

How does the precision medicine initiative affect me?

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As the All of Us initiative (previously known as the Precision Medicine Initiative) and the collection of DNA sequences of one million Americans begins this year, with at least 65,000 people already enrolled in the program, health care is transitioning from population-based approaches to individualized health care that focuses on the genetic makeup of each patient. Precision medicine will extend beyond prediction, diagnosis and treatment of disease to also include broader health initiatives, including prevention, nutrition and wellness. These new procedures raise novel legal, policy and ethical issues.

The symposium session at the 2018 Society for Risk Analysis (SRA) Annual Meeting will address cutting edge risk communication, [risk assessment](#) and risk management issues with respect to [precision medicine](#), addressing issues such as trust, governance, tort liability and data access and quality.

Liability is a powerful risk management tool, incentivizing parties to take adequate precautions, but it can also potentially impede innovation and over-deter some individuals. Gary Marchant, Ph.D., J.D., MPP, Arizona State University, conducted a research study, "Genomic medicine and malpractice risks," that quantifies the medical malpractice lawsuits against doctors and other [healthcare professionals](#) relating to genetic medicine.

The study analyzed more than 300 cases in which healthcare providers were sued for allegedly applying genetic test opportunities or data in a

negligent manner, referred to as "genomic malpractice." Most doctors lack training in genetics so many are struggling to properly handle and understand genetic information about their patients. The study revealed that there has been a significant increase in genomic malpractice lawsuits and that these lawsuits have a higher probability of success and result in larger awards than other medical malpractice lawsuits.

"Many patients are not getting the best healthcare in terms of applying new genetic findings—perhaps the increase in liability will help to improve the quality of care relating to genetic medicine," states Marchant.

Trust in precision medicine is required because of the many, potentially far-reaching, uncertainties and risk that come with its development. This includes, risks to individuals who participate in DNA collection schemes, to patients who benefit from new therapies, to insurers and payers or to industry. In 2017, the International Risk Governance Council and Center (IRGC) organized a workshop on the governance of trust in precision medicine. Marie-Valentine Florin, Ecole Polytechnique Federale de Lausanne, will present the main findings from the workshop in her presentation, "Trust in precision [medicine](#)."

Florin's presentation will focus on assessing and managing trustworthiness in the collection of genetic, medical and other personal data, and issues of consent regarding who can access this data; the analysis of data and provision of information for diagnostics that increasingly rely on artificial intelligence; and the provision of health and medical care by professionals to improve prevention and therapies, in ways that are safe, accessible and affordable for patients.

Provided by Society for Risk Analysis

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