

PERSONALIZED MEDICINE IN THE CLINIC

A ROAD MAP FOR FACILITATING THE CLINICAL
ADOPTION OF PERSONALIZED MEDICINE

From Promise to Practice

The pace of innovation in personalized medicine presents a daunting challenge for health care providers. Although personalized medicines now account for nearly one of every four new molecular entities (NMEs) approved by the U.S. Food and Drug Administration (FDA), only 11 percent of patients say their doctors have discussed personalized medicine with them. Behind the relatively slow pace of adoption are multiple obstacles related to education and awareness, patient empowerment, value recognition, infrastructure and information management, and access to care.

To help providers move swiftly to integrate personalized medicine into health care, members of the Personalized Medicine Coalition's Health Care Working Group, which includes representatives from key stakeholders in health care delivery, recently published a list of the most successful strategies for integrating personalized medicine in clinical settings as an open-access article in the journal *Personalized Medicine*. The article, titled "Strategies for Integrating Personalized Medicine into Health Care Practice," highlights a progression of ideas to accelerate the transition from one-size-fits-all medicine toward a more personalized health care paradigm.

The table presented summarizes the research results, which are based on surveys, interviews, focus group discussions and the conversations from a national summit co-hosted by PMC and the Biotechnology Innovation Organization (BIO).

The article in *Personalized Medicine* is available at <http://www.futuremedicine.com/doi/abs/10.2217/pme-2016-0064>.

“We offer this report as a road map for the implementation of integration strategies to add more momentum toward effecting cultural change and a paradigm shift toward personalized medicine.”

- from “Strategies for Integrating Personalized Medicine into Health Care Practice,” published in *Personalized Medicine* (open access)

Integrating Insight

A Guide for Facilitating the Clinical Adoption of Personalized Medicine

1. EDUCATE STAKEHOLDERS

- Develop and publish freely available and accurate information about personalized medicine on websites and social media platforms
- Organize collaborative forums to agree on common terminology for describing personalized medicine
- Update current medical and pharmacy school curricula to include personalized medicine
- Incorporate personalized medicine into new and existing continuing medical education (CME) programs
- Organize regional events at which physicians, pharmacists and community leaders raise awareness for personalized medicine

2. EMPOWER PATIENTS

- Include patient representatives when developing policies and practices related to the use of molecular information
- Develop programs to help explain diagnostic test results to patients and facilitate access to counseling
- Include persons of various ethnicities, races, ages and genders in personalized medicine clinical trials
- Provide counseling and other supportive services to patients before, during and after they are confronted with ethical dilemmas related to molecular information
- Put in place and regularly update state-of-the-art cybersecurity measures to protect patients' data
- Incorporate patient-reported outcomes into all decision-making processes

3. DEMONSTRATE VALUE

- Organize forums at which payers, providers and the diagnostic and pharmaceutical industries discuss health technology assessment processes and the requirements necessary for coverage
- Conduct economic impact studies that are meaningful to payers
- Describe clinical studies to serve multiple purposes, including regulatory approval and demonstration of clinical utility
- Establish universally accepted standards for comparative effectiveness studies and coverage with evidence development programs
- Establish policies that incentivize health care providers for optimizing treatments based on molecular characteristics
- Develop a universally accepted, user-friendly process to collect and share treatment and outcomes data
- Prioritize studies on the costs and benefits of positive and negative coverage determinations in areas of unmet needs

4. MANAGE CLINICAL INFORMATION

- Include each patient's molecular information as well as information regarding clinically actionable variants within electronic health records
- Ensure that medical, clinical support, and outcomes information is interchangeable across information technology platforms
- Develop user-friendly platforms for inputting and accessing personalized medicine data in the clinic; platforms should be a net time-save for clinicians and should be capable of keeping pace with scientific advancements
- Coordinate inter-program communications that allow clinicians to factor molecular data into clinical decisions
- Incentivize data sharing

5. ENSURE ACCESS

- Identify strategies for encouraging payers to cover novel technologies
- Regularly update clinical guidelines and decision support tools to ensure that they reflect best practices in personalized medicine
- Agree on an approach to enroll patients in "basket studies" and other clinical trials focused on personalized medicine
- Ensure that professional fees for personalized medicine services are adequate
- Remove disincentives for using high-value services that are provided outside of network laboratories
- Incorporate personalized medicine principles into alternative payment and delivery models

