Prior to starting the webinar

- Please make sure you have audio **AND** web features
- For audio, dial 866-740-1260
  - Enter access code 8223833
- For video, go to www.readytalk.com
  - Enter access code 8223833
- To obtain materials for today's webinar, register at www.pharmacogenomics.ucsd.edu
- Please turn off cell phones, pagers, and program your phone to divert calls to voicemail
- You may use the "Chat" function to raise questions during the presentation. You may also ask questions directly during the Q&A session. Questions will be answered during the Q & A session

PharmGenEd™: Bridging the Gap Between Science & Practice

Train-the-Trainer Session
for Economic Issues

Tuesday, October 12, 2010

UNIVERSITY *of* CALIFORNIA, SAN DIEGO
SKAGGS SCHOOL *of* PHARMACY
and PHARMACEUTICAL SCIENCES

Disclaimer

This presentation was supported by Grant Number IU38GD000070 from Centers for Disease Control and Prevention (CDC). Its contents are solely the responsibility of the authors and do not necessarily represent the official views of CDC

The content is not intended to be a substitute for professional medical advice, diagnosis, or treatment. Patients should seek the advice of their physicians, pharmacists, or other qualified health providers with any questions they may have regarding a medical condition or a medication

Train-the-Trainer Agenda

1. Introduction
   - Objective of PharmGenEd™ program
   - Shared curriculum and format
   - Introduction of author
2. Review of educational content for selected therapeutic area
3. Future webinar dates
   - Program implementation
   - Other therapeutic areas
4. Contact information
5. Survey instruments
   - Post training survey for trainers
6. Question & Answer (Q & A) session

Overall Objective of PharmGenEd™ Program

- The "Pharmacogenomics Education Program: Bridging the Gap between Science and Practice" (PharmGenEd™) is an evidence-based pharmacogenomics education program designed for pharmacists and physicians, pharmacy and medical students, and other healthcare professionals
- The overall objective of the PharmGenEd™ program is to increase awareness about current knowledge of the validity and utility of pharmacogenomic tests and the potential implications of benefits and harms from use of the tests

 5

Shared Curriculum

- Educational Materials (each 1 hour)
  - Asthma
  - Cardiology I (warfarin & statins)
  - Cardiology II (clopidogrel & beta blockers)
  - Concepts and clinical applications
  - Economic issues
  - Oncology I (solid tumors)
  - Oncology II (hematologic malignancies)
  - Psychiatry I (depression)
  - Psychiatry II (antipsychotics)
- Future webinar dates for these sessions will be provided later

 6

Authors

Louis P. Garrison, Jr., PhD
Professor and Associate Director
and
David L. Veenstra, PharmD, PhD
Professor

Pharmaceutical Outcomes Research and Policy Program
Department of Pharmacy
University of Washington

 7

Learning Objectives

- Upon completion of this program, participants will be able to:
  - Identify economic issues related to pharmacogenomic testing that can be applied in the clinical setting
  - Summarize evidence-based economic recommendations for pharmacogenomic testing
  - Assess economic evaluations of pharmacogenomic testing based upon available scientific evidence

 8

Outline

- Brief introduction to health economics
- Economic evaluation using various cost analysis
- Overview of economic evaluation of pharmacogenomic technologies
- Economic evaluation of chemotherapy response and genetic testing
- Economic evaluation of warfarin therapy and genetic testing
- Economic barriers to personalized medicine

 9

Brief Introduction to Health Economics

 10

Health Economics

- Economics is the study of how societies allocate their inherently scarce resources to satisfy the demands of their citizens
- Health economics focuses on how these scarce resources are allocated to produce health and provide the medical services needed
- Economics posits that private markets are generally an "efficient" mechanism for allocating resources, thus maximizing the benefits received from limited resources
- However, in the case of health care markets, a number of special circumstances occur that require special interventions and adaptations to improve efficiency

 11

Health Care Markets: Features

- Pervasiveness of uncertainty (Arrow 1963)
  - In terms of what works and doesn't work
  - The demand for services difficult to predict
  - Insurance used to deal with financial risk
  - Limited learning from experience
  - "Informational asymmetry" between providers and patients and between insurers and subscribers

 12

Health Care Markets: Adaptations

- Interventions and institutions have arisen in response to this uncertainty:
  - Insurance and its regulation
  - Provider licensure
  - Drug and device regulation
  - Subsidized education
  - Health technology assessment

