



# Introduction to Pharmacogenomics

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## Outline

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

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# What is Pharmacogenomics?



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## 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.**

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## 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

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## NIH National Human Genome Research Institute Teaching Tools

Link to *Making SNPs Make Sense* Animation



Click to Play

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# PharmGenEd™: Bridging the Gap Between Science & Practice



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## 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

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# 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>

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The screenshot shows the PharmGenEd website interface within a browser window. The browser's address bar displays "Pharmacogenomics Education Program". The website header includes the University of California, San Diego logo and the text "Pharmacogenomics Education Program". A search bar is located in the top right corner. The main navigation menu consists of links for HOME, ABOUT US, CE/CME, SHARED CURRICULUM, RESOURCES, PUBCASTS, and VIRTUAL COMMUNITY. The page content is organized into several sections: a "PharmGenEd" banner with the tagline "Bridging the Gap Between Science & Practice"; a "Topics" section with a DNA helix image; a "Pubcasts" section with an image of a person using a computer; a "Calendar" section showing "Wednesday, May 6" and options to "Look for earlier events" or "Look for more"; a "What is PharmGenEd?" section with a detailed description of the program; a "News Feed" section featuring a "Recent Posts" widget with the title "The clinical relevance of Mycobacterial pharmacogenetics"; and an "Educational Resources" section with a list of resources including "Web-based or live CE/CME presentations", "Evidence-based pubcasts and videocasts", and "A shared curriculum platform to".

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About Us - Pharmacogenomics Education...

Pharmacogenomics  
Education Program

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HOME ABOUT US CE/CME SHARED CURRICULUM RESOURCES PUBCASTS VIRTUAL COMMUNITY

**About Us**

Welcome  
Funding Agency  
UCSD Faculty  
Consultants  
Expert Reviewers  
Speakers  
PharmGenEd Objectives  
Program Map  
FAQ  
Contact Us

**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:

- Grace M. Kuo, PharmD, MPH

Co-Investigators:

- Kelly C. Lee, PharmD, BCPP
- Joseph D. Ma, PharmD
- Philip E. Bourne, PhD
- Theodore Ganiats, MD
- James R. Halpert, PhD
- Palmer Taylor, PhD

Assistants:

- Jessica Bryan, MPH
- Trina Huynh
- WeiWei Qn, MS
- Ashley To
- Lilian Wong, PharmD, MBA

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CE/CME - Pharmacogenomics Education...

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**Topics**

Module I:  
Pharmacogenomic Principles and Concepts  
Module II:  
Evidence-Based Pharmacogenomic Recommendations for Clinical Practice: an Overview  
National Speakers Bureau  
Contact Us

**CE/CME**

The objective of *PharmGenEd* 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. 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 materials to pharmacists and physicians.

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 Licensing 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](mailto:pharmacogenomics@ucsd.edu).

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Shared Curriculum - Pharmacogenomics ...

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# Pharmacogenomics

## Education Program

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### Topics

- Principles and Concepts
- Evidence-Based Recommendations for Clinical Practice: an Overview
- Oncology I
- Oncology II
- Psychiatry
- Cardiology
- Anticoagulation
- Neurology
- Infectious Diseases
- Other Diseases/Conditions
- Laboratory Basis of Tests
- Clinical Applications
- Ethical, Social, & Legal Issues
- Economic Perspectives

### Shared Curriculum

Because the field of pharmacogenomics is developing rapidly, it is critical that clinicians and students learn to appropriately interpret emerging data on pharmacogenomic tests and become familiar with resources applicable to their practice.

*PharmGenEd* prepares shared curriculum, open-access educational materials to train future healthcare providers about the various pharmacogenomic tests and their applications to clinical practice. *PharmGenEd* collaborates with the American Association of Colleges of Pharmacy (AACP) and uses a "Train-the-Trainer" approach to disseminate educational materials to faculty from all colleges of pharmacy in the U.S. The content materials will also be available to schools of medicine faculty members.

The *PharmGenEd* materials can be used in the classroom, for students in the health professions, or as training for licensed clinicians. Modules related to specific therapeutic areas will be developed in the coming months. 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 Licensing Agreement](#). *PharmGenEd* materials can be used only for non-commercial teaching and research purposes and cannot be used for profit.

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Resources - Pharmacogenomics Educatio...

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### Resources

- Resources
- News and Publications
- References
- EGAPP
- Recommendations
- Textbooks
- Journal Articles
- Drug Toxicity and Adverse Drug Reactions
- Drug Response
- Drug Transporter
- Suggestions

### Resources

#### Drug Toxicity and Adverse Drug Reactions

Hirata K, Takagi H, Yamamoto M, Matsumoto T, Nishiya T, Mori K, Shimizu S, Masumoto H, Okutani Y. Ticlopidine-induced hepatotoxicity is associated with specific human leukocyte antigen genomic subtypes in Japanese patients: a preliminary case-control study. *Pharmacogenomics J*. 2008 Feb;8(1):29-33. Epub 2007 Mar 6. PMID: [17339877](#)

