Introduction to Pharmacogenomics

Grace M. Kuo, PharmD, MPH
Associate Professor of Clinical Pharmacy
Associate Adjunct Professor of Family & Preventive Medicine

Outline

• What is Pharmacogenomics?
• PharmGenEd™:
  Bridging the Gap Between Science & Practice
• Where are we now?
What is Pharmacogenomics?

Pharmacogenetics/genomics Definitions

• **Pharmacogenetics**
  - “the study of genetic causes of individual variations in drug response” (AAPS, Pharmacogenomics Focus Group)

• **Pharmacogenomics**
  - “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.**
Current Drug Therapy

- Drug response rate
  - 30-60% response rate of drug therapies for Alzheimer’s, depression, rheumatoid arthritis, hypertension, osteoporosis
    - (Physician’s Desk Reference, 2007)

- Adverse drug reactions
  - ADRs have increased from 30-90/1000/year
    - (Moore et al 2007)
  - ↑ Mortality
  - ↑ Cost

- Knowledge and practice gaps related to pharmacogenomics
  - There is a gap between healthcare professionals’ knowledge and expectation/demand from patients
  - There is lack of practice tools (e.g., protocols or infrastructure support) to integrate pharmacogenomics information into practice

NIH National Human Genome Research Institute Teaching Tools

Click to Play
PharmGenEd™: Bridging the Gap Between Science & Practice

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

PharmGenEd™ Program

• Timeline: 2008 - 2011
• Target Audience >100,000 healthcare professionals
  – Pharmacists
  – Physicians
  – Students / trainees
• Will provide
  – Continuing education credits to healthcare professionals
  – Shared curriculum platform
    • Free access to materials for teaching, in-service, grand rounds, or professional meetings
PharmGenEd™
Delivery Methods

• Live presentations
  – National, regional, local meetings
• Online presentations
  – Web-based lecture materials
  – Shared curriculum platform
  – Use of SciVee for pubcasts & videocasts
    • The “YouTube™ and Facebook™ for scientists
• Website
  – http://pharmacogenomics.ucsd.edu
• To join the virtual community
  – http://www.scivee.tv/node/7981
About Us

The program core team members are faculty and staff at the University of California, San Diego (UCSD) Skaggs School of Pharmacy and Pharmaceutical Sciences (SSPPS) and the School of Medicine.

Principal Investigator:
- Diane M. Hays, PharmD, MPH

Co-Investigators:
- Kelly C. Lee, PharmD, BCPP
- Joseph D. Ma, PharmD
- Patricia O. Doune, PhD
- Theodore Ganata, MD
- James R. Hapgood, PhD
- Palmer Taylor, PhD

Assistant:
- Jessica Bryen, MPH
- Tina Roych
- WeiWei Qin, MS
- Ashley To
- Lilian Wong, PharmD, MSA

CE/CME

The objective of PharmGenEd is to increase awareness about current knowledge of the validity and utility of pharmacogenomics tests and the potential implications of benefits and harms from use of the tests. Our target population exceeds 100,000 healthcare professionals and students. Materials developed from PharmGenEd will be accessible to healthcare professionals who have participated in the PharmGenEd train-the-trainer program and are capable of presenting the PharmGenEd CE/CME modules to pharmacists and pharmacy students.

We openly share our materials with others at no cost; however, all persons who receive any component of the PharmGenEd Program must complete an online registration process which includes acceptance of our End User License Agreement. PharmGenEd materials can be used only for non-commercial teaching and research purposes and cannot be used for profit. To gain access to downloadable program materials from the PharmGenEd Internet site, please register here:

If you have completed the PharmGenEd train-the-trainer program for CE/CME and are interested in becoming a member of the National Speakers Bureau for PharmGenEd, please contact us at pharmacogenomics@ucsd.edu.
Where are we now?
Evidence-Based Recommendations

- CDC
  - Evaluation of Genomic Applications in Practice and Prevention (EGAPP) Working Group
    - Available at: http://www.egappreviews.org/about.htm
  - GAPP Translation Programs
    - 5 Programs funded by the CDC Office of Public Health Genomics

- FDA
  - 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 June 5, 2009
    - http://www.fda.gov/Drugs/ScienceResearch/ResearchAreas/Pharmacogenetics/ucm083378.htm

Therapeutic Areas (Examples)

- Infectious Diseases: Abacavir
- Oncology: Tamoxifen; Trastuzumab; Azathioprine; Irinotecan
- Anticoagulation: Warfarin
- Psychiatry: SSRIs
- Neurology: Carbamazepine
- Respiratory Disease: Albuterol
- Cardiovascular Disease: Metoprolol; Atorvastatin
- Pain Management: Codeine
Health Economics & Implication to Public Health

- No strong evidence to support cost-effectiveness of pharmacogenomic tests
  - Currently being investigated
  - Willingness to pay from payers variable
- Unlikely to disrupt the current public health system
  - Gradual and incremental progression
  - Our system has flexibility to adapt (Garrison et al 2008)

Acknowledgments

- UCSD
  - Principal Investigator
    - Grace M. Kuo, PharmD, MPH
  - Co-Investigators:
    - Kelly C. Lee, PharmD, BCPP
    - Joseph D. Ma, PharmD
    - Palmer Taylor, PhD
    - James R. Halpert, PhD
    - Philip E. Bourne, PhD
    - Theodore Ganiats, MD

- Consultants
  - Magnus Ingelman-Sundberg, PhD
    - Karolinska Institute
  - Karen S. Hudmon, DrPH, MS, RPh
    - Purdue University

- Assistants
  - Trina Huynh
  - Ashley To, BA
  - Jessica Bryan, MPH
  - WeiWei Qin, MS
  - Lilian Wong, PharmD, MBA

Acknowledgement of Federal Support: 100% funded by the CDC $1,047,991 (Grant Number IU38GD000070)
PharmGenEd™ Contact

- Program Director: Grace M. Kuo, PharmD, MPH
- Phone: 858-822-7754
- Email: pharmacogenomics@ucsd.edu
- Website: http://pharmacogenomics.ucsd.edu