Arrow 1963

Economic Evaluations to Determine Cost-Effectiveness

Need for Economic Evaluations

- The unique nature and features of the health care market combined with the need to allocate scarce medical resources has led to the development and widespread use of a set of economic evaluation tools that can broadly be called "cost-effectiveness analyses" as part of health technology assessment
- "Cost" refers to the monetary value of the resources used to provide a new intervention or service
- "Effectiveness" refers to the impact on patient health outcomes in the real-world (i.e., not in an experiment)
- There is a range of types of cost analysis

Types of Economic Evaluations to Assess Cost-Effectiveness

Method of Analysis	Cost Measurement	Outcome Measurement
Cost-Minimization	**$**	**Equivalence demonstrated in comparative groups**
Cost-Consquences	**$**	**Multidimensional listing of outcomes**
Cost-Effectiveness (CEA)	**$**	**"Natural" units (life-year gained, mg/dL blood glucose, mm Hg blood pressure); single outcome**
Cost-Utility (CUA)	**$**	**Life years adjusted for quality of life (QALY)**
Cost-Benefit (CBA)	**$**	**$; multiple outcomes combined into one value**

Strengths and Weaknesses of Types of Economic Evaluations

Study design	Costs measured?	Effects measured?	Strengths	Weaknesses
Cost-minimization	Yes	No	Easy to perform, no ratio	Only useful if outcomes are the same for both
Cost-consequences	Yes	Yes, in clinical terms (e.g., events or measures)	Simple interpretation; no ratio	No framework for decision making
Cost-effectiveness	Yes	Yes, in clinical terms	Relevant for clinicians; easily understandable	Cannot directly compare interventions across disease areas
Cost-utility	Yes	Yes, in QALYs	Widely used; can compare across disease areas	Requires evaluation of patient preferences; can be difficult to interpret
Cost-benefit	Yes	Yes, in monetary terms	Good theoretical foundation; no comparison needed	Measuring willingness to pay is difficult in health care

Reprinted with permission from the American College of Clinical Pharmacy. Originally published in: Veenstra DL and Carlson JJ. Cost-Effectiveness, Economic Incentives and Reimbursement Issues. In McLeod HL, DeVane CL, Haga SB, et al., eds. Pharmacogenomics: Applications to Patient Care. Lenexa, Kans.: American College of Clinical Pharmacy, 2009.

Comparing Economic Evaluation Methods

- Each of these methods is used, depending on the circumstances
- "Cost-utility analysis" is generally the preferred method (when feasible) for comparisons across very different technologies in terms of "value of money" and incorporates length and quality of life as a benefit
  - The principal metric used is the "incremental cost-utility ratio" (ICUR; also called "ICER")
  - For example, comparing spending on cardiac care vs. public health immunization programs

Gold et al 1996

The Incremental Cost-Effectiveness Ratio

Incremental Cost-Effectiveness Ratio (ICUR; aka ICER)

- Numerator (C) is measured in monetary terms
- Denominator (E) in the case of a CUA is measured in two dimensions—length of life and quality of life and then combined into one dimension-- the quality-adjusted life year (QALY)
- ICUR measures: Does a medical intervention (drug, device, program, surgery) improve QALYs gained when used to prevent or treat a condition improve health outcomes in patients enough to justify the additional dollars spent compared to the next best medical strategy?

Gold et al 1996

"League Table" for Comparing Interventions

Intervention	$/LY
Neonatal intensive care, 1000-1499g	5,500
CABG[1], three vessel	7,200
Implantable defibrillator	17,400
Treatment of mild hypertension	23,200
HRT[2], post-menopause	33,700
PTCA[3], two vessel	49,000
Hospital hemodialysis	59,500
Annual mammography, age 40-49	94,500
Prophylactic IV IG, chronic leukemia	6,000,000

Weinstein & Stason 1977

(1) (CABG) Coronary Artery Bypass Graft
(2) (HRT) Hormone Replacement Therapy
(3) (PTCA) Percutaneous Transluminal Coronary Angioplasty

Overview of Economic Evaluation of Pharmacogenomic Technologies

Economic Approach and Challenges

- The methods of economic evaluation are not fundamentally different for pharmacogenomic applications
- However, there can be challenges in application:
  - Uncertainty about strength of association between the genetic marker and clinical outcomes
  - Lack of direct evidence of improvements in clinical and health outcomes
  - Valuing reductions in uncertainty and "information for information's sake"

Economic Evaluation in 'Genomics' vs. 'Pharmacogenomics'

- Principles of economic evaluation of medical technologies can apply to genomics
  - Genetic testing to assess disease risk or prognosis (genomics)
  - Genetic screening to "predict" drug response (pharmacogenomics)
- It is useful to consider these separately

Questions to ask when evaluating the cost-effectiveness of a PGx test

Gene

- Prevalence
  - How common is the genetic variant?
    - How many patients would have to be tested to identify a patient with a variant?
    - What are the positive and negative predictive powers of the test in a patient population?
- Penetrance
  - What is the relationship (association) between the genetic variant and drug response?
    - What is the relative risk of an adverse event in patients with a variant genotype vs. those without?
    - What is the probability of drug response in patients with a variant genotype vs. those without?

