B2 Implementing Precision Medicine into Primary Care

Nicole Scovis, PharmD, BCPS, BCACP

Sandra Leal, PharmD, MPH, FAPhA
Learning Objectives

At the completion of this activity, participants should be able to:

• Define precision medicine and the role in patient care.

• Differentiate between precision medicine and evidence-based medicine.

• Identify the impact of precision medicine on patient-related outcomes in a primary care setting.

• Discuss the future of implementing precision medicine in primary care.
Continuing Pharmacy Education Credit

• Login to AMCP Learn at http://amcplearn.org/
• Follow instructions available on amcpmeetings.org
• Have available:
  – NABP e-profile ID
  – Birth month and birthday
  – Session-specific attendance code
• Complete and submit session evaluation no later than November 7, 2016 (5:00 PM ET)
• Information in CPE Monitor approximately 72 hours after submission completion
Financial Relationship Disclosures

Nicole Scovis, PharmD, BCPS, BCACP & Sandra Leal, PharmD, MPH, FAPhA report having no financial relationships with any commercial interests during the past 12 months.
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This session will be monitored for any antitrust violations and will be stopped by the session monitor if any such violation occurs.

Please refer the final program or www.amcp.org/antitrust for more information.
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Faculty

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SinfoniaRx,
Tucson, AZ
B2.LQ1: What is the role of precision medicine in primary care?

a. Can be used when patients are stable on therapy
b. Is useful in determining initial therapy
c. There is not a role for precision medicine yet
d. Not sure what precision medicine is
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Basics of Precision Medicine

Disease Treatment & Prevention

Genes
Environment
Lifestyle

Pharmacogenomics

- Medication
- Genes
- Science of

Pharmaco-gen-omics
Pharmacogenomics

- Poor Metabolizer
- Intermediate Metabolizer
- Extensive Metabolizer
- Ultra-rapid Metabolizer

Toxicity → Treatment Failure
Pharmacogenomics in the PMI

The *right* drug for the *right* patient at the *right* dose

https://www.whitehouse.gov/precision-medicine
Costs of Drug-related Problems

- 1.5 Million people injured yearly
- $3.5 Billion in costs
- 700,000 emergency room visits yearly
- 120,000 hospitalizations
Patient Impact

Percent of the time where drug therapy is ineffective

- Arthritis
- Diabetes
- Asthma
- Depression

Therapeutic Areas

- Pain
- Hypertension
- Dyslipidemia
- Antiplatelet
- Arrhythmia
- Depression
- Anxiety
- Bipolar
- Schizophrenia
- ADHD
- Migraine
- Seizure
B2.LQ2: What is the highest level of evidence?

a. Systematic review
b. Case-control
c. Randomized controlled trial
d. Cohort
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Levels of Evidence

SYSTEMATIC REVIEWS

RCT

COHORT

CASE-CONTROL

CASE SERIES

OPINION, ANECDOTAL

Evidence-based Medicine (EBM)
Evidence-based Care

- Guidelines
- Drug approvals
- Outcomes focus
Precision Medicine in Care

- Patient-centered care
- CPIC guidelines
- FDA labeling
Drug Response

- Conditions
- Diet
- Exercise
- Weight
- Smoking
- Alcohol
- Drug interactions
- Genetics
- Age

Evidence-based Medicine
B2.LQ3: What do you think is the most challenging aspect of implementing pharmacogenomic testing into clinics?

a. Translation of genetic information into clinical action
b. Clinician and patient resistance or ethical concerns
c. Cost
d. Integration into medication record
e. All of the above
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Coverage

• Medicare
• Local Determination by Medicare Administrative Contractors (MACs)
Coverage

• PGx testing is considered investigational from the viewpoint of most health insurers, thus, most payers still do not provide coverage for it
• Review prior authorization criteria
Implementation Issue
Considerations

• Workflow integration
• Acceptance
• Documentation
• Clinical impact
Implementing Pharmacogenomics at Your Institutions

- Identify required components of the service
  - Stakeholders: Institutional leaders, Service leader, Clinicians, Laboratory specialists, PGx test results interpreter, IT/informatics staff, Educators (for physicians and patients)
  - Facilities: CAP/CLIA-certified laboratory environment, PGx testing platforms/kits, Electronic health record
  - Funding

- Develop service workflow and educate all stakeholders

- Approve from administration

- Develop lab test
  - Select platform
  - Design alerts
  - Validation/verification
  - Design algorithm
  - Decide upon reporting mechanism for results
  - Test CDS

- Education to providers on available PGx testing

- Optimize the workflow

- Expand the service
  - Monitor and collect KPI and outcomes data
  - Launch the service
Implementation in Primary Care

- **Screening**
  - Person responsible: pharmacist
  - Criteria: 2+ meds, insurance coverage

- **Testing**
  - Person responsible: medical assistant/nurse

- **Interpreting results**
  - Person responsible: pharmacist

- **Intervention**
  - Physician intervention
  - Pharmacist visit
Implementation in Primary Care

• Ad-hoc testing
  – Patients with side effects
  – Failure to respond
  – Physician request
### Implementation in Primary Care

<table>
<thead>
<tr>
<th>Neuropsychiatric</th>
<th>Cardiology</th>
</tr>
</thead>
<tbody>
<tr>
<td>Depression</td>
<td>Hypertension</td>
</tr>
<tr>
<td>Anxiety</td>
<td>Dyslipidemia</td>
</tr>
<tr>
<td>Bipolar</td>
<td>Arrhythmia</td>
</tr>
<tr>
<td>Schizophrenia</td>
<td>Anticoagulation</td>
</tr>
<tr>
<td>ADHD</td>
<td>Antiplatelet</td>
</tr>
<tr>
<td>Pain</td>
<td></td>
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<tr>
<td>Migraine</td>
<td></td>
</tr>
<tr>
<td>Seizure</td>
<td></td>
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</tbody>
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Impact on Patients

