Health Issue Brief:

Personalized Medicine and Genetic Information

Background

Personalized medicine refers to the development of therapies that are customized to work with an individual's genetic code. Genes influence the efficacy of treatment, especially for diseases like cancer. Providers and drug manufacturers often use an individual's genetic information to create personalized medicine or in clinical research trials to develop new therapies.

Key Highlights:

- Personalized medicine is a promising practice that has the potential to treat or cure challenging diseases, like cancer.
- Genetic information and pharmacogenomics help drug developers target therapies to the individual.
- Adequate protections from federal and state agencies, as well as clinical research institutes, are essential to creating a safe, robust environment for research and treatment.
- Nondiscrimination based on genetic information is generally enforced at the state and federal levels.
- Individuals should be aware of the difference between privacy protections extended by clinical trials and health care providers versus consumer market genetic tests.

Personalized Medicine

Individuals can be predisposed to diseases such as breast cancer, melanoma and even cardiovascular disease because of their genetic code.[1] The benefits of personalized medicine include better medication selection, safer dosing options, improvements in drug development and targeted preventive care.[2] The development and selection of therapies under personalized medicine relies on the collection and analysis of individual patient genetic information.

Different Drugs for Different People

Genes are the body's code for creating different proteins, including enzymes, which can change how an individual interacts with a drug. It is important to note:

- Genes influence metabolic factors that can impact the effectiveness of drugs.
- Pharmacogenetics focuses on optimizing drug therapies based on a genetic profile.

[1] Personalized Medicine Coalition, The Case for Personalized Medicine

[2] Vogenberg, F., Barash, C., Pursel, M., Personalized Medicine: Evolution and Development into Theranostics

Gene-based Diseases Need Targeted Medicine

Genetic testing relies on the collection of genetic information to identify whether an individual has a mutation that could result in a disease. The World Health Organization estimates that 10,000 diseases are caused by single genetic mutations.[3] Breakthrough gene editing therapy has the capability to correct some of these genetic aberrations. Many diseases, like cancer, involve genetic mutations that result in abnormal cell growth or function. Some of the most effective therapies involve customization using an individual's genetic code.

Protecting Genetic Information

Patient confidence in the protection of genetic information is key to the long-term growth of personalized medicine. The Genetic Information Nondiscrimination Act (GINA) was passed in 2008, which instituted a federal prohibition on health insurance providers and employers from discriminating on the basis of genetic information. This law, along with the Health Insurance Portability and Accountability Act (HIPAA), provides most of the protections for genetic information at the federal level. The Food and Drug Administration (FDA), as well as the Centers for Medicare and Medicaid Services (CMS) administer regulations for genetic testing. Below are issues to consider regarding the protection of genetic information:

- To develop treatments that will be effective for everyone, scientists need diverse populations to participate in genetic research. Assurances of privacy and confidentiality are instrumental in encouraging participation.
- Protections of genetic information may vary by state.
- While clinical research trials that collect genetic information generally only use this for research purposes, consumer-focused commercial testing services may sell this data to other companies, usually in a deidentified form.

[3] World Health Organization, Genes and Human Diseases