 25

Test

- Accuracy
  - What are the specificity and sensitivity of the test for detecting the genetic variant of interest?
- Cost
  - What is the cost of the test and related services such as counseling?
- Timeliness
  - What is the time frame for obtaining test results?
- Alternatives
  - Are there alternative approaches to drug selection and dose optimization?

 26

Disease

- Prevalence and risk
  - How common is the drug-related adverse event? What is the difference in absolute risk for variant and nonvariant genotype patients?
  - How common is drug nonresponse? What is the difference in likelihood of drug response in variant vs. nonvariant genotype patients?
- Outcomes and economic impacts
  - How expensive is the adverse event or drug nonresponse?
  - What is the impact of the adverse event or disease on life expectancy and quality of life?

 27

Treatment

- Outcomes and economic impacts
  - Is there a clear intervention based on the result of the pharmacogenomic test?
  - How effective is the intervention?
  - What risks are associated with the intervention?
  - What is the cost of the intervention?
  - What alternatives to individualized therapy are available other than pharmacogenomic testing?
  - What is the likelihood that treatment decisions suggested by test will be followed?

 28

Case Example 1: Economic Evaluation of Chemotherapy Response and Genetic Testing

Example: Gene Expression Profiling (GEP) to Identify Women With Localized Breast Cancer Who May Benefit From Chemotherapy

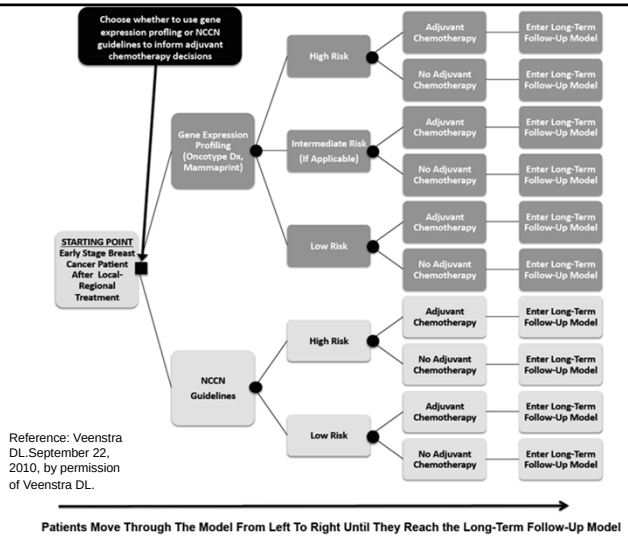
NIH criteria

- Clinical algorithm
- Recommends chemotherapy for:
  - Tumor > 1cm
  - Positive lymph nodes
- Many women who meet criteria ultimately will not benefit from chemotherapy

MammaPrint Gene Expression Profiling (GEP)

- Fluorescent-labeled RNA from tumor hybridized to 25,000- gene DNA arrays
- Profile applied to new tumors, tumors classified "good"/"poor" prognosis
- May be superior to NIH criteria in predicting women whose cancers will and will not progress

Van de Vijver et al 2004



Reference: Veenstra DL.September 22, 2010, by permission of Veenstra DL.

Cost-Effectiveness (cost/QALY) of GEP vs. NIH Guidelines

	Gene expression profiling	NIH guidelines	Difference
Sensitivity	84%	98%	−14%
Specificity	51%	5%	46%
Proportion of women treated with chemotherapy	61%	96%	−35%
Expected proportion of distant recurrences prevented	29%	34%	−5%
Costs	$29,754	$32,636	−$2,882
Quality-adjusted life years	9.86	10.08	−0.21

Permission Granted from Wolters Kluwer Pharma Solutions. Oestreicher N et al 2005

Cost-Effectiveness Considerations

1. Gene:
   - a significant proportion in low risk category
   - test results associated with recurrence risk
   - no data showing association with treatment (chemotherapy) response
2. Test:
   - Costly
3. Disease:
   - Significant consequences of BrCA recurrence
4. Treatment:
   - Significant costs and quality of life impacts
   - Patient tx. decisions not clear

