, had it in the past, or never had it. Data was requested in one of five common data models (OMOP, ACT, TriNetX, PCORNet, and FHIR) and placed in a centralized repository. Approximately 2000 people have voluntarily contributed to this effort, and the dataset currently includes diverse EHR data for 1.2 million COVID patients and about 5 million patients total. N3C data governance is managed by a data transfer agreement signed between the institutions involved. After the data enters the repository and goes through a harmonization process, the dataset becomes available as a synthetic dataset, de-identified dataset, or limited dataset that is free to use. Investigators gain access to the data by registering with the N3C, signing a data use agreement, and then submitting a data use request that a committee assesses. The data use agreement prevents any attempt to identify patients or sell data, but it also allows for broad access to the data as a federal resource. Researchers bring their tools to the data which reside in a private enclave and are encouraged to share new insights from their work with communities. Kenneth explained that it would be helpful to link EHR data with social determinants of health data. However, combining external datasets that provide this information with N3C data will raise new governance issues and privacy risks that should be addressed.

*Insights driven by the burning platform of COVID-19 – Discussion*

- **Richard Platt, Harvard University**, compared Sentinel governance methods with N3C methods. The Sentinel project operates under FDA's public health authority, and while participating organizations have agreed to share data with the FDA, the project cannot aggregate datasets at the same level as N3C. **Kenneth Sands** also compared Sentinel to the CHARGE initiative, which is designed more for broad-based delivery. Both are similar in combining information from multiple disparate sources and creating new ways to access information.
- **Richard Kuntz, Medtronic**, asked how these initiatives could be scalable and sustainable after the pandemic. **Kenneth Gersing** answered that N3C was built to be scalable thanks to the use of commercial products such as from Amazon. There is more of an issue of financial sustainability in broadening the N3C work after COVID-19 since the project relied mainly on volunteers. David Meyers emphasized that who the value accrues to is also crucial when thinking about sustainability and getting other institutions to join.

*Nation-wide Data Governance: Progress and Promise – Session*



- [Micky Tripathi, ONC](#), presented considerations for data governance given the current health data environment. The field has made remarkable progress over the past decade. Through the passage of [HITECH](#) and \$40 billion in public investments (accompanied by a similarly large private investment portfolio), EHR technology is now adopted by over 90% of hospitals and ambulatory practices nationwide. However, advancing the field necessitates better management of patient-controlled and generated data and a critical look at de-identification in a manner that keeps pace with advanced algorithms, evolving technologies, and growing digital footprints. Incorporating Application Program Interfaces (APIs) into policy, creating guidelines for ethical data use that falls outside of HIPAA purview and protecting privacy in a manner that encourages data sharing will be touchstones for the immediate future. Moving forward, promising efforts may include federated queries, network-governed data, and information blocking rules such as that enacted on April 5, 2021. Noted organizations making strides in this direction include the ONC, the Center for Democracy and Technology, the CARIN Alliance, the YODA Project, and the NIH and the All of Us Research Program.
- [Peter Margolis, CCHMC](#), explained that data sharing in a learning health system chiefly relies on patient interests, an interest in scientific progress, and a complex calculation of costs and benefits. CCHMC and the ImproveCareNow network have worked effectively within this space, engaging 15 health networks, tens of thousands of clinician and patient teams, and 700 data use agreements/IRB protocols within a data-sharing community organized around four shared goals: 1) an unrelenting focus on outcomes that fuels trust; 2) engagement in network co-design relying on shared motivations; 3) shared platforms and infrastructure; and 4) rapid learning. Undergirding each aspect are the core values of agency, accountability, and responsibility. A major issue is onboarding new institutions to join the network; a process that takes less than nine months is considered successful in terms of timeliness. Decision support tools, similar to a “network nutrition label” could operate similarly to Apple’s privacy labels for apps and the data nutrition labels for machine learning developed by the Data Nutrition Project, providing relevant information on the values, purpose of the network, standards for data sharing and the risks involved to help stakeholders evaluate a partnership. To support ongoing monitoring of these partnerships, in addition to informing the initial decision to join, a certification framework similar to the LEED Certification could help organizations to identify, design and implement practical and measurable attributes of trustworthy data collaboratives. These tools would empower stakeholders to participate as equal partners in effective, efficient, and transparent data sharing initiatives. Nationally, policy must grow to inform practice (especially in the arena of decision support tools), while practice must grow to inform policy; linking policies with real world efforts in a solutions-oriented, approach steeped in continuous learning.
- [Amy Abernethy, FDA](#), described the DH COVID-19 Sector Impact Assessment, picking up from the introduction Peter Lee provided earlier in the day. The upshot of the paper is that without an overarching architecture, data almost inevitably leads to silos, severely reducing potential for aggregation and at-scale leveraging. The COVID-19 pandemic has revealed the need for the nation’s health care and biomedical science systems to embrace a national architecture for health data, analogous to building a house. Much like a home, an architecture for health data must have an underlying blueprint, skilled tradespeople to construct it, an infrastructure, and composite elements, with substantial modularity imbued throughout. Implementing and following codes/standards ensures that homes are livable, but adding a capacity for customization in terms of uses and preferences is critical as well. Like a housing market, business imperatives must incentivize this structure, and inspire continued innovation that builds on what exists. Learning what works and falls short within current data governance initiatives—as well as continued innovation for new elements—is a key foundation for the modular architecture envisioned, especially paired with a focus on public trust/security, public-private partnerships, and a concerted effort to learn from past/ongoing initiatives. . Rightsized data standards within these efforts will fuel this modular architecture, contingent on system-wide agreement and an investment in an overarching digital health vision for the nation.

