Boyce – Addendum to IMEDS Research Application
July 2014 – Added to Current Agreement

Very few studies are available in the literature that report on the potential return on investment for pre-emptive pharmacogenomics testing. The PREDICT program recently published a cohort analysis of examining medication exposure, allele frequencies, and adverse event risk estimates in 52,942 medical home patients to find the value of pre-emptive genotyping (4). They found that 65% of their "real-world" population was expected to receive at least one, and more than 10% were expected to receive at least four medications with a pharmacogenetic link within five years. Based on pharmacogenetic data for risk and event probability, they determined that 383 clinically serious adverse events could be prevented. Medications that posed the greatest risk included: clopidogrel (MI, stroke, death), abacavir (hypersensitivity), azathioprine (leukopenia), simvastatin (myopathy), tamoxifen (breast cancer recurrence), and warfarin (bleeding). A pharmacoeconomic analysis was not performed, but the authors reported adverse event costs per patient for abacavir ($121-$36,850, depending on severity of hypersensitivities), tamoxifen ($24,400-$56,521), and warfarin ($11,542), that were substantial compared to testing costs.

**RESEARCH OBJECTIVES AND AIMS:**

**Research Objective:** These data suggest that pre-emptive pharmacogenomics testing is feasible and may produce a return on investment. However, the data are limited to relatively localized settings and might not be of generalizable use to other health organizations. **The objective of this study is to derive reliable data that government payers and large healthcare organizations can combine with emerging data on adverse event risks and costs to conduct cost-effectiveness analyses for pre-emptive pharmacogenomics testing.**

**SCOPE/PROPOSED APPROACH:** We have already conducted an analysis of the availability, costs, and turn-around times of genetic testing assays that could be potentially employed for pre-emptive testing. We aim to combine this data with population-level data on the likelihood that a patient will be an incident user of each drug for which pre-emptive pharmacogenomics testing is available. The results should enable "large payer" health organizations to do hypothetical cost-benefit analyses using data from other sources relevant to their organization on the probable number of harms prevented by clinician knowledge of genotype. We propose to use the CDM version of the Truven datasets provided by the Reagan Udall lab to perform the second task. The Table lists the tasks, inputs, goals, and output of the proposed work.

**Impact:** The primary impact of this study would be to provide to the public a new method for determining the value of pre-emptive pharmacogenomics at a population level by combining population statistics on drug exposure with emerging data on adverse event risks.

**Timeline:** We anticipate requiring one year of access starting 7/22/2014 and ending 6/22/2015.

*Table. IMEDS PDDI research activities and tasks.*

| Tasks | Input | Goals | Output |
|---|---|---|---|
| Conduct an analysis of the availability, costs, and turn-around times of genetic testing assays that could be potentially employed for pre-emptive testing | An existing list of drugs for which pre-emptive pharmacogenomics testing is available | Derive drug exposure incidence statistics using the Truven datasets provided by the Reagan-Udall lab | Population-level data on the likelihood that a patient will be an incident user of each drug for which pre-emptive pharmacogenomics testing is available |

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**Experience:** *(Please refer to as the Translational Informatics Applied to Drug Safety (TRIADs) Investigator Group):*

- (Principal Investigator) Richard D Boyce, PhD, Assistant Professor, Department of Biomedical Informatics, University of Pittsburgh
- Philip Empey, PharmD, PhD , Assistant Professor, School of Pharmacy, University of Pittsburgh
- Matthias Samwald, PhD, Postdoctoral researcher, Section for Medical Expert and Knowledge-Based Systems, Medical University of Vienna

**References**

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