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Personalized Medicine: DNA pioneers

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Toronto pharmacy partners with genetic testing firm to assess potential for pharmacogenomics in community pharmacy.

Canadians are leaders in trialing pharmacogenomics in community pharmacy. UBC pharmacists were the first to pilot genetic testing in a groundbreaking study that recently concluded. Now, two Toronto-based projects are underway. In this mini-series we look at these innovative initiatives, starting with a proof-of-concept study at a Toronto Shoppers Drug Mart location.

Always searching for new ways to enhance patient care, community pharmacist John Papastergiou sees powerful potential in point-of-care testing. Case in point: when Bayer released its at-home A1C kit in 2010, the Shoppers Drug Mart associate owner built a clinic around it. The drugstore chain was so impressed with the program it rolled it out nationwide.

Then last year at the Ontario Pharmacists Association's professional practice committee meeting he saw another enticing opportunity. Presenter Ruslan Dorfman, CEO of genetic testing firm GeneYouIn, gave an update on advancements in pharmacogenomics. The process of testing a patient's DNA to determine how well they'd metabolize medications was rapidly evolving, he said. Papastergiou saw a natural fit.

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"Community pharmacists are frontline healthcare providers dealing with medications—I thought we should be the ones at the forefront of this technology," he says. The pharmacy owner struck up a conversation with Dorfman after his talk, and they agreed to collaborate on a proof of concept study around delivering GeneYouIn's PillCheck genetic testing service at the retail level.

They aimed to answer two burning questions around pharmacogenomics: was it feasible to do in a community pharmacy setting and how accepting would physicians be of the recommendations pharmacists made using the results.

It's only the second research project of its kind in North America. In the first groundbreaking study out of the University of B.C., pharmacists took samples and analyzed the results. Dorfman says his collaboration with Papastergiou goes a step further. "It's actually the first study where the test is no only done but recommendations are provided back to the patient right away and the treating physician."

Test maker's first foray into community pharmacy
GeneYouIn had never worked with a community pharmacy, and much of its business is direct-to-consumer. The company tried to produce an easy to interpret report using colour-coded charts to show how well the client would metabolize dozens of commonly used drugs. Still, many of these customers would ask the company for advice on how to use the results to change their treatment.

"We are a group of geneticists—we are not qualified to give specific advice [on] how to make these changes," says Dorfman. "So that's why we started to work with community pharmacists, because they are qualified professionals to give advice on personal treatment optimization."

Before they started administering the tests Papstergiou and his team underwent 60 hours of training. They took a series of online modules and in class schooling. The geneticists then came into the pharmacy to host mock clinic days, where they worked through different case scenarios and patient profiles. "I wanted to make sure pharmacists in the program had a real comfort level analyzing the results," says Papastergiou.

Patients get customized report
The pharmacy team started facilitating the tests late last year. The study involves two patient encounters. While conducting a medication review, the pharmacist asks the patient if they're interested in taking part in the program if they suspect that they would benefit. If they agree to it, the pharmacist takes a cheek swab and sends the sample off to the lab. GeneYouIn then loads the DNA data into its propriety software program, which matches it against guidelines from the Clinical Pharmacogenetics Implementation Consortium and generates a customized report.

The document outlines how well the patient would metabolize 60 medications. It also flags any drugs the patient should be wary of taking in an upfront summary. GeneYouIn sends the report to Papastergiou's pharmacy team, which then invites the patient back in to review their results.

"In that follow up interview it's definitely important to have that discussion with the patient to help them understand why certain drugs there's a potential to intervene and for others there's not," says Papastergiou. The pharmacist then sends the patient's physician a letter with any recommended changes. Ontario reimburses the pharmacy $15 for each intervention the pharmacist recommends as part of its Pharmaceutical Opinion program for eligible patients.

What's the business model?
This links to an important question: what is the business model for offering this service? GeneYouIn is donating the tests for the study, which cost $500. While Papastergiou says it's too early to look seriously at the financial aspect of the service, he recognizes it's an issue he'll have to address if he wants to continue offering it after the study.

The pharmacist has casually considered a few revenue options. He feels patients on certain high impact drugs would pay for the service. For instance, he cites clopidogrel as a good candidate. That's because studies have found 30% of people are poor to intermediate metabolizers of the drug. Papastergiou also believes insurers would be interested in reviewing the test results before clients start medications, especially if it's an expensive drug.

The pharmacist has enrolled 35 patients in the program thus far, with a goal of 100 participants. While it's too early to assess the clinical impact of the service, Papastergiou is pleased with what he's observed thus far. "Once we've completed the study we'll sit back, analyze the data and see if it's a service we want to offer regularly but based on early anecdotal feedback I think it's something we'll continue to offer."

Dorfman insists tests like PillCheck shorten the time to optimal treatment and improve patient safety. Take mental health, for example. He says that only 50% of patients prescribed psychiatric medications respond to first-line treatment. The other half requires multiple dose changes and drug switches. "The test allows physicians to select the most absorbed treatment right away," he says. "So this improves patient safety by eliminating the possibility the person will take the drug at the wrong dose or a drug that doesn't agree with their profile."

The tests also help clinicians avoid misconceptions, Dorfman adds. Say a patient taking opioids for pain complains that the drug is ineffective. "Most of the time you'd assume they have an addiction problem," says the geneticist. "At the same time if they're a poor metabolizer it's not an effective drug for them." In those cases, he suggests the patient could be switched to a slow-release fentanyl or non-opioid therapy.

Opens door to collaboration

In terms of the other aspect the researchers are measuring, Papastergiou says physicians have thus far been receptive to his team's recommendations. "Our goal is to work collaboratively with doctors and review their feedback" he adds.

Dorfman believes pharmacogenomics can actually improve collaboration between pharmacists and physicians. With the test results, it's no longer the physician's professional opinion versus the pharmacist's, he points out. "For the first time we're bringing in something objective to help reconcile this situation," says Dorfman.

The geneticist believes physicians appreciate pharmacists taking the lead on this service because they themselves are too busy to comb through the reports. "At the same time pharmacists are able to provide these consultation services, taking the time to review the results and provide physicians with an abbreviated summary only focusing on drugs that require a switch."

In the years to come, Papastergiou thinks pharmacogenomics will have an increasingly prominent role in community pharmacies. "Personalized medicine is a buzzword out there. There's a lot of effort being put into this area. As the technology becomes cheaper, more people will get involved. Healthcare professionals will embrace it because it really does help us make better clinical decisions, and that's ultimate what we want for our patients."