

ICPerMed Conference 2018

Personalised Medicine in Action

Berlin, November 20-21, 2018

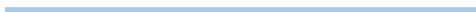


CLINICAL IMPLEMENTATION – CHALLENGES AND SOLUTION STRATEGIES

20 November, 2018

Daryl Pritchard, Ph.D.

Senior Vice President, Science Policy
Personalized Medicine Coalition





Personalized
medicine

Precision medicine

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

- The Personalized Medicine Report, PMC, 2017

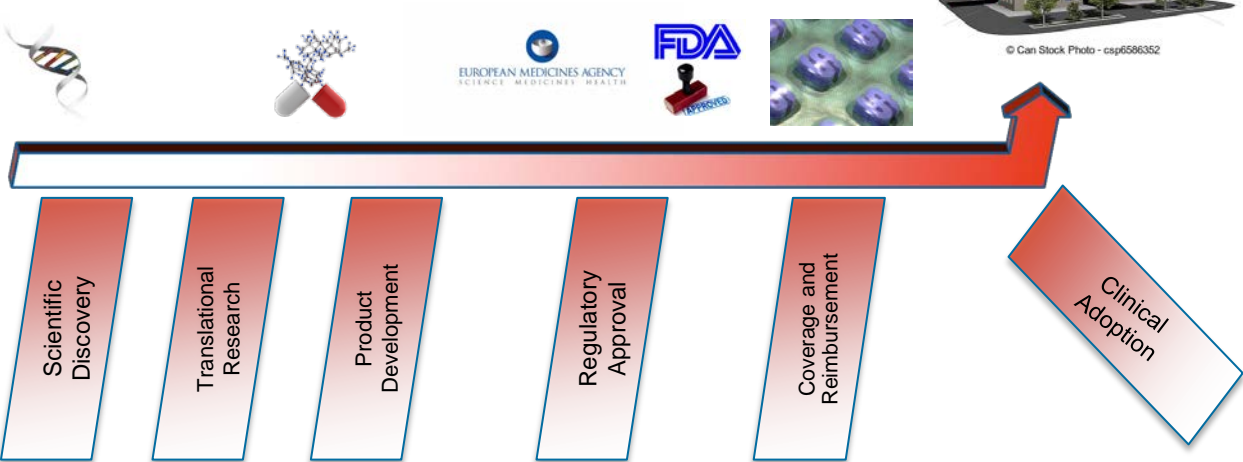
Stratified medicine

Individualized medicine

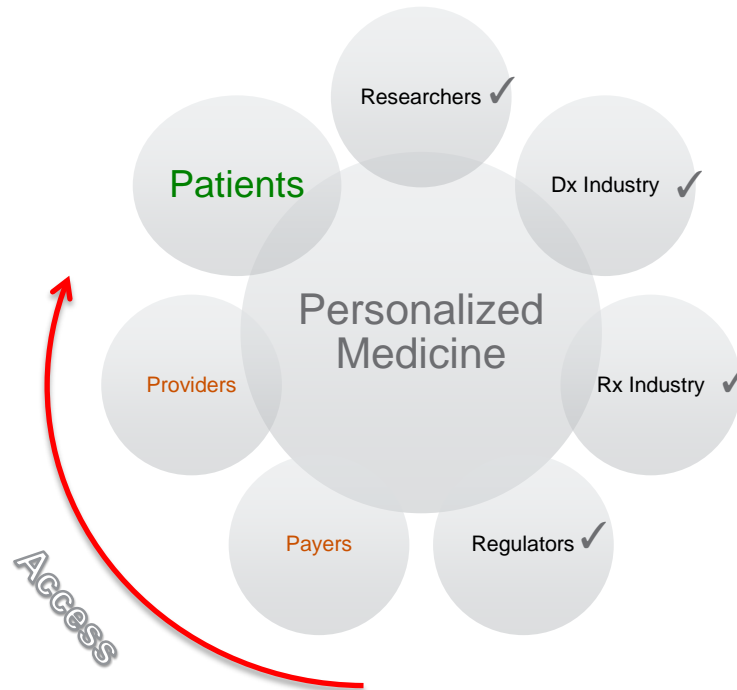
Targeted therapy

Personalized Medicine: From Bench to Bedside

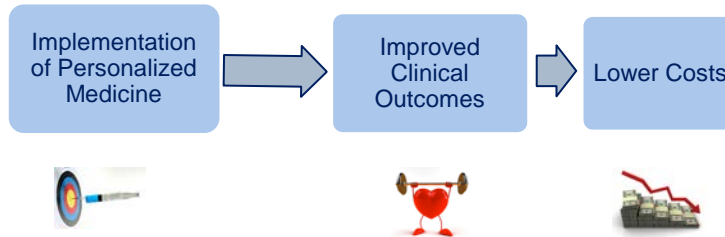
How do we Implement Personalized Medicine In Clinical Care?



Key Stakeholders



Personalized Medicine Value Proposition



Implementation of Personalized Medicine:

- New Technologies: Diagnostic Testing - Genomic Sequencing, Information Management, Targeted Therapies
- Practices: Patient-centered care, Clinical Laboratory, Genetic counseling, etc.
- Culture: Prevention and Early Diagnosis, Workforce and patient education, Value-based care vs. fee-for-service

Implementation Challenges

Integration of Personalized Medicine into HealthCare Initiative

- Identify and Understand Barriers to Clinical Adoption of Personalized Medicine



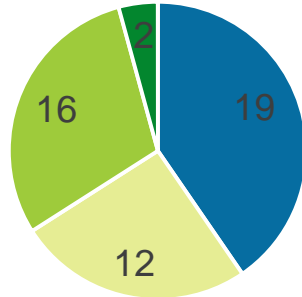
- Examine Different Strategies for Overcoming Barriers



