

IMPACT Newsletter

1st Edition | November 2014

Introduction

The goal of the IMPACT newsletter is to provide you with exciting news, updates and study milestones. Without your referrals and continuous support, we would not have been able to reach the high number of patients who have already received pharmacogenomic testing through IMPACT. **Thank you for all of your efforts!**



Meet the IMPACT team! Visit us at www.im-pact.ca.

IMPACT Study Milestones

- The IMPACT study was initiated in June 2011 after receiving \$19.5 million from the Ontario Ministry of Research and Innovation, the CAMH Campbell Family Health Research Institute and Larry & Judy Tanenbaum.
- In May 2012, the first IMPACT patient was consented.
- In January 2013, for the first time in Canada, patients were able to receive genetic testing at their family physicians office; this was made possible through the IMPACT study.
- In November 2013, CAMH and Assurex Health signed a partnership agreement to bring the benefits of a *personalized approach to psychiatric treatment* to more Canadians.
- Beginning on November 10th, 2014, patients enrolled in the IMPACT study will be tested using the Assurex Health proprietary technology, GeneSight Psychotropic.

Testimonials

"Patient had complete symptom control, but profound apathy and psychomotor slowing on paliperidone LAI. He was switched to aripiprazole LAI, at 50% of the usual starting dose based on results of pharmacogenetic testing. Now total remission of schizoaffective symptoms with no apathy or slowing on only 200 mg every 4 weeks. Fast and easy service, meaningful results. My other patient also benefited directly from the test results, reducing trial and error. Thank you!"

Thank you for the excellent service. Please continue to develop this initiative."

-Dr. Darryl Vance, Thunder Bay, ON

Please let us know if you would be interested in sharing one of your patients' experiences with pharmacogenomic testing. We are always interested in feedback— reach us by email at Canada.Clinical@assurexhealth.com.

Important Study Reminders

Participants are asked to provide the following information at each stage of the study:

Baseline (upon consent)

- Symptoms
- Medication History
- Side Effects

Week 4

- Symptoms
- Current Medications
- Side Effects

Week 8

- Symptoms
- Current Medications
- Side Effects

Symptomology is gathered through scales such as BDI and PANSS, depending on the patient's diagnosis.

Please discuss with your patients the importance of completing these scales at each time point of the study.

Clinic Registration

In early November, you received an email requesting that you please complete the IMPACT Clinic Registration Form. Please complete and return this form via email to registrations@assurexhealth.com or fax to 1.888.894.4344.

If you have not yet done this, please complete this process in order to receive your enrolled patients' GeneSight Psychotropic reports. Visit <http://impact.camhx.ca/en/docs/IMPACT-AssureRx-RegistrationForms>.

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IMPACT Study Status

As of October 1, 2014, the IMPACT study has recruited ~2,500 patients for pharmacogenomic testing, averaging just over 150 patients enrolled per month!

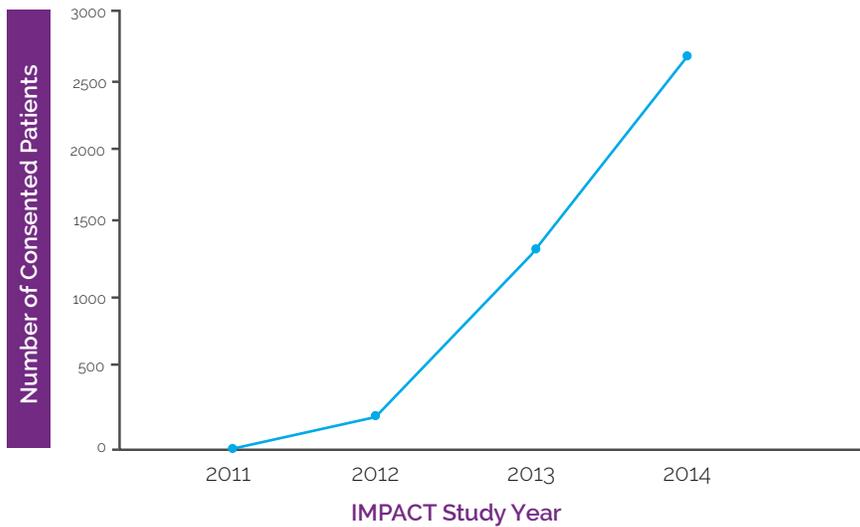


FIGURE 1 Number of patients consented to participate in the IMPACT study.