 33

Case Example 2: Economic Evaluation of Warfarin Therapy and Genetic Testing

 34

Warfarin

- Warfarin is an anticoagulant used since 1954, and in 2009, over 25 million prescriptions were dispensed in the US
- Currently, there are no competing oral drugs on the market
- Warfarin is a highly effective drug for reducing the risk of thromboembolic events
  - Reduces ischemic stroke risk by 68% (CI: 50-79%) compared to no antithrombotic therapy and by 52% (CI 37-63%) compared to aspirin in AF patients

Drug Topics 2009
Fihn et al 1993
Singer et al 2004

 35

Warfarin Safety

- The incidence of serious and life threatening bleeding events is approximately 2-10% in the first year and less thereafter (Landefeld et al 1989)
- Approximately 1% of serious/life threatening bleeds are fatal (Lafata et al 2000)
- Costs (Lafata et al 2000)
  - Serious: $3,000
  - Life threatening: $21,000
  - Fatal: $11,000
- Warfarin is under-utilized, in part due to the perceived risk of bleeds (Bungard et al 2000)

 36

Monitoring Warfarin Therapy

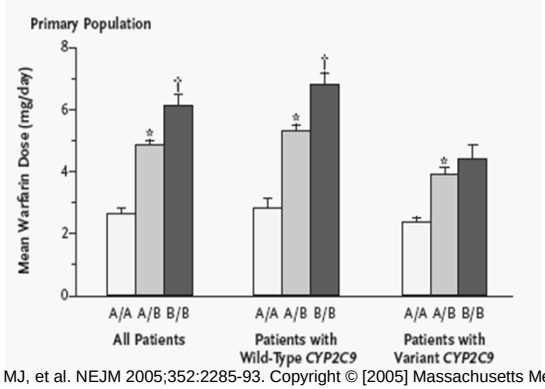
- The INR (International Normalized Ratio) is a measure of blood clotting
  - Optimal INR range for most indications (including AF): 2-3
- High INRs increase the risk of bleeds, low INRs increase the risk of clotting events (Lafata et al 2000)
  - Bleeds are approximately 3 times as common for above range INRs
  - Clotting events are 3.5 times as common for below range INRs
- When INR is out of range, more frequent monitoring is necessary

Landefeld et al 1989

What is the Incremental Clinical Utility?

- An individualized approach to warfarin management is the 'standard of care'
- Can the warfarin management approach be improved using pharmacogenomics?

CYP2C9 & *VKORC1* Variants and Dose



Rieder MJ, et al. NEJM 2005;352:2285-93. Copyright © [2005] Massachusetts Medical Society. All rights reserved.

CYP2C9 Variants and Bleeding Risk

- *CYP2C9* variants *2 and *3 found to have
  - significantly higher risk of serious or life threatening bleeds (HR 2.39), and
  - took significantly longer (~90 days) to stabilize than wild type patients
- *CYP2C9* variants have a 40% increased risk of a high INR (>4.0)

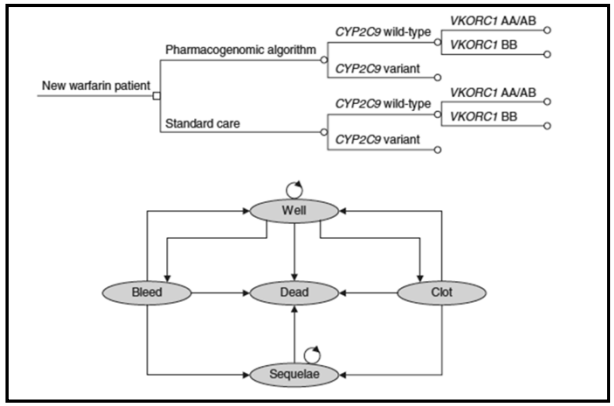
Higashi et al 2002

Cost-Effectiveness

- An early analysis suggested testing could save $1B annually in the US
  - However, assumptions have been criticized (e.g., 100% 'effective' test)
- Several recent studies have similarly concluded that testing is unlikely to be cost effective unless:
  - testing costs drop significantly, and
  - effectiveness is established

McWilliam et al 2006; Veenstra 2007; Hughes et al 2007; Patrick et al 2009; Eckman 2009; Meckley et al 2010

