

Genetics to Genomics and New Liability Considerations for Healthcare Providers

September 23, 2020

A major 21st century shift in healthcare has been the transition from genetics to genomics. More specifically, single-gene testing for diagnosis is being replaced by multi-genic tests for disease diagnosis, prediction, prognosis, and treatment.

Whereas genetics includes the study of hereditary diseases such as cystic fibrosis, genomics involves the study of complex illnesses arising from a complex combination of the genetic and environmental factors in a person's life. Diseases in the field of genomics include heart disease, asthma, diabetes, and cancer.

Though relatively new, genomics is already offering promising new possibilities for therapies and treatments for some complex diseases, as well as new diagnostic methods.

In turn, this transition has triggered expansions and novelties in liability risks for health care providers and test laboratories.

Why Genomics?

The transition from genetics to genomics began in 2001 and is still ongoing, largely fueled by the limitations of genetic testing for clinical utility and accuracy.

After the completion of a draft sequence of the human genome, new technologies could emerge to perform genomic assessment of patients by testing larger panels of genes, performing microarrays, conducting exome sequencing and whole genome sequencing. (1)

Examples of new techniques and therapies developed from genomics include proteomics, pharmacogenetics, pharmacogenomics, stem cell therapy, and cloning.

With the new and emerging applications and complexities of genomic testing, health care providers and institutions will have greater responsibilities imposed on them. This is likely to lead to new medical malpractice and other liability claims and exposure.

How Will Genomics Change Healthcare Liability Risks?

Following are just a few examples of some expanded responsibilities of health care providers and test labs in the age of genomic medicine:

1. A wider array of practitioners will increasingly be using genetic and genomic testing, and not all of these practitioners will have the skills or experience to navigate the complexities of genomic analysis. At the same time, this means that new challenges and responsibilities will fall on these practitioners as they learn these tools.
2. Those who direct and operate clinical laboratories will also face new challenges and liabilities as this new class of medical tests creates new demand.
3. Genomic analysis has given rise to precision medicine, involving personalized treatment for a variety of illnesses. Shifts like this require clinicians to be knowledgeable about new medicine techniques and to keep up to date with ethical and legal responsibilities.
4. Claims could arise from diagnostic tests of which there are currently no formal policies to guide decisions about appropriate breadth of testing to implementation. Since the onus of these decisions typically fall on the practitioners (e.g. the medical oncologist, genetic counselor, or medical geneticist), they will be put at increased risk for accusations of inappropriate or inadequate testing - either held liable for testing too broadly or not broadly enough. (1)
5. Laboratories may be at risk for including genes on offered panels despite insufficient information about those genes and their associated health risks. Down the road, this could lead to unnecessary medical care or surveillance of a patient.

Misinterpretation of data, testing errors, and insufficient knowledge of the emerging field of genomics, are all causes for increased liability risk to clinicians and laboratories as the transition to genomics continues to evolve.

Examples of liability claims may include:

- failure to test
- over-testing and incomplete information
- inappropriate use of or reliance on a test
- incorrect variant calls
- failure to recommend results to a patient accurately
- failure to communicate results and share data with clinicians within a healthcare system
- failure to analyze and offer incidental findings or secondary results
- failure to update
- failure to warn family members
- errors and failures direct-to-consumer (DTC) testing (1)

Effectively Managing The Risks

Managing emerging liability threats ultimately requires continued advances in knowledge as well as policies for testing. That is why it is important to have a healthcare specialist insurance broker who understands the risks and can advise on the best course of action.

Medical malpractice liability is a good starting point, both for practitioners and institutions. It has the dual purpose of deterring healthcare providers from engaging in negligence, while providing potential compensation to patients who are injured by substandard medical care.

Visit our website for more information on how MedThree Insurance can [meet the needs of your organization or practice](#).

Content is current as of the date of broadcast and is subject to change without notice.

Sources:

1. <https://journals.sagepub.com/doi/full/10.1177/1073110520916994>