



*Health Plan Perspectives on Optimizing
Value in Personalized Medicine*

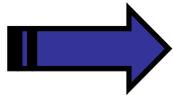
Joanne Armstrong, MD, MPH

SACGHS, March 13, 2009

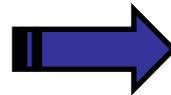
The Big Picture

- Health care spending in the US is increasing rapidly
 - In 2003, 15% of GDP was spent on health care
 - By 2015, 20% GDP projected to be for health care

- Appropriately delivered care is often ineffective¹

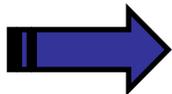


Only 58% of patients achieve a target BP of 140/90 while on anti-hypertensive treatment

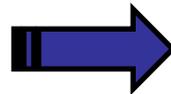


Only half of patients experience a 50% reduction in symptoms after anti-depressant therapy

- Poor quality and misallocation of resources are well documented²



Rand studies demonstrate compliance with reasonable evidence-based guidelines is about 53%.



Americans spend an estimated \$70 billion per year on incorrectly prescribed drugs

1. L Lesko, Personalized Medicine Coalition, Clinical Science Committee, Feb 12, 2009

2. "To Err is Human - Building a Safer Health System", IOM Committee on Quality of Health Care in America, National Academy Press, Washington DC, copyright 1999

Personalized Medicine

Potential Impact & Opportunity

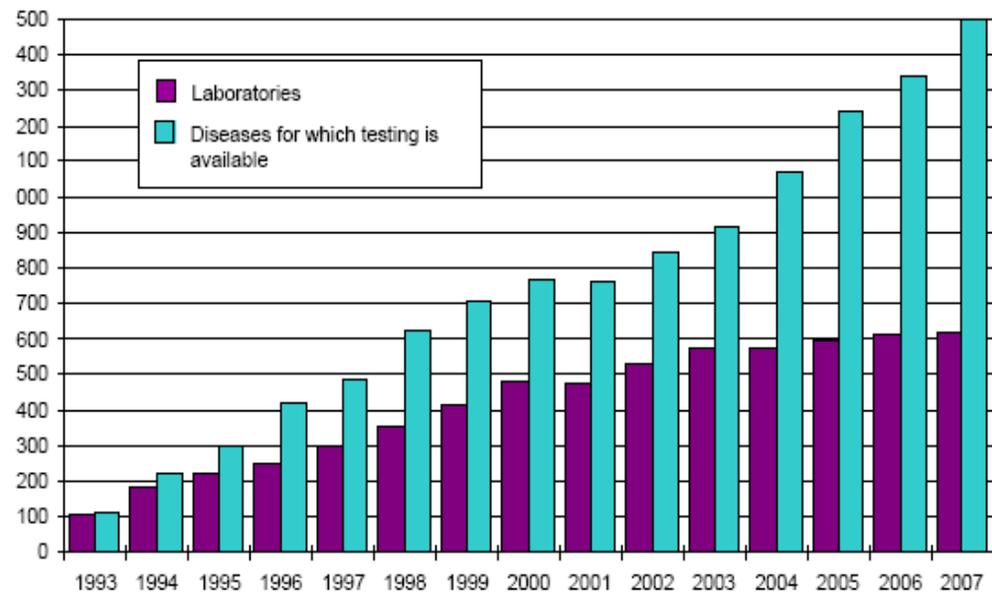
Rank	Cause of Death	Number of Deaths in 2000 ¹	Genetics a Factor ²
1	Heart Disease	709,894	Yes
2	Cancer	551,833	Yes
3	Stroke	166,028	Yes
4	Chronic lower respiratory disease	123,550	Yes
5	Accidents (unintentional injuries)	93,592	Unknown
6	Diabetes mellitus	68,662	Yes
7	Pneumonia and influenza	67,024	Yes
8	Alzheimer's disease	49,044	Yes
9	Kidney disease	37,672	Yes
10	Septicemia	31,613	Maybe
11	Suicide	28,332	Yes
12	Chronic liver disease	26,219	Yes
13	Hypertension	17,964	Yes
14	Pneumonitis	16,659	Unknown
15	Homicide	16,137	Unknown

Personalized Medicine

The Emergence of New Diagnostics

- Rapid increase in the availability of genetic tests
 - 10% increase in availability of new genetic diagnostic tests per year.¹
- Rapid increase in utilization of genetic tests
 - 20% increase in utilization of genetic diagnostic tests per year vs. 1%-3% for non-genetic diagnostic tests.²

