

# the Translator

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## Pharmacists and Point-of-Care Testing

**T**echnology has advanced sufficiently to allow the assessment of laboratory tests at the point-of-care delivery through various point-of-care testing (POCT) kits. An ever-expanding number of tests are becoming available for use outside the laboratory setting. Pharmacists were early adopters of POCT by offering pregnancy testing when the technology made it possible to perform the testing in the pharmacy. Today, a wide variety of tests can be conducted in the pharmacy setting to enhance patient care.

As the scope of practice of pharmacists expands, access to lab tests will allow pharmacists to make better informed decisions. POCT offers an alternative to traditional lab testing and provides results that are current, rather than relying on results that may be weeks to months old.

Several recent studies have examined the feasibility and impact of pharmacy-based POCT. This issue of *the Translator* focuses on four studies that provide evidence of the utility and feasibility of POCT in the provision of patient care by pharmacists.

- A new Canadian model to screen for A1c in community pharmacies
- Community pharmacists screen for HIV using rapid testing
- Pharmacist's Intervention in Chlamydia screening – an example in Australia
- Pharmacist use of point-of-care testing to manage anticoagulants results in improved control

## A new Canadian model to screen for A1c in community pharmacies

Papastergiou J, Folkins C, Li W. Community pharmacy-based A1c screening: A Canadian model for diabetes care [published online ahead of print December 16, 2015]. *Int J Pharm Pract*. doi:10.1111/ijpp.12228

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**Issue:** In Canada, diabetes is an increasingly common chronic disease affecting both people and the health care system. Currently, there are about 2.7 million individuals with diabetes, which results in a financial burden of \$11.7 billion to the health care system. The economic costs are anticipated to reach about \$16 billion in 2020. More than 80%

of the expenses arise from patients developing complications from diabetes such as kidney failure, blindness and heart attack.<sup>1,2</sup> According to the 2013 Canadian Diabetes Association (CDA) guidelines, it is critical to implement a multifactorial approach to reduce the risk of cardiovascular complications in patients with diabetes. One of the

important interventions mentioned in the CDA guidelines is to maintain glycemic levels within the normal A1c value of  $\leq 7\%$ .<sup>3</sup> Sadly, seeing as over 50% of diabetic patients fail to regularly check and manage their A1cs, Canadians may be far from this goal.

**A solution:** Pharmacists are the most acces-

## Community pharmacy-based A1c screening – a Canadian model for diabetes care (cont.)

sible health care professionals and have the potential to be at the forefront of diabetes prevention and management. The development of devices that test HbA1c rapidly, and with only small amounts of blood, have provided pharmacists with tools to better manage their patients' diabetes. Additionally, the expanded scope of practice enables pharmacists to play a greater role in chronic disease management. For example, pharmacists in Ontario can now perform a procedure on tissue below the skin (e.g., collect blood by finger prick) for the purpose of chronic disease education and monitoring.

Out of 1111 patients who were screened nationally, a total of 871 met the inclusion criteria of the study. According to the A1c thresholds set by the 2008 CDA guidelines, 40.9% of patients had controlled glycemic levels ( $A1c \leq 7.0\%$ ), 43.3% had hyperglycemia ( $A1c > 7$  and  $< 9\%$ ) and 15.8% had marked hyperglycemia ( $A1c \geq 9.0\%$ ). Thus, 59.1% of patients had  $A1c$  values  $\geq 7.0$ , which increases their chance of developing diabetes-related complications. Moreover, the majority (76.9%) of untreated patients (e.g., patients on neither insulin nor oral anti-hyperglycemic medications) had optimal glycemic control. Among patients treated with anti-hyperglycemic therapy, those on oral therapy alone had the highest rate of optimal glycemic control (45.7% of oral therapy patients had  $A1c \leq 7.0\%$ ). Patients on insulin or combined (insulin plus oral) therapy had comparatively lower rates of optimal glycemic control (30% and 27.7% respectively). In general, a trend towards poorer glycemic control among patients on more intensive treatment regimens was observed. These findings may be partially explained by disease progression, but may also indicate a degree of psychological



