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VOLUME 47:1 • SPRING 2019

Symposium Articles

SYMPOSIUM

Sharing Data  
in a Medical  
Information  
Commons

Guest Edited by  
Robert Cook-Deegan,  
Mary A. Majumder,  
and Amy L. McGuire

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Letter from  
the Editor

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**Introduction**

*Robert Cook-Deegan, Mary A. Majumder,  
and Amy L. McGuire*

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**Importance of Participant-Centricity  
and Trust for a Sustainable Medical  
Information Commons**

*Amy L. McGuire, Mary A. Majumder,  
Angela G. Villanueva, Jessica Bardill,  
Juli M. Bollinger, Eric Boerwinkle,  
Tania Bubela, Patricia A. Deverka,  
Barbara J. Evans, Nanibaa' A. Garrison,  
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Laura L. Rodriguez, Tania Simoncelli,  
Sharon F. Terry, Adrian M. Thorogood,  
Michael S. Watson, John T. Wilbanks,  
and Robert Cook-Deegan*

Drawing on a landscape analysis of existing data-sharing initiatives, in-depth interviews with expert stakeholders, and public deliberations with community advisory panels across the U.S., we describe features of the evolving medical information commons (MIC). We identify participant-centricity and trustworthiness as the most important features of an MIC and discuss the implications for those seeking to create a sustainable, useful, and widely available collection of linked resources for research and other purposes.

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**Characterizing the Biomedical Data-  
Sharing Landscape**

*Angela G. Villanueva, Robert Cook-  
Deegan, Barbara A. Koenig, Patricia  
A. Deverka, Erika Versalovic, Amy L.  
McGuire, and Mary A. Majumder*

Advances in technologies and biomedical informatics have expanded capacity to generate and share biomedical data. With a lens on genomic data, we present a typology

characterizing the data-sharing landscape in biomedical research to advance understanding of the key stakeholders and existing data-sharing practices. The typology highlights the diversity of data-sharing efforts and facilitators and reveals how novel data-sharing efforts are challenging existing norms regarding the role of individuals whom the data describe.

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**Genomic Data-Sharing Practices**

*Angela G. Villanueva, Robert Cook-  
Deegan, Jill O. Robinson, Amy L.  
McGuire, and Mary A. Majumder*

Making data broadly accessible is essential to creating a medical information commons (MIC). Transparency about *data-sharing practices* can cultivate trust among prospective and existing MIC participants. We present an analysis of 34 initiatives sharing DNA-derived data based on public information. We describe data-sharing practices captured, including practices related to consent, privacy and security, data access, oversight, and participant engagement. Our results reveal that data-sharing initiatives have some distance to go in achieving transparency.

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**What is a Medical Information  
Commons?**

*Juli M. Bollinger, Peter D. Zuk, Mary A.  
Majumder, Erika Versalovic, Angela G.  
Villanueva, Rebecca L. Hsu, Amy L.  
McGuire, and Robert Cook-Deegan*

A 2011 National Academies of Sciences report called for an "Information Commons" and a "Knowledge Network" to revolutionize biomedical research and clinical care. We interviewed 41 expert stakeholders to examine governance, access, data collection, and privacy in the context of a medical information commons. Stakeholders' attitudes about MICs align with the NAS vision of an Information Commons; however, differences of opinion regarding clinical use and access warrant further research to explore policy and technological solutions.

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**The Role of Participants in a Medical Information Commons**

*Mary A. Majumder, Juli M. Bollinger, Angela G. Villanueva, Patricia A. Deverka, and Barbara A. Koenig*

Meaningful participant engagement has been identified as a key contributor to the success of efforts to share data via a “Medical Information Commons” (MIC). We present findings from expert stakeholder interviews aimed at understanding barriers to engagement and the appropriate role of MIC participants. Although most interviewees supported engagement, they distinguished between individual versus collective forms. They also noted challenges including representation and perceived inefficiency, prompting reflection on political aspects of engagement and efficiency concerns.

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**Who Owns the Data in a Medical Information Commons?**

*Amy L. McGuire, Jessica Roberts, Sean Aas, and Barbara J. Evans*

In this paper, we explore the perspectives of expert stakeholders about who owns data in a medical information commons (MIC) and what rights and interests ought to be recognized when developing a governance structure for an MIC.

We then examine the legitimacy of these claims based on legal and ethical analysis and explore an alternative framework for thinking about participants’ rights and interests in an MIC.

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**Hopeful and Concerned: Public Input on Building a Trustworthy Medical Information Commons**

*Patricia A. Deverka, Dierdre Gilmore, Jennifer Richmond, Zachary Smith, Rikki Mangrum, Barbara A. Koenig, Robert Cook-Deegan, Angela G. Villanueva, Mary A. Majumder, and Amy L. McGuire*

A medical information commons (MIC) is a networked data environment utilized for research and clinical applications. At three deliberations across the U.S., we engaged 75 adults in two-day facilitated discussions on the ethical and social issues inherent to sharing data with an MIC. Deliberants made recommendations regarding opt-in consent, transparent data policies, public representation on MIC governing boards, and strict data security and privacy protection. Community engagement is critical to earning the public’s trust.

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**BRCA1/2 Variant Data-Sharing Practices**

*Juli M. Bollinger, Abhi Sanka, Lena Dolman, Rachel G. Liao, and Robert Cook-Deegan*

Accessing *BRCA1/2* data facilitates the detection of disease-associated variants, which is critical to informing clinical management of risks. *BRCA1/2* data sharing is complex and many practices exist. We describe current *BRCA1/2* data-sharing practices, in the United States and globally, and discuss obstacles and incentives to sharing, based on 28 interviews with personnel at U.S. and non-U.S. clinical laboratories and databases. Our examination of the *BRCA1/2* data-sharing landscape demonstrates strong support for and robust sharing of *BRCA1/2* data around the world, increasing global access to diverse data sets.

