Moving Beyond Single Gene-drug Pairs in Clinical Pharmacogenetics Testing

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Disclosure

- None
Update on Molecular Genetics
Testing by NGS
Molecular Genetics Testing for Inherited Diseases at ARUP Laboratories

- Molecular Genetics
  - Fragment Analysis
  - Sanger
  - NGS NIPT
  - NGS Non-NIPT
Indications and Molecular Testing

Strategies

- **Recognizable phenotypes or specific indications (confirm diagnosis, familial mutations, career screening, PGx etc.)**
  - Targeted genotyping
    - MLPA
  - Single gene by Sanger or NGS (single-gene or panels, +/- del/dup)
  - Whole exome or whole genome, +/- CNV by array or NGS

- **Less recognizable or specific phenotypes**

- **Undiagnosed inherited conditions**
Why NGS?

• Multiplex: many genes/or all known hotspots tested in a single test
• Cost effective
  – for disorders with numerous causative genes (such as skeletal dysplasias, retinitis pigmentosa) the total cost of determining the underlying genetic cause by traditional molecular testing such as Sanger sequencing routinely > $10k
  – reduced cost for both patients and clinical laboratory
• Quicker to reach molecular diagnosis
• Flexible applications: single gene tests (e.g., BCR-ABL1 testing) -> panels -> whole exome sequencing -> whole genome sequencing
ARUP Genomics/NGS Overview

- NGS-based testing has been available at ARUP for 5+ years
- One of the first reference labs offering clinical NGS testing
- Current offerings include NGS testing for ~25 germline disease panels including whole exome sequencing and rapid Mendelian gene sequencing panel), 1 solid tumor hotspot test and 2 hematologic malignancy tests.
- All LDTs
- Developed overtime using different chemistries across various sequencing platforms (the Illumina MiSeq, NextSeq 500, HiSeq 2500, and IonTorrent PGM), followed by individualized bioinformatics pipelines
Current State-of-art NGS Testing at ARUP

Standardization-Scalability-Automation

Single chemistry, single sequencing platform
- Panel 1
- Panel 2
- Panel 3
- Panel 4, 5, 6...n

Single bioinformatics pipeline, cloud based

Standardized analysis and interpretation
Full Automation

ARUP’s Genomics Laboratory
Moving Beyond Single Gene-drug Pairs in Clinical Pharmacogenetics Testing
Outline

- WHY pharmacogenomics (PGx)?
- WHAT to test?
  - How PGx variants were discovered?
  - Single-gene PGx testing
  - Panel-based PGx testing
- Update on ARUP’s clinical PGx practice
Percentage of 1013 RIGHT subjects among groups carrying actionable PGx variants in 0 to 5 of the PGx genes (*CYP2C9*, *CYP2C19*, *CYP2D6*, *VKORC1*, and *SLCO1B1*)

Medications: one size does not fit all!

- ~30% people take at least one medication within a 30-day period
- Most medications cause adverse drug response events (ADEs)
- Many drugs don’t work well
- ~7 million ADEs-related ER visit and cost ~$4 billion in US annually
- Genetics play a role in individual variations in response to many drugs with narrow therapeutic indexes
Utilities of Clinical PGx Testing

• Patient selection
  – Identify people at high risk of a serious adverse drug reaction
  – Identify people not likely to respond
  – Identify people that are likely to be sensitive or resistant to a drug, and require non-standard dosing

• Optimize therapy
  – Optimize dosing to a specific drug for maximum efficacy and minimum toxicity
  – Avoid toxicity and drug-drug interaction
  – Reduce medical expense
"Variability is the law of life, and as no two faces are the same, so no two bodies are alike, and no two individuals react alike and behave alike under the abnormal conditions which we know as disease."

