THE POINT-OF-CARE TESTING (POCT) ENVIRONMENT:

CONSIDERATIONS IN DEVELOPING A FRAMEWORK FOR POCT IN PHARMACY PRACTICE

VERSION 9.0

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Foreward

Point-of-care testing (POCT) continues to expand into community and acute care settings. This is driven in part by new developments and technologies that allow testing and analysis outside of central laboratories as well as healthcare reforms aimed at improving access to health services for the public. Individuals are also demanding greater involvement in the management of their health and so the convenience, autonomy and direct engagement that comes with POCT is attractive to the consumer.

POCT is increasingly making its way into the practice of pharmacy in the community, ambulatory, continuing care and acute care settings. Various healthcare jurisdictions are now seeking ways to engage pharmacy professionals to provide improved and cost-effective access to healthcare services such as POCT, particularly for people with chronic disease.

This paper examines the POCT landscape for the purpose of informing POCT guidelines and standards for practice by pharmacy professionals in Alberta.

The Alberta College of Pharmacists and the Alberta Pharmacists' Association led development of this report that was guided by input from a POCT Advisory Committee consisting of:

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This paper is the product of consultation with experts and stakeholders across various professions and in the field of POCT. It was informed by reviewing source documents, performing literature reviews, and through the discussions and deliberations of the POCT Advisory Committee. The Alberta College of Pharmacists and the Alberta Pharmacists' Association commissioned the services of an independent consultant to prepare the discussion paper on behalf of the POCT Advisory Committee.

The POCT Advisory Committee chose to identify federal, provincial and professonal policies, guidelines and standards of practice that may guide or govern the delivery of POCT. Standards of practice from the provincial governing bodies for pharmacy professionals were reviewed. Standards of practice from the College of Physicians and Surgeons of Alberta were also reviewed and Alberta Health Services' Laboratory POCT Network leads were consulted.

A review of the literature was performed seeking evidence of clinical or economic consequences for POCT in acute and ambulatory/community settings. A systematic review sought from the Canadian Agency for Drugs and Technologies in Health (CADTH- Canada's health technology assessment body) focused on the area of infectious diseases, an area where POC tests are being used in community pharamacy practice.

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Abbreviations

ACP	Alberta College of Pharmacists
ACTH	Adrenocorticotropic Hormone
AHS	Alberta Health Services
CADTH	Canadian Agency for Drugs and Technoloiges in Health
CCOH	Canadian Centre for Occupational Health and Safety
CLIA	Clinical Laboratory Improvement Ammendments
CLSI	Clinical & Laboratory Standards Institute
CMDR	Canadian Medical Devices Regulations
CMS	Centers for Medicare and Medicaid Services
CPSA	College of Physicians and Surgeons of Alberta
DTC	Direct to Consumer
FDA	Food and Drug Administration (US)
GH	Growth Hormone
GLP	Good Laboratory Practices
HbA1c	Glycated Hemoglobin
HC	Health Canada
HCV	Hepatitis C Virus
HIV	Human Immunodeficiency Virus
INR	International Normalized Ratio
ISO	International Organization for Standardization
LDL-C	Low Density Lipoprotein Cholesterol
MDALL	Medical Devices Active License Listing
MDB	Medical Devices Bureau
MRSA	Methicillin-resistant Staphylococcus aureus
NPT	Near Patient Testing
OECD	Organization for Economic Cooperation and Development
OSHA	Occupational Safety and Health Administration
POC	Point of Care
POCT	Point of Care Testing
PTH	Parathyroid Hormone
RxA	Alberta Pharmacists' Association
SOP	Standard Operating Procedure
TPD	Therapeutic Products Directorate

Executive Summary

This document examines the POCT landscape in Canada for the purpose of informing POCT guidelines and standards for the practice of POCT by pharmacy professionals in Alberta. We recommend that this framework be built upon the following principles:

1. Person-centered care: Person-centered care is foundational to good pharmacist practice. Being one of the most accessible of all healthcare professionals, pharmacists are uniquely positioned to engage with, educate and support individuals to manage their health needs. POCT is a tool that enables pharmacists to better deliver on the value that they bring to patients and to the health system via their application of knowledge and expertise about drugs, drug therapy and disease in response to individual's health needs. In keeping with the principles of person-centered care, the public's health and safety is of the highest importance in the delivery of POCT by pharmacists. Pharmacists have a responsibility to identify and confirm the clinical need for testing, the frequency of testing and the benefits of testing for each individual. Pharmacists also have a duty to interpret and report test results and to follow-up with individuals tested, to discuss results and next steps if any. Reporting of test results can involve adding data to individuals' pharmacy record, uploading data to Netcare, informing other members of the individuals' health team (as appropriate), and/or notifying health authorities if the disease is considered notifiable.

2. Quality management systems that support POCT: In offering POCT, high quality accurate test results must be guaranteed and prevention of harm to individuals being tested and pharmacy personnel ensured. Quality management systems that minimize risk to individuals and to the facility need to be developed and implemented. Such programs must address concerns that have been identified in the pre-test, test, and post-test phases of POCT delivery (refer to **Table 2**) and should be consistent with programs that have been developed elsewhere (e.g., in the USA for CLIA-waived testing).

3. Training and competency evaluation programs that support POCT: To provide optimal care that uses new POCT technologies, it is imperative that pharmacists and pharmacy personnel are fully knowledgeable about the equipment they are using and the diseases that they are actively managing. Training in POCT and its applications and ongoing competency evaluation is essential.

4. Professional oversight: To ensure consistent high-quality POCT services are delivered across Alberta and to support the advancement of POCT in pharmacy practice, it is the responsibility of the Alberta College of Pharmacists to define standards and guidelines that support the safe and effective use of new POCT in pharmacies. The rigor of standards and guidelines will vary depending upon who was performing the test (individual/consumer, pharmacist), the purpose of the test (screening, therapeutic monitoring), and the risk associated with test results. The College will also require appropriate mechanisms to monitor pharmacies that they govern for compliance. The Alberta Pharmacists' Association has a key role in providing training that optimally prepares pharmacists for delivering new POCT services in pharmacies.

5. Partnership: The scale and scope of POCT is broad and expanding. Inter-professional collaboration with stakeholders and partners having interest, experience and expertise in this area can inform the development of a meaningful and effective framework for POCT practices in pharmacy. Partners may include CPSA, AHS Laboratory Services - and other health professional

colleges and associations that are facing similar evolutions in the adoption of POCT into their practices.

6. Research, innovation and evaluation: POCT is a quickly emerging opportunity. As the field progresses and as the Alberta College of Pharmacists and the Alberta Pharmacists' Association move forward to develop professional standards, guidelines, and programs in this area it will be essential to self-monitor and evaluate activities. Rigorous self-monitoring, research and evaluation strategies can contribute to Alberta becoming professional leaders in the delivery of POCT.