Model Structure



Permission Granted from Wolters Kluwer Pharma Solutions. Meckley et al 2010

Influence of PGx testing on INR outcomes

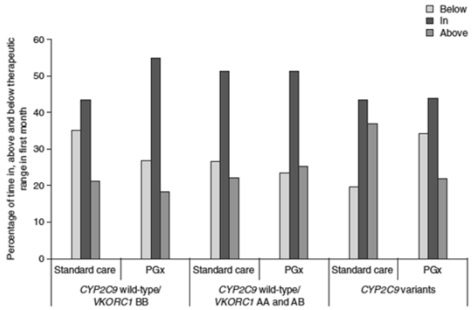


Fig. 2. COUMAGEN reanalysis. These data were calculated based on a reanalysis of patient-level data from the COUMAGEN trial,[16] calculated using the Rosendaal et al.[20] method. The bars represent the percentage of time below, in and above therapeutic international normalized ratio range during with first month of the COUMAGEN trial, stratified by genotype and warfarin initiation strategy. ***CYP***=cytochrome P450; **PGx**=pharmacogenetic initiation.

Permission Granted from Wolters Kluwer Pharma Solutions. Meckley et al 2010

INR as a surrogate marker

Table I. Parameters: probabilities, costs ($US; year 2007 values) and utilities

Parameter	Base case	Range
Genotype (%)		
CYP2C9 variants	31	10–50
VKORC1 variants/*CYP2C9* wild-type	30	23–38
VKORC1 wild-type/*CYP2C9* wild-type	39	29–49
Adverse events [annual incidence] (%)		
Major bleeds (above therapeutic INR range)	15.7	12–20
Major bleeds (within therapeutic INR range)	5.7	4–7
Major bleeds (below therapeutic INR range)	6.5	5–8
TEs (above therapeutic INR range)	2.4	2–3
TEs (within therapeutic INR range)	3.0	2–4
TEs (below therapeutic INR range)	16.2	12–20

Permission Granted from Wolters Kluwer Pharma Solutions. Meckley et al 2010

Results

Table III. Results: bleeds, thromboembolic events (TEs), deaths, costs, QALYs and incremental cost-effectiveness ratios (ICERs)

Population	Strategy	Δ Bleeds[a] (%)	Δ TEs[a] (%)	Δ Deaths[a] (%)	QALYs	Costs[b]	ICER[b]
All patients	PGx	6.76	5.11	6.64	12.0851	46 970	
	StC	6.93	5.08	6.77	12.0825	46 808	
	Δ	−0.17	0.03	−0.13	0.0027	162	60 750

 45

Uncertainty – single inputs

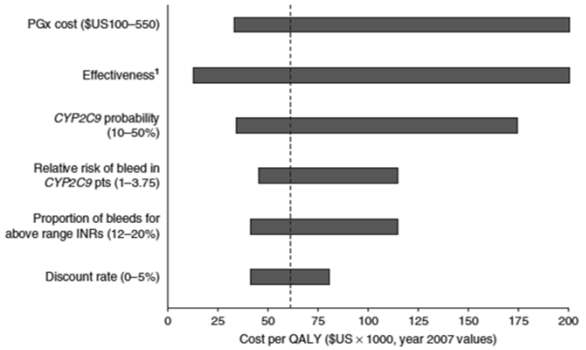


Fig. 3. Tornado diagram: incremental cost-effectiveness ratios (ICERs). The horizontal bars represent the range of the ICER for one-way sensitivity analyses over the range of the parameter in parentheses. The wider the horizontal bar, the more uncertainty that parameter introduces. The vertical line represents the base-case ICER. **1** The effectiveness parameter is based on the difference between the pharmacogenomic-based and standard of care warfarin initiation in the COUMAGEN trial.[16] Time within, above and below therapeutic range were simultaneously varied over the 95% confidence interval of the difference between the two trial arms. ***CYP***=cytochrome P450; **INR**=international normalized ratio; **PGx**=pharmacogenetic initiation.

 46

Uncertainty – multiple inputs

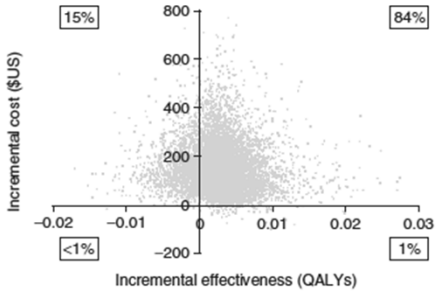


Fig. 4. Cost-effectiveness scatter plot. Each point represents the incremental cost (year 2007 values) and QALYs between pharmacogenomics and standard of care from the Monte Carlo simulation. The percentages in boxes represent the percentage of simulations in that quadrant.

