PGx America

St. Judes Children's / Memphis Demonstrates PGx As 21st Century Diagnostic Standard

—St. Jude Children's Research Hospital, Memphis, brings a razor-sharp focus to its mission: the 78-bed institution cares for children with catastrophic illnesses, including leukemias and lymphomas, solid tumors, hematology disorders (including sickle cell disease), and infectious diseases. It doesn't have an emergency department. Consistent with its goal of advancing cures, all its patients are enrolled in research protocols.

It makes sense, then, that St. Jude would bring a similarly sharp focus to its laboratory testing, in the form of therapeutic drug monitoring and pharmacogenetics testing.

I**t does so with a twist: a clinical pharmacist tells clinicians what the results mean. "We don't release results into the record until the pharmacist has entered an interpretive consultation note for that result,"** says Alejandro Molinelli, PhD, director of the clinical pharmacokinetics laboratory at St. Jude.

The laboratory also pages the pharmacist once a result is ready. It's different from the usual routine, Dr. Molinelli says, "where basically results are posted to the medical record just by themselves, with no interpretive consult. If the ordering physician has a question, they usually call the lab and get any clarification." At St. Jude, "We're pushing an interpretation together with the results."Among the tests: thiopurine methyltransferase (TPMT), which is critical to managing thiopurine medications used to treat pediatric leukemia; and **CYP2D6, which is involved in metabolizing a variety of common medications,** including codeine.

"We have a fairly limited number of clinical genotypes that we are testing," says Dr. Molinelli. These tests are done at reference labs, an approach that works "because we have a manageable number of patients," he says.

Dr. Haidar suggests that one reason pharmacogenetics has been relatively slow to ratchet up, at least in the United States, is that despite all the initial excitement at its

promise, **"Once they [clinicians] got the results, nobody had the training to interpret the results." Call it an early case of information overload. Says Dr. Haidar: "I know colleagues who work in cardiology institutions who used to tell me that cardiologists used to order certain genotypes—and they don't anymore, because they don't know how to interpret these results."Making the pharmacist consults de rigueur probably helped to create strong physician buy-in from the start at St. Jude, Dr. Haidar says.**

St. Jude has moved smoothly through several chokepoints that can slow acceptance of pharmacogenetics testing. One is turnaround times. The preemptive approach virtually eliminates that problem, Dr. Haidar says. Once a patient has a St. Jude medical record number and will actively be treated at the institution, genotyping begins. "We have genotype results in the medical record before we ever anticipate [using] a certain drug," she says. Nor is reimbursement a deciding factor for doing a test. The hope, of course, is that a patient's insurance will cover the cost of testing. **But if not, or if the patient is uninsured, the test is still done.** Families never receive a bill from St. Jude for treatment, travel, housing, and food.

University Of Indiana Adopts Widespread PGx Realizing Significant Cost & Outcome Benefits

The University of Illinois (UI) Personalized Medicine Program led by Dr. Edith Nutescu, is one of three finalists for the 2015 Award for Excellence in Medication-Use Safety, which is given by the American Society of Health-Systems Pharmacists (ASHP) Foundation. **The program at the UI Hospital and Health Sciences System has genotyped over 1,500 patients to help guide warfarin and clopidogrel dosing. According to Dr. Nutescu, the program has led to significant decreases in hospital readmission rates due to drug-related adverse events, while simultaneously saving UI health an estimated $600,000 annually.**

CytochromeP450, abbreviated CYP450, is a complex of genes that controls liver enzymes that digest certain drugs. Those drugs include Plavix®, Coumadin®, warfarin, beta blockers, common pain medications and antidepressants . Just as gene variation controls hair or eye color, it also controls how the body reacts to certain drugs. A Pharmacogenomic test, (PGx Test) is done to make sure that a patient's prescription drugs will be safe and effective. A PGx test lets a doctor know how quickly a patient's body filters a given drug out of the bloodstream. A high metabolizer flushes drugs out of the body quickly, and might never realize any benefit from taking a "normal" dose. A poor metabolizer is just the opposite, with a "normal" dose building to potentially dangerous levels. Understanding how quickly a patient metabolizes a drug helps the doctor calculate the safest, most effective dose. Knowing a patient's genotype will help the doctor choose the most effective treatment path.

PGx AMERICA is dedicated to bringing this inexpensive buccal swab test, which is essential to avoiding ADRs and HACs to healthcare providers of all range and scope. Please speak with your Account Executive to discuss solutions and implementation.