Drivers of POCT and Their Implications in Pharmacy Practice

Point of care testing (POCT) is defined as diagnostic or screening testing performed at or near the site of interaction with the person receiving care services with the result leading to possible change in the care of the patient[1]. Those performing the test may or may not be laboratory technologists and the site of testing may or may not be under the auspices of an accredited diagnostic laboratory. Sites for POCT can be in hospitals, including emergency departments, intensive care units, and neonatal units - or performed outside of tertiary centres (e.g., ambulances, the workplace, pharmacies, physician clinics, dental clinics, long term care centres and in an individuals' homes).

In recent years, the types of available point of care tests and the volume of tests performed have increased substantially. Test performance has also improved. Reasons for this are multifactorial and reflect a convergence of emerging forces. These forces include (1) current unsustainable models of health care and the need for cost containment while assuring access, (2) public's demand for more involvement, control and convenience in their care, and (3) the emergence of disruptive testing technologies that are entering new and 'unregulated' consumer and community healthcare markets.

Pressures in health systems aimed at decreasing costs and increasing access to health services are strong drivers supporting POCT although it remains unknown whether POCT will be cost effective overall. Noteably, the direct costs of POCT are generally reported as exceeding the cost of performing tests within the centralized laboratry setting where testing volume and automation reduce costs per test. The premise is that POCT can shorten turn around time for test results thus providing health professionals with information required to make immediate decisions about care. Availability of actionable information during a health/medical visit can mean earlier treatment of health issues and potentially a reduction in subsequent health encounters, possibly impacting health system costs overall, as well as costs to the individual being treated (e.g., out of pocket expenses, time lost from work due to health visits).

Health systems are also placing substantial emphasis on person-centered models of care that provide individuals with more convenient access to improved services. Health services are increasingly being offered at the point of medical/health encounter or contact (clinics, pharmacies, public health centres) to better meet individuals' needs and preferences as well as to address the increasing burden of chronic disease management. As the proportion of elderly increases, the burden of age-related chronic conditions is also increasing. This poses significant challenges to health-care systems in terms of cost and delivery of services – thus the trend to decentralize care decreases use of more costly hospital services (emergency room visits, hospital length of stays). Person-centered care also focuses on early

[1] ISO 22870:2006. Pay to download at: http://www.iso.org/iso/catalogue_detail.htm?csnumber=35173

detection of disease as well as disease prevention strategies to minimize treatment costs.

Person-centered care meets the demand from individuals for greater awareness and more involvement and control over their health and the services that they receive. In this context, the advent of POCT is certain: it is convenient for the individual (in fact many technologies are home-based products); it is usually less invasive compared to the standard laboratory setting (many tests rely on a finger prick for blood sampling); and it provides individuals with a degree of autonomy of testing plus tools and information to practice preventative care.

The explosion of new portable technologies that allow consistent and accurate onsite testing is also fundamental to driving POCT into healthcare. Sensor technologies are enabling rapid analyses of blood samples for gases and other tests in the disciplines of chemistry, hematology, and infectious disesases. Assay automation, 'cloud computing' and new cell phone capabilities are also contributing to the POCT market. The growing economic pressures on hospitals/health systems and the change in public demands - coupled with advances in diagnostic technologies – has meant that POCT suppliers are entering markets that have never before been available. Companies are marketing direct to consumers and health professionals and away from central laboratories. This new market access and diffusion is also made possible by the current lack of regulatory and policy frameworks governing the sale and implementation of new technologies. The trend toward consumer focus on health and wellness combined with new technologies has driven a new market for health monitoring equipment and applications. Many individuals are actively involved in collecting data about their well-being including tracking fitness activity via GPS, and vital signs such as body weight, sleep patterns, heart rate and glucose levels.

This constellation of large-scale social and economic factors is altering modern healthcare. The disruptive impact of point of care tests will be to change care pathways including the role of health professionals in the delivery of testing and care.

Although POCT can provide rapid results and the opportunity for more timely intervention, its challenges and shortcomings must be understood and minimized. Disadvantages of POCT are related to the potential risks of performing unnecessary tests, the triggering of redundant testing, the potential for poor quality of analysis, inadequate or inappropriate result interpretation and failure to detect erroneous results. The lack of regulation governing the use of POCT at sites outside of hospital settings is a concern. Instrument maintenance, record keeping, result reporting and other quality assurance standards are not necessarily in place in these settings, as they are for hospitals. Also, national and provincial structures for post market surveillance of issues and post market recalls of testing equipment appear to be not well developed. Finally, consideration must be given to proper training and competency evaluation of non-laboratory personnel operating POCT equipment in order to ensure optimal testing standards are achieved. Oversight/monitoring of pharmacy professionals performing POCT to ensure standards are being met must be considered.

POCT in pharmacies supports pharmacists to apply their knowledge and expertise about drugs and drug therapy when responding to individual's health needs. POCT can empower pharmacists with information needed to perform therapeutic monitoring, population screening, and to make therapeutic decisions that improve outcomes and potential costs to the health system. Many point of care devices are intended for home use and pharmacy professionals have a valuable education and monitoring role in this context as well.

The areas where pharmacists have a role in POCT can be categorized (with examples) as follows:

1. Home-based tests
   - blood glucose, INR, consumer-sourced genomic testing from commercial entities
2. Screening tests performed in the pharmacy
   - Influenza, HIV
3. Therapeutic monitoring for drug efficacy and/or disease control performed in the pharmacy
   - INR, cholesterol
4. Pharmacogenetic testing performed in the pharmacy or through a reference laboratory
   - CYP P450 enzyme testing for drug metabolism
5. Diagnostic tests performed in a pharmacy or through a reference laboratory
   - N. gonorrhoeae

The pharmacist's role and thus degree of support and/or regulatory oversight required for each category will vary depending on parameters such as who is performing the test and for what purpose, and characterisitcs of the individual being tested such as severity of illness.

This document provides an overview of the POCT landscape in Canada and the role that pharmacy professionals have in using them to inform practice decisions. This document highlights important considerations that the Alberta College of Pharmacists and the Alberta Pharmacists Association must consider in implementing POCT in pharmacy practice and in doing so provides context for the development of standards of practice for pharmacy professionals.

The summary of principles provided in this document are considered in the context of the drivers of POCT in the community setting and include a focus on (1) person-centered care, (2) the need for appropriate and effective testing, and (3) the role of POCT as a valuable tool to support pharmacist's roles as drug and disease management experts.

