



CPIC: Facilitating the implementation of pharmacogenomics through guideline development

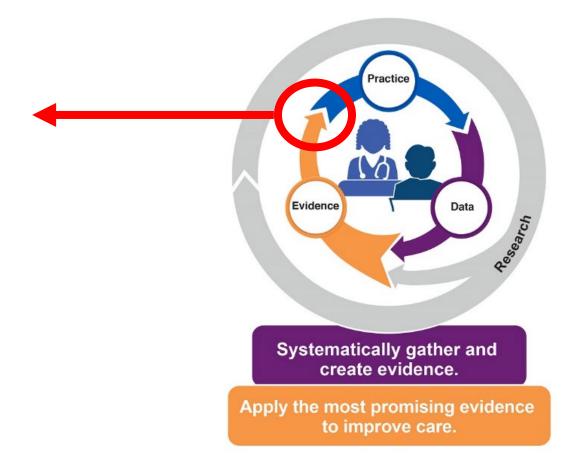
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I do not have any relevant disclosures or conflicts of interest

How do we achieve the potential of PGx?

Learning Health Systems

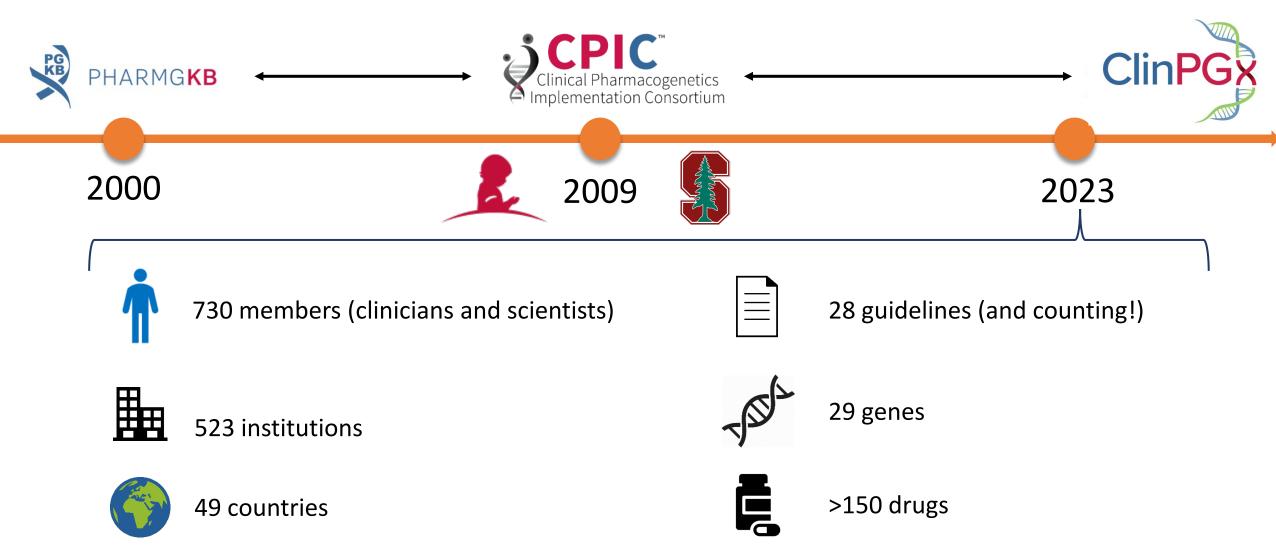
How do we get from the evidence to clinical practice?







CPIC was formed in 2009 to provide freely available, evidence-based, and updated PGx clinical practice guidelines



CPIC guidelines provide recommendations for what to do if test result in hand; not to discuss the merits of doing the test

CPIC is a global organization



www.cpicpgx.org





What is CPIC?

The <u>Clinical Pharmacogenetics Implementation Consortium (CPIC®)</u> is an international consortium of individual volunteers and a small dedicated staff who are interested in facilitating use of pharmacogenetic tests for patient care.