- Develop a Roadmap/Set of Best Practices for implementing Personalized Medicine



Identifying Barriers: PMC HealthCare Working Group



- Academic Health Center
- Community Health Care System
- Health Care Delivery Support
- Physician Group

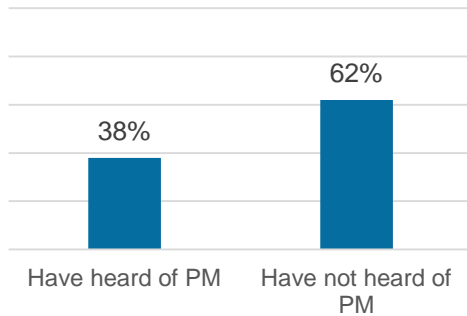
* Source: Jan 20, 2016, from [Health Catalyst](#)

Categories of Barriers to Implementation

- **Awareness & Education:** Healthcare providers, policy makers, and patients need to have a better understanding and knowledge of personalized medicine concepts and technologies, as well as its value to care;
- **Patient Empowerment:** Policies and practices related to patient engagement, data protections and other ethical, legal, and societal issues regarding the use of individual molecular information must be acceptable to patients;
- **Value Recognition:** Evidence and appropriate incentives are needed for personalized clinical decision-making based on its value to care;
- **Infrastructure & Information Management:** Effective healthcare delivery infrastructure and data management systems should be developed and applied so that individual patient and clinical support information is comprehensive, useful, and user-friendly, and so that it can be harnessed in real-time to better inform clinical decisions; and
- **Reshaped Delivery Processes that Ensure Access:** Move away from fee-for-service and towards value-based care.

