GENETIC TESTING: COMING TO A PHARMACY NEAR YOU

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LEARNING OBJECTIVES

• Discuss specific medications whose effectiveness can be altered by genetics;
• Relate how pharmacogenetics can be used to select the best drug and dose for a patient;
• Discuss the potential use of genetic testing in pharmacies to optimize patient response to medications; and

Discuss the options available to pharmacy owners who wish to provide PGx testing.

ACPE # 0207-0000-16-027-L04-P
ACPE # 0207-0000-16-027-L04-T
Activity Type: Application-based
1.0 contact hours (0.1 CEUs)
IMPORTANCE

• Drug manufactures and the FDA incorporation of pharmacogenomics information
  • Drug development, labeling, approval process

• Accreditation Council for Pharmacy Education (ACPE) “Standards 2016”
  • “Pharmacogenomics/genetics • Genetic basis for disease and individual differences in metabolizing enzymes, transporters, and other biochemicals impacting drug disposition and action that underpin the practice of personalized medicine.”

• Pharmacies are currently providing genetic services

IMPORTANCE

• American Pharmacists Association (APhA)
  • Integrating pharmacogenomics into pharmacy practice via medication therapy management
    • “Pharmacist can serve an integral role in applying pharmacogenomics into clinical practice to improve the quality and safety of health care.”
    • “One avenue…is by integrating it into clinical pharmacy practice through medication therapy management.”

Integrating pharmacogenomics into pharmacy practice via medication therapy management.

IMPORTANCE

• American Pharmacists Association (APhA)
  • Integrating pharmacogenomics into pharmacy practice via medication therapy management
    • “Moving forward, the pharmacy profession must define a process for the application of pharmacogenomic data into pharmacy clinical practice that is aligned with MTM service delivery, develop a viable business model for these practices that encourages and promotes the use of the clinical expertise of pharmacists working in collaboration with other health care providers and labs, and encourage and direct the development of technology solutions that support the pharmacist’s role in this emerging field.”

WHY DO WE USE THE DRUGS WE USE TODAY?

• Fact: Many diseases have multiple drugs that would work to cure or control the disease

• Question: Why do we pick one drug over another?
WHY DO WE USE THE DRUGS WE USE TODAY?

SESSION CLINICAL TRIAL

- Candy Experiment
PHARMACOGENOMICS

• “Pharmacology”: the science of drugs
• “Genomics”: the study of genes and their functions
• Pharmacogenomics: the study of how genes affect an individual’s response to drugs

PHARMACOGENETICS VS. PHARMACOGENOMICS

• Pharmacogenetics – the study of a gene involved in response to a drug
• Pharmacogenomics – the study of all genes in the genome involved in response to a drug

PharmGKB. Questions about pharmacogenomics: What is the difference between pharmacogenetics and pharmacogenomics? Available at: www.pharmgkb.org/resources/faqs.jsp.
RELATING PHARMACOGENOMICS TO PHARMACY PRACTICE

• Pharmacogenomics is currently being used to:
  • Understand an individual’s metabolism
  • Determine drug responses and adverse reactions
  • Development of new drugs

• Improves safety and efficacy of drugs

FUNDAMENTALS OF PHARMACOGENOMICS

• Terminology:
  • “Loss-of-function”
  • “Reduced-function”
  • “Normal-function”
  • “Gain-of-function”

http://www.clker.com/clipart-homozygous-allele-loci.html
FUNDAMENTALS OF PHARMACOGENOMICS

- Ultrarapid metabolizer (UM)
- Extensive metabolizer (EM)
  - “Normal”
- Intermediate metabolizer (IM)
- Poor metabolizer (PM)

MEDICATIONS AFFECTED BY GENETICS

- Abacavir
- Allopurinol
- Amitriptyline
- Azathioprine
- Carbamazepine
- Citalopram
- Clopidogrel
- Codeine
- Doxepin
- Escitalopram
- Fluorouracil
- Fluvoxamine
- Mercaptopurine
- Nortriptyline
- Paroxetine
- Phenytoin
- Ribavirin
- Sertraline
- Simvastatin
- Tacrolimus
- Warfarin
CLOPIDOGREL