The Value Proposition for POCT

The cost of health care versus the value underlying it are distinct from one another but related. Users of the health system (the public) will have unique and diverse perspectives about their idea of 'value' versus health care organizations - and health professionals, policy makers and system funders will also differ in their definitions of value. For individual users of health services, value is defined through their experience and interaction with the health system and with healthcare providers. Individuals value health, wellness, convenience and timely access to health services when needed, and recovery of health when ill. In their role of overseeing the health system, health administrators value affordability and sustainability of the system while ensuring that quality health services are met. Health professionals value a health system that allows for the provision of optimal care and services to th public that in return support best outcomes. As individuals migrate toward the convenience and empowerment that POCT offers, health administrators are examining how the new technologies and new models of care will impact costs to the system. Detailed understanding of these and other issues including individuals interest and threshold to pay for POCT are still unknown. Certainly the true value of point of care testing ultimately lies in the appropriate use of tests within the system; and their impact on supporting individuals meet their health goals – and it is the responsibility of healthcare providers to ensure such occurs.

For POCT to have value, it should demonstrate improved clinical outcomes and ideally decrease costs and/or increase efficiencies to the health system. With POCT a basic premise is that testing perfomed at

the time and place of health/medical consult leads to actionable information within a single clinical encounter. An improvement in outcomes can be expected because of immediate treatment and improvements in cost can be expected because of potential elimination of additional health encounters. Although simple in principle, the factors that effect these assumptions are complex. Currently there is little peer reviewed literature to document improved health or enhanced operational or financial outcomes with the use of POCT, particularily in the primary care or community setting. As POCT continues to grow in acute and community care settings (including community pharmacy) its impact and usefulness in specifc environments will become more evident.

The Canadian Agency for Drugs and Technologies in Health (CADTH) recently evaluated POCT for cost and health benefits across several clinical areas. The reports cited represent publications and data from hospital and related clinic settings and not from community pharmacy (private) practices. The information presented therefore represents results from health professionals performing POCT in hospitals or ambulatory clinics. Some of CADTH's findings are as follows[2]: In the case of cardiac marker and creatinine testing, overall POCT increased the proportion of individuals discharged from hospital and was deemed to have an important impact on care. POCT in this area was also deemed acceptable for use in critical care settings and considered superior to laboratory troponin-only testing in triaging individuals with chest pain. In the United Kingdom an economic assessment found that wide-spread use of POCT for cardiac markers was not recommended because it did not meet the required cost-effectiveness threshold. In the case of lactate, overall POCT was effective and timely for the diagnosis of bacterial meningitis and supported risk stratification in the emergency department. In the hospital setting, blood glucose POCT showed variable results: overall, when compared to standard laboratory testing POC glucose testing was found to be inferior and not precise enough to manage critically ill people who require tight glycemic control or those with suspected ketoacidosis. In the pediatric population, POCT was found to be acceptable for bilirubin testing and it reduced the blood volume needed for multi-parameter tests. Results for glucose testing were mixed.

In another comprehensive review, CADTH evaluated clinical and health economic evidence and compared POC INR testing with standard laboratory testing[3]. Findings indicate that POC INR testing with any currently available POC INR device is an accurate alternative to lab INR testing and that individual self-management (POC INR testing + dose adjustment) versus clinic-based POC INR testing may be the most cost-effective option. Individuals' self-testing with health care provider dose adjustment may be an option when lab INR testing is difficult. CADTH suggests that POC INR testing may be helpful for individuals in rural or remote settings or those who may be isolated for other reasons (elderly people confined to their homes) particularly if laboratory services are not easily accessible or INR results cannot be obtained in a timely manner. However, evidence for POC INR testing in these settings is still required.

Of interest is the offering of POCT specificcaly by pharmacy professionals. In an outpatient hospital-based pharmacist-managed clinical setting, POCT used to obtain lipid results for making therapy adjustments during face-to-face visits improved lipoprotein cholesterol (LDL-C) goal attainment[4]. Also, a

[2] Canadian Agency for Drugs and Technologies in Health. Rapid Response Report. Point of Care Testing Technologies for Routine Clinical Chemistry Compared to Standard Laboratory Testing Methods: Clinical Effectiveness, Diagnostic Precision and Accuracy, Cost Effectiveness, and Guidelines [Internet]. Ottawa: The Agency, 2013 Sept. [cited 2015 December 11]. Available from: https://www.cadth.ca/point-care-testing-technologies-routine-clinical-chemistry-compared-standard-laboratory-testing

[3] Canadian Agency for Drugs and Technologies in Health. Rapid Response Report. Point-of-Care Testing: A Canadian Agency for Drugs and Technologies in Health. Point-of-Care INR Testing Compared with Lab INR Testing: What Does the Evidence Say? [Internet]. Ottawa: The Agency, 2015 Apr. [cited 11 December 2015]. Available from: https://www.cadth.ca/poc-inr-tool

[4] Gerrald KR, Dixon DL, Barnette DJ, Williams VG. Evaluation of a pharmacist-managed lipid clinic that uses point-of-care lipid testing. J Clin Lipidol. 2010 Mar-Apr;4(2):120-5.

pharmacist-directed physician-supported anticoagulation management clinic within a hospital setting achieved significantly better INR control and reduced rates of thromboembolic complications compared with standard care. Resource utilization was also substantially reduced in this setting.[5]

Community pharmacy-based POCT has been occuring for decades in areas including diabetes, cardiovascular disease and osteoporosis. However, studies citing health and economic impact of POCT in community pharmacies in Canada and elsewhere are only beginning to emerge. This is due to many factors including challenges associated with performing clinical trials in the community environment. Also, changes in care pathways and processes that result from POCT are not well understood thus making it difficult to ascribe resource utilization in that context.

Several studies using POCT in community pharmacies to manage disease are described: In a randomized trial evaluating the effect of community pharmacists' intervention on the process of cholesterol risk management in individuals at high risk for cardiovascualr disease, 54 pharmacies across Alberta participated[6]. Of the 675 people enrolled those in the intervention group received education, point of care cholesterol measurement, referral to physician, and regular follow-up for 16 weeks by the pharmacist. The study was terminated early because of striking evidence of benefit (improved cholesterol panel or addition/increase in dose of cholesterol-lowering medication) in the invervention group compared with the usual care group.[7] In a study designed to implement and evaluate acceptability and feasibility of pharmacist-provided rapid testing for HIV infection in two independent community pharmacies, participants and pharmacists cited favorable perceptions and experience of HIV testing in pharmacies.[8] Pharmacists provided HIV tests to 69 participants; one participant had a reactive HIV test and was referred for appropriate confirmatory testing. In a US study designed to evaluate impact of pharmacy-based influenza testing and treatment, 55 independent and chain pharmacies across 3 states partnered with physicians to develop a program to curtail antibiotic resistance.[9] Pharmacists screened 121 people, 13 (11%) of which tested positive for influenza and received antivirals. In this study 39% of tests were performed after physician hours and 35% of individuals tested had no primary care physician. Just over 90% of individuals reported satisfaction with testing in pharmacies.[10]

