UNC
INSTITUTE FOR PHARMACOGENOMICS AND INDIVIDUALIZED THERAPY

APRNs' Knowledge and Attitudes About Pharmacogenetic Testing

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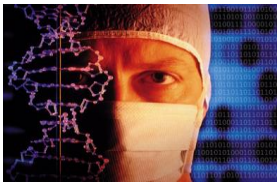
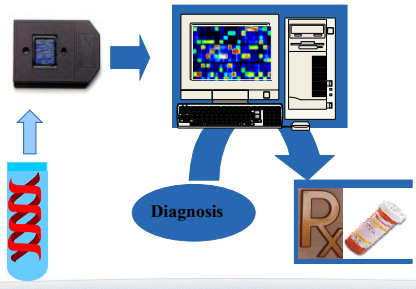
Pharmacogenetic Testing (PGx)

- Will most likely be one of the most profound and earliest influences of the Human Genome Project on clinical practice



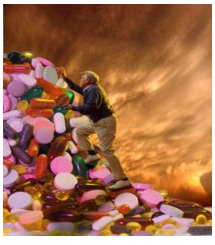
Goal of Pharmacogenetic Testing: Deliver Right Medicine to Right Patient



- Early expectations regarding "amazing benefits" may have been premature
- But, more modest benefits continue to be widely anticipated

Benefits of Personalized or Genotype-Guided Drug Therapy

- Better, safer drugs the first time
- More accurate methods of determining appropriate drug dosages



Other Benefits

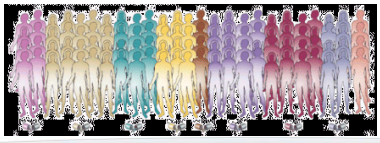
- Better Vaccines
- Decrease in Overall Cost of Health Care
- Improvements in the Drug Discovery and Approval Process

Growing Recognition that…

- Individualized or Genotype-Guided Drug Therapy is an improvement over the current "one size fits all" approach to drug therapy

However,

- *After more than half a century of pharmacogenomic research, the clinical use of pharmacogenomic testing remains uncommon, despite many examples showing that inherited genomic variation causes substantial interindividual differences in drug effects…"* Relling, Altman, Goetz, & Evans (2010)



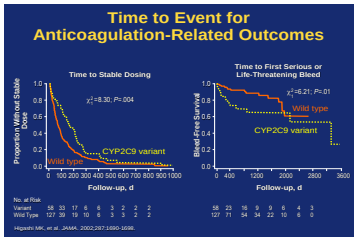
Genetics & Warfarin

- Genetics factors account for 35-40% of the variation in how patients respond to Warfarin.
- In 2007 the FDA approved updated labeling for Warfarin

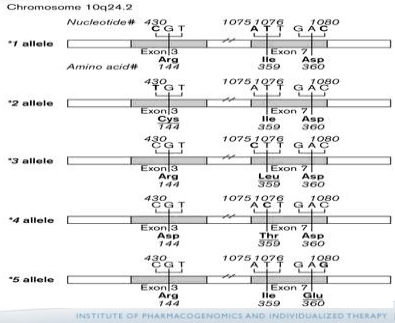
- http://www.aacc.org/publications/cln/2008/feb/Pages/series_0208.aspx

Patients with a CYP2C9 variant

- Take a median of 95 days longer to achieve stable dosing when compared to those with the wild type
- Have a higher risk of acute bleeding complications



CYP2C9 Variants/ Polymorphisms



(*1) wild type

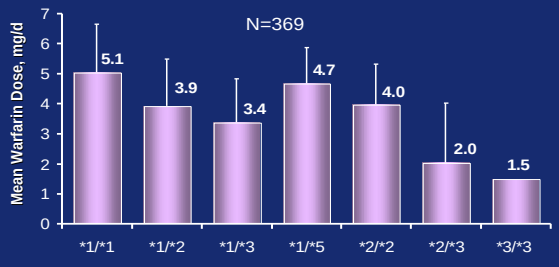
(*2) Arg → Cys codon 144

(*3) Ile → Leu codon 359

(*4) Ile → Thr codon 359

(*5) Asp → Glu codon 360

Cytochrome P450 Genotype and Warfarin Dose



B. Gage et al. *Thromb Haemost.* 2004;91:87-94.

Sample of FDA Approved Drug Labels Containing Genomic Biomarkers Information

Genomic Biomarkers	Drug	Testing
Her2/neu Over-expression	Herceptin (trastuzumab)	Required
*HLA B*5701*	Ziagen (abacavir)	Recommended
CYP2C9 Variants	Coumadin (warfarin)	Recommended
Vitamin K epoxide reductase (VKORC1) Variants	Coumadin (warfarin)	Recommended
CYP2D6 Variants	Prozac (fluoxetine)	Information

Currently

- Little is known about understanding of and attitudes toward pharmacogenetic testing among APRNs and other clinicians.

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Clinicians' Knowledge & Attitudes about Pharmacogenetic Testing

Core Research Project for the UNC Genomics & Society CEER
Funded by NIH: NHGRI Grant Number P50HG004488

CENTER for GENOMICS and SOCIETY at UNC-CHAPEL HILL

Online Survey

- Interdisciplinary group of experts developed an online survey to assess knowledge and attitudes of clinicians about pharmacogenetic testing
  - Initially, included a specific focus on PGx with Warfarin
  - Eventually expanded to include a focus on PGx and Tamoxifen

Over 2200 Respondents

- Pharmacology
  - 753 pharmacists
  - 88 pharmacy students
- Nursing
  - 560 advanced practice nurses
  - 244 registered nurses
  - 35 licensed practical nurses
  - 428 nursing students
- Medicine
  - 4 physicians
  - 9 residents/fellows
  - 48 medical students
  - 1 physicians assistant
- Genetic Counselors
  - 35 genetic counselors
- Other - 35