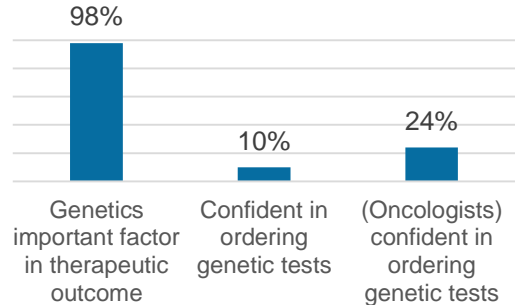
Awareness and Education

*2014 PMC Public
Opinion Survey



■ % general public responding

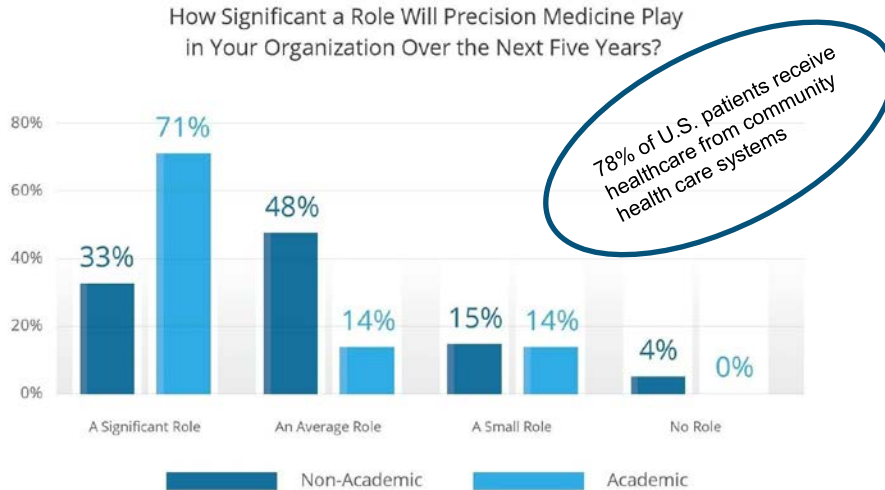
2011 MEDCO Clinician
Survey



■ % physicians responding

*Updated in 2018: Still only 40% of the public is aware of personalized medicine

Gap between Academic Health Centers and Community Hospital Systems



* Source: Jan 20, 2016, from [Health Catalyst](#)

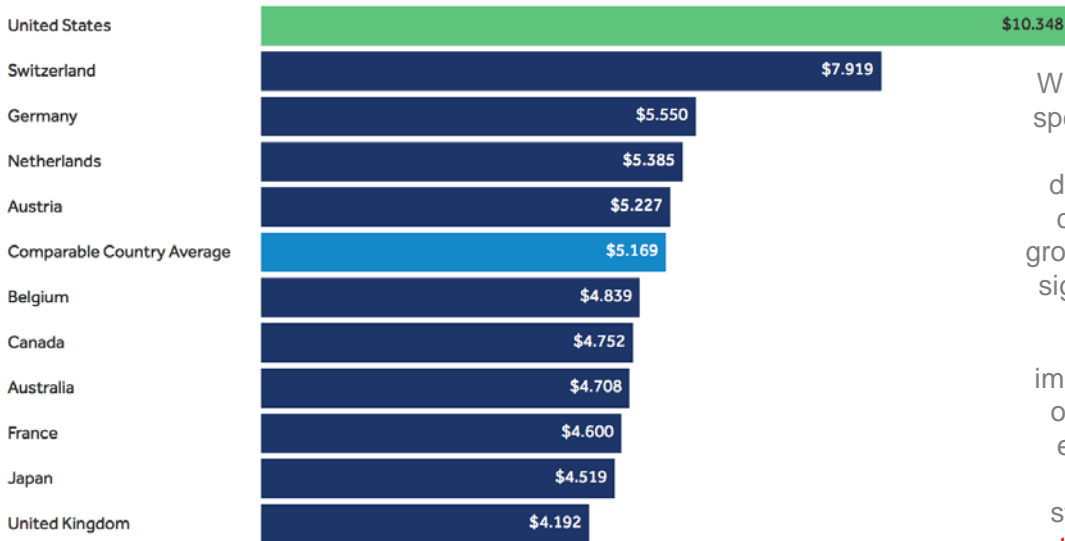
Patient Empowerment

Ethical, Legal,
Social Issues



Managing Healthcare Costs:

Total health expenditures per capita, U.S. dollars, PPP adjusted, 2016



With healthcare spending = ~ **8 - 11% GDP** depending on country (and growing), this is a significant cost.

