

# THE JOURNAL OF LAW, MEDICINE & ETHICS

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*Kellen Russoniello, Cailin Harrington, Sarah Beydoun, and Lucrece Borrego*

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VOLUME 51:2 • SUMMER 2023

Symposium Articles

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**International  
Collaborations:  
The Future of  
Health Care**

Guest Edited by  
Jamie S. King and  
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**Introduction**

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**The Coalition for Epidemic  
Preparedness Innovations (CEPI)  
and the Partnerships of Equitable  
Vaccine Access**

*Sam Halabi, Lawrence O. Gostin,  
Kashish Aneja, Francesca Nardi, Katie  
Gottschalk, and John Monahan*

This article highlights and evaluates the role of CEPI and its contribution to global equitable access to COVID-19 vaccines through its established partnerships for vaccine development. The article adds to the understanding of how and when such partnerships can work for public health, especially under emergency citations. The relatively spontaneous and effective cooperation between major international organizations shortly after the pandemic declaration played a significant role in reducing to a material extent COVID-19's burden of disease and death. Future pandemic preparedness, prevention, and response will require that collaborations of this kind be sustained and effective going forward.

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**Increasing Equity in the Transnational  
Allocation of Vaccines Against  
Emerging Pathogens: A Multi-Modal  
Approach**

*Ana Santos Rutschman*

This article proposes the adoption of a multi-modal system for allocating vaccine doses during large transnational outbreaks of infectious diseases. The chosen allocative criteria (public health need; country-income level; qualification through funding; and, subsidiarily, a modified lottery system) are adapted from a current embodiment of allocative multi-modality outside the context of public health: the New York City Marathon, a disproportionately over-subscribed international event in which the allocation of participation slots operates according to mix-and-match criteria.

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**Enhancing Reciprocity, Equity and  
Quality of Ethics Review for Multisite  
Research During Public Health  
Crises: The Experience of the COVID-  
19 Clinical Research Coalition Ethics  
Working Group**

*Vasiliki Rahimzadeh, Jennyfer Ambe,  
and Jantina de Vries*

In this paper we report findings from a commissioned report to the COVID-19 Clinical Research Coalition on approaches to streamline multinational REC review/approval during public health emergencies. As currently envisioned in the literature, a system of REC mutual recognition is theoretically possible based on shared procedural REC standards, but raises numerous concerns about perceived inequities and mistrust. We argue future initiatives be cooperative, evidence-based, and prioritize trust-building among RECs across the Global North and South.

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**In this Together: International  
Collaborations for Environmental and  
Human Health**

*Jaime S. King, Joanna Manning,  
and Alistair Woodward*

Climate change exacts a devastating toll on health that is rarely incorporated into the economic calculus of climate action. By aligning health and environmental policy and collaborating across borders, governments and industries can develop powerful initiatives to promote both environmental and human health.

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**Telehealth in the Metaverse: Legal  
& Ethical Challenges for Cross-Border  
Care in Virtual Worlds**

*Barry Solaiman*

This article examines the legal and ethical challenges for the provision of healthcare in the metaverse. It proposes that the issues arising in the metaverse are an extension of those found in telehealth and virtual health communities, albeit with greater complexity. It argues that international collaboration between policymakers, lawmakers, and researchers is required to regulate this space and facilitate the safe and effective development of meta-medicine.

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**Genomic Data as a National Strategic Resource: Implications for the Genomic Commons and International Data Sharing for Biomedical Research and Innovation**

*Kyle McKibbin and Mahsa Shabani*

This article provides a critical review of new policies in China, the United States, and the European Union that characterize genomic data as a national strategic resource. Specifically, we review policies that regulate human genomic data for economic, national security, or other strategic purposes rather than ethical or individual rights purposes. These policies contrast with the openness that has historically persisted in genomics research and could have negative consequences for global collaboration and biomedical innovation.

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**Challenges and Opportunities in Modernizing Clinical Trial Recruitment**

*Amirala S. Pasha and Richard Silbert*

Clinical trial recruitment is ripe for innovation. The current model is costly, often results in poor recruitment and offers inequitable access. To improve this system, we envision a peer-to-peer blockchain platform where patients control the depth and breadth of how their medical information is shared. Such a system could reduce costs, expedite recruitment, and allow more participation from underrepresented populations. We outline how this new model could function, and some of the anticipated challenges and benefits.

