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Genomic medicine

Building the foundation for successful integration into clinical care

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Since the first full draft of the human genome sequence was released in 2001, we've moved from the familiar world of genetics to a new era of genomics. While genetic tests have been used as diagnostic tools for decades, the new capabilities and vast amount of data generated by genomic sequencing raises new questions and opportunities in every sphere of health care.

As genomic sequencing evolves from being primarily a research tool to clinical application, a project funded by the National Institutes of Health (NIH) entitled LawSeq™ is focusing on building the legal foundation for genomic medicine. The law of genomics is currently unclear, poorly understood and contested. Scholars at the University of Minnesota and Vanderbilt University are collaboratively leading a national working group to analyze federal and state genomics law and then recommend changes to support successful integration of genomics into clinical care.

Genomic sequencing—including whole exome sequencing (WES) and whole genome sequencing (WGS)—offers crucial diagnostic insights and treatment opportunities in a range of scenarios. These include diagnosis of children with puzzling neu-

rodevelopmental conditions and identification of new therapeutic targets and strategies in cancer patients. In addition, many patients can benefit significantly from treatment options tailored to their genotype. The field of pharmacogenomics—tailoring drug selection and dosing to relevant differences in genes affecting drug metabolism—offers to revolutionize medication prescribing practices. These exciting developments call for clear standards and law governing the use of genomics in clinical care.

Health care providers are already grappling with legal issues raised by genomics. Physicians may feel their training left them ill-equipped to recognize when genomic testing is indicated and poorly prepared to interpret the results. Patients may even come to clinical appointments with genetic information they've

received as a result of direct-to-consumer (DTC) testing. Medical geneticists, genetic counselors and expert laboratory personnel will be crucial partners, offering expert interpretation and recommendations. Physicians may nonetheless have concerns about their own exposure to liability as genomics increasingly pervades cancer care and other medical domains. Physicians may also worry about divergent genomic interpretations across laboratories and what quality standards are in place. And because genomic analyses rely on the collection of large amounts of genetic information from individuals and interpretation using genomic databases, concerns about how to secure the privacy and confidentiality of genomic information loom large. All of these issues—liability, quality, and privacy—are central concerns in the LawSeq™ project.

The need to clarify the law and standards governing use of genomics in health care is the catalyst for the LawSeq™ project. The project brings together researchers, clinicians, laboratory experts, informaticians, attorneys and policymakers to clarify what the law currently is and to formulate recommendations on what the law should be. The project is focused on the law addressing liability (including tort and contract exposure of clinicians, laboratory personnel and their institutions); quality (analytic validity, clinical validity and utility of genomic sequencing results); and privacy and access (including what results should be entered into medical records, and what access patients have to laboratory reports). LawSeq™ will help establish a framework for when the law and rules of research should apply versus those of clinical care, a growing challenge with the rise of translational research approaches that blend research with clinical care.

To support the translation of genomics into the clinical setting, the LawSeq™ team is developing a website offering tools to search and retrieve federal and state law on genomics. It will provide a free public database of the relevant statutes, regulations and reported judicial decisions. In addition, the site will offer a curated selection of core articles, so users can access commentary and scholarly analysis.

The project is also conducting empirical research, in order to analyze what key professional stakeholders see as the major legal issues affecting genomics and query them on possible solutions. This empirical research is helping inform the LawSeq™ team as we generate forward-looking recommendations for legal improvements to support genomic medicine.

In many domains of medicine, genomics is playing a key role in creating the future. The LawSeq™ project will significantly advance the resources available to researchers, clinicians, their institutions, research participants, patients and the public. By creating a central resource on genomics law, the project promises to advance the integration of genomics into clinical practice in Minnesota and across the country.

A national public LawSeq™ conference and webcast will be held on the campus of the University of Minnesota on April 25, 2019. To learn more and register, visit z.umn.edu/LawSeqConference.

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