The Path to Widespread Pharmacogenomics Implementation

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No financial conflicts of interest to disclose
Overview

• Current state of Pharmacogenomic (PGx) testing

• Challenges in making PGx testing more widespread

• What is needed to expand the use of testing

• Possible models for PGx testing expansion
Pre-emptive vs. reactive testing

- **Reactive** testing is done when needed for a specific drug-gene interaction.

- **Pre-emptive** testing is done before results are needed.
Current state

• Pre-emptive testing is largely for research purposes

PHASER  PG4KDS
PREDICT  eMERGE-PGX
PREPARE
Funding

- **Research-funded testing**
  - Federal grants
  - Foundational funds
  - Philanthropic donations

- Centers for Medicare and Medicaid Services has very limited coverage for *reactive* testing
  - CYP2C19 for clopidogrel
  - CYP2D6 for amitriptyline/nortriptyline

- Almost no coverage with private insurance
Why is funding limited?

• Lack of sufficient evidence of improved outcomes

• Lack of pharmacoeconomic demonstration
  • Those that do exist tend to be for single drug-gene pairs
The evidence of PGx benefits

- PGx testing benefits for drug-gene pairs have been demonstrated in numerous studies.

- These results have led to published guidelines on how to use/interpret test results.

- Guidelines do not specify when testing should occur.
Improving the evidence of benefit

• Need additional studies showing **benefit** and **cost effectiveness** to help make a case for testing being medically necessary

• Pre-emptive testing needs to show evidence of benefit from a **panel** of pharmacogenes
Education

• Relatively new and expanding field that might not have been covered in health sciences education

• Current providers need some level of education to understand when to order and how to interpret results
Standardization

• Standardization in gene panels could help expansion
  • What genes are tested
  • What polymorphisms are tested

• Standards for reporting

• Interoperable systems
Need for usable results

<table>
<thead>
<tr>
<th>Gene</th>
<th>Status</th>
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</thead>
<tbody>
<tr>
<td>CYP2C9</td>
<td>poor</td>
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<tr>
<td>CYP2D6</td>
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<tr>
<td>VKORC1</td>
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</tr>
<tr>
<td>HLAS1502</td>
<td>sensitive</td>
</tr>
</tbody>
</table>
Need for usable results
Need for usable results

*WARNING*

Based on the genotype result, this patient is predicted to be a CYP2D6 ultra-rapid metabolizer. If codeine is prescribed to a CYP2D6 ultra-rapid metabolizer, adverse events are likely. Other pain medications such as morphine, HYDROMORPHINE (e.g.: Dilaudid®) or acetaminophen/hydroCODONE (e.g.: Lortab®, Vicodin®) are recommended. Please consult a clinical pharmacist, review the pharmacogenetics tab or click on the link below for more information.

Alert Action

- Cancel entry
- Continue w/order

Possible protagonists in PGx expansion

- Organizational funding
Possible protagonists in PGx expansion

- Federal reimbursement
Possible protagonists in PGx expansion

• Private health insurance
Possible protagonists in PGx expansion

• Direct-to-consumer (DTC)/patient push

• 23andMe was the first (and currently only) company to have an FDA approved DTC pharmacogenetic test

• DTC testing should not be used for medical decision making and should be confirmed with clinical testing
Summary

• Most PGx testing is currently research-funded

• Increased evidence of benefit and pharmacoeconomic studies are needed

• There are challenges in optimizing the usefulness of PGx data

• A possible shift in funding could drive an increase in PGx testing
Questions?