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DNA Today

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Genelex Offers New 5HTT Test

The YouScript® Panel examines five of the most commonly variant genes, but sometimes prescribers need more specialized information. Genelex has always offered supplemental genetic tests such as HLA-B for specialized prescribing, but now Genelex is offering a 5-day turnaround time for the 5HTT gene test. Psychiatrists may be very interested in this gene. 5HTT is a protein found in neurons

“Genelex has always offered supplemental genetic tests such as HLA-B for specialized prescribing, but now Genelex is offering a 5-day turnaround time for the 5HTT gene test.”

that helps regulate serotonin levels—the same chemicals many antidepressants (including Prozac® and Paxil®) target. Genetic variations to 5HTT can decrease the efficacy of these medications.

By making these genetic tests more easily available for specialized prescribing, Genelex is establishing itself as the go-to company for personalized prescribing. These genes will allow

more prescribers to prescribe with confidence and save patients time and money.

Prescribers who are initiating patients on certain antidepressants, or whose patients are experiencing adverse effects or treatment failure on these antidepressants should consider 5HTT genotyping. 5HTT genotyping can be billed to insurance. To learn more about pharmacogenetic testing, go to <http://bit.ly/KmXAb1>.

Cardiologist Espouses Team-Based Treatment with YouScript®

What does cardiology have in common with the popular TV series, *House*? On the show, every patient had a whole team of doctors who brainstormed their case and potential care plan. Cardiology can often be similar, requiring a team-based approach for each individual patient. YouScript is helping at least one doctor achieve that goal.



Dr. David N. Smith is an invasive cardiologist at the Novant Health Heart and Vascular Institute in Charlotte, North Carolina.

Dr. David N. Smith is an invasive cardiologist at the Novant Health Heart and Vascular Institute in Charlotte, North Carolina. He and his team see

cases ranging from preventative care —treating patients with a history or risk of cardiovascular diseases—to more complex cases such as nuclear imaging and stent placement.

Dr. Smith's team uses YouScript to help tailor therapy as part of his emphasis on comprehensive and personalized cardiovascular disease care. The efficacy of many of the medications he commonly uses, such as statins, beta-blockers, anti-coagulants and ACE inhibitors, can be affected by common genetic variations, which makes

“Cardiology needs to be individualized and personalized.”

YouScript an important tool in his prescribing process.

While the Novant Health Heart and Vascular Institute is very busy (it's one of the largest cardiology clinics in the state), Dr. Smith has found an easy way to integrate YouScript into his workflow. By introducing the patient's doctors to YouScript and having designated staff

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Dear Warfarin Study: Don't Neglect Patient Safety

On December 12, 2013 the New England Journal of Medicine published the results of one of the largest clinical warfarin trials ever undertaken. Written by Dr. Stephen Kimmel *et al*, the paper questions the clinical utility of genotyping prior to warfarin administration.

The pharmacogenetic testing industry is one of the next-generation industries most at need for comprehensive studies due to its large amount of information and constant new discoveries. As such, Kimmel's paper is an extremely valu-

“Genetic variants may play a role in the incidence of bleeding events.”

able resource. However, there are a few points that deserve more investigation before any conclusive statements can be made with regards to warfarin genotyping.

Patient Safety

Kimmel *et al* examined two groups of patients—one whose warfarin dose was adjusted based on a clinical algorithm and one based on a genotype-powered algorithm—and concluded there was no significant difference overall between the

mean percentage of time in the therapeutic range.

However, while the time in therapeutic range is very useful for prescribers, Kimmel's study was not powered to examine the incidence of adverse events, which may in fact be the more important endpoint for patient safety. Warfarin has been known to cause severe, sometimes fatal bleeding events in some patients and genetic variants have been

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Dr. John Nelson Joins Genelex as Medical Director

Genelex's YouScript® Personalized Prescribing System is already changing the way prescribers look at medicine. Now the company is strengthening their prescriber relationships with Dr. John Nelson as their new medical director. Dr. Nelson will be Genelex's high-level liaison to physicians, specialists, and organizations, helping to them to understand the clinical benefits and develop protocols for how to incorporate gene-based prescribing into their workflow to achieve improved patient care.

Dr. John Nelson, MD, MPH is a board-certified OB/GYN with over 30 years of clinical practice and served as the president of the American Medical Association from 2004-2005. "For many years, I avoided any



"...the opportunity is now available for all clinicians to apply this meaningful intervention to their patients."

relationship with companies and products—until now," says Dr. Nelson. "As I have become familiar with the YouScript program at Genelex, I am finally impressed. By personalizing the drug and dose of medication to an individual patient, I can achieve better outcomes and do so at reduced costs." As up to 20% of readmissions may

be due to adverse drug events, "the opportunity is now available for all clinicians to apply this meaningful intervention to their patients."

Dr. Nelson's had personal experience with adverse drug events. At one point, his wife was on a combination of ibuprofen, low-dose aspirin, and Plavix®. YouScript analysis

revealed that both the ibuprofen-aspirin combination and certain variations in her genotype increased her risk of potentially serious bleeding. Dr. Nelson spoke with her doctor about this and her drug regimen was changed.