Need for improved patient outcomes and effective cost savings strategies and **technologies**

The US value was obtained from the 2016 National Health Expenditure data

Source: Kaiser Family Foundation analysis of data from OECD (2017), "OECD Health Data: Health expenditure and financing: Health expenditure indicators", OECD Health Statistics (database) (Accessed on March 19, 2017). • Get the data • PNG

Value: from Concept to Evidence

Concept –

- Targeted therapies improve outcomes → provide the best treatment to each patient as early in their care as possible.
- This in turn reduces costs → ineffective or harmful treatment options are avoided, downstream expenses are reduced.
- Next Generation Sequencing (NGS) allows for the identification of multiple genomic molecular pathway alterations in a single test → identify more patients who could potentially benefit from targeted therapies/streamline diagnostic processes

Evidence –

- Although arguments for the clinical and economic benefits of NGS have a solid foundation based on proof of concept and research data, health care decision-makers have been reluctant to change policies and practices without having convincing evidence of clinical and economic value.

Interpretation –

- What is “convincing” evidence?

- No matter how much a new technology can improve medical practice, its uptake can be a slow process because most users need first-hand experience with it.

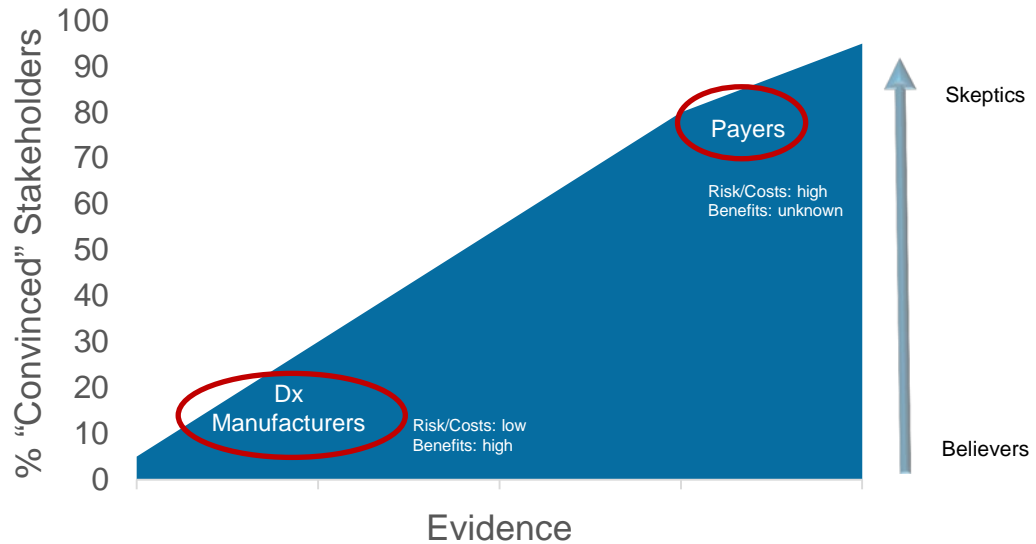
Most people “do not believe in anything new until they have actual experience of it.” - Machiavelli

