**MINUTES**

**CPIC CONFERENCE CALL**

**ST. JUDE CHILDREN'S RESEARCH HOSPITAL**

**DATE:** November 4, 2010

**PRESENT:** Russ Altman, Michelle Carrillo, Kristine Crews, Robert Freimuth, Matt Goetz, Andrea Gaedigk, Fran Greeson, James Hoffman, Ogechi Ikediobi, Amalia Issa, Teri Klein, Audrey Papp, Steven Scherer, Stuart Scott, Todd Skaar, Mike Stein, Rachel Tyndale, Russell Wilke, Sook Wah Yee

| **TOPIC** | **DISCUSSION/ACTION** | **FOLLOW-UP** |
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| NIH GTR interactions (Rochelle)  Report from PGRN meeting in Nashville (Mary, Dick)  Confidentiality for in-progress publications (Teri)  Copyright agreement for CPT (Teri)  Progress on CYP2D6/codeine (Todd/Kris)  CYP2C19/clopidogrel (Stuart)  Carbamazepine/HLA | Rochelle Long gave an overview of the NIH’s genetic test registry; she is part of an NIH advisory panel for the GTR. She attended a meeting for the GTR and saw a prototype recently. The GTR will link Test/Gene/Disease; it is clearly a test-centric database. It is designed to include information on the laboratories that offer genetic tests. It will be a voluntary registry; original intent is for data not to be reviewed as it is submitted, but numerous comments have been received that the submitted data should be reviewed before going in the registry (and CPIC members supported more review of the information and the importance of populating the GTR with high quality tests). Appears that the PGRN’s input on pharmacogenetics will be of interest to the GTR. CPIC previously indicated to Genetest.org that we would link to their website for gene test info, and GeneReviews would link to CPIC guidelines for pharmacogenetic test use info. Some initial ideas: need to better define the audience (e.g. clinicians), prioritize clinically actionable tests, and link to interpretation (e.g. CPIC and PharmGKB). GTR is also involving FDA for advice.  CPIC and issues relevant for CPIC discussed several times at PGRN October meeting. This included cementing support of PGRN leadership for CPIC’s endeavors, that a “Clinical Implementation of Pharmacogenetics” project might be a PGRN-wide signature project for the next few years, and that there may be initiatives for a clinically-actionable CLIA-lab genotyping array.  It was emphasized for the group that publications in development are confidential, cannot be shared with other groups, and should be treated with same confidentiality as any other publications in development. Confidentiality issues have prompted changes in the MOU for publications, which was circulated prior to the meeting. The new MOU highlights confidentiality requirements and allows individuals to be contributors to CPIC documents without being CPIC members. The group agreed on new MOU.  It was discussed that CPIC guidelines authors will also need to agree to the copyright form for any guidelines published in the journal (e.g. CPT). The “Authorship responsibility” clause engendered considerable discussion that CPIC should have a standard “disclaimer” incorporated into each CPIC guideline---similar to disclaimers accompanying clinical guidelines from other Professional Societies.  Draft Tables and key elements of guideline were circulated. There was discussion of how the evidence should be graded since much of the research is from case reports and small studies. It was decided that some of the clinical evidence may have relatively low quality and yet strength of recommendations may be “strong” due to availability of alternative agents and due to strength of preclinical data evidence. Also the recognition that there may be many CPIC recommendations that are based on scenarios where large randomized clinical trials will never be done due to good alternatives, strong preclinical data.  Stuart and Alan had met to discuss guideline this week. Progress is being made. Pls note   recent papers posted to site on clopidogrel.    Susan Leckband offered to lead and Daniel offered to help. | Plan is for Rochelle to circulate her improvement ideas to CPIC for feedback before she submits, and this will be the first step in giving feedback.  PharmGKB to include link to GeneTests from TPMT/thiopurines guideline and Mary/Teri to work on link from GeneReviews to TPMT/thiopurines guideline on PharmGKB.  None.  New MOU will apply to all existing and new members.  Standard disclaimer will be circulated to the group for quick turn-around for comments and incorporated into the CPIC guidelines template. (Update: see below)  Authors will continue to work on guidelines for CYP2D6/codeine.  Daniel Muller expressed interest in working on CYP2D6 guidelines for some psychiatric drugs.  Continue to work on guidelines---engage others (e.g. Mike Stein).  Draft to be circulated when ready. |

Draft Disclaimer language to be finalized November 9th, 2010:

"CPIC’s guidelines reflect expert consensus based on clinical evidence and literature available at the time they are written and are intended to assist clinicians in decision-making and identify questions and settings for further research. New pharmacogenomic evidence may have emerged since the time a guideline was submitted for publication.

Guidelines are limited in scope and are not applicable to interventions or diseases not specifically identified. Guidelines cannot account for individual variation among patients and cannot be considered inclusive of all proper methods of care or exclusive of other treatments. It is the responsibility of the health care provider to determine the best course of treatment for the patient. Accordingly, adherence to any guideline is voluntary, with the ultimate determination regarding its application to be made by the clinician. CPIC assumes no responsibility for any injury or damage to persons or property arising out of or related to any use of CPIC's guidelines, or for any errors or omissions."