As part of our scan, the POCT Advisory Committee commissioned a Rapid Response Report from CADTH that examined the clinical and cost-effectiveness of various POC tests performed in pharmacy settings for HIV, hepatitis C, influenza, and Streptococcal infections. Testing in the area of infectious diseases is particularly pertinent to community pharmacists where implementation of disease screening programs make practical sense due to pharmacist accessibility and content expertise. The study found that (1) POC tests provide a reliable testing strategy for hepatitis C virus or group A streptococcal pharyngitis infections, (2) performance may vary among POC tests for hepatitis C and group A streptococcal organisms, and (3) POC tests for influenza A and B show high specificity but low sensitivity suggesting

[5] Bungard TJ, Gardner L, Archer SL, Hamilton P, Ritchie B, Tymchak W, Tsuyuki RT. Evaluation of a pharmacist-managed anticoagulation clinic: Improving patient care. Open Med. 2009 Feb 2;3(1):e16-21.

[6] Tsuyuki RT, et al, for the SCRIP Investigator. A Randomized Trial of the Effect of Community Pharmacist Intervention on Cholesterol Risk Management: The Study of Cardiovascular Risk Intervention by Pharmacists (SCRIP). Arch Intern Med. 2002;162(10):1149-1155.

[7] Ditto

[8] Darin KM, Klepser ME, Klepser DE, Klepser SA, Reeves A, Young M, Scarsi KK. Pharmacist-provided rapid HIV testing in two community pharmacies. J Am Pharm Assoc. 2015 Jan-Feb;55(1):81-8.

[9] Klepser Michael E., Adams Alex J., and Klepser Donald G. Antimicrobial Stewardship in Outpatient Settings: Leveraging Innovative Physician-Pharmacist Collaborations to Reduce Antibiotic Resistance. Health Security. June 2015, 13(3): 166-173.

[10] Ditto

that negative POC tests need confirmation testing[11]. The Report has been included as **Appendix 1** to this document.

Implications for Pharmacist Practice[12]

New technologies combined with the movement toward person-centered care and increased 'personal autonomy' in the management of their health means that both consumer home-testing and POCT in pharmacies will increase. POCT has the potential to support and enhance the value that pharmacists provide to the health system through their role in disease screening, disease management and in the monitoring of drug therapy to improve medication outcomes. On all accounts, pharmacists must bear in mind that the priority goal of POCT is to seek and ensure health and safety to individuals being tested.

Pharmacists in the community are ideally positioned to develop disease screening or risk assessment programs to support public health efforts. Diseases of interest and where point of care tests are available include HIV, HCV, influenza, and streptococcal pharyngitis. In the interests of individuals' health, pharmacists must ensure that policies and procedures are in place for interpreting, reporting and responding to test results. Reporting of results can mean a number of actions including adding data to individuals' pharmacy record, uploading data to Netcare, informing other members of the indviduals' health team (as appropriate), and/or notifying health authorities if the disease is considered notifiable. Actions resulting from testing could include educating individuals about their results, treatment of the condition, and/or referral to other appropriate healthcare professionals,

It is essential that pharmacists are fully versed in both the unique health applications of chosen testing technologies as well as the technical specifications and limitations of the equipment being used. Understanding for example the sensitivity and specificty of a test is critical to providing optimal care to individuals. As the CADTH Rapid Response Report on infectious diseases brings to light[13], low test sensitivty can lead to false negative results that will often require further investigation. In some cases POCT will be presumptive only and clinical decisions should not be made on the results because of the potential for false positives and false negatives (e.g., toxicology testing) for a given technology. Decisions to test and then to possibly re-test (e.g., through central laboratory services) will depend upon a host of considerations that include characteristics inherent with the testing equipment (sensitivity, specificity; quantitative versus qualitative results), reason for testing, and the health status of the individual being tested. Thus critical thinking around testing devices, device specifications/limitations, and the nature of the test result must also form part of pharmacists' critical assessement of individuals and their health.

POCT in pharmacy practice also supports pharmacists' role in disease management particularly with chronic diseases where early intervention and/or proper ongoing management has potential to alter outcomes. Diseases in this category include hyperlipidemia, diabetes, and hypertension. Point of care tests that measure disease activity (lipids, HbA1c, INR) and the effectiveness of drug therapy are instrumental to supporting pharmacists' role as disease and medication managers.

Tests that detect drug levels (particularily for those drugs with small therapeutic indices) and signs of drug toxicity (liver and kidney function tests) also provide valuable information for pharmacists to

[11] Canadian Agency for Drugs and Technologies in Health. Rapid Response Report. Point of Care Testing Technologies for Infectious Diseases: A Review of Clinical and Cost-Effectiveness, and Guidelines. Ottawa: The Agency, 07 March 2016.

[12] As ACP and RxA develop a POCT framework for pharmacy practice, roles and responsibilities of pharmacists and pharmacy technicians will be considered.

[13] Canadian Agency for Drugs and Technologies in Health. Rapid Response Report. Point of Care Testing Technologies for Infectious Diseases: A Review of Clinical and Cost-Effectiveness, and Guidelines. Ottawa: The Agency, 07 March 2016.

monitor drug therapy. In Alberta where pharmacists can initiate therapy or adapt prescriptions (e.g. adjust doses) mechanisms to monitor an individual's condition are necessary.

Choosing to use POC technologies must be done wisely. Central to choosing and using a point of care test in practice is to identify the population that may achieve significant clinical benefit from having the test available. For each test administered it is equally important to justify from a disease management perspective the appropriate use of that test at that particular time. In all instances the health and safety of the individual must be at the core of any testing regimen. 'Choosing Wisely Canada'[14] is a campaign to engage physicians and the public with the goal to eliminate unnecessary testing and treatments and to make effective choices to ensure high quality care. Inappropriate testing potentially exposes individuals to harm by leading to more testing to investigate 'positives' or to treatments and interventions that are unwarranted. Pharmacists must ensure that all testing, whether resourced by the individual, the pharmacy or the system is warranted.

In order to provide testing under such conditions, pharmacists will require appropriate training in point of care testing and must also ensure they are experts in the disease areas and knowledgeable about related clinical guidelines for testing in which they are focusing POCT efforts.

Tests and Technologies

POCT is known by other terms including near-patient testing (NPT), bedside testing, extra-laboratory testing, rapid testing (RT), and direct to consumer (DTC) testing, to name a few. Typically, RT refers to tests that are for preliminary or emergency screening and often used in health facilities with limited resources. DTC testing includes genetic tests sold directly to the public.

Advances in technology have allowed testing to occur outside of the traditional centralized laboratory. For the most part, the testing technologies were devised years ago; however, advances in assay automation, low cost sensors, instrument miniaturization and access to 'cloud computing' have contributed to the point of care market.