Ingelman-Sundberg M. Pharmacogenomic biomarkers for prediction of severe adverse drug reactions. *N Engl J Med*. 2008 Feb 7;358(6):637-9. PMID: [18256400](#)

Mallal S, Phillips E, Carosi G, Molina JM, Workman C, Tomazic J, Jagel-Guedes E, Rugina S, Kozlyrev O, Cid JF, Hay P, Nolan D, Hughes S, Hughes A, Ryan S, Fitch N, Thorburn D, Benbow A; PREDICT-1 Study Team. HLA-B\*57:01 screening for hypersensitivity to abacavir. *N Engl J Med*. 2008 Feb 7;358(6):568-79. PMID: [18256392](#)

SEARCH Collaborative Group, Link E, Parish S, Armitage J, Bowman L, Heath S, Matsuda F, Gut I, Lathrop M, Collins R. SLCO1B1 variants and statin-induced myopathy--a genomewide study. *N Engl J Med*. 2008 Aug 21;359(8):789-99. Epub 2008 Jul 2. PMID: [18650507](#)

Simon T, Verstuyft C, Mary-Krause M, Quteineh L, Drouet E, Meneveau N, Steg

Pubcasts - Pharmacogenomics Education ...

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Topics

- Principles and Concepts
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- Cardiology
- Anticoagulation
- Neurology
- Infectious Diseases
- Other Diseases/Conditions
- Laboratory Basis of Tests
- Clinical Applications
- Ethical, Social, & Legal Issues
- Economic Perspectives

Pubcasts

PharmGenEd works with SoVee to present evidence-based pharmacogenomic information to healthcare professionals and the general public. SoVee ([www.scivee.tv](http://www.scivee.tv)) is a YouTube for scientists but much more. The SoVee features allow the author(s) to describe scientific findings using narrative or animated video features. The video content is then integrated with the open access published article. Through SoVee, the audience can simultaneously read and listen to pharmacogenomic information.

New Releases: Coming Soon!

Virtual Community - Pharmacogenomics ...

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Pharmacogenomics Education Program

Pharmacogenomics Education Program

Manager: gmkuo | send a message

Description: Program Description. The field of genomics and its scientific discoveries are developing at a dazzling pace. Pharmacogenomics has a promising potential to increase the response rate of drug therapy and decrease the events of adverse drug reactions. It may help us focus on safe and effective drug management to provide personalized medicine by delivering therapy with the right drug at the right dose to the right patient. Currently, however, pharmacogenomics education materials are not readily available to healthcare professionals. Furthermore, there appears to be a gap between healthcare providers' knowledge and the expectations of patients regarding pharmacogenomics testing. 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 program team at UCSD Skaggs School of Pharmacy and Pharmaceutical Sciences is collaborating with national pharmacy and medical associations (e.g., the American Association of Colleges of Pharmacy, the American College of Clinical Pharmacy, the American Medical Association, the American Society of Health-System Pharmacists, the American Pharmacists Association) to promote the PharmGenEd educational campaign to more than 100,000 pharmacists, physicians, and Healthcare Professionals.

Members

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`<a href="http://www.scivee.tv/r`

The objective of the proposed PharmGenEd program is to increase awareness about current knowledge of the validity and utility of pharmacogenomic tests and the



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username ..... Log in Register Request new password Search SciVee


SCIVEE™  
make your research known

browse upload community

Pharmacogenomic Biomarkers for Prediction of Severe Adverse Drug Reactions

Submitted by: bhuynh  
DOI: 10.4015/10761.01  
Description: Dr. Magnus Ingelman-Sundberg presents his recent paper on "Pharmacogenomic biomarkers for prediction of severe adverse drug reactions" published in the New England Journal of Medicine on Feb 2008.  
Abstract: The accumulating knowledge of human genomic variation is being used for the development of personalized medicine, with the aims of decreasing the number of adverse drug reactions and increasing the efficacy of drug treatment. Considerable pharmacogenomic research has focused on understanding the molecular mechanisms behind adverse drug reactions and finding biomarkers that identify people at risk. Serious adverse drug reactions have been shown to cause or contribute to 6 to 7% of all hospitalizations, a 2-day increase in the average length of hospitalization, and 100,000 deaths annually in the United States — and may, according to some estimates, cost about ...  
Conference: University of California, San Diego  
Rating:   
Upload: Friday, April 10, 2009  
Views: 643

Where are we now?



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## Evidence-Based Recommendations

- CDC
  - Evaluation of Genomic Applications in Practice and Prevention (EGAPP) Working Group
    - Available at: <http://www.egapproviews.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>

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## 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**

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## 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)

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## Acknowledgments

- **UCSD**
  - Principal Investigator
    - Grace M. Kuo, PharmD, MPH
  - Co-Investigators:
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    - Joseph D. Ma, PharmD
    - Palmer Taylor, PhD
    - James R. Halpert, PhD
    - Philip E. Bourne, PhD
    - Theodore Ganiats, MD
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  - Magnus Ingelman-Sundberg, PhD
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  - Karen S. Hudmon, DrPH, MS, RPh
    - Purdue University
- **Assistants**
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  - Jessica Bryan, MPH
  - WeiWei Qin, MS
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