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ER visits decline 71%, hospitalizations 39% in elderly patients evaluated by predictive medication analytics system and DNA testing

New University of Utah research reveals the potential of medication informatics and DNA drug-sensitivity testing to reduce overall healthcare resource use and costs in elderly patients treated with multiple medications

Seattle, WA YouScript predictive medication analytics, a clinical decision support tool used by doctors to guide genetic testing and improve drug treatments, has been shown to cut ER visits by almost three-quarters and reduce hospitalizations by more than one-third in elderly patients taking multiple medications.

Researchers from the University of Utah compared those who received YouScript-guided genetic testing and analysis in a prospective group to those who did not in a matched retrospective cohort. The retrospective cohort was obtained from Inovalon's More2 Registry, a large nationally representative, deidentified claims database. Researchers devised this strategy to meet the challenge of providing closely matched controls to the elderly patients taking multiple medications, also called polypharmacy.

YouScript was shown to reduce ER visits by 71 percent and hospitalizations by 39 percent in the tested population compared to the statistically matched group.

"To our knowledge, this is the first study to demonstrate the potential of a technology to reduce the adverse drug event epidemic caused by polypharmacy," said Howard Coleman, co-founder and CEO of Seattle-based Genelex, which invented the YouScript system.

"Designing a study capable of tackling the polypharmacy problem was a major challenge, and our hats are off to the University of Utah scientists and others who helped with the study design."

The data showed YouScript prevented one hospitalization for every 16 patients tested, and one ER visit for every nine tested. Researchers estimated potential cost savings per patient in the tested group at \$218 in just four months. The results of this IMPACT study (Improving Medication Protocols and Abating Cost of Treatment), a collaboration of researchers at the University of Utah and Genelex Corporation, were published October 21, 2015, in the <u>Journal of Medical Economics</u>.

The YouScript system combines comprehensive predictive medication management analytics with pharmacogenetic testing, or DNA drug-sensitivity testing as it is also known, to analyze the complex web of medication and genetic interactions affecting how patients respond to drug treatments. The software analyzes patient medication regimens and genetic test results to predict the potential for negative side effects and treatment failure.

When potential problems are identified, YouScript suggests alternative medications with reduced interaction risk, while taking into account all other relevant medications and genetic factors. The testing

reveals natural variations present in more than 90 percent of people that determine how the body processes more than three-quarters of commonly prescribed medications.

The study examined two groups of 65-and-older patients taking three-or-more medications:

- The first group, a prospective patient registry, received testing for differences in six liver enzymes that process most commonly prescribed drugs. YouScript analytics were then used to analyze the test results, and a clinical pharmacist provided personalized dose change recommendations.
- The second group, a matched untested control group, was obtained from a large healthcare data warehouse.

The study compared healthcare resource utilization and estimated costs between the two groups to determine the impact of YouScript testing and analysis. Genelex provided an unrestricted research grant to fund the study.

"Real world evidence is limited in the field of pharmacogenetic testing with clinical decision support. This study provided an innovative methods approach to provide preliminary data to support health technology assessment for public and private payer reimbursement decisions," said primary investigator Dr. Diana Brixner, PhD, RPh, Professor of the Department of Pharmacotherapy at the University of Utah College of Pharmacy.

"Our results warrant contingent reimbursement and further validation through a randomized trial in a unified population."

Polypharmacy in the Elderly

Polypharmacy has become one of the most serious medical problems facing the elderly today. On average, individuals 65 to 69 years old take 14 different prescribed drugs per year, while those 80 to 84 take an average of 18.

Interactions between drugs are a well-known cause of negative side effects but are in the minority compared to the cumulative effective of drug-drug, drug-gene and drug-drug-gene interactions that are taken into account by the YouScript system. These potential interactions involving genetics further increase the risk of unintended drug treatment consequences, especially in the elderly.

The potential cost-savings that can result from widespread deployment of the YouScript system, in addition to other medication management advances, is significant. According to the Centers for Disease Control and Prevention, adverse drug events cost the U.S. health system approximately \$3.5 billion annually.¹

Limited Medicare Coverage

The growing body of evidence supporting the importance of genetic variation and drug response may assist Medicare in reconsidering the currently limited coverage of many of these tests. Payment denial could impact as many as 19 million of the 49 million Medicare beneficiaries in the U.S. who are at special risk of costly adverse drug events.²

"If we extrapolate these results to all 52 million Medicare recipients, it would mean almost \$1 billion in predicted savings," Genelex Chief Operating Officer Kristine Ashcraft said.

