The Path to Widespread Pharmacogenomics Implementation

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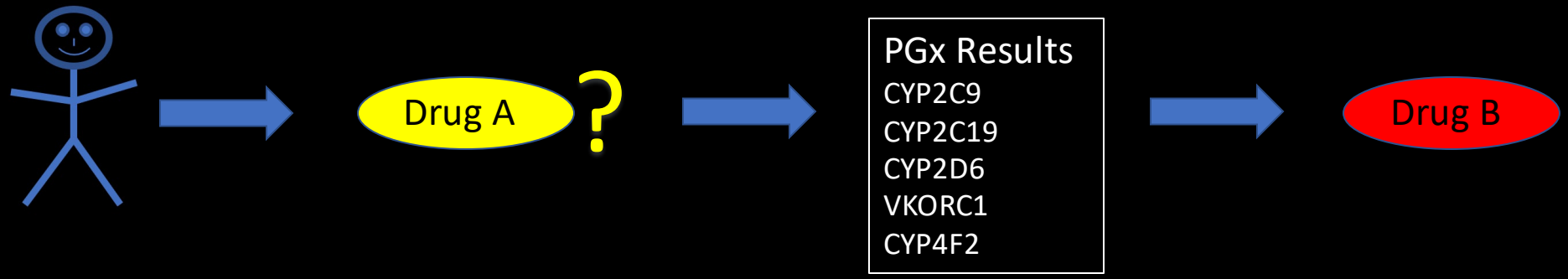
No financial conflicts of interest to disclose

Overview

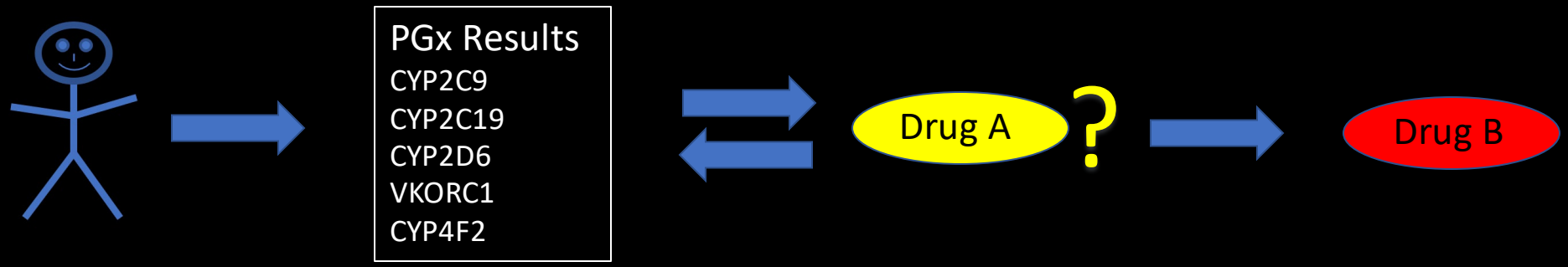
- Current state of Pharmacogenomic (PGx) testing
- Challenges in making PGx testing more widespread
- What is needed to expand the use of testing
- Possible models for PGx testing expansion

