

**“Show Me the Money”
Why Understanding Economic
Value is Critical to
Pharmacogenomics**

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The Typical Economist?

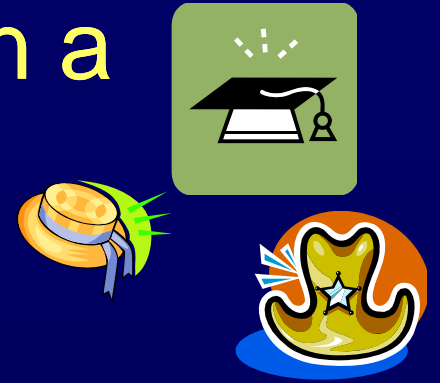


Objective

To discuss why understanding of economic value is critical to adoption of PGx into clinical care & health policy

- **Economics = Value!**
 - Success of PGx will depend upon *value* placed on PGx by patients, providers, insurers, industry, government, & society
- **Economics = Incentives!**
 - Incentives must facilitate adoption

What is an Economist Doing in a Nice Place Like This? *Wearing Three Hats*



1. Academic (primary role)

- Research on clinical & economic issues relevant to adoption of PGx

2. Government

- Advisor to the FDA on PGx
- Member of CDC-sponsored national group on application of genetic testing (EGAPP)

3. Industry

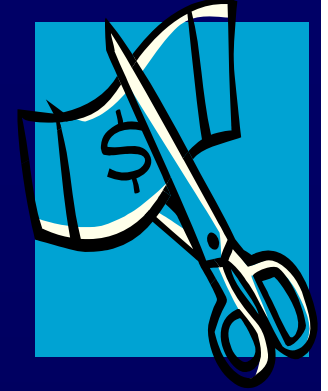
- Board member/consultant to biotechnology companies on how to measure value

Increasing Pressure to Demonstrate Value of PGx



- *We need to speed up the use of PGx... to give people more health benefit for the money...*
 - Former FDA Commissioner McClellan
- *How much will the expanded use of genetic information further escalate the cost of health care, and who will pay for it?*
 - H. Varmus, NEJM
- *Get on the bus or get run over*
 - Industry consultant

Evidence of Value Is Lacking



- From societal perspective, little documentation yet of value of PGx
- Our systematic review found only 11 cost-effectiveness analyses of PGx interventions (Pharmacogenomics, 2004)
 - Limited range of conditions studied
 - Mixed results as to whether cost-effective

Example of Successful Adoption Despite Concerns about Value: HER2/neu testing & Herceptin

- Herceptin is expensive ~ \$4000/month
 - For HER2/neu+ tumors
 - Increases median survival by few months
- Cost-effectiveness analyses are inconclusive
 - Elkin (2004): \$125,000 per QALY gained
 - >\$50K threshold commonly used
 - Outside of US, approval was slow because of concerns about cost-effectiveness
 - Increasing cost concerns as tx moves to non-metastatic cancers

Example of Slow Adoption Despite Potential Wide Impact: CYP450 Testing

- AmpliChip tests for CYP2D6 & 2C19 mutations
- CYP2D6 testing COULD have large impact because many drugs metabolized
 - Relevant to 189M prescriptions and \$12.8B expenditures/annually in US
 - Particularly mental health and heart disease drugs
- BUT insufficient data to assess impact of CYP2D6 testing
 - Very limited data on clinical outcomes of testing

Challenges to Determining Value of PGx



Challenges: New Paradigms

- Diagnostics & co-developed diagnostics/drugs will play *increasingly* important role
 - Requires integration of historically divided industries and regulatory mechanisms
 - Requires early consideration of diagnostics

Challenges to Determining Value of PGx

Challenges: Technical Issues

- Lack of data
 - Linking PGx to outcomes
 - Comparative effectiveness of therapeutics
 - On products themselves (proprietary)
- Need to evaluate complex multi-factorial conditions
 - Diagnostic/drug combinations more complex to analyze than separate interventions
 - Often relevant multiple drugs & diseases
 - Then stakeholders are less clear

Challenges to Determining Value of PGx

Challenges: Policy & Political Issues

- PGx often has benefit of PREVENTING what has not occurred
 - Value of prevention harder to measure
 - E.g., avoiding adverse events
- Value of diagnostics often harder to measure
 - Up-front PGx testing cost perceived as higher than downstream savings
 - Medicare covers only diagnostic – not screening – tests
 - But distinctions are unclear

Conclusions: “GET ON THE BUS OR GET RUN OVER”



- PGx & personalized medicine are wave of future.....
- Demonstrating value of PGx will be critical
- Will require more data & impetus to assess societal value
- Will occur w/in policy context of high drug expenditures, safety concerns, & need to bring beneficial drugs to market