POCT is an activity (not a test, per se) that embodies a broad range of testing technologies or systems that can be categorized as follows:[15]

1. **Non-instrument systems** – disposable systems and devices that are typically for a single analyte (e.g., pregnancy tests)
2. **Small analyzers, usually hand-held devices** - providing qualitative or quantitative determination of an increasing range of analytes. Examples are biosensor strips (glucose meters), and lateral flow-through strips using immobilized antibodies (cardiac markers, infectious pathogens).
3. **Desk-top analyzers** - are essentially laboratory instruments that have been reduced in both size and complexity. Examples are critical care analyzers, hematology and immunology analyzers, and PCR machines used for detection of infectious pathogens.

Using these and other emerging technologies, specific tests can be used to screen, diagnose, and monitor disease progression/recession including the effectiveness as well as the toxicity associated with drug therapy.

[14] Choosing Wisely Canada: http://www.choosingwiselycanada.org/about/what-is-cwc/ (accessed 25March2016).
[15] St John A, Price CP. Existing and Emerging Technologies for Point-of-Care Testing. Clin Biochem Rev 35(3) 2014.

Emerging and future developments in POCT will continue to transform the healthcare landscape. New technologies are capitalizing on the widespread use of smartphones and apps along with advanced computing power that allows individuals to communicate information directly to health professionals many miles away. These types of technologies are being built on the backbone of the 'Internet of Things' which consists of networks of data gathering sensors embedded potentially 'everywhere' and sending information up to cloud servers to power applications and analysis.

As for the types of tests available and the end products they detect, there is a broad range of tests and this area continues to grow at a fast pace. Examples of available point of care test modalities are shown in **Table 1.**

Table 1: Examples of common, less common and emerging point of care tests available in Canada

Common	Less Common	Emerging
Blood glucose Blood gas analysis /electrolytes Urine dipsticks Occult blood Hemoglobin Rapid Strep	Cardiac markers Drug toxicity Drug metabolism INR Heparin Bilirubin Calcium Lipids Hemoglobin 1Ac Creatinine HIV Influenza H. pylori Opioids	Complete blood count White blood count Coagulation Platelet function testing Microbiology: outbreaks, MRSA Endocrine testing: PTH, ATCH, gastrin, GH Sepsis markers Stroke markers Patient DNA testing

Molecular tests are becoming available that provide a genomic analysis of individuals, and have a role in informing about a wide range of chronic diseases and medication management. Genetic testing involves analysis of person's DNA in order to detect genotypes related to inheritable diseases or mutations of interest for clinical purposes. These tests are normally performed in central laboratories. In fact it is estimated that one in four individuals present to their physician or pharmacy taking a medication linked to a pharmacogenomic relationship.[16,17] Further, over 150 FDA-approved medications refer to pharmacogenomic information in their package inserts.[18] As examples, atomoxetine - a drug used for attention-deficit hyperactivity disorder is linked to liver damage for individuals with a mutation in the CYP2D6 gene – and genetic variations in the CYP2C19 isozyme are partly responsible for variable antiplatelet response seen with clopidogrel. As medication experts, pharmacists should be aware of genetic variances to drug handling and those individuals that possess such.

An emerging area of interest is direct-to-consumer genetic testing where genetic tests are marketed directly to consumers. Individuals purchase the genetic test directly from the company and provide a

[16] Grice GR, Seaton TL Woodland AM, McLeod HL. Defining the opportunity for pharmacogenetic intervention in primary care. Pharmacogenomics. 2006;7(1):61–65.
[17] Freuh FW. Considerations for safety pharmacogenetics in clinical practice. Drug Discov Today. 2011;16(19–20):898–901.
[18] FDA website: http://www.fda.gov/Drugs/ScienceResearch/ResearchAreas/Pharmacogenetics/ucm083378.htm (accessed 18 Feb 2016).

DNA sample, typically by swabbing cells from the inside of the cheek for analysis. It is also feasible that a direct-to-consumer genetic test could be purchased in a pharmacy. The individual is informed of test results and provided with varying levels of information often via a protected website portal. There is considerable controversy over direct-to-consumer genetic testing in part because of the complex interplay between genetics and health, and the lack of genetic counselling that accompanies test results. Test results are also difficult to accurately interpret and issues also arise with the respect to the fact that there are often limited effective interventions to address the diagnostic maladies that are identified. This is an area where pharmacists with enhanced professional training may have a role in educating individuals.

Implications for Pharmacist Practice

The availability of point of care devices for screening, diagnosis and monitoring has allowed broad diffusion of POCT to the patient's/person's bedside, physicians' offices, pharmacies, other healthcare facilities, and into peoples' homes. This shift provides tremendous opportunity for pharmacists to add greater value in managing individuals and disease by having the tools to monitor disease and its treatment.

Undertaking a POCT strategy in a pharmacy setting however requires many considerations. These may be broken down into stages representing the course of testing events: pre-testing, testing, and post-testing. **Table 2** outlines the three stages of testing and important considerations associated with each. POCT considerations are many, including identification of individuals and tests that may be relevant to them, regulatory requirements, environmental considerations, equipment maintenance, personnel training, quality assessment and more. To implement POCT into pharmacy practice involves careful consideration, planning and rigor around the 3 stages of pre-testing, testing and post-testing.

Table 2: Leading pre-testing, testing and post-testing considerations associated with POCT[19]

Pre-testing	• Identification of patients to test • Test/technology selection; Test appropriateness • Ethical considerations: marketing and promotion by commercial entities • Preparation of materials and testing area (e.g., confidential testing area, sample collection/examination rooms having the appropriate utilities) • Environmental requirements for equipment (e.g., temperature, humidity, vibration control) • Definitions of role and responsibilities of pharmacy staff using POCT • User competency programs • Preparation of individual being tested • Sample collection, labelling and handling
Testing	• Development of Standard Operating Procedures (SOP's) • User training – credentialing • Test evaluation and validation (e.g., imprecision, bias, interferences, comparison with reference method) • Instrument calibration, quality assurance, quality control, maintenance • Test performance on an ongoing basis (imprecision/bias) • Environmental considerations (e.g., exposures to biohazards, sample disposal)

[19] Adapted from: Lippi G, Plebani M, Favaloro EJ, Trenti T. Review: Laboratory Testing in Pharmacies. Clin Chem Lab Med 2010; 48(7):943-953.