Sir William Osler (1903)
Cost Effectiveness of PGx

**Legend**
- **Cost-saving/dominant**: PGx was more effective at lower cost
- **Cost-effective**: PGx was more effective at acceptable additional cost
- **Undetermined**: Reviewed study did not reach unequivocal conclusion
- **Not cost-effective**: PGx was not cost-effective
- **Not estimated**: Study did not report enough detail to estimate impact on conclusion

**Pie Chart**
- Cost-saving: 22 (50%)
- Cost-effective: 11 (25%)
- Undetermined: 3 (7%)
- Not cost-effective: 5 (11%)
- Not estimated: 3 (7%)

**Bar Chart**
- Number of economic evaluations for different drugs.
Pharmacokinetics
The principles of ADME

Absorption
How will it get in?

Medicine

Metabolism
How is it broken down?
Liver

Distribution
Where will it go?
Transporte

Excretion
Drug Metabolizing Enzymes: Highly Polymorphic

TPMT and Thiopurines

TPMT and Thiopurines

Weinshilboum and Sladek, 1980
Evolution of PGx Research: Discovery Phase of PGx
# Table of Pharmacogenomic Biomarkers in Drug Labeling

Pharmacogenomics can play an important role in identifying responders and non-responders to medications, avoiding adverse events, and optimizing drug dose. Drug labeling may contain information on genomic biomarkers and can describe:

- Drug exposure and clinical response variability
- Risk for adverse events
- Genotype-specific dosing
- Mechanisms of drug action
- Polymorphic drug target and disposition genes

The table below lists FDA-approved drugs with pharmacogenomic information in their labeling. The labeling for some, but not all, of the products includes specific actions to be taken based on the biomarker information. Biomarkers in the table include are not limited to germline or somatic gene variants, functional deficiencies, expression changes, and chromosomal abnormalities.

The table does not include non-human genetic biomarkers (e.g., viral or bacterial) i.e., microbial variants that influence sensitivity to anti-infectives; biomarkers that are used solely for diagnostic purposes unless they are linked to drug activity or used to identify a specific subset in whom prescribing information differs (e.g., for allergic diseases). Therapeutic areas do not necessarily reflect the FDA review division.

Pharmacogenomic information can appear in different sections of the labeling. Relevant sections of the labeling with such information are noted in the last column of the table. For more information on the relevance of pharmacogenomic information in various parts of drug labeling (e.g., Indications and Usage, Dosage and Administration, Boxed Warning, etc.), please refer to the appropriate labeling guide. For information on the FDA's initiative to improve prescription drug labeling, visit the [FDA/CDER Learn website](http://www.fda.gov/Drugs/DrugSafety/ReviewandApprovalofNewDrugsandBiologics/ucm206888.htm).

## Pharmacogenomic Biomarkers in Drug Labeling

<table>
<thead>
<tr>
<th>Drug</th>
<th>Therapeutic Area</th>
<th>HUGO Symbol</th>
<th>Referenced Subgroup</th>
<th>Labeling Sections</th>
</tr>
</thead>
<tbody>
<tr>
<td>Abacavir</td>
<td>Infectious Diseases</td>
<td>HLA-B</td>
<td>HLA-B*5701 allele carriers</td>
<td>Boxed Warning, Contraindications, Warnings and Precautions, Patient Counseling Information</td>
</tr>
</tbody>
</table>

FDA Drug Label Information

- **NSAID (flurbiprofen) tablet**

  _Poor Metabolizers of CYP2C9 Substrates:_ In patients who are known or suspected to be poor CYP2C9 metabolizers based on genotype or previous history/experience with other CYP2C9 substrates (such as warfarin and phenytoin), reduce the dose of flurbiprofen to avoid abnormally high plasma levels due to reduced metabolic clearance.

- **Coumadin (warfarin sodium) tablets**

  **Dosing Recommendations with Consideration of Genotype**

  Table 1 displays three ranges of expected maintenance COUMADIN doses observed in subgroups of patients having different combinations of CYP2C9 and VKORC1 gene variants [see Clinical Pharmacology (12.5)]. If the patient’s CYP2C9 and/or VKORC1 genotype are known, consider these ranges in choosing the initial dose. Patients with CYP2C9 *1/*3, *2/*2, *2/*3, and *3/*3 may require more prolonged time (>2 to 4 weeks) to achieve maximum INR effect for a given dosage regimen than patients without these CYP variants.