Value Recognition Conundrum

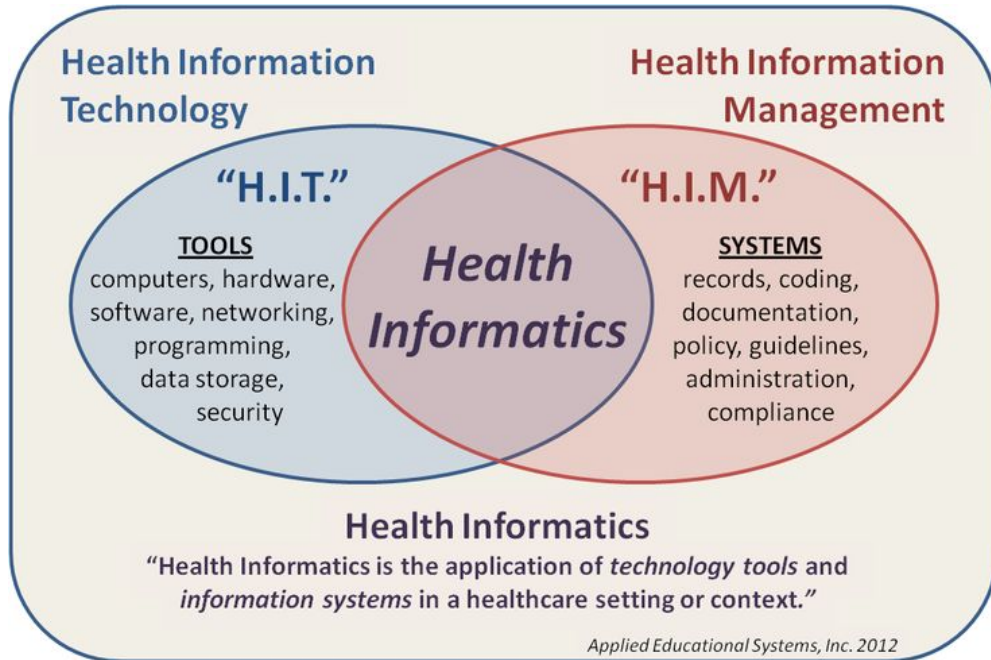


Which comes first the Evidence or the Access

Interpretation of evidence regarding the value of diagnostic testing



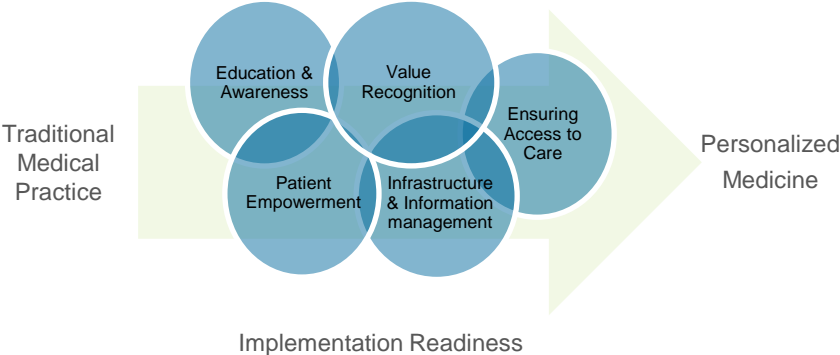
Infrastructure & Information Management



Reshaped Delivery Processes that Ensure Access to Personalized Medicine

- **Value-Based Care:** Traditional fee-for-service processes provide a system-wide incentive for ordering services based on volume rather than value.
- **Practice Incentives:** Some physicians are reluctant to adopt personalized medicine practices.
 - There is a perception that personalized medicine techniques require time without adequate compensation.
 - There is a perception that it is too cumbersome to involve genetics experts/counselors in patient care.
- **Updated Clinical Guidelines:** Current clinical guidelines do not reflect concepts in personalized medicine.
- **Clinical Decision Support Tools:** Most information management processes that support clinical decision making are not equipped for integrating patient biomarker information.
- **Access to Supplies and Services:** Products and services are not always available, particularly in rural settings, and many patients are reluctant or unable to travel to other health centers.
 - Geneticists/genetic counselors/molecular pathologists are not always accessible, especially in rural settings.
- **Personalized Medicine Business Models:** Sustainable business models for preventative and value-based care are yet to be developed.

