**MINUTES**

**CPIC CONFERENCE CALL**

DATE: June 5, 2014

| TOPIC | DISCUSSION/ACTION | FOLLOW-UP |
| --- | --- | --- |
| Ivacaftor guideline updated on PharmGKB | Since the publication of the CPIC *CFTR*-Ivacaftor guideline, the indication section of the FDA-approved label for ivacaftor has been amended to include more *CFTR* variants along with *G551D*. The guideline authors agreed to update this guideline on PharmGKB to include these additional variants but with a ‘moderate’ recommendation (FDA recommendation based on unpublished studies). The interactive dosing, recommendation table and figure have been updated on PharmGKB (http://www.pharmgkb.org/drug/PA165950341). | None needed. |
| Pgx nomenclature project | Mary gave a brief overview of a pharmacogenetics (pgx) nomenclature project being led by Lisa Kalman from the CDC who coordinates the CDC’s Genetic Testing Reference Material Coordination Program (GeT-RM) (http://wwwn.cdc.gov/clia/Resources/GetRM/default.aspx). The purpose of GeT-RM is to facilitate the development and characterization of genomic DNA for materials for genetic testing. One GeT-RM project is to characterize 137 genomic DNA samples in 9 labs for over 200 pgx genes using a variety of platforms. However, because of nomenclature issues (e.g., labs use different nomenclature system, genotypes called from different strands, ref seqs can be different because labs not using the Human Reference Assembly) and differences in assays (e.g., not all assays test for same SNPs resulting in inconsistent assignment of haplotype) it has been very difficult to compare results between assays and identify a common genotype for the samples. Lisa is organizing solutions to these problems. To date, there have been two conference calls with a lot of feedback from participants (including several CPIC members and other “stakeholders” from NIH GTR, HGVS, ClinVar, etc.). There are direct implications for CPIC. For example, CPIC guidelines define a \* allele but do not list the minimum variants that should be tested. Discussed ACMG’s Laboratory Quality Assurance Committee as a possible arbiter of such standars (see “Laboratory testing of CYP2D6 alleles in relationto tamoxifen therapy” (attached). Next call scheduled for the week of June 16th. Because each gene will likely have its own specific nomenclature issues, gene specific expertise needed. Please email Lisa Kalman ([ljk0@cdc.gov](mailto:ljk0@cdc.gov)) if you are interested in participating or know individuals with gene-specific expertise who may want to participate. | Mary/Kelly will follow-up on progress. |
| Follow-up to request to work with ACMG on pharmacogenes | In 2013, the ACMG published a policy statement on the disclosure of incidental findings from exome and genome sequencing and recommended a set of reportable genes.[PMID: 23788249] However, the list largely excludes pharmacogenes. ACMG has also created a working group to discuss procedures for recommending additional genes. CPIC leadership sent a letter encouraging ACMG to include more pharmacogenes and volunteered to be a part of this working group, and ACMG responded with interest. | Mary will follow-up on progress. |
| ASCPT endorsement of CPIC guidelines | ASCPT has agreed to endorse the CPIC guideline development process. The ASCPT Board will evaluate each individual CPIC guideline for relevance to the scientific interests of its members, and will consider endorsing each of these on a case by case basis. | Kelly will follow-up on progress. |
| CPIC Informatics working group update | -Working group finalized implementation workflow diagrams and tables that combine both *CYP2C9* and *HLA-B* phenytoin recommendations (instead of two separate recommendations). Circulated to CPIC members for review. Guideline will be submitted this week.  -Informatics working group continues to work on translation tables for upcoming guidelines and guideline updates.  -HL7 is starting to pay attention to pharmacogenetics and CPIC informatics leaders are evaluating how CPIC can fit into this. | James, Michelle, and Bob will continue to update CPIC group on progress. |
| Updates to CPIC authorship guidelines | Changes being considered for CPIC authorship guidelines:   1. Add that COIs due to employment by an entity in clear conflict will be considered problematic for authors. 2. Start with draft of Table 2 to gauge consensus of the group; however, lack of prescribing recommendations does not preclude a guideline (can be level C). 3. Add desirable characteristics for authorship:    1. Include leaders in the specific CPIC topic    2. Importance of authorship that lends credibility to the prescribing recommendations    3. international representation    4. evidence of prior publications relevant to the gene, drug, disease state    5. expertise in clinical pharmacogenetics    6. adequate representation of senior individuals    7. limited to those with an identified authorship role 4. Updates: not exactly q 2 yrs 5. Emphasize role of Steering committee in approving authorship   CPIC members gave feedback. Discussed the need to better define a conflict of interest due to employment by an entity in conflict (e.g., academic lab versus commercial lab) and report any conflict and the management of the conflict in the guideline manuscript. One CPIC member suggested writing a paper discussing the management of COI in CPIC guidelines. Discussed that the CPIC gene/drug pair list on PharmGKB does include FDA label information (http://www.pharmgkb.org/cpic/pairs). | Mary/Kelly will draft changes to current CPIC authorship guidelines for Steering Committee approval. |