 **GeneTests: Growth of Laboratory Directory**



Data source: GeneTests database (2007) / www.genetests.org

1. GeneTests, 2006

2. SunTrust Robinson Humphrey, March 2002

Personalized Medicine

Diagnostic Cost Impact

- The financial cost of genetic diagnostic tests is modest, but the trends are steep
 - Genetic tests costs 0.70pmpm - 2007¹
 - Genetic tests cost trends: 17% - 2005-2006; 21% 2006-2007¹
- Blockbuster diagnostics are emerging
 - Oncotype Dx - \$3,400
 - Familion Index - \$5,400
- “Value based” reimbursement discussed but scant literature linking pricing to value

1. Aetna Health Analytics, 2007

Personalized Medicine

Emergence of New Biologic Therapies

- Rapid increase in availability of new biologic/PB medications
 - Biologics represent 25% of new drugs approved by FDA since 2000¹
- The cost and trend of biologic therapy is high.
 - Biologic drug cost trend 17% - 2006-2007
 - Non-biologic drug cost trend 8% - 2006-2007²
- Per prescription cost rising significantly³
 - Herceptin - \$43,000 per treated member per year
 - Cerazyme - \$200,000 per treated member per year

1. K Phillips. Health Affairs 25, no.5 (2006):1271-1280

2. New York Times, 4/21/2008

3. Aetna Health Analytics, 2006

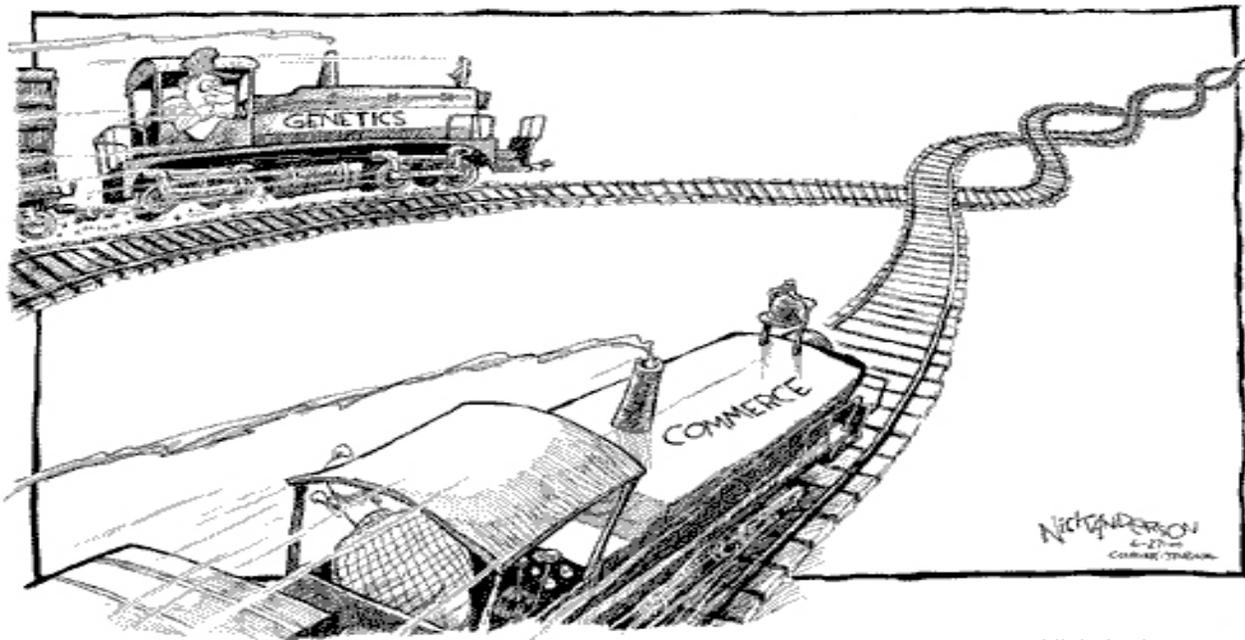
Personalized Medicine

The Value Proposition

- Will personalized medicine improve the quality, safety, and/or cost effectiveness of delivered health care?

or....

- Will personalized medicine drive additive medical costs with marginal health care gains?



Challenges to Optimizing Value in Personalized Medicine

- Evidence base to support coverage needs to be strengthened
- Clinical and economic outcome data demonstrating value of personalized medicine strategies needs to be generated
- Clinicians and consumers need tools to use personalized medicine services effectively
- CPT system for laboratory testing hinders ability to analyze impact of genetic tests on medical management and reimbursement strategies

Aetna Coverage Policy Principles for Genetic Technologies

- Services related to prevention, diagnosis, or treatment of an illness.
- Information will affect the course of treatment of the member
- Care and/or treatment is likely to improve outcome
- Improvement must be attainable outside investigational settings
- Services are consistent with plan design.

...Same coverage policy principles for genetic technologies as for all other technologies.