	• Results recording and maintenance of confidentiality
Post-testing	• Result interpretation and subsequent action • Result reporting and retention and possible integration into the EHR • Maintenance of patient confidentiality • Confirmatory testing (if necessary) • Follow-up with tested individuals • Biohazard waste/disposal • Instrument maintenance programs • Post market surveillance of recalls and revisions

Other important considerations with POCT are in understanding the advantages and limitations of the instruments being used. This includes knowledge surrounding quality assurance of the instruments and the diagnostic consumables (e.g., test strips), the interpretation of test results given the technology [specificity and sensitivity (e.g. false positive and false negative results)] and the limitations of use of the system. A common concern with POCT is the reliability and accuracy of results. In contrast to core laboratory testing where errors most frequently occur in the pre-test and post-test phases, POCT errors occur more often in the testing phase.[20] Potential sources of error can relate to non-laboratory staff involved in testing as well as test limitations and misuse of equipment in certain environmental conditions.[21]

It is important for pharmacists to understand that screening tests are not definitive. This is poignantly put forth in a review paper examining false-positive interferences of common drug screen immunoassays.[22] The review highlights the many causes for false-positive results in urine drug screen assays as well as the fact that most causes remain unknown. Thus all immunoassays for drug screening are considered 'presumptive' until confirmed by an independent chemical technique. This is important also from an ethical standpoint. Those individuals being screened for drug use are at risk of losing employment or eligibility in rehabilitation programs based on test results. Therefore it is essential that results are accurate.

Ideally test results should also be provided in units and ranges that are consistent with centralized laboratory testing, particularly if test data will be entered into individuals' health files. Indeed, a major limitation of POCT in the community setting is the lack of data integration into laboratory management systems and/or individuals' electronic health records. Further, as with any other health information it is critical that appropriate safeguards are in place to protect the privacy of personal health information including test results.

Relying on methods and procedures guided by the manufacturers recommendations to ensure quality test results is not enough and processes for validation of equipment and results against 'gold standards' within central labs is recommended. There are examples where considerable variation occurs between results obtained via laboratory testing versus POCT. Validation of instruments and results can occur on a 'vendor basis' and in collaboration with a central laboratory versus on an individual pharmacy basis.

[20] Njoroge S, Nichols JH. Managing Risk at the Point-of-Care. AACC. Clinical Laboratory News. July 2014. https://www.aacc.org/publications/cln/articles/2014/july/managing-risk-at-the-point-of-care (accessed 18 Feb 2016).
[21] Ditto.
[22] Saitman A, Park HD, Fitzgerald RL. False-Positive Interferences of Common Urine Drug Screen Immunoassays: A Review. J. Anal. Toxicol. 2014;38:387-396.

Further, maintaining knowledge of instruments entering the market (technology scanning) as well as post-marketing surveillance becomes an important consideration for pharmacists and their responsibility to keep abreast of the POCT landscape for the benefit of individuals they serve.

Regulation of Medical Devices

Medical devices are regulated through Canada's *Food and Drugs Act.* Under the Act, medical devices have a broad definition that includes any item sold to diagnose, treat, mitigate, or prevent a "disease, disorder or abnormal physical state, or any of their symptoms," including contraceptive devices. Health Canada's Therapeutic Products Directorate (TPD) is the Canadian federal authority that regulates pharmaceutical drugs and medical devices for human use. Point of care technologies fall under the definition of 'medical devices' and are thus regulated by the Medical Devices Bureau (MDB) of Health Canada's TPD.

Prior to being granted market authorization, a manufacturer must present substantive scientific evidence of a product's safety, efficacy and quality to the MDB as required by the *Food and Drugs Act* and the Canadian Medical Devices Regulations (CMDR) that supports the Act. Therefore the approval of medical devices by Health Canada is similar to that for drugs in that the main considerations relate to public protection and product safety.

Medical devices are classified into one of four categories (Class I, II, III, and IV) according to their risk primarily to the individual (**Table 3**). In vitro diagnostic devices (IVDD; **Table 4**) are classified using similar risk categories. The emphasis on IVDD's is on transmissible agents and the impact of the result (true and false) to the individual and/or to 'public health'. Other criteria used to determine the risk of an IVDD include its indication for use, its application (screening, diagnosing, monitoring), and the relative importance of the information for diagnosis in the context of other disease and/or disorder considerations (e.g., is the test the sole determinant or one of several other diagnostic considerations).

Generally the higher the risk assigned to a device the higher its classification and greater are the data requirements to demonstrate the device's safety, effectiveness and performance. POC technologies are not limited to any one risk classification and can be non-IVD devices (blood glucose monitors) or IVD devices (HIV test kits).

Class II, III and IV medical devices require a license before they can be advertised or sold in Canada – whereas Class I devices are not subject to any regulatory review and are also exempt from the usual full licensing requirements. Class I products however must be sold via a distributor that holds a license to sell products. This is to ensure that Health Canada's TPD is informed about establishments selling devices (be they in Canada or abroad) and that appropriate distribution, problem-solving, complaint-handling and recall procedures are maintained.

Health Canada maintains a public record of all active and archived medical device licenses in Canada: the Medical Devices Active License Listing (MDALL; http://www.hc-sc.gc.ca/dhp-mps/md-im/licen/mdlic-eng.php). This system is designed to help health care workers (pharmacists) who are contemplating the purchase of a medical device, to verify that the manufacturer has an active medical device license in Canada and is an important step to the use and/or sale of medical devices in practice.

Table 3: Canadian medical device classification system

Classification	Risk Level	Examples
Class I	Lowest	Reusable surgical scalpel, bandages, (non-invasive)
Class II	Low	Contact lenses, epidural catheters, pregnancy test kits, surgical gloves, blood pressure monitors (includes invasive)
Class III	Moderate	Orthopedic implants, glucose monitors, dental implants, hemodialysis systems, blood touching, lasers (invasive)
Class IV	High	HIV test kits, pacemakers, angioplasty catheters, human tissues (active implantables)

Reference[23]

Table 4: Canadian in vitro diagnostic device (IVDD) classification system

Classification	Risk Level	Examples
Class I	Lowest	Microbiology tests (Streptococcus A)
Class II	Low	Disease status, patient management (cholesterol)
Class III	Moderate	Sexually transmitted diseases sexually transmitted agents and infectious agents that cause nosocomial infections (Methicillin Resistant Staphylococcus aureus)
Class IV	High	Death or serious injury diseases (HIV, HCV)

Reference[24]

In the USA medical devices are regulated by the US Food and Drug Administration Centre for Devices and Radiologic Health[25] and are classified into Class I, II, and III whereby regulatory control increases from Class I to Class III. It is generally accepted that although similar in nature, US regulatory oversight of medical devices is more stringent than in Canada and Europe.

Implications for Pharmacist Practice

Health Canada approval does not provide assurance of the clinical effectiveness, utility and testing accuracy in relation to centralized laboratory testing but rather assesses the safety, efficacy and quality of a given product. Validation and calibration/standardization of POC technologies against central laboratory 'gold standards' are important considerations to ensure accuracy and relevance of POC test results in community pharmacy practice. This level of due diligence must fall to the pharmacist.