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**Medical Information Commons to Support Learning Healthcare Systems: Examples From Canada**

*Tania Bubela, Shelagh K. Genuis, Naveed Z. Janjua, Mel Krajden, Nicole Mittmann, Katerina Podolak, and Lawrence W. Svenson*

We explore how principles predicting the success of a medical information commons (MIC) advantaged or disadvantaged three MIC initiatives in three Canadian provinces. Our MIC case examples demonstrate that practices and policies to promote access to and use of health information can help improve individual healthcare and inform a learning health system. MICs were constrained by heterogeneous health information protection laws across jurisdictions and risk-averse institutional cultures. A networked approach to MICs would unlock even more potential for national and international data collaborations to improve health and healthcare.

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**Whose Commons? Data Protection as a Legal Limit of Open Science**

*Mark Phillips and Bartha M. Knoppers*

Open science has recently gained traction as establishment institutions have come on-side and thrown their weight behind the movement and initiatives aimed at creation of information commons. At the same time, the movement’s traditional insistence on unrestricted dissemination and reuse of all information of scientific value has been challenged by the movement to strengthen protection of personal data. This article assesses tensions between open science and data protection, with a focus on the GDPR.

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### **Living Donation by Individuals with Life-Limiting Conditions**

*Lainie Friedman Ross and  
J. Richard Thistlethwaite*

The traditional living donor was very healthy. However, as the supply-demand gap continues to expand, transplant programs have become more accepting of less healthy donors. This paper focuses on the other extreme, asking whether and when individuals who have life-limiting conditions (LLC) should be considered for living organ donation. We discuss ethical issues raised by 1) donation by individuals with progressive severe debilitating disease for whom there is no ameliorative therapy; and 2) donation by individuals who are imminently dying or would die by the donation process itself.

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### **Do Community Treatment Orders in Psychiatry Stand Up to Principlism: Considerations Reflected through the Prism of the Convention on the Rights of Persons with Disabilities**

*Giles Newton-Howes*

Compulsory psychiatric treatment is the norm in many Western countries, despite the increasingly individualistic and autonomous approach to medical interventions. Community Treatment Orders (CTOs) are the singular best example of this, requiring community patients to accept a variety of interventions, both pharmacological and social, despite their explicit wish not to do so. The epidemiological, medical/treatment and legal intricacies of CTOs have been examined in detail, however the ethical considerations are less commonly considered. Principlism, the normative ethical code based on the principles of autonomy, beneficence, non-maleficence and justice, underpins modern medical ethics. Conflict exists between patient centred commentary that reflects individual autonomy in decision making and the need for supported decision making, as described in the Convention on the Rights of Persons with Disabilities (CRPD) and the increasing use of such coercive measures, which undermines this principle. What appears to have been lost is the analysis of whether CTOs, or any coercive measure in psychiatric practice measures up against these ethical principles. We consider whether CTOs, as an exemplar of coercive psychiatric practice, measures up against the tenets of principlism in the modern context in order to further this debate.

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### **Thought Leader Perspectives on Participant Protections in Precision Medicine Research**

*Catherine M. Hammack, Kathleen M. Brelsford, and Laura M. Beskow*

Precision medicine research is rapidly taking a lead role in the pursuit of new ways to improve health and prevent disease, but also presents new challenges for protecting human subjects. The extent to which the current “web” of legal protections, including technical data security measures, as well as measures to restrict access or prevent misuse of research data, will protect participants in this context remains largely unknown. Understanding the strength, usefulness, and limitations of this constellation of laws, regulations, and procedures is critical to ensuring not only that participants are protected, but also that their participation decisions are accurately informed. To address these gaps, we conducted in-depth interviews with a diverse group of 60 thought-leaders to explore their perspectives on the protections associated with precision medicine research.

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### **Breastfeeding with HIV: An Evidence-Based Case for New Policy**

*Marielle S. Gross, Holly A. Taylor, Cecilia Tomori, and Jenell S. Coleman*

To help eliminate perinatal HIV transmission, the US Department of Health and Human Services recommends against breastfeeding for women living with HIV, regardless of viral load or combined antiretroviral therapy (cART) status. However, cART radically improves HIV prognosis and virtually eliminates perinatal transmission, and breastfeeding's health benefits are well-established. In this setting, pregnancy is increasing among American women with HIV, and a harm reduction approach to those who breastfeed despite extensive counseling is suggested. We assess the evidence and ethical justification for current policy, with attention to pertinent racial and health disparities. We first review perinatal transmission and breastfeeding data relevant to US infants. We compare hypothetical risk of HIV transmission from breastmilk to increased mortality from sudden infant death syndrome, necrotizing enterocolitis and sepsis from avoiding breastfeeding, finding that benefits may outweigh risks if mothers maintain undetectable viral load on cART. We then review maternal health considerations. We conclude that avoidance of breastfeeding by women living with HIV may not maximize health outcomes and discuss our recommendation for revising national guidelines in light of autonomy, harm reduction and health inequities.

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**articles** are essays unrelated to the symposium topic, and can cover a wide variety of subjects within the larger medical and legal ethics fields. These articles are peer reviewed.

**Columns** are written or edited by leaders in their fields and appear in each issue of JLME.

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