Dr. Nelson has been in active clinical practice of obstetrics and gynecology since 1975 and currently sees patients at the Health Clinics of Utah. He was a charter member of the Prospective Payment Assessment Commission (now MedPAC) and has recently served on the Advisory Committee to the Director of the National Institutes of Health (NIH). He is currently the Chief Medical Officer at Leavitt Partners in Salt Lake City, Utah. Dr. Nelson graduated from the University of Utah School of Medicine.

Cardiologist Espouses Team-Based Treatment with YouScript®

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members collect DNA samples and confirm each patient's medications, his team can effectively coordinate medication management. This allows Dr. Smith to focus his time on reviewing the YouScript Personalized Prescribing Report and other print outs, examining alternative medications and making his recommendations to the primary or referring physician.

This emphasis on cooperation and teamwork within his clinic also extends to when Dr. Smith reaches out to general practitioners outside of his practice.

"I have no problem picking up the phone and talking to any of the referring physicians," said Dr. Smith. Because patients often see multiple doctors, they can be taking an amalgam of medications, some of which may negatively interact. He often uses the clinical notes provided by YouScript to share information with other doctors.

Many are very receptive to these collaborations. "I'll do genomic or an individualized approach and the next thing you know we're coming up with a whole new perspective... I saw this perfect marriage

where I could use YouScript to enhance what I'm trying to do in the cardiology community."

Dr. Smith's initial interest came from his background in laboratory research. "We've all spent decades learning that patients are unique and the scientific mechanisms behind that uniqueness, yet we still treat on clinical patterns and syndromes. The disconnect there is huge and I think therein lies a lot of the detriments, adverse reactions and disparate outcomes that we're currently seeing. I think genomic medicine plays a huge

role in bridging the two and eradicating mistakes."

"I'd love for people to know this is not the wave of the future anymore. This is now. Genomic testing is here. We need the application now... The answers to all of our questions: healthcare dollars that could be saved, the volume of patients we're going to see, how we're going to handle and manage it, how we're going to deal with the limited time to address so many issues—all of these things can be mitigated, if not eliminated, by going back to the genetics and genomics."

YouScript® Alternates Selector Improves Medication Choice

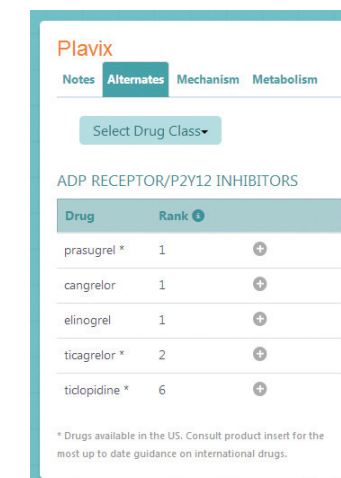
The FDA recognizes more than 2,000 different molecular entities, the molecules that make up drugs, which are in turn combined or purified into the even more staggering number of different medications available today. So when a prescriber decides to change medications and reaches towards their prescription pad how can they be sure they're picking the best replacement?

With the YouScript Alternates Selector, prescribers gain an at-a-glance view of safer alternatives. But the Alternates Selector doesn't just present a list of alternates—it prioritizes the list by drugs least likely to have an adverse reaction with the patient's genetics and current drug regimen. With one click, prescribers can audition alternate drugs and explore possible implications prior to prescribing.

Using it is simple. Just click any medication in the Interaction Report, then choose a drug class and the Alternates Selector will display possible alternatives, with the safest drugs listed first.

The YouScript Alternates Selector makes it easy to personalize drug selection each and every time.

For a free trial, go to: www.youscript.com/getstarted



Warfarin/Genotyping Study: Don't Neglect Patient Safety

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previously implicated in the risk of these events. Prescribers should keep this in mind.

Clinical Effectiveness

There may also be some hidden effects of how the study was set up. In 55% of the genotyped group, the individuals received their first dose of warfarin *without using genetic information*. It's possible that the genotyped group would have reached therapeutic dose faster if all 100% were genotyped prior to administration. This may seem like a minor point, but methodological discrepancies should be scrutinized in any clinical trial.

Comparison Groups

Kimmel's paper examines the benefit of genotype-guided warfarin dosing over clinical algorithm-based dosing and found little benefit. Both the genotyping and clinical algorithms included patient age,

race, and other demographic or health information.

This comparison is relatively unique—many previous warfarin studies examined the effectiveness of genotyping versus a *standardized* dosing strategy. In these previous trials, there was a significant difference between genotyped vs. non-genotyped groups. Because there isn't a single universally agreed-upon way to dose warfarin, more studies should investigate multiple dosing methods. In the meantime, clinics using standardized dosing strategies may benefit from using genotype-based dosing tools such as YouScript.

Conclusions

Overall, Kimmel's paper is very valuable and interesting, but don't throw out the clinical utility of genotyping just yet—more endpoints need to be investigated, trial methods

need to be refined, and more people need to take a look at it before conclusions can be drawn from Kimmel.

The most important point, however, is patient safety. Given the role genetic variants

may play in the incidence of bleeding events, more large-scale studies are needed before definite statements can be made about patient safety.

To read the full Kimmel article, go to <http://bit.ly/1CLpF6x>.

Are you a healthcare provider? 

And ready to make Personalized Prescribing part of your practice or pharmacy?

Visit www.youscript.com/getstarted to request a free Personalized Prescribing Kit today.

Are you a patient? 

Is Personalized Prescribing right for you?

Call Genelex at 800-TEST-DNA or visit www.youscript.com.