• Statistics:
  • Up to 30% of patients on clopidogrel carry a genetic variance:
    • 15% of Caucasians
    • 15% of African Americans
    • 29-35% of Asians
    • 7-16% of Hispanics
  • 2010 BBW: Up to 14% of Americans are poor metabolizers and the FDA recommends alternative treatment

<table>
<thead>
<tr>
<th>Likely phenotype</th>
<th>Genotypes</th>
<th>Examples of diplotypes</th>
<th>Implications for clopidogrel</th>
<th>Therapeutic recommendations</th>
<th>Classification of recommendations</th>
</tr>
</thead>
<tbody>
<tr>
<td>Ultrarapid metabolizer (UM) (~6-30% of patients)</td>
<td>An individual carrying two increased activity alleles (*1'7') or one functional allele (*1') plus one increased activity allele (*17')</td>
<td>*1'17, *17'17</td>
<td>Increased platelet inhibition; decreased residual platelet aggregation ¹</td>
<td>Clopidogrel - label recommended dosage and administration</td>
<td>Strong</td>
</tr>
<tr>
<td>Extensive metabolizer (EM) (~35-50% of patients)</td>
<td>An individual carrying two functional (*1') alleles</td>
<td>*1'1</td>
<td>Normal platelet inhibition; normal residual platelet aggregation</td>
<td>Clopidogrel - label recommended dosage and administration</td>
<td>Strong</td>
</tr>
<tr>
<td>Intermediate metabolizer (IM) (~18-45% of patients)</td>
<td>An individual carrying one functional allele (*1') plus one loss-of-function allele (*2'-8') or one loss-of-function allele (*2'-8') plus one increased activity allele (*17')²</td>
<td>*1'2, *1'3, *2'17</td>
<td>Reduced platelet inhibition; increased residual platelet aggregation; increased risk for adverse cardiovascular events</td>
<td>Alternative antiplatelet therapy (if no contraindication); e.g., prasugrel, ticagrelor</td>
<td>Moderate</td>
</tr>
<tr>
<td>Poor metabolizer (PM) (~2-10% of patients)</td>
<td>An individual carrying two loss-of-function alleles (*2'-8')</td>
<td>*2'2, *2'3, *3'3</td>
<td>Significantly reduced platelet inhibition; increased residual platelet aggregation; increased risk for adverse cardiovascular events</td>
<td>Alternative antiplatelet therapy (if no contraindication); e.g., prasugrel, ticagrelor</td>
<td>Strong</td>
</tr>
</tbody>
</table>

**CLOPIDOGREL**

**Considering antiplatelet therapy with clopidogrel for ACS/PCI**

![CYP2C19 genotype results](http://depts.washington.edu/hemeweb/seminars-conferences/Fitzmaurice%20Slides%2012-13-13.pdf)