Unlike pharmaceuticals which undergo thorough and objective evaluations of clinical, economic and patient evidence via CADTH's Common Drug Review process to guide reimbursement recommendations to Canada's drug reimbursement plans - medical devices do not undergo any form of evidence assessment following approval by Health Canada. With point of care medical device vendors more readily approaching pharmacists for product sales, the onus is on pharmacy professionals to ensure that any product being implemented is approved for use in Canada and is the right product choice for the patient population being tested. Ensuring that the right product is chosen requires that pharmacists investigate the various products available, assessing parameters such as test limitations, and test specificity and sensitivity.

[23] Health Canada Medical Devices: http://www.hc-sc.gc.ca/dhp-mps/md-im/index-eng.php (accessed 27March2016)
[24] Ditto
[25] FDA: http://www.fda.gov/MedicalDevices/DeviceRegulationandGuidance/Overview/ (accessed 18 Feb 2016)

Further, there is not a robust formal process by Health Canada to provide information to health professionals about medical device issues and recalls. Current adverse event reporting for medical devices relies on a system of spontaneous reports from various sources (health professionals, consumers) and mandatory reporting by manufacturers and importers of medical devices. The Canadian Medical Devices Sentinel Network (CMDSNet)[26] is a group of dedicated and trained representatives from over 14 acute or community based healthcare facilities across Canada that have organized to report high quality data to the regulator about adverse events associated with medical devices. CMDSNet provides a complementary data source for post market evaluations – but overall the 'checks and balances' around safety monitoring and sharing of pertinent information regarding medical device issues are not well established or understood in Canada.

Regulation of Sites Performing POCT

Canada

The regulation of POCT in Canada includes a milieu of national, provincial, and jurisdictional regulations and policies – all contributing to the complexity of the regulatory landscape. Generally POCT performed in association with a centralized laboratory such as the case in hospitals and related clinics, is overseen and regulated by the central laboratory and their accreditation standards. POCT performed in the community setting (out patient clinics, home care, extended care, ambulances) and by the independent/private sector (family practices, pharmacies, dental clinics, some health centres) is much less regulated, if at all.

There is not a federal agency in Canada that oversees POCT within the health system. The Standards Council of Canada (SCC; http://www.scc.ca/en) is Canada's national accreditation body that among other areas of responsibility accredits medical laboratories and grants recognition to the OECD Good Laboratory Practice (GLP) program. The SCC participates with the International Organization for Standardization (ISO; http://www.iso.org/iso/home.html) to ensure that Canada is included in development of ISO standards as they relate to laboratory accreditation. However SCC accreditation and ISO adoption is not a federal mandate for laboratory facilities.

The international standard for POCT is ISO 22870:2006 Point-of-care testing (POCT) – Requirements for quality and competence[27], and it provides specific requirements applicable to POCT. It is intended to be used in conjunction with ISO 15189:2007 Medical Laboratories – Particular requirements for quality and competence[28].

In Canada, provinces are responsible for delivering health services as guided by the Canada Health Act (1984). Therefore, the regulation of facilities and potentially POC testing itself falls to each individual province.

In Alberta the responsibility for the delivery of acute, tertiary, long term, and palliative care is under a single health authority, Alberta Health Services (AHS). Covenant Health is the province's Catholic health system and works in collaboration with AHS to provide healthcare.

[26] Canadian Medical Devices Sentinel Network: http://www.hc-sc.gc.ca/contact/dhp-mps/hpfb-dgpsa/cmdsnet-resscmm-eng.php (accessed 27March2016).
[27] ISO 22870. Available for purchase at: http://www.iso.org/iso/catalogue_detail.htm?csnumber=35173
[28] ISO 15189. Available for purchase at: http://www.iso.org/iso/catalogue_detail?csnumber=56115

Alberta does not have legislation that governs laboratory services and testing, including POCT. Rather centralized laboratories and diagnostic services in AHS are accredited by the College of Physicians and Surgeons of Alberta (CPSA). Although not mandated, virtually all bodies responsible for laboratory accreditation – including CPSA – follow standards put forth by ISO and also the Clinical and Laboratory Standards Institute (CLSI) in the US. These are complemented by other occupational health and safety standard ads and guidelines (i.e. Occupational Health and Safety Act).

CPSA identifies standards required of facilities that it accredits in Section 25 and 27.6 (regarding quality assurance) of its Major Laboratory Standards and Guidelines.[29] CPSA guidelines also exist for non-laboratory physicians who employ or rely on select POC tests for their patients in an unaccredited environment.[30]

Only locations overseen by a Medical Director of Laboratory Services require accreditation by CPSA. In this situation POCT is seen as the responsibility of 'Lab' and CPSA POCT guidelines apply - thus ensuring that testing is performed at the rigor of ISO standards for POCT (e.g., ISO 22870 is followed). In the end, POCT is regulated in some of Alberta's health zones and not in others, depending upon whether a Laboratory Medical Director oversees POCT services.

The CPSA standards for POCT outline a comprehensive Quality Management system for the delivery of POCT that minimizes risk to patients and to the facility. It provides for:

- Evaluation of new or alternative POCT instruments and systems
- Evaluation and approval of end-user proposals and protocols
- Purchase and installation of equipment
- Maintenance of consumable supplies and reagents
- Training, certification, and recertification of POCT system operators
- QC and QA of equipment and processes

AHS Laboratories provide POCT in a number of specific clinical areas overseen by the AHS Laboratory POCT Network. These are outlined in the accompanying table. The AHS POCT Network is part of AHS Laboratory Services. Therefore testing standards are consistent with the College of Physicians and Surgeons standards and guidelines in relation to point of care testing.

Clinical areas where AHS provides POCT
Transcutaneous Bilirubin Testing
Cardiac Biomarkers for Acute Coronary Syndromes
Coagulation
Critical Care
Diagnosis and Management of Diabetes Mellitus
Drugs and Ethanol
Infectious Disease
Occult Blood
Intraoperative Parathyroid Hormone

[29] reference

[30] College of Physicians and Surgeons of Alberta – Unaccredited Point-of-Care Laboratory Testing Guideline for Physicians (2007). http://www.cpsa.ca/accreditation/diagnostic-laboratory-testing/

pH Testing Renal Function Testing Reproductive Testing

As various professions take on responsibilities for POCT, governing colleges must also respond with standards of practice for their registrants.

Each provincial physician regulatory body will have variations in the governance of POCT but each is ultimately guided by the same standards that Alberta uses (ISO; CLSI). Unlike Alberta and more recently Nova Scotia, other provinces are divided into regional health jurisdictions (British Columbia has 5, Saskatchewan has 13, and Ontario has 14) thus adding to the complexity of regulating POCT services. In Saskatchewan the College of Physicians and Surgeons will release POCT accreditation standards for the province in 2016.