Purpose of this Presentation

- To examine knowledge and attitudes about pharmacogenetic testing among APRNs

Participants

- 560 APRNs
  - NONPF listserve
  - ONS listserve

NONPF

ONS Oncology Nursing Society

Demographics of Participants

- Highest Level of Education
  - 22% PhD
  - 13% DNP or Other Doctorate
  - 63% MS/MA/MSN
  - 2% BS/BSN
- 52% Educator/Faculty Member
- Years in Practice
  - 54% >20 years
  - 37% 10-20 years
  - 9% <10 years
- Prescriptive Privileges
  - 82% Yes
  - 18% No

Results

- Most participants rated their understanding of genetics as good (28%) or fair (48%)
- Most participants rated their understanding of PGx as fair (44%) or poor (33%)

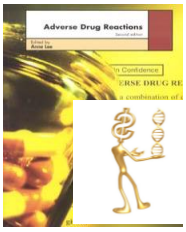
Basic Genetic Questions: True or False?

	Correct
•Humans are over 99% identical at the DNA level.	57%
•Most cells in the human body contain 47 chromosomes.	68%
•Every time the human body produces a sperm or an egg, approximately 3 billion nucleotides (bases) must be copied and packaged so they can be passed along to future offspring.	50%
•The nucleotides (bases) in DNA, always match up the same way - Adenine (A) always pairs with the Cytosine (C) and Guanine (G) always pairs with the Thymine	69%
•A number of genetic conditions, such as sickle cell anemia, are caused by a mutation in a single gene.	76%

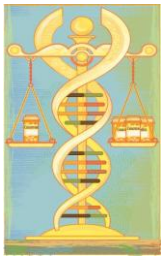
Questions about Pharmacogenetic Testing: True or False?

	Correct
Subtle differences in a person's genome can have a major impact on how the person responds to medications	87%
Genetic determinants of drug response change over a person's lifetime.	33%
Genetic variations can account for as much as 95% of the variability in drug disposition and effects.	58%
The package insert for warfarin includes a warning about altered metabolism in individuals who have specific genetic variants.	44%
Pharmacogenetic diagnostic testing is currently available for most medications	61%

Attitudes: Benefits



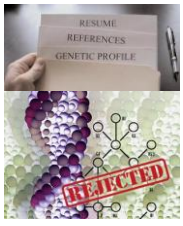
- 65% of the participants thought it was likely that PGx would help decrease the number of adverse drug reactions
- 18% thought PGx would help decrease the cost of new drugs



- 56% thought it was likely that PGx will help decrease the time it takes to find an optimal dose of Warfarin.
- 63% thought it was likely that PGx will help decrease adverse drug reactions to Warfarin

- 66% were comfortable having genetic information used to help determine their patient's initial dose of Warfarin
  - 72% were comfortable having genetic information used to help determine their own initial dose of warfarin

Attitudes: Concerns



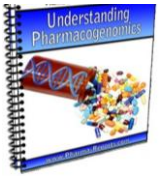
- 47% expressed concern that PGx may result in discrimination by employers and insurance companies
- 41% expressed concern that unauthorized individuals may gain access to PGx information

APRNs and Pharmacogenetic Testing

- **26% would be comfortable interpreting and using the results of pharmacogenetic testing on their own**
- **1% have ordered pharmacogenetic testing before prescribing Warfarin**
- **Reasons for not ordering pharmacogenetic testing for Warfarin**
  - 65% I was not aware this type of testing was available
  - 50% I do not feel confident about how to interpret & apply results
  - 49% I do not know of or have access to a lab that performs this type of testing
  - 39% Clinical guidelines on how to use the results of this type of testing are lacking
  - 31% This type of testing is not covered by my patient's insurance plans
  - 21% Ordering the testing and waiting for results would delay patient's tx
  - 21% I am concerned about patient confidentiality and privacy issues
  - 14% I have not seen convincing evidence of the clinical utility of this testing

Interest in learning more about Pharmacogenetic Testing

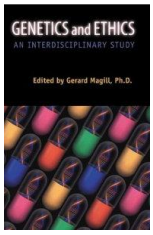
- 96% Yes
- 4% No



- Type of education offerings they would be interested in attending
  (able to chose multiple options)
  - 66% CME/CE Course
  - 56% Web-Based CME/CE Course
  - 38% Seminar or lecture
  - 35% Half-Day Conference
  - 20% All Day Conference 17% Grand Rounds
  - 8% AHEC

Conclusion

- The APRNs who responded to this survey are interested in receiving additional education about pharmacogenetic testing
- Moreover, concerns about ethical and social implications may prevent APRNs from ordering pharmacogentic testing



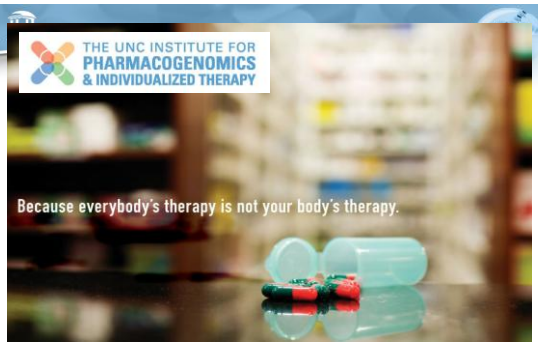
Future of Pharmacogenetic Testing?

- Implementation of pharmacogenetic testing into clinical practice ultimately depends upon patients' and clinicians' acceptance of, and requests for, this type of testing

Therefore,

We Need Your Help

- You and other APRNs will play a critical role in determining whether or not pharmacogenetic testing is successfully integrated into clinical practice.



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