CODEINE

• Non-functional CYP2D6: no analgesic effect

• Ultrarapid CYP2D6: morphine toxicity

• 2013 BBW: advises against the use of codeine-containing products in children who are ultrarapid metabolizers
<table>
<thead>
<tr>
<th>Likely phenotype.</th>
<th>Activity score</th>
<th>Genotypes</th>
<th>Examples of diplotype</th>
<th>Implications for codeine metabolism</th>
<th>Recommendations for codeine therapy</th>
<th>Classification of recommendation for codeine therapy</th>
<th>Considerations for alternative opioids</th>
</tr>
</thead>
<tbody>
<tr>
<td>Ultrarapid</td>
<td>&gt;2.0</td>
<td>An individual carrying more than two copies of functional alleles</td>
<td>*1°/*1°N, *1°/*2°N</td>
<td>Increased formation of morphine following codeine administration, leading to higher risk of toxicity</td>
<td>Avoid codeine use due to potential for toxicity</td>
<td>Strong</td>
<td>Alternatives that are not affected by this CYP2D6 phenotype include morphine and non-opioid analgesics. Tramadol, and to a lesser extent hydrocodone and oxycodone, are not good alternatives because these metabolism is affected by CYP2D6 activity.</td>
</tr>
<tr>
<td>Extensive</td>
<td>1.0-2.0°</td>
<td>An individual carrying two alleles encoding full or reduced function or one full function allele together with either one nonfunctional or one reduced function allele</td>
<td>*1°/*1°, *1°/*2°, *2°/*2°, *1°/*4°, *2°/*4°, *2°/*10°, *1°/*10°</td>
<td>Normal morphine formation</td>
<td>Use label recommended age- or weight-specific dosing.</td>
<td>Strong</td>
<td></td>
</tr>
<tr>
<td>Intermediate</td>
<td>0.5-0.9°</td>
<td>An individual carrying one reduced and one nonfunctional allele</td>
<td>*4°/*10°, *5°/*41</td>
<td>Reduced morphine formation</td>
<td>Use label recommended age- or weight-specific dosing. If no response, consider alternative analgesics such as morphine</td>
<td>Moderate</td>
<td>Monitor tramadol use for response.</td>
</tr>
<tr>
<td>Poor</td>
<td>0</td>
<td>An individual carrying no functional alleles</td>
<td>*4°/*4°, *5°/*4°, *4°/*6</td>
<td>Greatly reduced morphine formation following codeine administration, leading to insufficient pain relief</td>
<td>Avoid codeine use due to lack of efficacy.</td>
<td>Strong</td>
<td>Alternatives that are not affected by this CYP2D6 phenotype include morphine and non-opioid analgesics. Tramadol, and to a lesser extent hydrocodone and oxycodone, are not good alternatives because their metabolism is affected by CYP2D6 activity; these agents should be avoided.</td>
</tr>
</tbody>
</table>

**WARFARIN**

http://www.mdpi.com/2072-6651/2/11/2584/htm
WARFARIN

Table 1  Recommended daily warfarin doses (mg/day) to achieve a therapeutic INR based on CYP2C9 and VKORC1 genotype using the warfarin product insert approved by the US Food and Drug Administration

<table>
<thead>
<tr>
<th>VKORC1: -1639G&gt;A</th>
<th>CYP2C9*1/*1</th>
<th>CYP2C9*1/*2</th>
<th>CYP2C9*1/*3</th>
<th>CYP2C9*2/*2</th>
<th>CYP2C9*2/*3</th>
<th>CYP2C9*3/*3</th>
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<tr>
<td>GG</td>
<td>5-7</td>
<td>5-7</td>
<td>3-4</td>
<td>3-4</td>
<td>3-4</td>
<td>0.5-2</td>
</tr>
<tr>
<td>GA</td>
<td>5-7</td>
<td>3-4</td>
<td>3-4</td>
<td>3-4</td>
<td>0.5-2</td>
<td>0.5-2</td>
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<tr>
<td>AA</td>
<td>3-4</td>
<td>3-4</td>
<td>0.5-2</td>
<td>0.5-2</td>
<td>0.5-2</td>
<td>0.5-2</td>
</tr>
</tbody>
</table>

Reproduced from updated warfarin (Coumadin) product label.

RESOURCE

PharmGKB is a comprehensive resource that curates knowledge about the impact of genetic variation on drug response for clinicians and researchers.

What is the PharmGKB?
Find out how we go from extraction of gene-drug relationships in the literature to implementation of pharmacogenomics in the clinic...