"We look forward to working with Medicare to further deploy this technology to improve the lives of our most at-risk seniors while reducing healthcare costs."

The study results came as no surprise to Elise Astleford, a 74-year-old Washington State resident whose life was changed by the YouScript system. YouScript pharmacogenetic testing revealed that her genetic makeup was likely causing her to poorly process a common antihistamine, resulting in forgetfulness and what appeared to her to be the beginnings of dementia.

After Astleford was taken off the medication, her memory returned to normal. Now Astleford brings her YouScript test results with her to every doctor visit.

"I just believe in it because I feel so much more confident, and I feel I'm armed for my own benefit whenever a doctor wants to prescribe me a new drug," Astleford said.

"For me, it's the peace of mind that's quite wonderful."

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About Genelex

Genelex is a pioneer in comprehensive medication analytics and pharmacogenetic testing. Its patented YouScript® Personalized Prescribing System is the only commercially available medication management system to assess the cumulative effect of a patient's genetics and entire drug regimen. YouScript is an Allscripts Developer Program Approved Application and is used by healthcare providers, clinical researchers and managed and accountable care organizations. Founded in 1987, Seattle-based Genelex is one of the first clinical laboratories to provide pharmacogenetic testing and interpretation. For more information, visit: www.youscript.com.

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More about the IMPACT Study: www.genelex.com/youscript-impact/

IMPACT Study Citation: Brixner D, Biltaji E, Bress A, Unni S, Ye X, Mamiya T, et al. The effect of pharmacogenetic profiling with a clinical decision support tool on healthcare resource utilization and estimated costs in the elderly exposed to polypharmacy. Journal of medical economics. 2015:1-40. PubMed PMID: 26478982.

Pharmacogenetic testing Information for patients: http://genelex.com/patients/

Genelex Media Kit: www.genelex.com/media

About Dr. Diana Brixner and the Department of Pharmacotherapy at the University of Utah College of Pharmacy

Dr. Diana Brixner, PhD, RPh, is a Professor and Executive Director of the Pharmacothearpy Outcomes Research Center in the Department of Pharmacotherapy College of Pharmacy, and Director of Outcomes at the University of Utah Program in Personalized Health. She is a past president of the International Society for Pharmacoeconomics and Outcomes Research.

The <u>Department of Pharmacotherapy</u> in the <u>College of Pharmacy at the University of Utah</u> is committed to developing the highest level of work in the education of future pharmacists, research in the pharmaceutical sciences, and service to the institution, the community, and the profession. Through this commitment, the department strives to be a national leader in the application of the pharmaceutical sciences to personalized medicine, thereby realizing improved healthcare delivery to patients through optimized medication outcomes.

About Inovalon

Inovalon is a leading technology company that combines advanced cloud-based data analytics and data-driven intervention platforms to achieve meaningful insight and impact in clinical and quality outcomes, utilization, and financial performance across the healthcare landscape. Inovalon's unique achievement of value is delivered through the effective progression of Turning Data into Insight, and Insight into Action[®]. Large proprietary datasets, advanced

integration technologies, sophisticated predictive analytics, data-driven intervention platforms, and deep subject matter expertise deliver a seamless, end-to-end capability that brings the benefits of big data and large-scale analytics to the point of care. Driven by data, Inovalon uniquely identifies gaps in care, quality, data integrity, and financial performance – while bringing to bear the unique capabilities to resolve them. Providing technology that supports hundreds of healthcare organizations in 98.2% of U.S. counties and Puerto Rico, Inovalon's cloud-based analytical and data-driven intervention platforms are informed by data pertaining to more than 769,000 physicians, 261,000 clinical facilities, and more than 123 million Americans providing a powerful solution suite that drives high-value impact, improving quality and economics for health plans, ACOs, hospitals, physicians, consumers and pharma/life-sciences researchers. For more information, visit www.inovalon.com.

Sources

- 1. Based on current figures from the Kaiser Foundation in a recent study about the incidence of high-risk medications in patients 65 and over, and phenotype frequency data.
- 2. http://www.cdc.gov/medicationsafety/basics.html