Pharmacists help patients achieve better control of blood thinners by using POCT.

insulin resistance (PIR) in the patient population. PIR refers to reluctance on the part of patients and/or physicians to initiate or intensify insulin therapy. The erosion of glycemic control with intensifying therapy and evidence of possible PIR that was observed indicate a particularly urgent need for clinical interventions in patients on more intensive treatment regimens. This represents an opportunity for pharmacists to significantly contribute to helping patients improve their glycemic control.

Pharmacists conducted 1711 clinical interventions. The three most common interventions were: 29% for counselling about lifestyle measures, 16.5% for referral to a physician and 13.7% for pharmacist reviewing A1c results. In general, there was an average of two interventions per patient. The lowest number of interventions was for patients

with optimal glycemic control (1.4), greater for patients with hyperglycemia (2.2) and greatest for patients with marked hyperglycemia (2.8). This trend shows that pharmacists provided more clinical support to patients who were in most need of it.

The patients' glycemic levels varied significantly depending on their geographic location. People living on the West Coast had better control over their glycemic levels, compared to the people living on the East Coast. In British Columbia, 46.3% of patients had optimal glycemic control, compared to only 31.6% of patients in Atlantic Canada. This can be attributed to the fact that different cities will have different access to health care, lifestyles and socioeconomic standing. Also, the mean number of interventions per patient (1.9) was consistent across Canada. The only exception was the Canadian Prairies with 2.2 interventions per patient. The increase in the number of interventions in this jurisdictional region was driven entirely by Alberta and can be attributed to their enhanced scope of practice.

**Implications:** Pharmacists play an important role in the management of diabetes. With the availability of rapid A1c tests and the expanded scope of practice, pharmacists can offer convenient disease monitoring, identify intervention opportunities to control A1c levels and help patients improve their diabetes management. For the various treatment options available, pharmacists are able to educate on the proper use of medications and clarify any misconceptions about insulin therapy. The integration of pharmacists into the model for diabetes care is essential since their interventions reduce potential complications, thereby providing better patient-centred care.

**Background or research methods:** For this community-based study, point-of-care tests were conducted using the Bayer A1C Now at Shoppers Drug Mart locations across Canada. These voluntary screenings were offered as a professional service to patients of the participating pharmacies. Pharmacists submitted non-identifying data centrally,

using an online form. After the A1c test, pharmacist performed medication reviews and assessments for glucose control, blood pressure, lifestyle behaviours and potential diabetic complications. The pharmacist's involvement and recommendations were based on the 2008 CDA guidelines, which was the most recent guideline available when

the data was collected over a course of eight months.<sup>4</sup> Thus, A1c values of  $\geq 9.0\%$  were used to identify marked hyperglycemia. The uploaded data included various information such as location of pharmacy, demographic information, A1c results, type of pharmacist intervention and type of diabetic diagnosis and treatment.

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# Community pharmacists screen for HIV using rapid testing

Weidle PJ, Lecher S, Botts LW, et al. HIV testing in community pharmacies and retail clinics: A model to expand access to screening for HIV infection. *J Am Pharm Assoc* (2003). 2014;54:486-92. doi: 10.1331/JAPhA.2014.14045. Corresponding author: CAPT Paul Weidle, pweidle@cdc.gov

**Issue:** In Canada at the end of 2011 it was estimated there were approximately 71,300 people living with HIV/AIDS. Of this population, approximately one-quarter, or 17,825 people, are unaware of their status.<sup>1</sup> Testing rates in the general population are low, but the Public Health Agency of Canada would like to see HIV testing offered routinely.<sup>2</sup> People under 30, in particular, are more likely to seek testing if it is rapid and easily accessible.<sup>3</sup>

With advances in technology that allow for rapid point-of-care testing (POCT), HIV testing is possible in a wide variety of settings. With increased availability, it is hoped that more people who are at risk will seek out testing. The interaction at the point of testing also allows for provision of some information on risk reduction and may permit referral to appropriate health care providers. Rapid HIV testing using saliva may fit into the community pharmacy environment along with other point-of-care tests (POCT) for a variety of conditions.