Clinically-Relevant PGx
- Well-known PGx associations
- Clinically relevant PGx summaries
- PGx dose titration guidelines

PGx-Based Drug Dosing Guidelines
- See at CPIC guidelines
- Recent guidelines
- VISTA/fantastic

PGx Research
- VIP: Very important PGx gene summaries
- PharmGKB pathways
- Annotate SNPs to gene

Latest News
- The Wall Street Journal Discusses PGx
- Integrating PGx throughout the Drug Development Process
- GTC genetic testing and the role of primary care providers
Clinical Pharmacogenetics Implementation Consortium (CPIC) guideline information for clopidogrel and CYP2C19

Last updated 01/27/2016

Specify a genotype for specific annotations

Pick alleles for CYP2C19 *1

Implications
Normal platelet inhibition, normal residual platelet aggregation

Metabolizer Status
Extensive metabolizer (EM) (~35-50% of patients)

Phenotype (Genotype)
An individual carrying two functional (*) alleles

Recommendations
Clopidogrel - label recommended dosage and administration

Classification of Recommendation
Strong

Summary
The CPIC Dosing Guideline for clopidogrel recommends an alternative antiplatelet therapy (e.g., prasugrel, ticagrelor) for CYP2C19 poor or intermediate metabolizers if there is no contraindication.
QUESTION #1

- Which of the following medications is/are **NOT** affected by a patient’s genetic makeup?

A.) warfarin  
B.) clopidogrel  
C.) codeine  
D.) simvastatin  
E.) All the above are affected by a patient’s genetic makeup

QUESTION #2

- RS in a 64 yof who will be initiated on warfarin due to atrial fibrillation. RS’s doctor knows about the variability with warfarin dosing and recognizes there is a genetic component. RS’s doctor learned from RS that she had genetic testing done previously and you have a copy of the results. RS’s doctor decides to call you for a consultation to discuss her results and asks you for a recommendation. After you review RS’s genetic results, you see her CYP2C9 is *2/*3 and her VKORC1 is AA. Which of the following would you recommend to the doctor as the most appropriate starting dose for RS?

A.) 10 mg  
B.) 5 mg  
C.) 3 mg  
D.) 1 mg
POTENTIAL FOR GENETIC TESTING IN PHARMACIES

• Have you ever had any genetic testing done for a health condition?

![Previous Genetic Testing (n=98)]

• On a scale of 1 to 5, how interested would you be in genetic testing?

![Mean Interest in Genetic Testing]
POTENTIAL FOR GENETIC TESTING IN PHARMACIES

Factors Increasing Interest in Paying for Pharmacogenetics Service

- If results affect quality of life
- If results improve effectiveness
- If results affect health/treatment of
- If results affect length of life
- If results decrease the risk of side
- If results decrease healthcare/insurance

Number of Participants

GROUP PARTICIPATION

- What potential do you see for genetic testing in your community?
GENETIC TESTING IN PHARMACIES

- Genelex
- Rxight
- MaxusRx
- PGxOne
- Transgenomic
- HarmonYX**

*Not an inclusive list*
GENELEX

- Available tests:

<table>
<thead>
<tr>
<th>PANELS:</th>
<th>INDIVIDUAL TESTS:</th>
</tr>
</thead>
<tbody>
<tr>
<td>Polypharmacy (useful for all specialties):</td>
<td>STAT Clotidkgrel (Plaxi) CYP2C19*</td>
</tr>
<tr>
<td>YouScript Polypharmacy (CYP2D6, CYP2C9, CYP2C19, CYP3A4, and CYP3A5)</td>
<td>ADRA2A</td>
</tr>
<tr>
<td>YouScript Polypharmacy Basic (CYP2D6, CYP2C9, CYP2C19)</td>
<td>COMT</td>
</tr>
<tr>
<td>Cardiology:</td>
<td>CYP1A2</td>
</tr>
<tr>
<td>YouScript Cardio (CYP2D6, CYP2C9, CYP2C19, CYP3A4, CYP3A5, VKORC1, F2/Factor II, F5/Factor V Leiden, MTHFR, and SLC01B1)</td>
<td>CYP2B6</td>
</tr>
<tr>
<td>Thrombosis (F2/Factor II, F5/Factor V Leiden, MTHFR)</td>
<td>CYP2C9</td>
</tr>
<tr>
<td>Warfarin (Coumadin) (CYP2C9, VKORC1)</td>
<td>CYP2C19</td>
</tr>
<tr>
<td>Psychiatric:</td>
<td>INR (6.28B)</td>
</tr>
<tr>
<td>YouScript Psychotropic (CYP2D6, CYP2C9, CYP1A2, HTR2A, and SLC6A4/5-HTT)</td>
<td>CYP2D6</td>
</tr>
<tr>
<td>YouScript Psychotropic Plus (CYP2D6, CYP2C9, CYP3A4, ADRA2A, CYP1A2, CYP2B6, COMT, GRIK4, HTR2A, HTR2C, MTHFR, and SLC6A4/5-HTT)</td>
<td>CYP2D6</td>
</tr>
<tr>
<td>YouScript ADHD (CYP2D6, COMT, ADRA2A)</td>
<td>CYP2D6</td>
</tr>
<tr>
<td>Pain:</td>
<td>CYP3A4</td>
</tr>
<tr>
<td>YouScript Analgesic (CYP2D6, CYP2C9, CYP3A4, CYP3A5, CYP2B6, COMT, and OPRM1)</td>
<td>CYP3A5</td>
</tr>
<tr>
<td></td>
<td>DPYD (DPD)</td>
</tr>
<tr>
<td></td>
<td>SLC6A4 (5-HTT)</td>
</tr>
<tr>
<td></td>
<td>F2 (Factor II)</td>
</tr>
<tr>
<td></td>
<td>SLC6A1 B1</td>
</tr>
<tr>
<td></td>
<td>F5 (Factor V) Leiden</td>
</tr>
<tr>
<td></td>
<td>TMT</td>
</tr>
<tr>
<td></td>
<td>GRIK4</td>
</tr>
<tr>
<td></td>
<td>HLA-A*31:01</td>
</tr>
<tr>
<td></td>
<td>VKORC1</td>
</tr>
</tbody>
</table>

- Payment:
  - Cash
  - Insurance
    - Private
      - Adverse drug reactions
      - Lack of response
      - Pain management
      - Cancer management
      - Management of “many co-morbid conditions”
  - Medicare – varies by plan
Pharmacogenetic Laboratory Test Report

Patient: John L. Doe  Date of Birth: 05/01/1994  Collected: 07/22/2015
Account: Johnson Primary Care  Lab #: 300134  Received: 07/22/2015
Referer: Mary Johnson, MD  Sample: Buccal Swab  Reported: 07/22/2015

RESULTS

<table>
<thead>
<tr>
<th>Test</th>
<th>Phenotype</th>
<th>Genotype</th>
</tr>
</thead>
<tbody>
<tr>
<td>CYP2D6</td>
<td>Intermediate Metabolizer</td>
<td>*1/*4</td>
</tr>
<tr>
<td>CYP2C19</td>
<td>Poor Metabolizer</td>
<td>*2/*2</td>
</tr>
<tr>
<td>CYP2C9</td>
<td>Normal Metabolizer</td>
<td>*1/*1</td>
</tr>
<tr>
<td>CYP3A4</td>
<td>Normal Metabolizer</td>
<td>*1/*1</td>
</tr>
<tr>
<td>CYP3A5</td>
<td>Non-Expresser</td>
<td>*3/*3</td>
</tr>
</tbody>
</table>

LABORATORY RESULTS INTERPRETATION

CYP2D6 Intermediate Metabolizers have decreased CYP2D6 activity. For CYP2D6-metabolized drugs, consider prescribign decreased doses to prevent adverse effects. For prodrugs that require activation by CYP2D6, consider prescribing increased doses or alternative treatment for optimal therapeutic response.

CYP2C19 Poor Metabolizers have greatly decreased CYP2C19 activity. For CYP2C19-metabolized drugs, consider prescribign decreased doses or alternative treatment to prevent adverse effects. For prodrugs that require activation by CYP2C19, consider prescribing increased doses or alternative treatment for optimal therapeutic response.

CYP2C9 Normal Metabolizers have normal (extensive) CYP2C9 activity. Prescribe CYP2C9-metabolized drugs at standard doses.