  **Table 1:** Three Ranges of Expected Maintenance COUMADIN Daily Doses Based on CYP2C9 and VKORC1 Genotypes

<table>
<thead>
<tr>
<th>VKORC1</th>
<th>CYP2C9</th>
</tr>
</thead>
<tbody>
<tr>
<td></td>
<td>*1/*1</td>
</tr>
<tr>
<td>GG</td>
<td>5-7 mg</td>
</tr>
<tr>
<td>AG</td>
<td>5-7 mg</td>
</tr>
<tr>
<td>AA</td>
<td>3-4 mg</td>
</tr>
</tbody>
</table>

  †Ranges are derived from multiple published clinical studies. VKORC1-1639G>A (rs9923231) variant is used in this table. Other co-inherited VKORC1 variants may also be important determinants of warfarin dose.
Single-gene PGx Testing

- Many guidelines are drug-gene pair based
  - Clinical Pharmacogenetics Implementation Consortium (CPIC), the Royal Dutch Association for the Advancement of Pharmacy – Pharmacogenetics Working Group (DPWG), the Canadian Pharmacogenomics Network for Drug Safety (CPNDS) etc.

- FDA drug label information

- Examples:
  - *TPMT* and 6-Mercaptopurine
  - *UGT1A1* and Irinotecan
  - *HLA-B*5701 and Abacavir
  - *CYP2D6* and Codeine
  - *CYP2D6* and Tamoxifen
  - *CYP2C19* and Clopidogrel

- Most LDTs using targeted genotyping platform
Applications of Clinical PGx testing

- Psychiatry: 14%
- Oncology: 32%
- Infectious diseases: 13%
- Neurology: 7%
- Cardiology: 6%
- Anesthesiology
- Cardiology
- Dental
- Dermatology
- Endocrinology
- Gastroenterology
- Gynecology
- Hematology
- Inborn errors of metabolism
- Infectious diseases
- Neurology
- Psychiatry
- Pulmonary
Panel-based PGX Testing

• Products of many genes in multiple pathways involved
• Patients are or will be taking multiple drugs – maximize the test utilities
• Drug response is a final outcome of many factors, e.g., genetic and non-genetic
• Multiplex genotyping/sequencing: streamlined wet-lab process
• Increased complexity of interpretation and reporting
Citalopram/Escitalopram SSRIs

Citalopram Biotransformation

Citalopram → Monodesmethylcitalopram → Didesmethylcitalopram

Plasma S-CT GWAS

\[ rs1074145 \quad P = 4.1 \times 10^{-9} \]

Plasma S-DDCT GWAS

\[ rs1065852 \quad P = 2.0 \times 10^{-16} \]
Citalopram and Warfarin Pathways

https://www.pharmgkb.org/pathway/PA164713429
Types of PGx Panels

• Single-drug and multiple genes, or pathway-based
  • Warfarin sensitivity testing (CYP2C9, VKORC1, +/- CYP4F2)

• Pan-PGx panels (CYPs: CYP2D6, CYP2C9, CYP3A5, CYP3A4, CYP2C8 etc.)

• A group of medications and multi-gene or application-based, with or without proprietary algorithm for interpretation
  • With or without proprietary algorithm for interpretation (GeneDose™, YouScript®, RightMed™ by ONEOME™, GeneSight® via Assurex Health etc.)
  • Some tools integrate genetics with patient’s other information, e.g., clinical and demographic
  • Provides clinical decision support for physicians/patients
Pros and Cons of Multi-gene PGx Testing

• Evidences of positive outcomes
  – Improved antidepressant efficacy (2.5-fold greater rate of remission of MDD with testing. Singh et al, 2015)
  – Reduced pharmacy costs ($1035.60 saving over 1 yr in total medication cost in tested psychiatric patients. Winner et al, 2015)
  – Reduced rates of hospitalization (9.8% with testing vs.16.5% without testing in patients ≥ 65 yr. Brixner et al, 2015)
  – Improved adherence with therapy