**A solution:** A study was conducted by the United States Centers for Disease Control

Pharmacists and patients  
see pharmacy-based, rapid  
HIV testing as feasible and  
acceptable.

and Prevention (CDC) to examine the feasibility of delivering rapid HIV testing in community pharmacies and retail clinics. A total of 21 sites participated including 18 community pharmacies. The sites either offered the testing directly, using pharmacists or pharmacy/clinic staff, or in cooperation with an agency such as a local health department.

The POCT used has a positive predictive value 97.78% and negative predictive value 99.61% (98.87-99.92%) when compared with standard enzyme immunoassay blood testing.<sup>4</sup> This indicates that POCT is a reliable tool to detecting the presence and absence of HIV, but confirmatory testing would be a reasonable next step in the process of providing care.

Each site advertised the availability of the testing through a variety of methods, including bag stuffers, newspaper articles, websites and social media. Each site connected with local public health services to ensure consistency.

Staff members were provided in-person or online training on delivery of the point-of-care HIV test and on counselling people before and after testing. The counselling process was found to take an average of seven minutes for pre- and post-test counselling. Waiting time for the test was a median of 23 minutes.

During the period May 2012 to July 2013, all sites performed 1540 HIV tests in total. The median number of tests performed was 93. The range was 1 to 370. Reactive (positive) tests were found in 24 situations. These people were counselled by the pharmacist or nurse practitioner and referred for confirmatory testing.

Two sites withdrew from the study. One site had been offering the service in collaboration with public health and the service was stopped due to challenges in maintaining staff for the testing process. The second

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Papastergiou et al.

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## Community pharmacists screen for HIV using rapid testing (cont.)

site to withdraw was a community pharmacy that closed.

Upon completion of the study, 17 of the sites indicated they would continue to offer the service and would seek assistance or support from appropriate local service providers.

**Implications:** The results of the study demonstrate that community pharmacies are appropriate venues for offering rapid point-

of-care HIV testing. The majority of sites indicated they would try to continue to offer the service, which indicates its value. The time commitment to conduct testing is minimal. Having the test available in the pharmacy setting allows for easy access in a confidential setting from the pharmacist, a qualified health care professional.

One systematic review indicated that youth under the age of 25 are particularly interested in rapid HIV testing and are more

likely to access such testing and receive the results. It is thought that the majority of the undiagnosed HIV population is in this age category. For young people, especially those without a primary care physician, a pharmacy is a convenient venue in which to seek testing. Having testing available in a pharmacy may also help to address some of the stigma associated with going to a designated testing centre or a sexual health centre.

**Background and research methods:** The ASHLIN Management Group Inc., was granted a two-year contract by the Centers for Disease Control and Prevention (CDC) to design a model for HIV testing that could be implemented by retail clinics and community pharmacies. An expert panel was assembled to help find locations in the US that are able to participate in this project and develop training for this model. In order to perform the

laboratory tests, location had to possess a Clinical Laboratory Improvements Amendments of 1988 (CLIA) Certificate of Waiver. Additional resources such as training modules were available for the staff at to assist with the proper management of the HIV testing. Local health departments from each location were engaged with the norms for HIV testing. They finalized a list of locations that confirm HIV testing and other services and developed

referral lists regarding potential problems of the HIV test. This project was applied in two phases: phase 1 trained 6 out of the 7 locations that were selected between March and July 2012 and phase 2 trained 16 more locations that were selected between October 2012 and May 2013. Overall, 21 locations in the US that performed at least one point-of-care HIV testing were included in the data.