PMC's Health Care Working Group

Amy Abernethy, M.D., Ph.D.
Flatiron Health

Amjaad Al-Hussain
Inova Health System

Scott Beck
Mayo Clinic

Jeremy Berg, Ph.D.
University of Pittsburgh Medical
Center

Jane Binger, Ed.D.
Sutter Health

Murray Brilliant, Ph.D.
Marshfield Clinic

Jake Chen, Ph.D.
Indiana Institute of Personalized
Medicine

Joseph Carroll, M.D.
Oregon Health and Science
University Knight Cancer
Institute

Alexis Carter, M.D.
Association for Molecular
Pathology

Larisa Cavallari, Pharm.D.
University of Florida

Steve DeCherney, M.D.
Health Decisions CRO+

Lynn Dowling
Dowling Associates

Lynn Dressler, Dr. P.H.
Mission Health

Brian Druker, M.D.
Oregon Health and Science
University Knight Cancer
Institute

Gianrico Farrugia, M.D.
Mayo Clinic

Gregory Feero, M.D., Ph.D.
National Institutes of Health

James Ford, M.D.
Stanford Clinical Cancer
Genomics Center

Julie Goonewardene
University of Texas System

Susan Hager
Foundation Medicine

Dennis Hansen
Health Synergy Solutions, LLC

Jonathan Hirsch
Syapse

Damon Hostin
Catholic Health Initiatives

Andro Hsu, Ph.D.
Syapse

Candace Johnson, Ph.D.
Roswell Park Cancer Institute

Todd Knepper, Pharm.D.
Moffitt Cancer Center and
Research Institute

Selin Kurnaz, Ph.D.
Massive Bio

Philip Leming, M.D.
Christ Hospital

Jennifer Levin Carter, M.D.
N-of-One

Lawrence Lesko, Ph.D., F.C.P.
University of Florida

Stephen Liggett, M.D.
University of South Florida

Nita Limdi, Pharm.D., Ph.D.
University of Alabama,
Birmingham

Dermot McGovern, M.D., Ph.D.
Cedars-Sinai Medical Center

Amy McGuire, J.D., Ph.D.
Baylor Health Care System
Precision Medicine Institute

Robert Mennel, M.D.
Baylor Health Care System
Precision Medicine Institute

Funda Meric-Bernstam, M.D.
MD Anderson Cancer Center

Lincoln Nadauld, M.D.
Intermountain Healthcare

Martin Naley
Cure Forward

Kenneth Nesmith
Counsyl

David Nixon
Informed DNA

Robin North
Vanderbilt University Medical
Center

Jeffrey Otto, Ph.D.
Catholic Health Initiatives

Richard Pollack
Virginia Commonwealth
University Health System

Jamie Renbarger, M.D.
Indiana Institute of Personalized
Medicine

Dan Roden, M.D.
Vanderbilt University Medical
Center

Lorna Rodriguez, M.D., Ph.D.
Rutgers Cancer Institute

David Roth, M.D., Ph.D.
Penn Medicine, University of
Pennsylvania Health System

Marshall Ruffin, M.D.
Inova Health System

Steven Shapiro, M.D.
University of Pittsburgh Medical
Center

Kenna Shaw, Ph.D.
MD Anderson Cancer Center

Sam Smith
Mayo Clinic

Edgar Staren, M.D., Ph.D.
Ashion PMED

Scott Steele, Ph.D.
University of Rochester

**Agnieszka Swiatecka-Urban,
M.D.**
University of Pittsburgh Medical
Center

Scott Weiss, M.D.
Partners HealthCare Center for
Personalized Genetic Medicine

Rina Wolf
Xifin

Ian Wright
Cedars-Sinai Medical Center

Susan Zook
Cancer Treatment Centers of
America

CONTACT US

PERSONALIZED MEDICINE COALITION

1710 Rhode Island Ave. NW

Suite 700

Washington, D.C. 20036

pmc@personalizedmedicinecoalition.org

202.589.1770