Framework for Implementation: A Progression

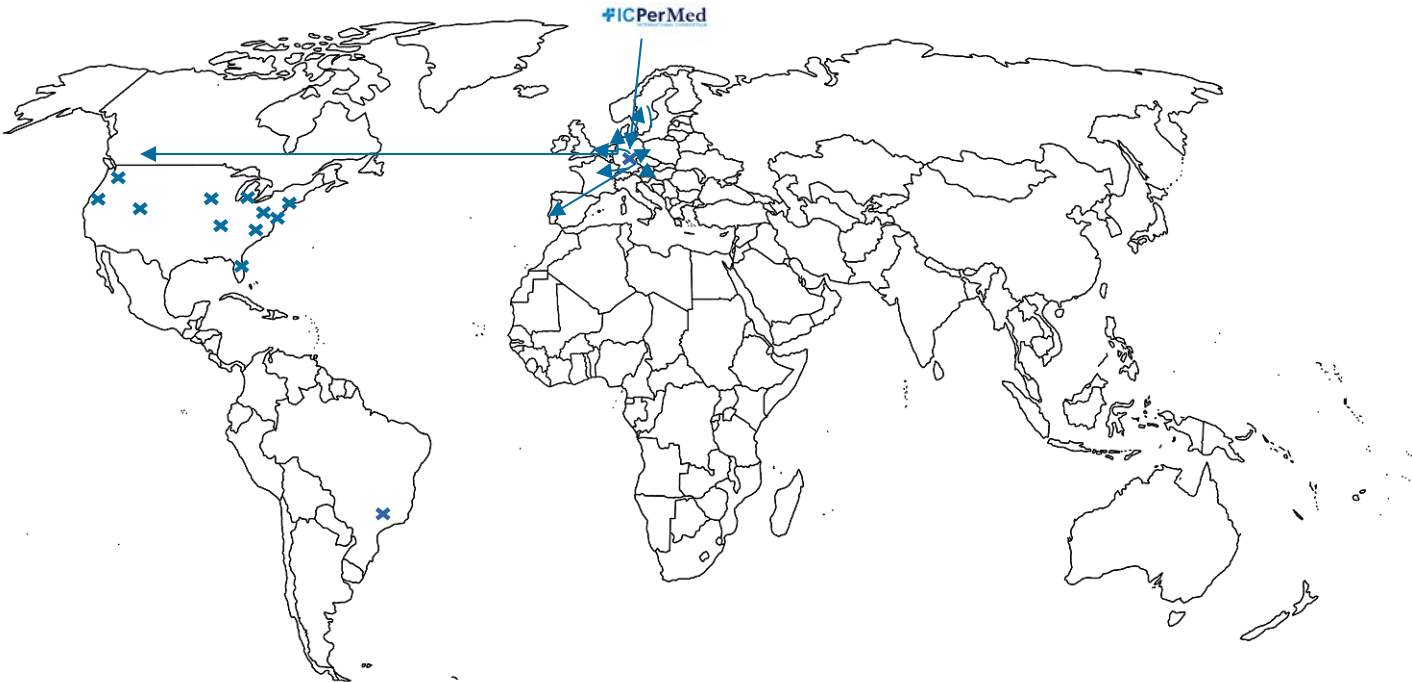


Emerging Strategies for Clinical Adoption of Personalized Medicine

PMC interviewed leaders from pioneer personalized medicine programs at 11 U.S. Health Care Delivery Institutions



New Global Emerging Strategies?



Case Examples: Programmatic Strategies for Implementing Personalized Medicine

- Inova: MediMap



- Optional pharmacogenomics test offered to newborns as part of our standard package of care.
- Analyzes 7 genes involved in drug metabolism for changes that influence response to 21 prescription medications.