 47

Summary of findings

- Warfarin PGx testing may be both effective and cost-effective, but significant uncertainty at this time
- Clinical and economic effects likely to be modest
- Additional clinical data would be valuable, and cost-effectiveness should be reassessed

 48

Recommendations and Guidelines

- The 2008 American College of Chest Physicians anticoagulation management guidelines state "we suggest against pharmacogenetic-based dosing until randomized data indicate that it is beneficial (Grade 2C)."

Ansell et al 2008

Coverage Decisions

- In August 2009, CMS issued a coverage decision that specifies testing will only be reimbursed for patients initiating warfarin who are enrolled in an RCT that measures major bleeding and thromboembolic events (coverage with evidence development) (CMS 2009)

Cost-Effectiveness Considerations

1. Gene:
   - ~30% of patients have a variant
   - variant associated with increased bleeding risk
2. Test:
   - Moderate cost, timing an issue
3. Disease:
   - Bleeds and clots clinically and economically important
4. Treatment:
   - Benefit of PGx information in setting of individualized care not clear

Summary of Pharmacogenomics & Cost-Effectiveness Evaluation

The use of genetic testing to improve drug therapy will be challenging. The tools of economic assessment can be used to:

- identify important areas of research
- refine study designs
- assess risk-benefit tradeoffs
- evaluate the economic value of these new technologies

Economic Barriers to Personalized Medicine

UW Backgrounder: Major Findings

- There are major scientific challenges facing the translation of basic pharmacogenomics scientific discoveries into clinical care
- Pharmacogenomics is thus unlikely to produce fundamental changes to our health care system in the near future
- Achieving the promise of pharmacogenomics will require both continued public support for research and effective public-private collaboration to facilitate the translation of pharmacogenomics to the bedside

Garrison et al 2007

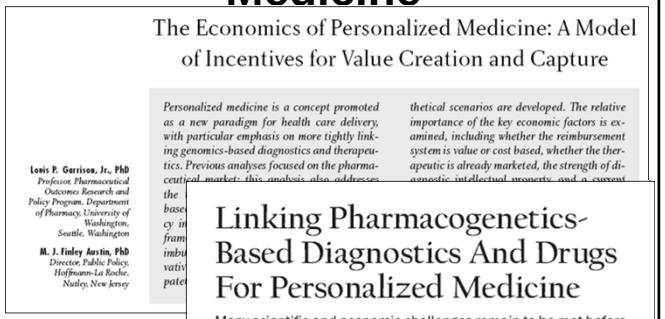
Commercial and Policy Challenges

- Regulatory pathways have not yet been optimized to encourage the co-development of diagnostics and therapeutics
- Current economic incentives—as reflected in our intellectual property and reimbursement systems for diagnostics and drugs—are generally not structured to reward value creation appropriately
- The integration of pharmaceutical and diagnostic development is difficult because of differences in the underlying business and translational science models

Commercial and Policy Challenges (cont.)

- Genomics technologies are perceived to raise ethical, legal, and social issues to such a degree that a special NIH program was established to address them
- Stakeholder literacy about pharmacogenomics is limited, and positions on public policy issues are not yet clearly defined

Economics of Personalized Medicine



The Economics of Personalized Medicine: A Model of Incentives for Value Creation and Capture

Personalized medicine is a concept promoted as a new paradigm for health care delivery, with particular emphasis on more tightly linking genomics-based diagnostics and therapeutics. Previous analyses focused on the pharma-

thetical scenarios are developed. The relative importance of the key economic factors is examined, including whether the reimbursement system is value or cost based, whether the therapeutic is already marketed, the strength of di-

Louis P. Garrison, Jr., PhD
Professor, Pharmaceutical Outcomes Research and Policy Program, Department of Pharmacy, University of Washington, Seattle, Washington

M. J. Finley Austin, PhD
Director, Public Policy, Hoffmann-La Roche, Nutley, New Jersey

Garrison & Austin 2007

Linking Pharmacogenetics-Based Diagnostics And Drugs For Personalized Medicine

Many scientific and economic challenges remain to be met before personalized medicine takes hold.