### *Nation-wide Data Governance: Progress and Promise – Q&A Discussion (responses adapted for succinctness)*

- **Why are more government regulations not focused on speeding up progress in the private sector?**  
The speed at which the requisite technology is developing in health care over the last decade is comparable to other industries. The main challenge at hand is industry-wide fragmentation. Public-private partnerships along with coordination across federal partners will be needed to accelerate progress. (Micky Tripathi).



- **Would more or fewer overarching federal guardrails move the field towards or away from the vision for a network of data sharing?** Network formation requires actor orientation, fueled by a common infrastructure, policies, and practices that enable people to attain needed information. National efforts are needed to facilitate these elements especially by coupling policy development with solution creation (Peter Margolis).
- **Is a lack of joint connectivity due to fragmentation problematic for architecture modularity?** Yes, but progress has been made. NCATs demonstrated that right-sized standardization enables workability within imperfect modularity. Moving forward, standards should balance potential value accrued with stakeholder burden. The ONC can assist with defining these standards and achieving the aforementioned balance (Amy Abernethy).
- **What priority standards should be implemented? Is forming an Office of Health Innovation a wise path forward?** Right-sized standards are critical. The [US Core Data for Interoperability](#) sets minimum expectations, but without additional initiatives, the pace of interoperability and innovation with regard to data sharing will be slow. The information-blocking rule of 2021 will help the system to progress more swiftly in this regard, providing that the system is ready to make use of the information that emerges. In the absence of a formal driver, collaboration is key, with or without a new federal office. Part of the ONC's current role is to coordinate processes across federal partners. (Micky Tripathi).
- **Are partners typically willing to share risk?** Risk sharing is critical and challenging. The cornerstone of building effective communities is to overcome the perception of risk by focusing on outcomes. Measuring health outcomes in real time is crucial as witnessed at CCHMC. Integrating the framework of community building to the policy sphere would build risk resilience within policies (Peter Margolis).
- **Will distrust hamper the work at hand?** At present, there is no general data policy that addresses end use. Patient control of data mitigates this, but appropriate assurances, protections, de-identification efforts, and policies to combat undue commercial coercion are still needed (Micky Tripathi). Innovation that solves for privacy is needed in particular (Amy Abernethy). Combatting disinformation will aid in this effort as well (Reed Tuckson). Addressing distrust can largely rely on demonstrating and communicating that data sharing produces positive outcomes (Peter Margolis).
- **What additional work is needed surrounding HIPAA?** Moving forward, national consensus around general governance and privacy will help to broaden HIPAA to offer protections for the wealth of emerging data types beyond a person's formal medical record (Amy Abernethy/Micky Tripathi). An indemnification program can help to balance moral imperatives with the risk of negative consequences from data sharing (Peter Margolis).
- **How should the system handle non-medical, but medically necessary data?** SDoH data are necessary to grasp the full concept of individual and population health. As more personalized health interventions come to fruition, documenting impact and implementing best practices to ensure positive results should be core elements of the health and health care system (Amy Abernethy). Community building will ensure that people are incentivized to pursue jointly- motivated outcomes. The trust this engenders will help to replicate and strengthen this process (Peter Margolis). The ONC is engaged in constant discussion with federal partners on this topic. Data collection on the social determinants of health is prevalent, but technology is currently outpacing policy (Micky Tripathi).
- **Where do state regulatory paradigms fit into this discussion?** Federalism and complex jurisdictions engenders fragmentation (Micky Tripathi).
- **Is there a strategic initiative surrounding HHS agency data?** Throughout the pandemic, data alignment efforts across HHS divisions have been emplaced; leveraging this data is a work in progress (Amy Abernethy).

*Action Steps for Collaborative Consideration:*

*Multi-stakeholder collaboration:* Facilitate an effort to learn best practices from each community currently engaged in different initiatives. Define common values, and merge motivations and outcomes that achieve these motivations and ensure a foundation of trust. Engage in work that embeds public health connectivity to unify the system.

- *Promote data sharing:* Discuss the use of data as a common good. Enhance understanding of the dichotomy between health information and data sharing. Highlight successful initiatives throughout the COVID-19 pandemic to demonstrate benefits and possibilities.

*Guideline and standards development:* Promote modularity, right-sized/well-timed standards, and connectivity. Address privacy issues. Design an approach to dataset standardization that mitigates jurisdictional difficulties across states. Orient measures towards the social determinants of health.

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