

INTRODUCTION

The Crucial Role of Law in Supporting Successful Translation of Genomics into Clinical Care

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Advances in human genomics have the potential to transform risk prediction, disease diagnosis, identification of treatment options, and selection of medications and dose. Yet integration of genomics into clinical care remains uneven, with some organizations and medical specialties in the vanguard, but many more at an earlier stage in the process. While others have examined knowledge and economic barriers (including lack of insurance coverage for genomic testing), few have considered how law supports or hinders genomics implementation. Yet it turns out that law — and fear of legal repercussions — loom large.

The goal of this Symposium is to analyze how law supports and impedes genomics implementation and to recommend changes to advance successful integration of genomics into clinical care. The work published here was funded by a unique grant from the National Human Genome Research Institute (NHGRI) and National Cancer Institute (NCI) at the National Institutes of Health (NIH) entitled, “LawSeq: Building a Sound Legal Foundation for Translating Genomics into Clinical Application.”¹ That grant has funded a Working Group of twenty-two experts² — including lawyers, genomics researchers, and clinicians,

informatics specialists, and colleagues from industry genomics — to collaborate with the principal investigator team to map the current law of genomics in the United States and to generate recommendations on how to transform law to undergird successful integration of genomics into clinical care.

Federal regulators such as the Food and Drug Administration (FDA) and Centers for Medicare & Medicaid Services (CMS) are struggling to ensure the quality of devices, software, and laboratory processes used in genomics analysis.³ Law plays a crucial role in this regulatory domain; unless clinicians and patients have justifiable confidence in the validity of genomic tests and accuracy of their interpretation, progress in genomic implementation will be halting.

Meanwhile, clinicians are facing questions of liability exposure in the fast-moving domain of genomics.⁴ They are caught between the Scylla of lagging behind and the Charybdis of going too fast.⁵ They face potential liability for failure to implement and properly understand genomic tools that have been successfully validated and incorporated into the standard of care, but also face potential liability if they rely on non-validated tools and tests whose clinical implications are not well established.

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Patients themselves face challenges. They may worry about the adequacy of privacy protections when they consider taking genomic tests up to and including whole genome sequencing (WGS).⁶ Even patients who understand that the federal Genetic Information Non-discrimination Act (GINA) and state statutes provide some protections against employment and insurance discrimination based on genetic tests will properly be concerned about the limits of those protections. At the same time, they may worry about gaining access to their results in order to share them with caregivers, relatives, and research teams.⁷ While federal law guarantees patient access to laboratory results as part of the Privacy Rule under the Health Insurance Portability and Accountability Act (HIPAA), patients asserting that right often face obstacles.

trials) cross two domains (in that case, research and clinical care), sorting out which body of law applies can be daunting.

The LawSeq project thus convened four Task Forces, to work on liability, quality, privacy, and framework. Each Task Force worked to map current law, ascertain the key legal challenges, and devise recommendations to improve the law in order to support successful integration of genomics into clinical care. This Supplement presents the analyses and recommendations of the Liability Task Force,¹⁰ the Quality Task Force,¹¹ and the Framework Task Force.¹² The analysis by the Privacy Task Force has already been published.¹³

In addition, the LawSeq project has supported Working Group members in researching and writing on specific legal issues. This Supplement presents five

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These quality, liability, and privacy concerns are among those that the LawSeq project has treated as focal. These legal concerns were reinforced by our empirical analyses and group processes.⁸ The project included the first empirical analysis of stakeholder views on the pressing legal issues posed by genomics. In addition, the project's Working Group used a modified Delphi process involving repeat surveys of Working Group members to ascertain what they saw as the major legal issues. We found and report in this Supplement on these perceptions of the landscape of legal concerns, including quality, liability, and privacy.

What we found in our project was that one additional set of concerns pervades these three domains — the overarching framework question of when research law and rules apply, when clinical law applies, when the law of public health screening (such as newborn screening) applies, and when the emerging commercial law of direct-to-consumer (DTC) testing applies.⁹ Genomics is a translational science that crosses all four domains. Yet the law in each of those domains is quite different. When genomics activities (such as clinical

of the articles they have produced.¹⁴ The LawSeq team has published extensively elsewhere as well.¹⁵

Supporting the project's analyses has required collecting and analyzing a massive amount of state and federal law. Our project committed to making the fruits of that analysis publicly available free of charge. We have posted the LawSeq Database on the internet at <https://lawseq.umn.edu/>.¹⁶ This searchable database allows clinicians, researchers, patients, research participants, and the public, as well as lawyers, legislators, and policy makers to search by topic or by jurisdiction to easily find the law on genomics. The Database includes a glossary, an annotated bibliography of secondary sources, and other tools to make the law of genomics in the United States more accessible than it has been in the past.

In addition, we have convened three conferences, with a fourth scheduled in 2020. In March 2017, we presented a conference and webcast on "The Future of Informed Consent in Research and Translational Medicine: A Century of Law, Ethics & Innovation." Papers from that conference were published in an

earlier symposium in the *Journal of Law, Medicine & Ethics*.¹⁷ Video from that conference is archived online for free public access.¹⁸

Our second conference was motivated by the recognition that law must play a crucial role in supporting not just the incorporation of genomics into clinical care, but incorporation in a way that avoids deepening health care disparities and instead promotes health equity. That conference and webcast on “Law, Genomic Medicine & Health Equity: How Can Law Support Genomics and Precision Medicine to Advance the Health of Underserved Populations?” was presented in November 2018 at Meharry Medical College in Nashville, Tennessee. The conference was co-sponsored by the Meharry-Vanderbilt Alliance; Vanderbilt University Medical Center; the University of Minnesota’s Consortium on Law and Values in Health, Environment & the Life Sciences; and the Minnesota Precision Medicine Collaborative. That conference has produced a symposium in *Ethnicity & Disease*¹⁹ as well as an archived conference video for public use.²⁰

Our third conference took place in March 2019 at the University of Minnesota. The goal of this conference and webcast on “LawSeq: Building a Legal Foundation for Translating Genomics into Clinical Application,” was to present our Task Force papers for public feedback. We also presented our empirical analyses and individual Working Group member papers. The day after that conference, the Working Group met behind closed doors to digest that feedback and agree on responsive amendments to the papers presented. This Symposium issue collects most of the papers presented. In addition, the conference video is posted for free public access.²¹

We have presented LawSeq analyses in multiple venues and continue to do so. We find that response is tremendous, as audiences realize the role law can play in promoting sound use of genomics and successful integration into clinical care. Law can undermine successful deployment of genomics in clinical care or support development of sound tools, appropriate standards of care, access to care and protections for patients, and clarity about what legal rules should apply as genomics progresses from research to clinical care, and public health uses. Law can also set the ground rules for commercial DTC uses.

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