Evidence Standards for Coverage of Genetic Technologies

Covered services must have:

- Published, peer reviewed, scientific evidence that permits conclusions concerning test performance and the effect of the technology on health outcomes.
 - Analytic validity
 - Clinical validity
 - Clinical utility
- Final approval from the appropriate governmental regulatory bodies, when required
- Demonstrate improved net health outcome and be as beneficial as any established alternatives

...Same evidence standards for genetic technologies as for all other technologies.

Personalized Medicine

Where is the Demonstrated Value?

- Clinical and economic outcome data to demonstrate value of personalized medicine strategies needs to be strengthened
 - Provides rationale for prioritization of medical management and reimbursement strategies
- Small number of cost-effectiveness analyses of targeted therapies available -N=11
 - Limited range of conditions studied
 - Deep vein thrombosis (n=4); Cancer (n=3); Viral infections (n=3)
 - Outcomes are mixed for pharmacogenomic-based strategies
 - Favorable cost-effectiveness ratio (n=7)
 - Unfavorable (n=2)
 - Equivocal (n=2)

Phillips KA. A systematic review of cost-effectiveness analyses of pharmacogenomic interventions. *Pharmacogenomics*. 2004 Dec;5(8):1139-49

Personalized Medicine Challenges

Clinician and Consumer Preparedness

- Clinicians and consumers are unprepared to effectively use personalized medicine technologies
- Shortage of trained genetic specialists and significant knowledge gaps in clinician workforce
 - Fewer than 900 Board certified medical geneticists and 2,000 genetic counselors in US¹
 - 72% non-genetics MDs rate their knowledge of genetics as fair to poor²
- Genetic decision making requires significant genetics literacy... and consumers are not up to the task
 - Fewer than 7% of Americans are scientifically literate³
 - 82% of consumers cannot correctly answer most genetic medicine knowledge questions in national surveys⁴



1. Judith Cooksey, MD, SACGHS Testimony, Oct 22, 2003
2. Menasha. The Mt. Sinai J of Med 67(2):144-51,2000

3. Genetics and Public Policy Center Survey 2002
4. Miller, Jon. 1998. *Public Understanding of Science* 7:203-223.

Personalized Medicine Challenges

Laboratory Coding

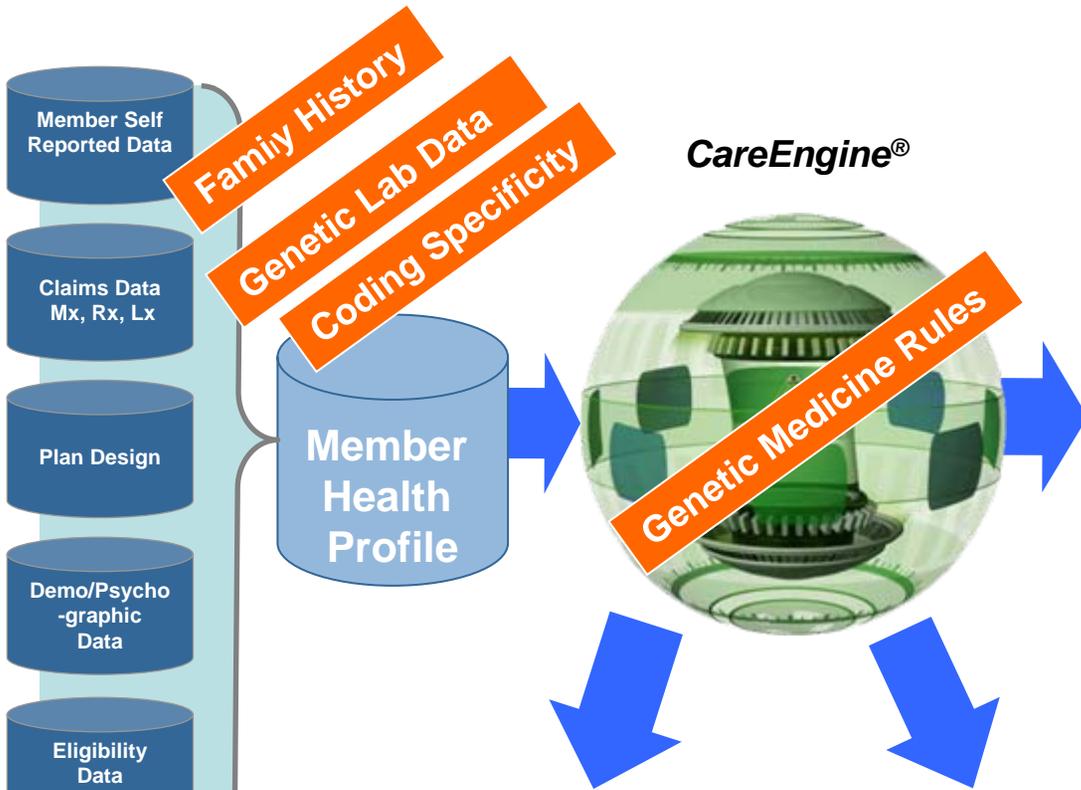
- CPT system for laboratory testing hinders ability to analyze specific laboratory test activity in administrative data bases
- Lack of coding specificity limits ability to:
 - Use administrative sets alone for clinical utility studies
 - Use codes to distinguish tests assigned enhanced reimbursement based on value
 - Track utilization
- Modifiers are of limited help

Programming in personalized medicine must be sensitive to individual privacy concerns.

