Embedding Pharmacogenotyping in an Integrated Health System for the Underserved

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Abstract:

The goal of Personalized Medicine is to implement advances in biomarker pharmacology, molecular diagnostics and genomics to improve public health. For the full benefits of this science to be realized, it is critical that scientific advances made in experimental settings and on a small scale be extended to community practice and that a business case can be made to support such dissemination. It is important that key innovations be extended beyond individual hospital settings to large health care systems, especially those that include underserved populations. Many scientific advances bypass underserved populations, and as a result inequalities in care and cost inefficiencies result. In 2011, the Indiana Institute for Personalized Medicine (IPM) was created to serve as an academic home for basic and clinical researchers committed to research in personalized medicine. A specific goal of the IPM is to move this science towards clinical practice. To that end, the purpose of this proposal is to pilot a genomic platform in a large safety-net health care system, and to measure the economic costs and clinical outcomes of doing so. Eskenazi Health handles over 1.2 million outpatient visits per year and > 15,000 admissions annually, with a payer mix that include 45% uninsured, 26% Medicaid and 18% Medicare patients. In this proposal, the IPM will partner with Eskenazi Health and the Regenstrief Institute to recruit a new "Eskenazi cohort" of genotyped patients. A multidisciplinary group of clinicians and information scientists will pilot an innovative approach to the implementation of pharmacogenomic science. The Regenstrief Institute has a proven track record of innovation in medical informatics, and has created an ideal environment in which to assess real clinical outcomes.

The specific aims of this proposal will be: 1) To test the hypothesis that a CLIA certified genotyping test targeted at 24 widely used drugs is associated with significant reductions in hospital and outpatient economic costs incurred over 1 year; and 2) To test whether such pharmacogenetic testing is associated with significant improvements in clinical outcomes over 1 year. Patients will be randomized either to an intervention arm, involving pharmacogenotyping, insertion of results in the medical record and dissemination of relevant results and decision algorithms to providers (n=2000 patients), or to usual care (n=4000 patients). This trial will be implemented in Eskenazi primary care clinics and 6 specialty clinics. Economic costs and clinical outcomes including clinic visits, hospital admissions, length of stay, adverse drug reactions, morbidity and mortality, will be followed prospectively and compared between the two groups. To sustain this effort, we will extend access to this testing to IU Health, and the affiliated NCI Simon Cancer Center and Riley Hospital for Children. Data from this study will allow for the first time the development of an objective business case for pharmacogenomic personalization based on real world costs and outcomes.