by Louis P. Garrison Jr. and M.J. Finley Austin

Garrison & Austin 2006

Public Policy Implications from a Economic Perspective

- Flexible and value-based pricing and reimbursement for diagnostics could provide drug and diagnostic manufacturers a stronger incentive to evaluate the business case for linked diagnostics and therapeutics during drug development
- Incentive-oriented reforms--linking pricing and reimbursement for drugs and diagnostics to value creation--will encourage personalized medicine
- Strong, consistent, predictable IP environment remains key to pharmaceuticals. How content vs. platform protection is resolved in diagnostics will affect long-term business prospects
- Public policy should not focus on PGx technologies alone, but should consider the broader linked diagnostic-therapeutic paradigm, looking at biomarkers more generally

Acknowledgements

- **Authors**
  - Louis P. Garrison, Jr., PhD
    Professor and Associate Director, Pharmaceutical Outcomes Research and Policy Program, Department of Pharmacy
    University of Washington
  - David L. Veenstra, PharmD, PhD
    Professor, Pharmaceutical Outcomes Research and Policy Program, Department of Pharmacy
    University of Washington
- **Reviewers and Editorial Staff**
  Primary Reviewer and Editor
  – Grace M. Kuo, PharmD, MPH
  Reviewers and Associate Editors
  – Joseph D. Ma, PharmD
  – Jan D. Hirsch, PhD
  – Kelly C. Lee, PharmD, BCPP
  Assistant Editors
  – Ashley To, BA

References

Ansell J, et al. Pharmacology and management of the vitamin K antagonists: American College of Chest Physicians Evidence-Based Clinical Practice Guidelines (8th edition). Chest. 2008;133(6 Suppl):160S-198S.

Arrow K, Uncertainty and the welfare economics of medical care. American Economic Review, 1963; 53: 941-73.

Bungard et al. Why do patients with atrial fibrillation not receive warfarin? Arch Intern Med. 2000;160(1):41-6.

Centers for Medicare & Medicaid Services (CMS). Decision Memo for Pharmacogenomic Testing for Warfarin Response (CAG-00400N). Accessed at http://www.cms.hhs.gov/mcd/viewdecisionmemo.asp?id=224, September 6, 2009.

Drug Topics. 2009 Top 200 generic drugs by total prescriptions. 2009. http://drugtopics.modernmedicine.com/drugtopics/data/articlestandard//drugtopics/252010/674982/article.pdf. Accessed September 2010

Drug Topics. 2009 Top 200 branded drugs by total prescriptions. 2009. http://drugtopics.modernmedicine.com/drugtopics/data/articlestandard//drugtopics/252010/674969/article.pdf. Accessed September 2010

Eckman MH, et al. Cost-effectiveness of using pharmacogenetic information in warfarin dosing for patients with noncalcular atrail fibrillation. Ann Int Med. 2009;150(2):73-83.

Fihn et al. Risk factors of complications of chronic anticoagulation. A multicenter study. Warfarin optimized outpatient follow-up study group. Ann Intern Med. 1993. 118(7):511-20.

Garrison LP and Austin MJ. The Economics of Personalized Medicine: a model of incentives for value creation and capture. Drug Information Journal 41: 501-509, 2007

References

Garrison LP and Austin MJ. Linking pharmacogenetics based diagnostics and drugs for personalized medicine. Health Affairs, 25(5): 1281-1290, September-October, 2006.

Garrison LP, et al. Backgrounder on Pharmacogenomics for the Pharmaceutical and Biotechnology Industries: Basic Science, Future Scenarios, Policy Directions. Report. Pharmaceutical Outcomes Research Policy and Program. Department of Pharmacy. University of Washington. February, 2007.

Gold MR, et al. Cost-Effectiveness in Health and Medicine. Oxford University Press 1996

Higashi MK, et al. Association between CYP2C9 genetic variants and anticoagulation-related outcomes during warfarin therapy. JAMA. 2002;287(13):1690-8.

Hughes DA, Pirmohamed M. Warfarin pharmacogenetics: economic considerations. Pharmacoeconomics. 2007;25(11):899-902.

McWilliam A, et al. Health care savings from personalizing medicine using genetic testing: the case of warfarin. AEI-Brooking Joint Center for Regulatory Studies. http://www.aei-brookings.org/publications/abstract.php?pid=1127. Accessed 4 January 2007.

Meckley LM, et al. A policy model to evaluate the benfits, risks and costs of warfarin pharmacogenomic testing. Pharmacoeconomics. 2010;28(1):61-74.

Oestreicher N, et al. Gene expression profiling and breast cancer care: what are the potential benefits and policy implications? Genet Med. 2005. 7(6):380-9.