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# Pharmacist's intervention in Chlamydia screening — an example in Australia

Gudka S, Marshall L, Creagh A, et al. To develop and measure the effectiveness and acceptability of a pharmacy-based chlamydia screening intervention in Australia. *BMJ Open* 2013;3:e003338. doi:10.1136/bmjopen-2013-003338 (Gudka S 2013). Corresponding author: Dr. Sajni Gudka, [sajni.gudka@uwa.edu.au](mailto:sajni.gudka@uwa.edu.au)

**Issue:** Chlamydia is the most prevalent sexually transmitted infection (STI) in Canada, especially among younger Canadians; however, rates in adults aged 40 to 59 have increased in recent years.<sup>1,2</sup> The need to provide widespread testing for chlamydia is important since many people will remain asymptomatic and at risk of infecting future partners and experiencing complications of untreated infections such as pelvic inflammatory disease.

Public health services promote regular testing for sexually active persons to help identify those with chlamydia infections and to ensure treatment. One of the major challenges with all STIs is accessing testing services. In the current health care environment in Canada, testing is available through family physicians, sexual health clinics and public health services; however, multiple factors contribute to the decision to not be tested routinely. Stigma associated with STIs plays a large role. Ease of access of testing also contributes to less than ideal testing rates among high-risk individuals, as does lack of awareness of the need for testing.<sup>3</sup>

**A solution:** In a selective, opportunistic, cross-sectional study conducted in Perth, Australia, pharmacies agreed to participate by discussing testing for chlamydia with women requesting emergency contraception (EC). Pharmacies were recruited to participate if they reported conducting at least eight EC consultations per month. Pharmacists at participating pharmacies were required to complete a two-hour training program.

Women who requested EC were provided usual EC consultation services and then were given information on the pharmacy-based chlamydia screening program. Pharmacists discussed the risks for STIs and obtained consent to participate or reasons for declining participation. Women who agreed to participate completed an eligibility assessment, which recorded age and a checklist of STI symptoms. Women who had STI symptoms were deemed ineligible for testing and referred to their primary care provider or a sexual health clinic for evaluation and possible treatment.

Women who were eligible were provided with a laboratory requisition and a test kit, which consisted of a low-vaginal collection



swab, a swab transport tube, a biohazard bag and detailed instructions on the study protocol, collection methods and transport of the sample. All test materials were provided in a plain white envelope. Each test kit was assigned a patient identifier code. Tests were completed at home and could be returned to the issuing pharmacy or to a designated laboratory. Women were given a designated phone number to call 72 hours after returning their specimen to obtain results of the test. Pharmacies were reimbursed an initial A\$1000 and A\$15 for each test that was issued and returned for testing.

Across the 20 participating pharmacies, 769 EC consultations were conducted during the study period. Chlamydia testing was discussed with 596 (78%) and 247 (41%) agreed to participate. Of the 188 ineligible women, 33 reported symptoms consistent with STIs and were referred for further investigation. Test kits were issued to 166 (67%). Of these, 46 (28%) women completed and returned the test kit. All returned a negative result. The effective screening rate was 6%.

The most common reasons to decline participating at the pharmacy were being in a stable relationship or having recently been tested for STIs. Women who were issued a

test kit were interviewed by phone. Reasons for not completing the test included: inconvenience of dropping off the completed test, self-assessment of low-risk for chlamydia and testing at primary care provider's office instead.

Women who completed the test were more likely to report feeling that they were given sufficient information at the pharmacy to be able to make a decision about risk. Women also reported that the process was acceptable and felt that it was non-judgemental and a "responsible approach and entirely the right timing." Although most women reported feeling the consultations were conducted in a private setting, many reported some degree of concern over privacy. Over-the-counter consultations were not acceptable.

Pharmacists involved in the study felt positively about their experiences, but would have preferred more information about STIs and better privacy for the consultations.