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**Delivering Culturally-Appropriate, Technology-Enabled Health Care in Indigenous Communities**

*Laszlo Sajtos, Nataly Martini, Shane Scahill, Hemi Edwards, Potaua Biasiny-Tule, and Hiria Te Rangi*

Indigenous health is becoming a top priority globally. The aim is to ensure equal health opportunities, with a focus on Indigenous populations who have faced historical disparities. Effective health interventions in Indigenous communities must incorporate Indigenous knowledge, beliefs, and worldviews to be culturally appropriate. Six studies in New Zealand and Canada were analyzed to assess the effectiveness of health care interventions in Indigenous communities. The motivation-opportunity-ability (MOA) framework was used to identify key success factors that drive behavior change. The role of technology in healthcare interventions for Indigenous communities was also analyzed and both opportunities and challenges were identified. The goal of this paper is to guide research teams in developing and implementing culturally-appropriate healthcare interventions for Indigenous communities, reducing health disparities both within and across countries.

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**Health Justice Partnerships: An International Comparison of Approaches to Employing Law to Promote Prevention and Health Equity**

*Elizabeth Tobin-Tyler, Tessa Boyd-Caine, Hazel Genn, and Nola M. Ries*

This article traces the development and growth of health justice partnerships (HJPs) in three countries: the United States, Australia and the United Kingdom. It describes the conceptual framework underlying these partnerships; traces their development and compares their priorities, practices, approaches and challenges; describes the existing research base supporting their benefits; and highlights the role of inter-professional education and training in preparing a workforce that can practice effectively in HJPs. Throughout the article, we discuss how international collaboration has fostered shared learning and promoted innovation in health, social and legal care.

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**Malleable Morality: Re-Shaping Moral Judgments in Health Policymaking**

*Shelly Simana*

When confronted with moral dilemmas related to health, governments frequently turn to “moral experts,” such as bioethicists and moral philosophers, for guidance and advice. They commonly assume that these experts’ moral judgments are primarily a product of deliberate reasoning. The article challenges this assumption, arguing that experts’ moral judgments may instead be primarily a product of moral intuitions which, often subconsciously, respond to the social setting.

## Independent Articles

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**Improving Labor Outcomes among People with Mild or Moderate Mental Illness through Law and Policy Reform**

*Benjamin A. Barsky, Richard G. Frank, and Sherry A. Glied*

Mild and moderate mental illnesses can hinder labor force participation, lead to work interruptions, and hamper earning potential. Targeted interventions have proven effective at addressing these problems. But their potential depends on labor protections that enable people to take advantage of these interventions while keeping jobs and income. In this paper, we highlight laws that protect people with mild or moderate mental illness who need flexibility to benefit from clinical and work-focused interventions. We find that two federal laws offer protections for those who require time and flexibility to benefit from work-focused and clinical interventions: the Family and Medical Leave Act and the Americans with Disabilities Act. States have also implemented policies that allow for individuals to take time off work to address their conditions, which include (1) paid sick leave; (2) paid medical leave; (3) and mandated short-term disability. We conclude that a federal paid medical leave program represents a concrete policy remedy that could improve the work outcomes of people with mild or moderate mental illness.

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**Improving Labor Outcomes among People with Mild or Moderate Mental Illness through Law and Policy Reform**

*David S. Kroll*

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**Risk Reduction Policies to Reduce HIV in Prisons: Ethical and Legal Considerations and Needs for Integrated Approaches**

