Precision Medicine

Question

What is the outlook for precision medicine and does it present liability or other concerns for healthcare providers?

Answer

The rapidly evolving approach known as precision medicine involves matching medical treatment with an individual's DNA, environment, and lifestyle. Using precision medicine, doctors and researchers will be able to predict more accurately which treatment and prevention strategies for a particular disease will work in which groups of people.

Although the day-to-day role of precision medicine in healthcare is still relatively limited, it is used for certain diagnostic and treatment approaches. For example, genetics and genomics are two components of precision medicine that have current applications in medical care and that will undoubtedly continue to advance over time.

The terms "genetics" and "genomics" are sometimes used interchangeably, but they are different.[1] Genetics is the study of genes and how certain traits and diseases/conditions (such as sickle cell disease, hemophilia, and cystic fibrosis) are passed from generation to generation. Genomics is the study of all of an individual's genes (the genome) and how they interact with each other and the person's environment. Genomics can provide valuable information about diseases/conditions that aren't solely hereditary but often occur as a result of genetics, the environment, and other factors (such as cancer, heart disease, and asthma).

Because precision medicine is an evolving practice, issues related to liability are still largely unknown and will continue to emerge as the practice of precision medicine becomes more

mainstream. However, some risks and liability exposures have been identified with genetic testing, the diagnostic approach that identifies mutations in chromosomes, genes, or proteins that may cause illness or disease. Areas of practice in which these have occurred include obstetrics, oncology, and cardiology.

A limited amount of MedPro Group's claims data indicates that allegations against healthcare providers were the result of:

- Failure to recommend, failure to order, or delays in ordering genetic testing
- Failure to refer a patient to a specialist for genetic counseling
- Failure to follow-up on a patient's genetic testing results
- Failure to follow the genetic specialist's recommendations
- Misinterpretation of diagnostic studies
- Failure to understand risks like a medical geneticist would

It is also important to remember that even though genetic testing provides valuable information for diagnosing, treating, and preventing illness and disease, it has limitations. For example, a positive result from genetic testing for a healthy person doesn't always indicate disease development. Similarly, a negative result doesn't always guarantee that a certain disorder won't develop.[2]

Explaining these limitations to patients/families and setting clear expectations for genetic testing can help support informed decision-making and avoid misperceptions. Providers should ensure that information about genetic testing is presented to patients/families in ways that they can understand. Using a technique such as teach-back can help providers gauge patient comprehension and address inaccuracies or confusion.

Beyond liability concerns, precision medicine also presents ongoing ethical issues. The *AMA Journal of Ethics* identifies these potential ethical dilemmas as privacy, informed consent, shared decision making, disclosure, social justice, valuation practices, regulation of human subjects research, etc.[3]

As precision medicine evolves and legal and ethical considerations become more apparent, so will best practices and strategies to address them. Healthcare providers who plan to incorporate aspects

of precision medicine into practice should stay abreast of these developments and determine how best to partner with patients to maximize the value of precision care and mitigate potential risks.

Resources

- Education & Resources in Genetics & Personalized Medicine (American Medical Association)
- Ethics in Precision Health (AMA Journal of Ethics)
- Genetic Testing (Mayo Clinic)
- Genetics Home Reference (U.S. National Library of Health, National Institutes of Health)
- Genomics & Precision Health (Centers for Disease Control and Prevention)
- Genomics and Precision Health (JAMA Insights)
- National Human Genome Research Institute (National Institutes of Health)

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[1] National Human Genome Research Institute. (2018, September 7). Genetics vs. genomics fact sheet. Retrieved from www.genome.gov/about-genomics/fact-sheets/Genetics-vs-Genomics

[2] Mayo Clinic. (2014, May 14). Genetic testing. Retrieved from www.mayoclinic.org/tests-procedures/genetic-testing/about/pac-20384827

[3] Batten, J. N. (2018, September). How stratification unites ethical issues in precision health. *AMA Journal of Ethics, 20*(9), E798-803. doi: 10.1001/amajethics.2018.798