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PharmGenEd™:
Bridging the Gap Between Science & Practice
Train-the-Trainer Session
for Economic Issues
Tuesday, October 12, 2010

Disclaimer

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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

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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

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

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and
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Professor

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Department of Pharmacy
University of Washington

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
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

Brief Introduction to Health Economics

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

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
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

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

<table>
<thead>
<tr>
<th>Method of Analysis</th>
<th>Cost Measurement</th>
<th>Outcome Measurement</th>
</tr>
</thead>
<tbody>
<tr>
<td>Cost-Minimization</td>
<td>$</td>
<td>Equivalence demonstrated in comparative groups</td>
</tr>
<tr>
<td>Cost-Consequences</td>
<td>$</td>
<td>Multidimensional listing of outcomes</td>
</tr>
<tr>
<td>Cost-Effectiveness (CEA)</td>
<td>$</td>
<td>“Natural” units (life-year gained, mg/dL blood glucose, mm Hg blood pressure); single outcome</td>
</tr>
<tr>
<td>Cost-Utility (CUA)</td>
<td>$</td>
<td>Life years adjusted for quality of life (QALY)</td>
</tr>
<tr>
<td>Cost-Benefit (CBA)</td>
<td>$</td>
<td>$; multiple outcomes combined into one value</td>
</tr>
</tbody>
</table>

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Strengths and Weaknesses of Types of Economic Evaluations

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

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

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?

“League Table” for Comparing Interventions

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

Gold et al 1996
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?

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?

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?

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?
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

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

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

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

---

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

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

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)
**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

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**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**

- 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)


---

**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


Model Structure

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

Influence of PGx testing on INR outcomes

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

INR as a surrogate marker

Table 1. Parameters: probabilities, costs ($US; year 2007 values) and utilities

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

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

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

<table>
<thead>
<tr>
<th>Population</th>
<th>Strategy</th>
<th>Δ Bleeds</th>
<th>Δ TEIs</th>
<th>Δ Deaths</th>
<th>QALYs</th>
<th>Costs</th>
<th>ICER</th>
<th>Δ</th>
</tr>
</thead>
<tbody>
<tr>
<td>All patients</td>
<td>PGx</td>
<td>6.76</td>
<td>5.11</td>
<td>6.64</td>
<td>12.08</td>
<td>48.97</td>
<td></td>
<td></td>
</tr>
<tr>
<td>SC</td>
<td>6.93</td>
<td>5.06</td>
<td>6.77</td>
<td>12.08</td>
<td>48.97</td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td>A</td>
<td>-0.17</td>
<td>0.03</td>
<td>-0.13</td>
<td>0.0027</td>
<td>182</td>
<td>69.75</td>
<td></td>
<td></td>
</tr>
</tbody>
</table>

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 analysis 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-cost ICER. The effectiveness parameter is based on the difference between the pharmacogenomics-based and standard of care arms in this figure. Differences greater than 10% and between $25,000 and $100,000 per QALY are considered significant.

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
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).”

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
Public Policy Implications from an 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

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  - Louis P. Garrison, Jr., PhD
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    University of Washington
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References


References


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  - Ashley To, BA

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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

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
Question and Answer Session