• Are more genes better?
Contents of PGx Panels: Genes

• In a review of 22 proprietary algorithms for clinical validity, there were 46 genes included (Bousman, Lancet Psychiatry, 2016)
  – 25 (53%) were associated with supporting evidence graded by the PharmGKB database as preliminary or low
  – 9 (20%) were associated with high levels of evidence: CYP2D6, CYP2C19 and HLA-B
  – All algorithms include CYP2D6 and CYP2C19; most also include CYP2C9 and CYP3A4/5

• 39.1% of patients ≥65 receive at least one drug metabolized by CYP2D6, CYP2C19 and/or CYP2C9 (Kuch et al, Health Informatics, 2016)

• Most tools/products are lacking support from randomized clinical trials, and no studies completely accessed the effectiveness of all genes tested
WARNING LETTER
Inova Genomics Laboratory
MARC-CMS 577422 – 04/04/2019

Your firm markets on its website the MediMap tests as genetic tests for predicting medication response, reducing negative side effects from certain medications, discovering the right drug and right dose for a patient, and avoiding trial-and-error prescribing by healthcare providers by testing patient receptivity to drugs that treat specific conditions. For example, your firm markets the MediMap Plus as providing insights into how a patient will respond to a variety of drugs including those used for anesthesia, cancers, infections, attention-deficit hyperactivity disorder, depression, anxiety, and diabetes. The MediMap Baby is marketed for testing newborns to analyze genes that influence response to 24 medications and provide guidance in prescribing safer and more effective medications. In addition, your website indicates that test reports generated by your MediMap tests provide “actionable and informational guidance” and that “Healthcare providers can use these results confidently in making treatment decisions.”

FDA is concerned that the clinical validity[1] of your MediMap tests has not been established for their intended uses. Specifically, we are unaware of data establishing the relationships between the genotypes assessed by your tests and your assertions regarding drug response for multiple drugs. For example, the relationship between CYP2C19 genotype and drug response to escitalopram and sertraline is not established and this relationship is not described in the FDA-approved labeling for these drugs.

Given these issues, these tests pose significant public health concerns as inaccurate test results could impact the decision-making of healthcare providers and patients in ways that are seriously detrimental to patient health. Healthcare providers may make inappropriate treatment decisions based on these test results, including inappropriate dosing adjustments, prescribing an ineffective therapy, and not prescribing a therapy that could benefit the patient. Such inappropriate treatments could lead to immediate serious health consequences for the

Effective June 3, 2019, we will no longer offer the GeneSight Analgesic and GeneSight ADHD tests. We will complete tests that are in process, but starting today, you will no longer be able to place new orders for GeneSight Analgesic or GeneSight ADHD.

Why take this step? As the number of available pharmacogenomics tests increases dramatically, we believe it is important for clinicians to utilize PGx tests that have demonstrated efficacy and safety in clinical studies. The science for GeneSight ADHD and GeneSight Analgesic does not currently meet this standard. As a result, we will no longer offer these products. We will instead focus on helping clinicians improve the treatment of depression with GeneSight Psychotropic, which has been studied extensively in multiple clinical trials.

We have compiled a FAQ document about the discontinuation of the GeneSight ADHD and GeneSight Analgesic tests which you can access on the www.mygenesight.com portal.

Inova Decides to End PGx Test Offerings in Response to FDA Warning Letter
Apr 15, 2019 | staff reporter
NEW YORK (GenomeWeb) – Inova Health System has decided to completely stop performing its suite of pharmacogenetic tests in response to a US Food and Drug Administration warning letter.
### Contents of PGx Panels: Variants

No two clinical PGx assays tested the same variants and/or haplotypes

<table>
<thead>
<tr>
<th>Assay (sample sets tested)</th>
<th>Affymetrix DMET (tier 1)</th>
<th>GenMark eSensor (tier 1)</th>
<th>Luminex xTAG (tier 1)</th>
<th>LifeTech Taqman laboratory-developed tests (tiers 1 and 2)</th>
<th>Agena Bioscience iPLEX ADME PGx Pro (tiers 1 and 2)</th>
<th>Agena Bioscience CYP2D6, CYP2C9, VKORC1, CYP2C19, UGT1A1 (tiers 1 and 2)</th>
</tr>
</thead>
</table>