- Geisinger: MyCode



- A system-wide biobank and genomic analysis program designed to store blood and other samples for clinical analysis and research use.
- Used to return results, find ways to diagnose medical conditions earlier – even before symptoms appear – and also to help find new treatments or medications to manage these diseases.
- More than 190,000 patient-participants have already signed up.

MyCode® results returned
317 patient-participants have received results*
Geisinger MyCode 100,000+ participants
June 1, 2019

Risk condition	Patients per risk condition	Gene	Patients per gene
CDC tier 1 conditions			
Hereditary breast and ovarian cancer (early breast, ovarian, prostate and other cancers)	193	BRCA1 BRCA2	64 119
Familial hypercholesterolemia (early heart disease and stroke)	30	APOB LDLR	12 18
Lynch syndrome (early colon, uterine and other cancers)	18	PMS2 MSHG MSH2 MLH1	9 5 2 2
Cardiovascular risk			
Cardiomyopathy (swollen or thick heart muscle with dangerous complications)	25	MYH7 MYBPC3 TPM1	4 12 2

Case Examples: Programmatic Strategies for Implementing Personalized Medicine

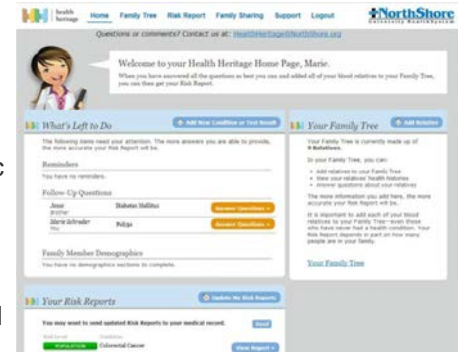
- Partners: GeneInsight

- Genetic reporting service used across multiple hospital systems
- Streamlines the clinical testing process; Manages the vast amounts of data generated in genetic testing; Facilitates the clinical interpretation process; and channels this information efficiently and effectively to clinicians to impact patient care.



- Northshore: EMR and Data Warehouse, Health Heritage

- Clinical data that flows daily from secure electronic medical record (EMR) system into a Enterprise Data Warehouse (EDW). Health Heritage app meshes family histories, genetic testing and health records.
- Allows development of predictive modeling programs based on the health records and outcomes of Northshore patients. Similar health profiles are compared and used to build clinical decision-making tools right into the EMR.



Oncology Precision Network (OPeN)



Community Care Center

- Not-for-Profit System; Renton, Washington, 50 hospitals, 7 Western States



Academic Health Center

- San Francisco, CA.
Opened Stanford Cancer Institute in 2014, 400 physicians and researchers,



Integrated Delivery System

- Integrated Payer/Provider; Salt Lake City, UT.
22 hospitals, Utah and Idaho, health plan covers 900K people

Strategies for Implementing Precision Oncology



Genomic Analysis / Registry Trial / Cloud-based Informatics / Multi-Institutional Shared Data



STAMP (NGS-based Solid Tumor Actionable Mutation Panel) / Interactive Molecular Tumor Board / Multi-Institutional Shared Data

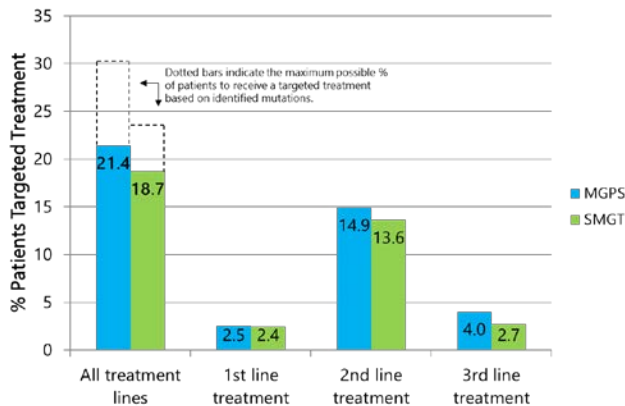


Genomic Analysis / Interactive Molecular Tumor Board / Multi-Institutional Shared Data / Integrated Drug-Procuring Services