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

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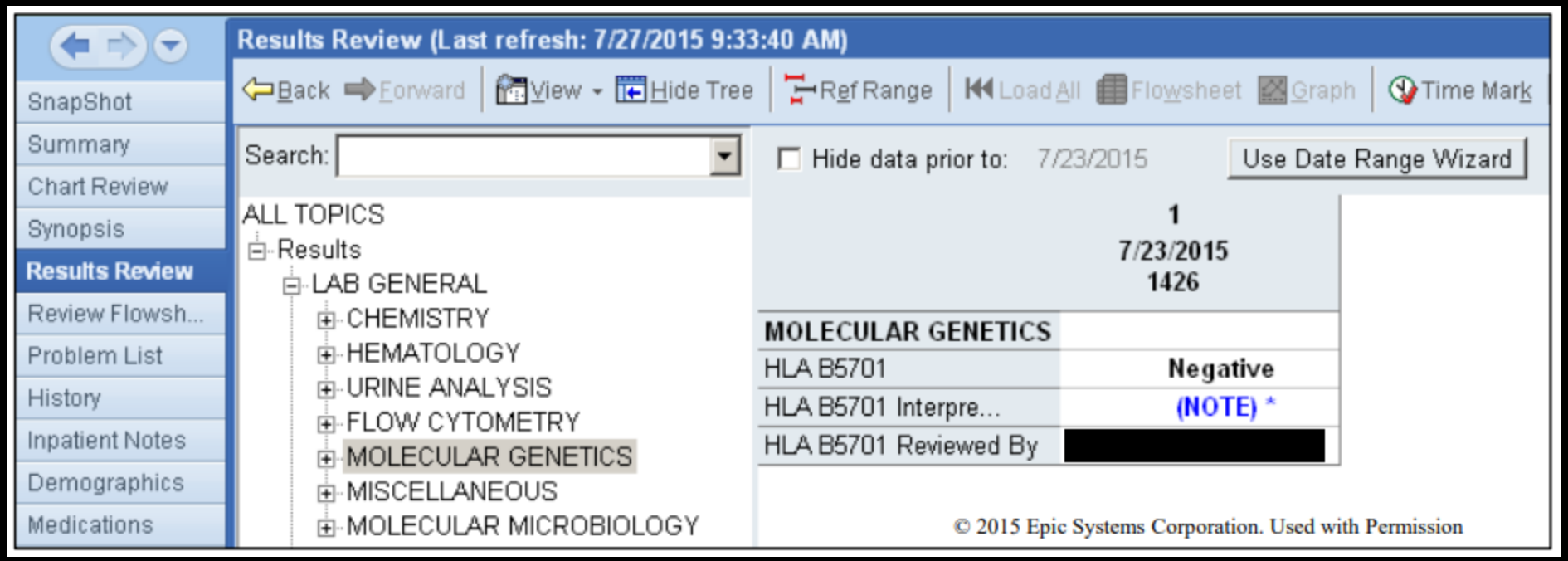
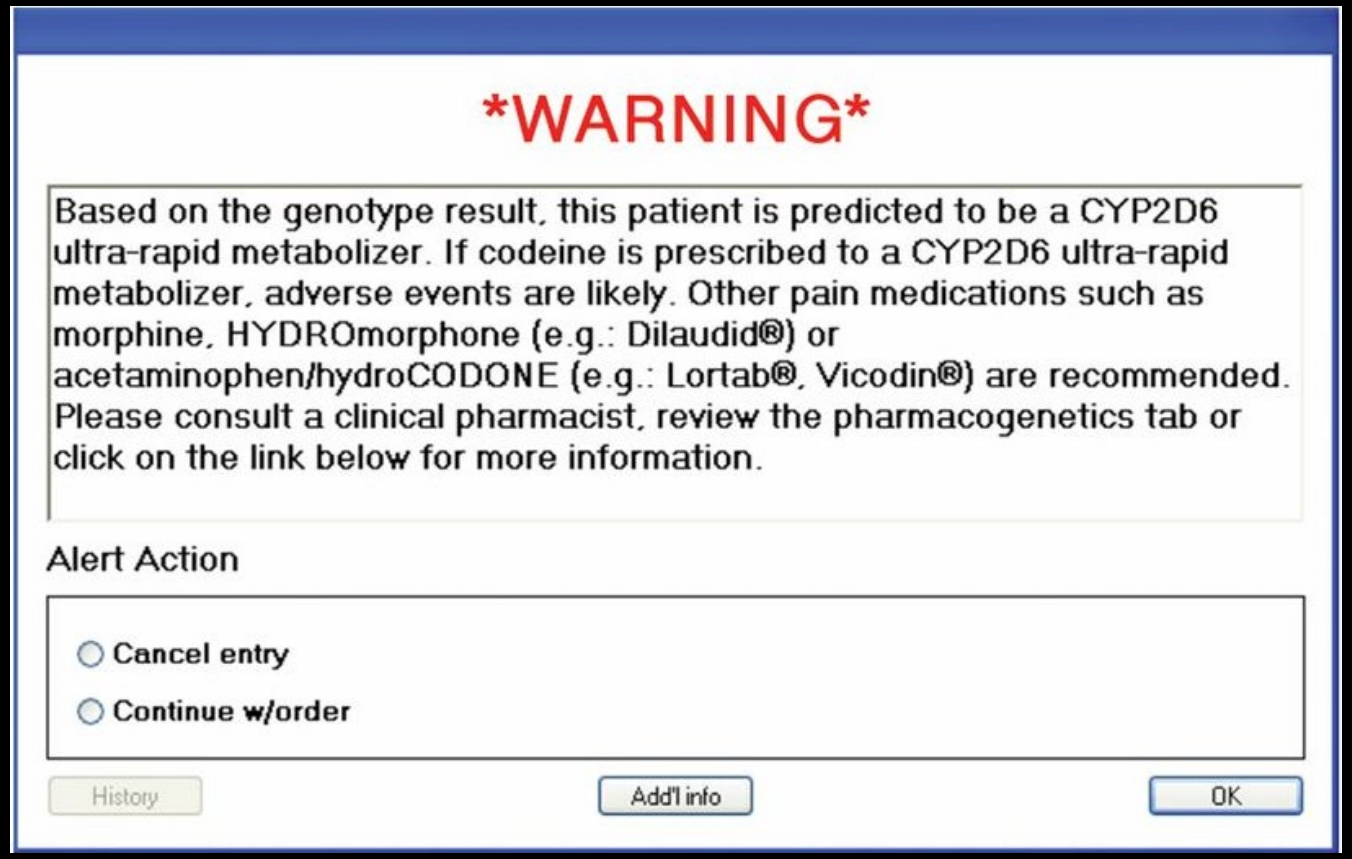


Hicks. Implementation of CPIC Guidelines into Clinical Practice: Cleveland Clinic Experience. 2016
http://cpicpgx.org/wp-content/uploads/2016/02/Hicks-presentation.pdf

Need for usable results



Gammal RS, Crews KR, Haider CE, et al. Pharmacogenetics for Safe Codeine Use in Sickle Cell Disease. Pediatrics. Jul 2016.

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?