Pratt VM, et al., 2016 (GeT-RM)
Guidelines for Clinical PGx Laboratories: Allele/Variant Selection

The Journal of Molecular Diagnostics
Available online 8 May 2019
In Press, Accepted Manuscript

Special Article
Recommendations for Clinical CYP2C9 Genotyping Allele Selection: A Joint Recommendation of the Association for Molecular Pathology and College of American Pathologists

ARUP PGx Testing Overview

TaqMan™ probes for 59 PGx targets on the OpenArray™ platform and QuantStudio™:
* Custom design with very high sensitivity and specificity
* High throughput = Can run up to 576 samples per instrument per day!
* Cost effective (vs. NGS)

* In use at ARUP Laboratories for 3.5 years

15 PGx genes, 59 SNPs:
- CYP2C9 (7 SNPs)
- CYP2C19 (10 SNPs)
- CYP2C (1 SNP)
- CYYP2D6 (17 SNPs)
- CYP3A4 (1 SNP)
- CYP3A5 (3 SNPs)
- CYP4F2 (1 SNP)
- DYPD (3 SNPs)
- HCP5 (1 SNP)
- IL28B rs60 (1 SNP)
- IL28B rs17 (1 SNP)
- ITPA (2 SNPs)
- OPRM1 (1 SNP)
- SLCO1B1 (3 SNPs)
- TPMT (4 SNPs)
- VKORC1 (3 SNPs)
• **Expanded content**
  - 59 targets → 120 targets
  - 15 genes → 35 genes (single-gene or panel-based testing)

• **Automation** (DNA extraction, normalization, and PCR setup)

• **Various specimen types** (EDTA blood, OraCollect swabs, OraGene saliva)

• **Enhanced report** and clinical decision support tools
ARUP Employee Health Clinic Outcome Project

- Goal: to demonstrate improvements in clinical outcomes and costs of both pharmacy and clinic/hospital visits, based on PGx information for targeted patients

- Based on pharmacy claims data for ~5000 patients, 83% of actionable drug-gene interactions relate to the CYPs.

- Implementing the CYP panel: drug-gene interactions are of the highest levels of evidence and CDS through CLS is established

- Inviting ~400 patients to obtain PGx testing, with enrolment began in May, 2019

- University of Utah studies also planned.