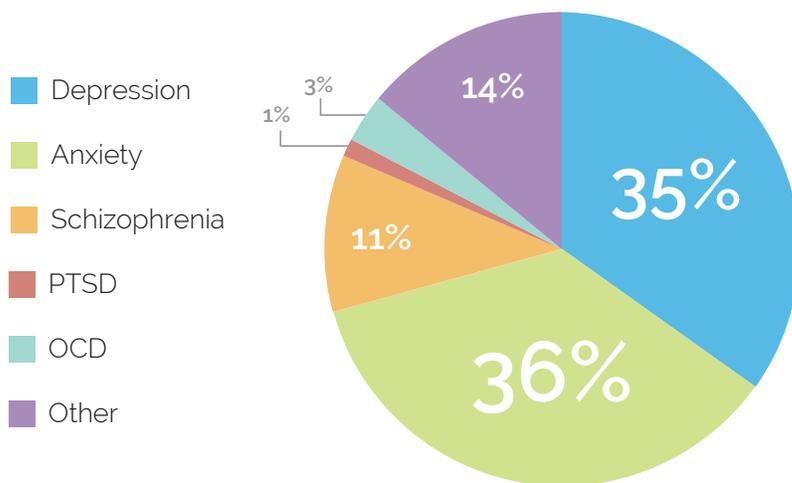


FIGURE 2 Percentage of IMPACT study participants with a primary diagnosis of depression, anxiety, schizophrenia, PTSD, OCD or other. Patients may have a secondary diagnosis.

Gene Spotlight

The CYP450 System

The CYP450 System is a family of 57 enzymes, responsible for drug metabolism, primarily in the liver. In mammals, the CYP450 enzymes are the primary catalysts for detoxification reactions responsible for breaking down insoluble molecules to water soluble components that can be excreted in the urine. The CYP450 family contains several highly polymorphic genes. GeneSight tests for CYP450 genes with common, clinically relevant polymorphisms.

CYP2D6 - *5

CYP2D6 is one of the most important liver enzymes involved in the CYP450 system and is highly variable between individuals. CYP2D6 - *5 is just one of the many CYP2D6 variations and describes a complete deletion of the gene. When this variation occurs, because the gene is deleted, no mRNA is produced. This results in zero protein syntheses. It is impossible for an individual with two copies of *5 to create the CYP2D6 enzyme. This variation has significant implications for medications metabolized by CYP2D6 such as duloxetine, imipramine, and fluoxetine. *5 is just one of the many gene variations that GeneSight tests for—check back next month for a new gene spotlight!

Webinars

Assurex Health offers educational webinars that provide treating clinicians with more information on the GeneSight technology and pharmacogenomics in general.

Upcoming webinars for 2014 include:

- Emerging Research in Pharmacogenomics: GeneSight Psychotropic - November 20, 2014
- Pharmacogenomics in Action: Clinical Case Studies - December 18, 2014

If you are interested in participating, register by visiting <http://genesight.com/educational-webinars/>

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GeneSight Psychotropic

The GeneSight Psychotropic laboratory developed test analyzes how eight genes may affect a patient's metabolism and response to 33 Health Canada approved antidepressant and antipsychotic medications.

GeneSight testing includes genotyping of pharmacokinetic genes from the Cytochrome P450 family and pharmacodynamic genes related specifically to the serotonin system.

GeneSight differs from other pharmacogenomic testing in that it is combinatorial. GeneSight takes into consideration how a combination of genetic variations can affect a patient's ability to respond to a medication.

For more information, visit:

www.genesight.com

In The News

On October 15, 2014, the Genome Application Partnership Program (GAPP), announced that Assurex Health and the Centre for Addiction and Mental Health (CAMH) would receive \$6 million from the Canadian federal government. The grant was allocated in support of the 'Matching the Drug to the Patient: Safer and More Effective Drug Therapy for Mental Health Patients' project.

GAPP allocates financial resources to academic research institutions, such as CAMH that partner with genomics organizations, such as Assurex Health. Elected partnerships must demonstrate innovative genomics-based technologies that will deliver major and immediate economic and social impacts to end-users.

The combined research that CAMH has done with its IMPACT study and U.S. clinical studies conducted by Assurex Health have demonstrated that pharmacogenomic testing for psychiatric patients can result in real economic savings for the government of Canada.

For more information on this exciting news visit:

<http://genesight.com/pr-canada-grant/>

<http://impact.camh.ca/en/home.php>

For More Information

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