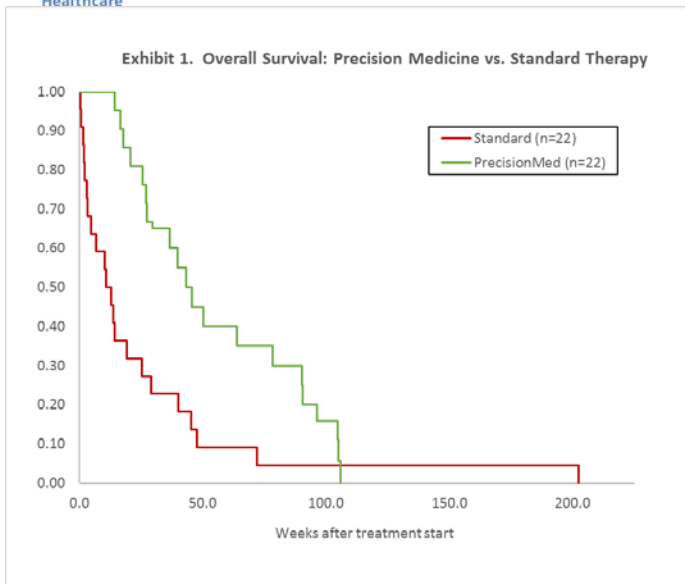
Clinical and Cost Effectiveness of Targeted Treatments in Lung Cancer (NSCLC)

ASCO 2018 –Steuten, et al.

Median OS (IQR), years	Targeted Treatments	Non-targeted Treatments
All (n=5688)	2.31 (0.31 – 4.12)	1.73 (0.28 – 3.59)
Age:		
<65 years (n=1858)	2.32 (0.32 – 4.37)	1.71 (0.33 – 3.88)
≥65 years (n=3415)	2.30 (0.30 – 3.75)	1.75 (0.27 – 3.46)



Clinical and Economic Value of Precision Oncology



Prolonged overall survival with precision medicine compared to standard therapy in advanced cancer patients at InterMountain Healthcare

Source: Halem DS, et al.; *Oncotarget*. 2018; 9(15).

Costs: Precision Medicine vs. Standard Therapy

Total healthcare-associated charge events (including costs for procedures, drugs, clinic visits, treatment for toxicities, and genomic tests):

Precision Medicine: \$2,720 per week of survival.

Standard Treatment: \$3,453 per week of survival. (P=0.036)

Cost savings = \$733 per week per precision medicine patient.

A primary caveat to this analysis was the increased survival time of the precision medicine cohort. While the per week costs were lower in the precision medicine cohort, patients in that cohort survived longer — which could result in higher overall costs for that cohort.

Personalized Medicine: Impacts Patients

“I’m here and I’m doing very well three years after my stage IV lung cancer diagnosis, and most of the time...my life feels pretty good....”

“I’ve been taking trips with my son that I never thought I would be able to take... what I’ve been trying to do is give him some good memories...and in the process, I’ve found that my life is more complete than ever before...”

- Deb Smith, EGFR+ Stage IV Lung Cancer Survivor
(Tarceva clinical trial)
(AZD9291 clinical trial)

The logo icon for the Personalized Medicine Coalition (PMCoalition). It consists of a 3x3 grid of squares. The top row has three blue squares. The middle row has a blue square, a light green square, and a blue square. The bottom row has a light green square, a blue square, and a light green square.

PMCoalition

PERSONALIZED MEDICINE COALITION

1710 Rhode Island Ave., NW
Suite 700
Washington, DC 20036

202.589.1770

www.personalizedmedicinecoalition.org

Daryl Pritchard, Ph.D.

Senior Vice President, Science Policy

dpritchard@personalizedmedicinecoalition.org