<table>
<thead>
<tr>
<th>Drug</th>
<th>% of Patients</th>
<th>Primary gene</th>
</tr>
</thead>
<tbody>
<tr>
<td>Hydrocodone</td>
<td>9.15%</td>
<td>CYP2D6</td>
</tr>
<tr>
<td>Omeprazole</td>
<td>8.31%</td>
<td>CYP2C19</td>
</tr>
<tr>
<td>Ondansetron</td>
<td>7.55%</td>
<td>CYP2D6</td>
</tr>
<tr>
<td>Bupropion</td>
<td>6.49%</td>
<td>ANKK1</td>
</tr>
<tr>
<td>Sertraline</td>
<td>6.02%</td>
<td>CYP2C19</td>
</tr>
<tr>
<td>Oxycodone</td>
<td>6.00%</td>
<td>CYP2D6</td>
</tr>
<tr>
<td>Citalopram</td>
<td>5.06%</td>
<td>CYP2C19</td>
</tr>
<tr>
<td>Metformin</td>
<td>4.92%</td>
<td>ATM</td>
</tr>
<tr>
<td>Fluoxetine</td>
<td>4.86%</td>
<td>CYP2D6</td>
</tr>
<tr>
<td>Trazodone</td>
<td>4.14%</td>
<td>CYP3A4</td>
</tr>
<tr>
<td>Atorvastatin</td>
<td>3.98%</td>
<td>CYP3A4</td>
</tr>
<tr>
<td>Codeine</td>
<td>3.72%</td>
<td>CYP2D6</td>
</tr>
<tr>
<td>Escitalopram</td>
<td>3.30%</td>
<td>CYP2C19</td>
</tr>
<tr>
<td>Amphetamine</td>
<td>3.08%</td>
<td>COMT</td>
</tr>
<tr>
<td>Tramadol</td>
<td>2.96%</td>
<td>CYP2D6</td>
</tr>
<tr>
<td>Diclofenac</td>
<td>2.74%</td>
<td>CYP2C9</td>
</tr>
<tr>
<td>Clonazepam</td>
<td>2.16%</td>
<td>CYP3A4</td>
</tr>
<tr>
<td>Alprazolam</td>
<td>2.16%</td>
<td>CYP3A4</td>
</tr>
<tr>
<td>Duloxetine</td>
<td>2.14%</td>
<td>CYP2D6</td>
</tr>
<tr>
<td>Simvastatin</td>
<td>1.94%</td>
<td>SLC01B1</td>
</tr>
<tr>
<td>Meloxicam</td>
<td>1.80%</td>
<td>CYP2C9</td>
</tr>
<tr>
<td>Quetiapine</td>
<td>1.70%</td>
<td>CYP3A4</td>
</tr>
<tr>
<td>Methylphenidate</td>
<td>1.60%</td>
<td>MTHFR</td>
</tr>
<tr>
<td>Buspirone</td>
<td>1.46%</td>
<td>CYP3A4</td>
</tr>
<tr>
<td>Tamsulosin</td>
<td>1.30%</td>
<td>CYP2D6</td>
</tr>
<tr>
<td>Amitriptyline</td>
<td>1.30%</td>
<td>CYP2D6</td>
</tr>
<tr>
<td>Venlafaxine</td>
<td>1.28%</td>
<td>CYP2D6</td>
</tr>
<tr>
<td>Propranolol</td>
<td>1.28%</td>
<td>CYP2D6</td>
</tr>
<tr>
<td>Ketoconazole</td>
<td>1.28%</td>
<td>CYP3A4</td>
</tr>
<tr>
<td>Diazepam</td>
<td>1.12%</td>
<td>CYP2C19</td>
</tr>
<tr>
<td>Metoprolol</td>
<td>1.04%</td>
<td>CYP2D6</td>
</tr>
<tr>
<td>Pantoprazole</td>
<td>0.92%</td>
<td>CYP2C19</td>
</tr>
</tbody>
</table>
Cytochrome P450 Genotyping Report

**Patient Results**

<table>
<thead>
<tr>
<th>Gene</th>
<th>Genotype</th>
<th>Gene</th>
<th>Genotype</th>
</tr>
</thead>
<tbody>
<tr>
<td>CYP2C19</td>
<td>*2/2</td>
<td>CYP2D6</td>
<td>*2A/9</td>
</tr>
<tr>
<td>CYP2C8</td>
<td>*1C/1C</td>
<td>CYP3A4</td>
<td>Neg/Neg</td>
</tr>
<tr>
<td>CYP2C9</td>
<td>Neg/Neg</td>
<td>CYP3A5</td>
<td>*3/3</td>
</tr>
</tbody>
</table>

Interpretation: Two copies of the CYP2C8*1C allele were detected. The functional status of this allele is not clear, but most likely this result predicts a phenotype between the normal and intermediate metabolizer phenotype. If metabolic phenotypes may confer sensitivity to drug-drug interactions with CYP2C8 substrates. Depending on metabolic pathway for the drug(s) of interest, the impact on dosing may depend on phenotype predictions for CYP2C8. Interpretation: No impaired CYP2C9 variants were detected, which is consistent with functional "1 allele" status for normal intermediate activity. This is typical in CYP2C9*3 homozygous states.

**Medication Summary**

- **Therapeutic Class**: Standard Precautions, Caution / Info, Consider Alternatives
  - **Anti-ADHD Agents**: Atomoxetine
  - **Antiarrhythmics**: Flecaïnine, Propafenone
  - **Anticoagulants**: Atenoacumol
  - **Anticonvulsants**: Phenytoïne, Clobazam
  - **Antidepressants**: Amimiptryline, Clomipramine, Desipramine, Donepezil, Dextropropranolol

**Legend**
- Typical response is expected
- Change recommended
- Response is uncertain
- Consider alternative therapy

**Clinical Evidence Level**
- Strong
- Moderate
- Emerging

**Medication Report Details (by therapeutic class)**

- **Anti-ADHD Agents**
  - **Atomoxetine (Strattera)**
    - FDA drug label: Actionable PGx
    - **CYP2D6**: Extensive metabolizer. One allele showing normal activity and one showing decreased activity.
    - Typical response is expected; no additional therapeutic recommendations.