Patrick AR, et al. Cost-effectiveness of genotype-guided warfarin dosing for patients with atrial fibrillation. Circ Cardiovasc Qual Outcomes. 2009 Sep;2(5):429-36. Epub 2009 Jul 21.

References

Rieder MJ, et al. Effect of VKORC1 haplotypes on transcriptional regulation and warfarin dose. N Engl J Med 2005; 352:2285-93

Singer et al. Antithrombotic therapy in atrial fibrillation: the Seventh ACCP conference on antithrombotic and thrombolytic therapy. Chest. 2004. 126(3 Suppl):429S-456S.

Lafata et al. The cost-effectiveness of different management strategies for patients on chronic warfarin therapy. J Gen Intern Med. 2000;15(1):31-7.

Landefeld et al. Guideline-based Consultation To Prevent Anticoagulant-related Bleeding. Am J Med. 1989;87(2):144-52.

Van de Vijver MJ, et al. A gene-expression signature as a predictor of survival in breast cancer. N Engl J Med. 2002. 19(347(25):1999-2009.

Veenstra DL. The cost-effectiveness of warfarin pharmacoeconomics. J Thromb Haemost. 2007;5(9):1974-5. Epub 2007.

Veenstra DL and Carlson JJ. "Cost-Effectiveness, Economic Incentives, and Reimbursement Issues," in Pharmacogenomics: Applications to Patient Care (2nd ed.), American College of Clinical Pharmacy, 2009.

Weinstein MC, and Stason WB. Foundations of cost-effectiveness analysis for health and medical practices. The New England Journal of Medicine, 1977, 296 (13): 716–721

END OF CONTENT SECTION

Contact for TTT for Faculty

PharmGenEd™ Training for Health Professional Schools
Kelly C. Lee, PharmD, BCPP
Phone: 858-822-3462
Email: kellylee@ucsd.edu

General Questions about PharmGenEd™
pharmacogenomics@ucsd.edu

Principal Investigator and Program Director
Grace M. Kuo, PharmD, MPH
Phone: 858-822-7754
Email: kuooffice@ucsd.edu

PharmGenEd™ Team

- **UCSD Faculty**
  - Grace M. Kuo, PharmD, MPH (PI)
  - Kelly C. Lee, PharmD, BCPP
  - Joseph D. Ma, PharmD
  - James R. Halpert, PhD
  - Theodore Ganiats, MD
  - Philip E. Bourne, PhD
  - Palmer Taylor, PhD
- **Consultants**
  - Magnus Ingelman-Sundberg, PhD (Karolinska Institute, Sweden)
  - Karen S. Hudmon, DrPH, MS, RPh (Purdue University)
- **Project Coordinator**
  - Ashley To, BA

The program is 100% funded by the CDC
(*Grant Number IU38GD000070*)
 65

Webinar Dates

(all times are PST)

- **Oncology II: Hematologic Malignancies**
  - Tuesday, Aug. 10, 2010 10am-12pm – COMPLETED
- **Concepts and Clinical Applications**
  - Wednesday, August 11, 2010 – COMPLETED
- **Psychiatry II: Antipsychotics**
  - Tuesday, Aug. 24, 2010 10am – 12pm – COMPLETED
- **Oncology I: Solid Tumors**
  - Thursday, Aug. 26, 2010 10 am – 12 pm – COMPLETED
- **Cardiology I: Warfarin and Statins**
  - Tuesday, Sept. 21, 2010 10am –12 pm – COMPLETED
- **Cardiology II: Clopidogrel and Beta Blockers**
  - Thursday, Sept. 23, 2010 10 am – 12 pm – COMPLETED
- **Economic Issues**
  - Tuesday, Oct. 12, 2010 9:30 am – 11:30 am

 66

Webinar Dates

(all times are PST)

- **Psychiatry I: Depression**
  - Thursday, Oct. 21, 2010 10am – 12pm
- **Asthma**
  - Tuesday, Nov. 2, 2010 10am – 12pm
- **PharmGenEd™ Program Implementation**
  - Thursday, Aug. 12, 2010: 10 am – 12 pm – COMPLETED
  - Thursday, Sept. 9, 2010: 10 am – 12 pm – COMPLETED
- Please register at www.pharmacogenomics.ucsd.edu to download materials prior to the scheduled webinar

 67

Survey Instruments: Evaluation

- Faculty trainers will complete a Post-Training Survey
  - Evaluate knowledge, attitudes, and self-efficacy
- All survey materials will be mailed after completion of all webinars in October 2010

 68

Question and Answer Session