

The Path to Widespread Pharmacogenomics Implementation

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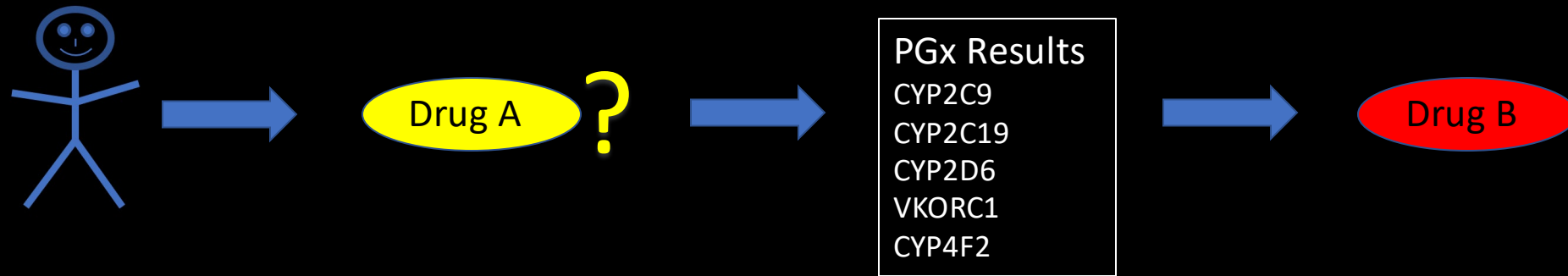
No financial conflicts of interest to disclose

Overview

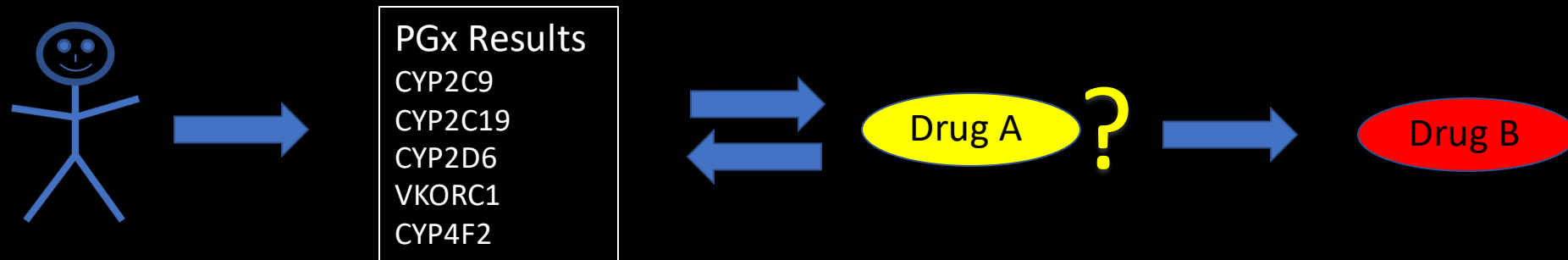
- Current state of Pharmacogenomic (PGx) testing
- Challenges in making PGx testing more widespread
- What is needed to expand the use of testing
- Possible models for PGx testing expansion

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

PDF

CYP2C9	poor
CYP2D6	ultrarapid
VKORC1	sensitive
CYP2C19	normal
G6PD	normal
SLCO1B1	unknown
HLA-B*57:01	sensitive

Need for usable results

The screenshot shows the 'Results Review' interface in Epic. The left sidebar contains navigation options: SnapShot, Summary, Chart Review, Synopsis, Results Review (highlighted), Review Flowsh..., Problem List, History, Inpatient Notes, Demographics, and Medications. The main area is titled 'Results Review (Last refresh: 7/27/2015 9:33:40 AM)'. It includes navigation buttons (Back, Forward), a search box, and a date filter set to '7/23/2015'. A tree view on the left shows 'ALL TOPICS' expanded to 'Results', with 'MOLECULAR GENETICS' selected. The main table displays results for 'MOLECULAR GENETICS' on '7/23/2015' with a count of 1426. The table rows are:

MOLECULAR GENETICS	1
HLA B5701	Negative
HLA B5701 Interpre...	(NOTE) *
HLA B5701 Reviewed By	[REDACTED]

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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, HYDROMORPHONE (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

History Add'l info OK

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?