- **Antiarrhythmics**
  - **Flecaïnine (Tambocor)**
    - FDA drug label: Not established for PGx
    - **CYP2D6**: Extensive metabolizer. One allele showing normal activity and one showing decreased activity.
    - Typical response is expected; no additional therapeutic recommendations.
**GENEDOSE™ LIVE Tool**


- Cloud-based software tool
- Incorporates both genetic and non-genetic risk factors, lifestyle factors, drug-drug interactions, Beers criteria, etc.
- Includes >35,000 drug products
- Mitigates risk of adverse drug reactions
Considerations for Selecting/Utilizing PGx Panels

• Understand the types and limitations of PGx panels
  – Application-based or pan PGX panels?
  – Genotypes ≠ phenotypes, e.g., due to undetected variants, drug-drug, drug-gene interactions
  – Contents of PGx: more genes ≠ better; variants need to be evaluated

• Performance and workflow of the testing, e.g., platform(s) and technical performance

• Who is offering the PGx testing? ‘Apply guidelines when appropriate: CPIC vs. AMP; tend to be based on single gene or small groups of genes – drug pairs

• Testing results should be interpreted by clinicians/pharmacists

• Testing results should be utilized together with patients’ other clinical information
Acknowledgements

• Dr. Gwen McMillin: Medical Director of Pharmacogenetics and Toxicology

• Dr. Hunter Best: Medical Director of Molecular Genetics and Genomics; Scientific Director, NGS and Biocomputing

• Dr. Whitney Donahue, ARUP PGx RD scientist
• Dr. Roberta Melis, ARUP PGx RD scientist
How Can We Help?

ARUP’s Consultative Services

Your Access to Expertise

Andrew Fletcher, MD, MBA, CPE
Medical Director, Consultative Services
Laboratory stewardship thought leader
Consultative Services program development
Strategic partnerships

Sandy Richman, MBA, C(ASCP)
Director of Consultative Services
Revenue cycle management
Financial analysis
Strategic planning

Andrew Fletcher, MD, MBA, CPE
Medical Director, Consultative Services
Laboratory stewardship thought leader
Consultative Services program development
Strategic partnerships

Sandy Richman, MBA, C(ASCP)
Director of Consultative Services
Revenue cycle management
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Strategic planning

Ladonna Bradley, MT(ASCP)
Sr. Healthcare Consultant
Technical operations
Compliance inspector
Field consultant

Ben Chacon, MBA
Sr. Healthcare Consultant
Laboratory stewardship
Dashboard product management
Project Management

Suzanne Carasso, MBA, MT (ASCP)
Director, Business Solutions Consulting
Strategic business planning
Outreach development
Public speaker and author

Robert Carpenter, MS, MT(ASCP)
Sr. Healthcare Consultant
Pediatric laboratory stewardship
Regulatory and compliance
Laboratory outreach

Suzanne Carasso, MBA, MT (ASCP)
Director, Business Solutions Consulting
Strategic business planning
Outreach development
Public speaker and author

Erik Forsman, BS
Sr. Business Data Analyst
Database development and management
Data analysis
Benchmarking

Suzanne Carasso, MBA, MT (ASCP)
Director, Business Solutions Consulting
Strategic business planning
Outreach development
Public speaker and author

David Shiembob, MBA, C(ASCP)
Sr. Healthcare Consultant
Laboratory operations
Analyzing test ordering patterns
Laboratory stewardship

Jennifer Tincher, MBA, RRT
Sr. Healthcare Consultant
Laboratory stewardship

Suzanne Carasso, MBA, MT (ASCP)
Director, Business Solutions Consulting
Strategic business planning
Outreach development
Public speaker and author

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Outreach development
Public speaker and author

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Database development and management
Data analysis
Contracting

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Satisfaction surveys

Jennifer Tincher, MBA, RRT
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Thank You!

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