What uses of genetic tests do you support?
How much trust do you have with your test results?¹

	<u>Access to Results</u>	<u>Trusted with Results</u>
Doctors to provide care	93%	86%
Researchers	93%	66%
Health insurance companies for eligibility and pricing	15%	24%
Employers for hiring and promotion	19%	16%

Personalizing Medicine in a Genetic Context



Disease Management
Wellness counseling

Delivery to Providers
MD Portals and Links

Aetna
Member Home
View Personal Health Record for: Elizabeth Smith - DOB: 01/31/1966

[Medications](#) | [Allergies](#) | [Conditions & Symptoms](#) | [Tests & Procedures](#) | [Hospital Visits](#) | [Alerts & Reminders](#)
[Health Summary](#) | [Personal Information](#) | [Emergency Contact](#) | [Insurance](#) | [Health Team](#) | [Immunizations](#) | [Family History](#)

You have one urgent alert & reminder >

Health Summary
Share this overview of your health with any new doctor or specialist. This information is also handy when you go to a hospital or other treatment center.

XYZ COMPANY
Company announcement for employees.

Personal Profile
Elizabeth Smith
517 Bellevue Court, Philadelphia, PA 19454
Date of Birth: 01/31/1966
Gender: Female
Race: White (Not Hispanic)
Marital Status: Married
Preferred Phone Number: 267-284-9358
Alternate Phone Number:
E-mail: lizsmith@yahoo.com

Height: 5' 4"
Weight: 190 lbs
Blood Type: O+
Blood Pressure: 140/90
Primary Citizenship(s): American
Foreign Countries Visited:
Preferred Language: English

Emergency Contact
Emergency Contact Name: Steven Smith
Relationship: Husband
I have signed an advanced directive

Emergency Contact Phone Number: 215-751-8594
Emergency Contact Alternate Phone Number: 215-985-9245
I am not an organ donor

Insurance
Medical: Aetna, Inc.
Dental: Aetna, Inc.

215-555-1212
800-689-4852

Health Team
Dr. Robert Goldberg, Endocrinologist
Patrick Wells, DC, Chiropractor
Dr. Sara Doshi, Ophthalmologist
Dr. Joyce Brown, Dermatologist
Eckerd Pharmacy
Rite Aid Pharmacy

610-934-9233
267-341-8886
610-345-9811
610-689-5985
215-546-9087
215-363-0000

Immunizations
Hepatitis A
Influenza

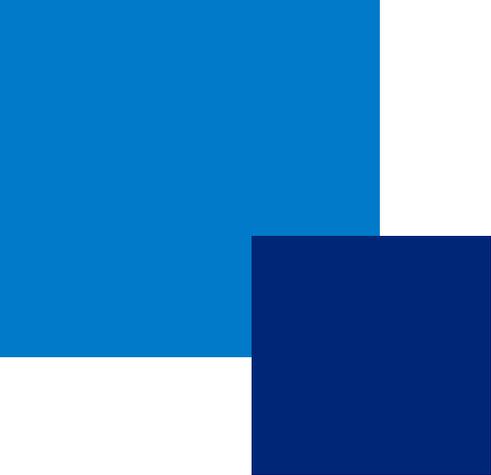
Date of Immunization: 01/15/06
Date of immunization: 11/18/05

Family History
Mary Jones, Mother (Age of Death: 68)
James Jones, Father
Mary Fredericks, Sister

Condition: Diabetes, GERD, Hypertension
Condition: Skin Cancer
Condition: Breast Cancer

Priorities in Personalized Medicine

- Improve evidence basis of technologies to support coverage decisions and rational use of services.
- Review evidence framework to support coverage policy
 - Are the right questions being asked to support coverage decisions?
 - What is ideal evidence vs. sufficient evidence?
- Generate outcome data to demonstrate clinical and economic value
 - Data sharing, demonstration projects
- Promote physicians and consumers engagement/education
 - Information “push” to providers on guidelines, best practices.
 - Promotion/creation of alternative vehicles for genetic counseling



Thank You!

Armstrongmj@aetna.com

281 637-3017