*Sayantane Das, Sameer Ladha, and Robert Klitzman*

The United States has the fastest growing prison population in the world, and elevated incarceration rates, substance use, and human immunodeficiency virus (HIV) prevalence are fueling each other. Yet without a national guideline mandated for HIV care within the prison system, standards for state and federal prisons vary greatly. Four diverse and distinctive projects to reduce HIV transmissions in prisons have been conducted across the United States — the “New York State Prison Project,” the “Seek, Test, Treat, Retain Cascade,” the “Positive Justice Project,” and the “Novel Condom Access Program.” We analyzed these programs, highlighting similarities and differences in outcomes, effectiveness, ethical considerations, areas of improvement, and future research and policy suggestions. A combination of the programs, including mandatory pre-exposure prophylaxis, screening, opt-out policies, and prison HIV data release, appears most effective for lowering HIV transmission, reducing stigma and providing quality HIV care. However, enactment of such initiatives faces obstacles, given ongoing questions about the minimum health care to which prisoners are entitled, and tensions regarding how much prisons should serve as punishment or rehabilitation. Heightened public and government recognition of the need and ethical duty to care for inmates are needed. States should consider these prevention mechanisms to reduce HIV transmission, incorporating as many aspects reasonably feasible.

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**The Sociological Context of Incarceration and Health**

*Jason Schnittker*

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**When Public Health Goes Wrong: Toward a New Concept of Public Health Error**

*Itai Bavli*

Studies of public health decisions that have had harmful effects tend to disagree about what constitutes a public health error. Debates exist about whether public health errors must be culpable or not, as well as about what the criteria for judging public health errors should be. This study provides a new concept of public health errors — defined as acts of commission or omission, culpable or not, by public health officials,

whose consequences for population health were substantially worse than those of an alternative that could have been chosen instead. This conception better corresponds to the task of public health, compared to policy failure literature, where achievement of political objectives is often used to measure success, and has practical and theoretical advantages. It also serves as a valuable analytical lens for understanding general mechanisms leading to public health errors, with utility for scholars who study policy errors and public health actors interested in preventing them.

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**State-Specific Barriers to Methadone for Opioid Use Disorder Treatment**

*Kellen Russoniello, Cailin Harrington, Sarah Beydoun, and Lucrece Borrego*

Opioid agonist treatment, including methadone, is the safest and most effective method for treating opioid use disorders and reducing opioid overdose deaths. However, access to methadone is limited by federal law and may only be accessed through an approved opioid treatment program. Many states go beyond the federal standard and impose additional barriers to access. We analyzed statutes and regulations pertaining to methadone access for each state, the District of Columbia, and Puerto Rico. We identified seven common barriers imposing stricter access requirements on methadone than required by federal law. We provide totals by each barrier category and highlight illustrative examples. To provide increased access to this life-saving medication, states should repeal or amend laws that impose more stringent burdens on methadone access than required by federal law.

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**“Death and Taxes”: Why Financial Compensation for Research Participants is an Economic and Legal Risk**

*Margaret Waltz, Arlene M. Davis, and Jill A. Fisher*

In the US, research payments are technically taxable income. This article argues that tax liability is a form of possible economic and legal risk of paid research participation. Findings are presented from empirical research on Phase I healthy volunteer trials. The article concludes by discussing the implications of these findings for the informed consent process, as well as for broader ethical issues in whether and how payments for research participation should be regulated.

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**Tax the Rich! Tax the Research Participants?**

*Emily A. Largent*

**Symposium articles** are solicited by the guest editor for the purposes of creating a comprehensive and definitive collection of articles on a topic relevant to the study of law, medicine and ethics. Each article is peer reviewed.

**Independent 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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### Seeking Reproductive Justice in the Next 50 Years

A Symposium Guest Edited by Nicole Huberfeld, Linda C. McClain, and Aziza Ahmed

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#### **Selling Clinical Biospecimens: Guidance for Researchers and Private Industry**

*Peter H. Schwartz and Jane A. Hartsock*

The recently revised Common Rule requires that donors of biospecimens for research be informed if their specimens might be used for commercial profit. The Common Rule, however, does not apply to sharing or selling de-identified biospecimens that are “leftover” from clinical uses. As a result, many medical researchers remain uncertain of their legal and ethical obligations when a commercial entity expresses interest in these specimens. In this paper, we argue that there is no absolute legal or ethical barrier to sharing leftover clinical specimens, regardless of purpose. Selling leftover biospecimens does not violate healthcare providers’ fiduciary duties to their patients, in principle, though certain commercial arrangements could create conflicts of interest that would raise both ethical and legal concerns. We further argue that health systems should do more to improve patient understanding of potential commercialization of their leftover specimens. We also identify actions that health systems can take to be more trustworthy and transparent in their use of such specimens.

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