Highlights from the Spring 2009
Applied Pharmacoeconomic and Outcomes Research Forum

The sixth Applied Pharmacoeconomic and Outcomes Research Forum was held June 8th at the University of California San Diego Faculty Club. The event was hosted by the Skaggs School of Pharmacy and Pharmaceutical Sciences and supported by grants from Allergan and Biogen Idec.

The topic for the Forum was "***Pharmacoeconomics of Pharmacogenomics***".

Speakers:

Introduction to Pharmacogenomics
Grace M. Kuo, PharmD, MPH
UCSD, Skaggs School of Pharmacy & Pharmaceutical Sciences and Family & Preventive Medicine

Genetic Technology: Practical Issues for Health Plans
Jill Van Den Bos, MA
Milliman

Impact of Pharmacogenomics on Drug Development & Commercialization: An International Perspective
Dave W. Miller, PhD
Miller Pharma Consulting

Forum participants included representatives from managed care, government, pharmaceutical and biotech companies, medical centers and academia. Each was invited because of mutual interest in expanding the practical application of pharmacoeconomic and outcomes research to enhance decision-making.

Speaker slides are posted at http://pharmacy.ucsd.edu

FORUM HIGHLIGHTS

- **What is Pharmacogenomics?**
  - Pharmaco***genetics***
    - "the study of genetic causes of individual variations in drug response" (AAPS, Pharmacogenomics Focus Group)
  - Pharmaco***genomics***
    - "more broadly involves genome-wide analysis of the genetic determinant of drug efficacy and toxicity" (AAPS, Pharmacogenomics Focus Group)
  - Both terms are used interchangeably. The preferred term is pharmacogenomics.

- **What drugs have pharmacogenomic information?**
  - Of 1200 drug labels from 1945-2005,121 drug labels contained pharmacogenomic information (Frueh et al 2008)

- Currently, FDA lists 61 drugs with information for Required, Recommended and Information Only recommendations for pharmacogenomic testing (Accessed February 8, 2009; http://www.fda/gov/CDER)

- **PharmGenEd™ Program – In Development**
  - G. M. Kuo: Program Director - funded by CDC (2008 – 2011)
  - Will provide
    - Continuing education credits to healthcare professionals
    - Shared curriculum platform (free access to materials for teaching, in-service, grand rounds, or professional meetings)
  - Website: http://pharmacogenomics.ucsd.edu
  - To join the virtual community: http://www.scivee.tv/node/7981

- **Pharmacogenomics is a Disruptive Technology**
  - Other examples; Muskets, Plastic, Mobile phones

- **Health Plan Perspective**
  - Net Income / Revenue is low compared to many other industries
    - Do not have a great deal of extra money to spend
    - Must spend wisely
  - Potential Benefits of Genetics in Medicine
    - Targeting populations for treatment
    - Targeting treatments for patients (pharmacogenomics)
  - Potential Pitfalls in Implementation – Health Plan Perspective
    - Coverage policy – are genetic and pharmacogenomic tests covered?
    - Procedure codes - lacking for genetic and pharmacogenomic tests
    - Reimbursement – complicated and may fall to patients

- **Drug Development Perspective**
  - Pharmacogenomics can be thought of two ways
    - *"After market" tests developed for marketed drugs*
      - *Warfarin—to identify potential PK issues and initial dose adjustments*
    - *Drugs that are co-developed with PGx tests*
      - *Herceptin—to identify patients who will respond to treatment*
      - *Much of drug development interest is in co-development*
  - Potential Benefits for Drug Development
    - Reduce Sample Size of Clinical Trials
    - Enriching Study Populations Promises Fewer Failed Studies
    - May Improve Benefit Risk Ratio by Screening Out Patients with Hih Severe Adverse Event Risk
  - Potential Challenges for Drug Development
    - Development and validation of pharmacogenomics test may require large clinical and epidemiological studies
    - Sponsors may be required to run larger trials, or additional smaller trials, to ensure adequate patient exposures in regulatory filings
  - To date, Impact on Drug Development Has Been Marginal

Purpose of Applied Pharmacoeconomic and Outcomes Research Forums

The number of individuals in the Southern California region with interest in pharmacoeconomics (PE) is growing rapidly across the healthcare system - from those involved with creation of PE data within pharmaceutical and biotech companies to those incorporating results into decision making within a plethora of managed care organizations. The region provides an excellent opportunity to gather individuals to debate issues, and propose solutions that are vetted from multiple perspectives – not just individual silos defined by employer.

The Applied Pharmacoeconomic and Outcomes Research Forum was created to facilitate this cross perspective communication. The goals of the forum are to:

1. Discuss commonly encountered obstacles to conducting or utilizing results of applied pharmacoeconomic studies and explore solutions from various perspectives of the health care system.
2. Create an environment and foundation to foster the creation of a Southern California Pharmacoeconomic and Outcomes Research Interest Group

Current steering committee members are:

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