CYP3A4 Normal Metabolizers have normal (extensive) CYP3A4 activity. Prescribe CYP3A4-metabolized drugs at standard doses. Patients may still have significant variation in CYP3A4 activity due to various patient and environmental factors, despite having a CYP3A4 normal metabolizer phenotype.

CYP3A5 Non-Expressers (also known as Poor Metabolizers) have greatly decreased CYP3A5 activity. The majority of the population (60-80%) have this genotype, except for people of African origin. Prescribe CYP3A5-metabolized drugs at standard doses.

Personalized Prescribing Report

CUMULATIVE DRUG-DRUG AND DRUG-GENE INTERACTIONS

DIRE GENE INTERACTIONS

<table>
<thead>
<tr>
<th>Impact</th>
<th>Medication</th>
<th>Genotyp(s)</th>
<th>Effects &amp; Management</th>
</tr>
</thead>
<tbody>
<tr>
<td>Liplus</td>
<td>CYP2D6 Intermediate Metabolizer</td>
<td>*1/*4</td>
<td>Prescribe alternative or adjust dose of Liplus</td>
</tr>
<tr>
<td>Liplus</td>
<td>CYP3A4 Normal Metabolizer</td>
<td>*1/*1</td>
<td>Prescribe alternative or adjust dose of Liplus</td>
</tr>
<tr>
<td>Liplus</td>
<td>CYP3A5 Non-Expresser</td>
<td>*3/*3</td>
<td>Prescribe alternative or adjust dose of Liplus</td>
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<tbody>
<tr>
<td>Leucovorin</td>
<td>CYP2D6 Intermediate Metabolizer</td>
<td>*1/*4</td>
<td>Prescribe alternative or adjust dose of Leucovorin</td>
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<tr>
<td>Leucovorin</td>
<td>CYP3A4 Normal Metabolizer</td>
<td>*1/*1</td>
<td>Prescribe alternative or adjust dose of Leucovorin</td>
</tr>
<tr>
<td>Leucovorin</td>
<td>CYP3A5 Non-Expresser</td>
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<tbody>
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<td>*1/*4</td>
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<td>Paclitaxel</td>
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<td>Prescribe alternative or adjust dose of Paclitaxel</td>
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<td>Prescribe alternative or adjust dose of Prednisolone</td>
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<td>CYP3A4 Normal Metabolizer</td>
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<td>Prescribe alternative or adjust dose of Prednisolone</td>
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<td>Prednisolone</td>
<td>CYP3A5 Non-Expresser</td>
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<td>Paroxetine</td>
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<td>Prescribe alternative or adjust dose of Propranolol</td>
</tr>
<tr>
<td>Propranolol</td>
<td>CYP3A5 Non-Expresser</td>
<td>*3/*3</td>
<td>Prescribe alternative or adjust dose of Propranolol</td>
</tr>
</tbody>
</table>
RXIGHT

• Available testing
  • One comprehensive panel
  • Results cover 200+ Rx and OTCs
    • Cardiology
    • Neurology
    • Oncology
    • Pain
    • Etc.
QUESTION #3

• Which of the following statements is false?

A.) HarmonYX is not accepting tests at this time
B.) Rxight can bill a patient’s insurance for genetic testing
C.) Genelex allows patients to pay cash for genetic testing
D.) All of the above are true
MARKETING

• Internal

• Community

• Physician offices

MARKETING

• Internal
  • Create a display (include a sign!)
  • Bag stuffers
  • Initiate conversations
    • Use real life examples
MARKETING

- Community
  - Add it to your website, Facebook, Twitter, etc.
  - Community outreach events
  - Contact reporters/press releases
MARKETING

• Physician offices
• Doctor detailing
  • Make list of top 10-15 doctors in your area
  • Drop off information about the service and your pharmacy
• Initiate conversations
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- Harmonyx
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GENETIC TESTING: COMING TO A PHARMACY NEAR YOU

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