One barrier to implementation of pharmacogenetic testing in the clinic is the difficulty in translating genetic laboratory test results into actionable prescribing decisions for affected drugs.

CPIC's goal is to address this barrier to clinical implementation of pharmacogenetic tests by creating, curating, and posting freely available, peer-reviewed, evidence-based, updatable, and detailed gene/drug clinical practice guidelines (click here for all CPIC publications). CPIC guidelines follow standardized formats, include systematic grading of evidence and clinical recommendations, use standardized terminology, are peer-reviewed, and are published in a leading journal (in partnership with Clinical Pharmacology and Therapeutics) with simultaneous posting to cpicpgx.org, where they are regularly updated.

CPIC started as a shared project between <u>PharmGKB</u> and the <u>Pharmacogenomics Research Network (PGRN)</u> in 2009. CPIC guidelines are indexed in <u>PubMed</u> as clinical guidelines, <u>endorsed</u> by <u>ASHP</u> and <u>ASCPT</u>, and referenced in <u>ClinGen</u> and <u>PharmGKB</u>.

Additionally, the College of American Pathologists (CAP) has stated: "CAP applauds and supports the objectives, processes and work completed as of December 2018 by the Clinical Pharmacogenetics Implementation



CPIC guidelines help clinicians translate from genotype to Clinical Pharmacogenetics
Implementation Consortium phenotype to clinical recommendation



Table 1



PHENOTYPE

Table 2



RECOMMENDATION

TPMT*3A/*3A



TPMT Poor Metabolizer



Decrease dose of thiopurine

STRONG

Guideline nominated; discussed on CPIC call and prioritized

Authors identified and approved by the Steering Committee





CLINICAL PRACTICE GUIDELINES WE CAN TRUST

> INSTITUTE OF MEDICIN OF THE NATIONAL ACADEMI

Guideline started: evidence review, conference calls, refine drugs/genes, revise as needed

Draft guideline discussed on CPIC call; posted on CPIC site for comment; submitted for publication

Final guideline posted on CPICpgx.org; updated on site as needed



Guideline revised if prescribing recommendations must change





Guideline writing committee

- Multidisciplinary, comprising a variety of scientists and clinicians
 - Track record of publication or expertise in the specific topic area of the guideline.
 - Leaders in the specific CPIC topic that will lend credibility to the prescribing recommendations
 - International representation
 - Evidence of prior publications relevant to the gene, drug, disease state
 - Expertise in clinical pharmacogenetics
 - Adequate representation of senior individuals
 - Lack of conflict of interest



Other challenges to PGx guideline development

- Not enough resources to provide efficient guideline development
- Evidence
 - Heterogeneity
 - Many rare variants
 - Studied populations
 - Unethical to have control group in some cases
 - Changing or new evidence between guideline updates





Other challenges to PGx guideline development

- Volunteer experts that have time to do the work needed (meeting deadlines is a HUGE challenge)
- Patient engagement
- Addressing equity at the guideline development stage
- Differences in recommendations between product label, other guideline writing groups and CPIC
- Dissemination



Lack of standardization has hindered widespread adoption of PGx

- Lack of standardization
 - Clinical laboratory testing
 - Reporting results
 - Test ordering and reimbursement
- Standardization of reporting
 - Phenotype terms used in reporting and EHR systems vary

Standardization can accelerate the adoption of pharmacogenomics: current status and the path forward

Kelly E Caudle*,1, Nicholas J Keeling1,2, Teri E Klein3, Michelle Whirl-Carrillo3, Victoria M Pratt4 & James M Hoffman1,5
Pharmacogenomics. 2018 Jul 1;19(10):847-860.



Key Takeaways

- Guidelines take resources and these are limited.
- Expert volunteers are essential but busy.
- PGx evidence is difficult to interpret and studies often difficult to design.
- Need better understanding of how to include discussion regarding equity at the guideline development stage.
- Lack of standardization has hindered widespread adoption of PGx.



Team

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