The investigators conclude that the offer of chlamydia testing at the time of EC consultation is ideal and acceptable to the women in the study. Improvements in options for dropping off completed tests are needed. Pharmacy privacy should be improved and pharmacists feel they need additional training in STIs.

**Implications:** Although not strictly POCT, the chlamydia testing process used in this study provides opportunities for the pharmacist to provide easily accessible, low-risk testing to women at risk of STI while referring women with symptoms of possible STI for care.

With the increasing rates of chlamydia seen in Canada in recent years and the identification of an older cohort of people at risk, increasing opportunities for testing could significantly improve understanding of risk and receipt of treatment in asymptomatic persons. The pharmacist is ideally situated to provide professional, confidential screening and advice to persons at risk of STIs.

Closer ties between pharmacists and public health could result in additional testing and a reduction in the spread of chlamydia among at-risk populations. Making testing available through pharmacists may help to improve access and make testing more acceptable.

## Pharmacist's intervention in Chlamydia screening – an example in Australia (cont.)

**Background and research methods:** Emergency Contraception Mediated Pharmacy Access to Chlamydia Testing (ECOMPACT) was used as a screening intervention in this selective, opportunistic, cross-sectional study located in 20 community pharmacies across Perth, Australia. The ECOMPACT model, developed through literature review and stakeholder consensus, allows pharmacists to screen patients and make sub-

sequent recommendations based on the presentation of their symptoms. Women eligible to participate in this model of study had to be asymptomatic, at least 18 years of age and requesting emergency contraception. Symptomatic women were referred to a physician. Those willing to participate were instructed to self-collect a lower-vaginal swab and then drop it off at the designated pathology laboratories or the primary issu-

ing pharmacy. The specimens were tested using nucleic acid amplification tests and the results were then disseminated 72 hours later by phone. This model was designed to be supplemental to the standard EC consultation that pharmacists would give; therefore, the usual workflow of the pharmacy generally remained unchanged. Chlamydia positive women were treated at Sexual Health Services of the Fremantle Hospital.

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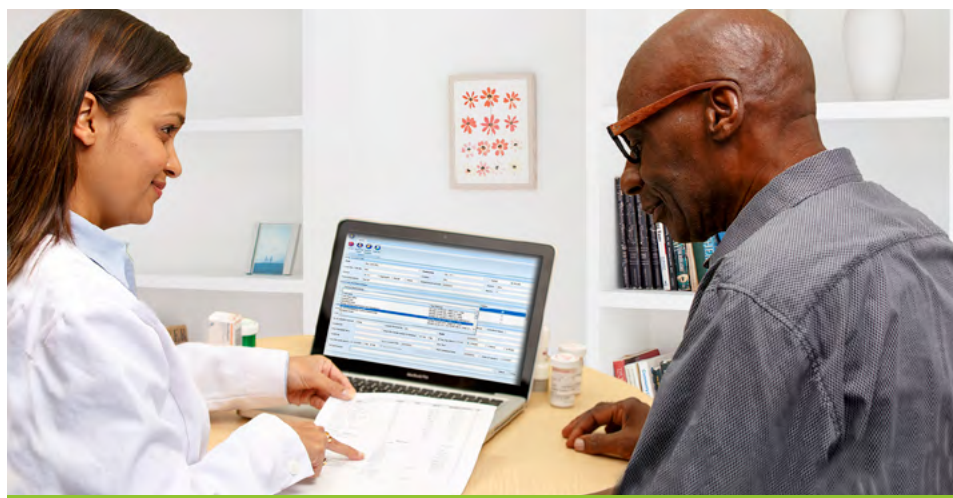
# Pharmacist use of point-of-care testing to manage anticoagulants results in improved control

