

Personalized Medicine 101

Improving Patient Care
in the 21st Century

WHAT IS PERSONALIZED MEDICINE?

Personalized medicine, sometimes referred to as precision or individualized medicine, is an evolving field in which physicians use diagnostic tests to determine which medical treatments will work best for each patient. By combining the data from those tests with an individual’s medical history, circumstances and values, health care providers can develop targeted treatment and prevention plans.

WHY IS PERSONALIZED MEDICINE IMPORTANT?

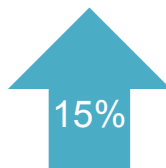
Personalized Medicine Improves Health Outcomes

Myelogenous Leukemia
5-Year Survival Rate



Following introduction of imatinib, a targeted therapy¹

Colorectal Cancer
5-Year Survival Rate



Following discovery of molecular receptors associated with tumor growth²

Heart Patient
Hospitalization Rate



Documented when genetic information was used in dosing warfarin³

Personalized Medicine Can Make the Health System More Efficient

Chemotherapy
Use



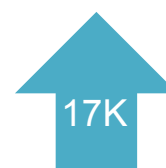
If women with breast cancer received genetic testing prior to treatment⁴

Colorectal Cancer
Costs



If metastatic colorectal cancer patients received genetic testing prior to treatment⁴

Strokes
Prevented



If a genetic test was used to properly dose blood thinners⁴

WHO IS ADVANCING PERSONALIZED MEDICINE?

FDA

Developing and refining the approval pathway for personalized medicines. Targeted therapies accounted for 1 in 5 FDA approvals in 2014.⁵

Academic Researchers

Conducting research to uncover new insights into human genetics and the molecular basis of disease, enabling greater precision in diagnosis and treatment.

Payers

Exploring new business models to incentivize the practice of personalized medicine through appropriate reimbursement of personalized medicine.

Patients

Participating in genetic testing and clinical trials and working with health care providers to proactively manage disease risk and/or treatment strategies.

Health Care Providers

Employing an understanding of the patient's genetic profile and utilizing new technologies to individualize the approach to disease prevention, detection and treatment.

Advocacy Groups

Advancing personalized medicine in patient care by educating providers, accelerating research and supporting necessary changes in policy and regulation.

Pharmaceutical Industry

Developing targeted therapies and conducting innovative research. More than 40 percent of all drugs in development today are personalized medicines.⁶

Diagnostics Companies

Developing tools and tests to improve both the understanding of disease at the molecular level and a patient's likelihood of responding to a treatment.

IT/Informatics Companies

Creating electronic tools and resources to collect and store patient health information, making it available to inform clinical decisions and improve safety while protecting privacy.

HOW CAN WE ENSURE CONTINUED PROGRESS?

Discovery

Support for personalized medicine research can accelerate the pace of progress in developing targeted therapeutics and molecular diagnostics.

Development

A clearly defined **regulatory process** is essential to the field's advancement. Policies should allow for efficient approval of personalized medicine products and services in order to sustain the rapid pace of innovation.

Delivery

Reimbursement policies must keep up with the pace of scientific innovation to support the timely adoption of personalized medicine technologies, including both diagnostics and therapeutics. Care should be taken to ensure that alternative payment models accurately depict the value of an intervention as well as the cost.

REFERENCES

1 American Society of Clinical Oncology, *Leukemia - Chronic Myeloid - CML: Statistics*, 2015 (accessed July 2015)

2 National Cancer Institute, *SEER Stat Fact Sheets: Colon and Rectum Cancer* (accessed July 2015)

3 Mayo Clinic, Medco, *Medco, Mayo Clinic Study Reveals Using a Simple Genetic Test Reduces Hospitalization Rates by Nearly a Third for Patients on Widely Prescribed Blood Thinner*, 2010 (accessed July 2015)

4 PMC, *Personalized Medicine by the Numbers*, 2014 (accessed July 2015)

5 PMC, *More Than 20 Percent of the Novel New Drugs Approved by FDA's Center for Drug Evaluation and Research in 2014 are Personalized Medicines*, 2015 (accessed July 2015)

6 PMC, PhRMA, *Biopharmaceutical Companies' Personalized Medicine Research Yields Innovative Treatments for Patients*, 2015 (accessed July 2015)