- 62 year old female with diabetes
- 10-year risk of an ASCVD event of 14%
- Failed “several” statins in the past
- Resistant to trying another

<table>
<thead>
<tr>
<th>No genetic interaction</th>
<th>Genetic interaction</th>
</tr>
</thead>
<tbody>
<tr>
<td>Atorvastatin</td>
<td>Simvastatin</td>
</tr>
<tr>
<td>Rosuvastatin</td>
<td>Fluvastatin</td>
</tr>
<tr>
<td>Lovastatin</td>
<td></td>
</tr>
</tbody>
</table>
Impact on Patients

- 30 year old female with depression
- Suicidal ideation
- Initiated on paroxetine 2 months prior
- No improvement in symptoms

<table>
<thead>
<tr>
<th>No genetic interaction</th>
<th>Genetic interaction</th>
</tr>
</thead>
<tbody>
<tr>
<td>Venlafaxine</td>
<td>Paroxetine</td>
</tr>
<tr>
<td>Mirtazapine</td>
<td>Citalopram</td>
</tr>
<tr>
<td>Vilazodone</td>
<td>Sertraline</td>
</tr>
<tr>
<td>Duloxetine</td>
<td></td>
</tr>
</tbody>
</table>
Impact on Patients

- 48 year old male with chronic pain
- Multiple emergency department visits for pain

<table>
<thead>
<tr>
<th>No genetic interaction</th>
<th>Genetic interaction</th>
</tr>
</thead>
<tbody>
<tr>
<td>Ibuprofen</td>
<td>Oxycodone</td>
</tr>
<tr>
<td>Meloxicam</td>
<td>Tramadol</td>
</tr>
<tr>
<td>Naproxen</td>
<td>Fentanyl</td>
</tr>
<tr>
<td>Buprenorphine</td>
<td>Morphine</td>
</tr>
<tr>
<td></td>
<td>Hydrocodone</td>
</tr>
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Performance Indicators

- **Service Process**
  - Turnaround time of results

- **Service Utilization**
  - Consult volume (per day, week, month)
  - Consult volume by medical service
  - Number of tests ordered per number of patients on medication

- **Satisfaction**
  - Overall satisfaction by patient and/or provider
  - Acceptance rate of recommendations
Outcome Indicators

- Number of adverse drug events (ADEs) due to PGx drug
- Use of less/more expensive alternative drugs
- Time to therapeutic PGx drug
- Specific test improvement like PHQ scores before and after PGx drug change
Potential Comparison Groups

- Comparison between patients with accepted PGx recommendations vs. non-use of PGx recommendations
- Comparison between PGx service patients vs. historical controls
Primary Care Data

- Medication name
- Recommendation
- Medication changes
- Outcomes
  - Blood pressure
  - Heart rate
  - Cholesterol
  - Pain scale
  - PHQ-9
  - GAD-7
Preliminary Results

- 216 tested
- 70 after pharmacist embedded

Therapeutic Area Tested

- 70% Cardio
- 17% Neuro/psych
- 13% Thrombophilia
**Recommendations**

**Drugs**

- **SSRI/SNRIs**: 52%
- **Other BH**: 13%
- **Opioids**: 13%
- **NSAIDs**: 13%
- **BZDs**: 3%
- **Anticoagulants**: 3%
- **Muscle relaxants**: 3%

*Academy of Managed Care Pharmacy*
Recommendations

Types of recommendations

- No change: 5%
- Change due to safety: 5%
- Change due to efficacy: 8%
- Monitor for ADE: 32%
- Monitor for efficacy: 18%
- Discontinuation: 24%
- Other: 8%
B2.LQ4: Which of the following is not an ethical issue raised by pharmacogenomic testing?

a. Widen disparities in access to testing
b. Increasing pharmacogenomics training in professional curriculums for health care providers
c. Genetic testing in newborn, infants and children
d. Protecting the confidentiality of stored genetic information
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**What’s Coming**

**WHAT IS IT?**

**Precision medicine** is a groundbreaking approach to disease prevention and treatment based on people’s individual differences in environment, genes and lifestyle.

The Precision Medicine Initiative® Cohort Program will lay the foundation for using this approach in clinical practice.

**WHAT ARE THE GOALS?**

Engage a group of 1 million or more U.S. research participants who will share biological samples, genetic data and diet/lifestyle information, all linked to their electronic health records. This data will allow researchers to develop more precise treatments for many diseases and conditions.

Pioneer a new model of research that emphasizes engaged research participants, responsible data sharing and privacy protection.

Research based on the cohort data will:

- Lay scientific foundation for precision medicine
- Help identify new ways to treat and prevent disease
- Test whether mobile devices, such as phones and tablets, can encourage healthy behaviors
- Help develop the right drug for the right person at the right dose

**WHY NOW?**

The time is right because:

- We have a greater understanding of human genes
- We have the tools to track health information and use large databases
- People are more engaged in healthcare and research
- Research technologies have improved

Follow the Initiative’s progress and be one of the first to join this landmark effort.

Growing Interest

- PharmGKB: Pharmacogenomics Knowledgebase
- Workgroups, whitepapers
- Training
- Accessibility, affordability, scale
Predictions

- Pharmacogenomics will become more mainstream in practice and training
- Testing for newborns, infants and children will become more mainstream
- Pharma industry will need to adjust to new market
- Medicine and payers will implement processes for genetic patient profiling
- Specialty pharmacy will continue to grow
Post-test
B2.LQ1.b: What is the role of precision medicine in primary care?

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Questions?
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