Rossiter J, Soor G, Telner D, Aliarzadeh B, Lake J. A Pharmacist-Led Point-of-Care INR Clinic: Optimizing Care in a Family Health Team Setting. *Int J Family Med.* 2013;2013:691454. doi: 10.1155/2013/691454. Epub 2013 Dec 12. (Rossiter J 2013) Corresponding author: Deanna Telner, deanna.telner@utoronto.ca

**Issue:** Maintenance of control of anticoagulation is important for both ensuring optimal reduction of stroke risk and for reducing risk of bleeding episodes. Patients who take warfarin adjust the dose of the medication to achieve an International Normalised Ratio (INR) within a given target range, depending on the reason for needing anticoagulation. The patient requires the anticoagulant to avoid developing blood clots that can result in pulmonary embolism or stroke. The INR must be managed closely to ensure the patient benefits from the reduced stroke risk, but also has low risk of bleeding.

**A solution:** In one primary care clinic in Toronto, Ontario, the integrated pharmacist took on responsibility for managing warfarin therapy by establishing an INR (International Normalized Ratio) clinic. Initially, the INR clinic used traditional laboratory INR results obtained by venipuncture. To maintain the patient within the prescribed INR target range, the pharmacist would adjust the dose of warfarin based on the INR values received from the laboratory. After ten months, POCT for INR was introduced. Instead of receiving lab results and communicating with the patient by telephone, the pharmacist would perform an INR POCT and make any necessary adjustments while the patient was in the clinic.

The amount of time during which a patient is within their INR target, "time in the therapeutic range (TTR)", is correlated to better outcomes by reducing risk of clots and bleeding events. Patients' TTR was compared for a three-month period before (2008) and after (2010) the implementation of POCT for INR. TTR was calculated using



Pharmacists help patients achieve better control of blood thinners by using POCT.

the Rosendaal method of linear interpolation. The TTR for the two periods was compared to determine if either method allowed for more TTR.

A total of 119 patients were identified for inclusion in the analysis. The average age was 78.8 years and 61 patients (51.3%) were women. Five patients were excluded from the analysis since they did not have an estimated TTR. Thirty-two patients had data for both time periods and were included in both the analysis. A total of 74 patients from the 2008 lab based testing group were compared to 72 patients from the 2010 group who were managed with POCT. Patients who had planned irregular warfarin use for reasons such as surgery, were excluded from the analysis. The group managed by POCT testing (2010) was found to have a TTR of

77.1% vs 64.4% for the 2008 group, a difference of 12.68% (CI: 1.18, 24.18), which was statistically significant ( $p = 0.03$ ).

The authors conclude that use of POCT testing by the pharmacist resulted in a significantly greater amount of time spent in the therapeutic range. This result was consistent with another study of INR POCT management by nurses.

**Implications:** This study provides valuable insight into the impact of POCT testing on a population that had previously been managed by the pharmacist using traditional lab services. The immediate nature of the result and ability to make any necessary changes while the patient and pharmacist are face-to-face may have played an important role in increasing TTR.

**Background and research methods:** A quasi-experimental study was done to select for patients taking warfarin by consulting the electronic charts from the family health team in south-east Toronto. Eligible patients were chosen when their INR levels were between 2 to 3 and they experienced atrial flutter or fibrillation. Data from these patients were collected from two different group settings during February 1 to April 30, separated by a two-year interval. Patients were either on

warfarin treatment in 2008 to get the baseline INR results whereas others were monitored in the POC INR clinics in 2010. The data was then obtained from the patient's chart review that included patient demographics, comorbidities and INR levels. For the warfarin treatment group, intended variations in drug administration due to beginning, discontinuing or holding therapy were recorded. The patients being monitored had at least half of their INR results recorded in the POC clinic

to be enrolled in the group. Both groups did not require a set number of individuals; it solely depended on the patient meeting all the requirements stated above. After measuring the TTR to monitor the warfarin levels in the 2008 and 2010 groups, linear models of the data were created using the Rosendaal method of linear extrapolation to measure the impact of the POC clinics.

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## the Translator

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