In Ontario, ordering and interpreting laboratory tests by pharmacists is pending legislation. Saskatchewan previously held very limited policy on the role of pharmacists in distributing diagnostic products and in laboratory and diagnostic testing. Recently (Oct 5, 2015) Bill 151 was passed that expands the scope of practice for pharmacists allowing them to order, access, and use medical laboratory tests with proper training and certification.

In Nova Scotia, standards of pharmacy practice support pharmacists to order, receive, interpret and conduct tests within the practice of pharmacy for drug therapy monitoring purposes. Standards outline the services pharmacists can provide, the training they require, and how pharmacists will notify other health-care providers when they conduct or order tests. Tests include those that are non-invasive or that involve a specimen such as capillary blood, saliva or urine (blood glucose, coagulation (INR), urinalysis (basic), HbA1c and cholesterol). Pharmacists must successfully complete a comprehensive education program in laboratory testing approved by the Council of the Nova Scotia College of Pharmacists.

The authority to order and interpret lab tests is not currently included in the 'scope of practice guidelines' for pharmacists in British Columbia. Despite this, in 2014, pharmacies in BC collaborated on an HIV testing pilot project with Vancouver Coastal Health, Island Health, the Ministry of Health, and various medical clinics. Also in BC, about 33 pharmacies are involved in a study called "Genomics for Precision Drug Therapy in Community Pharmacy". This study is the largest in North America to look at whether community pharmacists can gain the skills required to collect DNA samples from individuals, walk them through the consent process and explain how specific drugs may interact with their specific genetic makeup. Other efforts and projects are occurring in other provinces in light of the POCT landscape quickly evolving and emerging onto the primary care setting.

USA

In the USA all facilities that conduct laboratory testing on human specimens for health assessment, diagnosis, prevention or treatment of disease, including point of care tests, are regulated by the Centers for Medicare and Medicaid Services (CMS) through the Clinical Laboratory Improvement Amendments (CLIA) Program. A pharmacy providing tests for management of human health is therefore considered a laboratory facility and must conform to federal regulatory and quality standards for the level of testing being performed.

CLIA regulations establish quality standards for all laboratory testing, ensure testing accuracy, reliability and timeliness, and base their standards on the complexity of tests performed in a facility. Three levels of complexity exist: waived, moderate and high. The category of tests considered as 'CLIA-waived' are those defined as being simple to conduct and with minimal risk of error – and it is this type of point of care test that comprises most pharmacy-based POCT in the US[31]. Waived tests thus include test systems cleared by the FDA for home use and those tests approved for waiver under the CLIA criteria. Other considerations are variations of CLIA requirements for some states as well as state laws that govern the scope of practice for pharmacists and their ability to offer POCT.

To offer testing for CLIA-waived tests in the US, a pharmacy must apply for and receive and maintain a CLIA Certificate of Waiver and CLIA license.[32] CLIA states that waived laboratories must follow "good laboratory practice' when performing tests which address the following issues: proper physical environment; adherence to manufacturers testing instructions and quality control measures; and recording of test results and client information in a retrievable file.[33]

In the US, the Occupational Safety and Health Administration (OSHA) and individual state standards require employers to provide a safe and healthy work environment for employers and another regulatory body that is relevant to POCT. When considering POCT, the focus is on exposure of staff (pharmacists, technicians, others) to blood and infectious materials. General regulations put forth by OSHA related to POCT include consistent use of personal protective equipment such as gloves and laboratory coats, practices to prevent needle-sticks, and provision of Hepatitis B vaccination for employees. Other important requirements relate to employee training, recordkeeping, and existence of an exposure control plan in the event of exposure[34].

Implications for Pharmacist Practice

Compared to the USA, Canada lacks regulatory guidelines that facilitate the safe and effective use of POCT programs in pharmacy practice. In the USA pharmacies are the fourth highest-ranking facility of CLIA-waived laboratories by number, closely following physician offices, home health agencies and skilled nursing facilities.[35] The percentage of pharmacies in the US that are CLIA-approved is approaching 20%[36] thus the potential for growth in POCT in pharmacies is still substantial. Supporting this new testing paradigm, the National Association of Chain Drug Stores' (NACDS) launched a point-of-care testing certificate program that trains pharmacists to conduct select CLIA-waived lab tests in their pharmacies. POCT is becoming a significant component of pharmacy practice in the USA, supported both by regulatory frameworks (CLIA-waived tests and oversight) and POCT training programs.

As POCT continues to evolve into the primary care setting, regulatory frameworks that promote positive health outcomes and that minimize risks to individuals being tested as well as to the pharmacy and to pharmacy personnel are needed.

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[31] Centers for Meidcare and Medicaid Services: https://www.cms.gov/Regulations-and-Guidance/Legislation/CLIA/index.html?redirect=/clia/ (accessed 20Jan2016).

[32] Rodis JL, Thomas RA. Stepwise Approach to Developing Point-of-Care Testing Services in the Community/Ambulatory Pharmacy Setting. J Am Pharm Assoc. 2006;46(5):594-604.

[33] Centers for Disease Control and Prevention. Good laboratory Practices for Waived Testing Sites: Survey Findings from Testing Sites Holding a Certificate of Waiver Under Clinical Laboratory Improvement Amendments of 1988 and Recommendations for Promoting Quality Testing. MMWR. 2005;54(RR-13).

[34] Ditto

[35] Klepser ME Adams AJ, Srnis P, Mazzucco M, Klepser D U.S. community pharmacies as CLIA-waived facilities: Prevalence, dispersion, and impact on patient access to testing. Res Social Adm Pharm. 2015 Sep 28. pii: S1551-7411(15)00175-8.

[36] Ditto

POCT Reimbursement Models

POCT performed in hospitals and clinics that are governed under a publically-funded health system are usually paid for through central laboratory budgets or billing frameworks (provided that the test is an approved service for that facility). In non-public health systems such as in the USA, testing may be covered by Medicare or individual insurance companies; otherwise individuals may pay for the test. In community pharmacies those tests that are CLIA-waived and offered via a CLIA-licensed pharmacy can be reimbursed.

In community pharmacies in Canada and the US the cost of testing is primarily borne by the practice or the individual being tested. This is a considerable barrier to overcome as POCT becomes increasingly implemented in community pharmacies. Increasingly individuals are demonstrating increased willingness to pay for tests if they offer convenience and value. The increased importance placed on health and wellness by individuals also affects their threshold to pay for POCT. In order for public health systems to fund POCT performed by pharmacists, health benefits must be demonstrated – and importantly the test must be warranted.

Considerations for Implementing POCT into Pharmacy Practice

POCT in ambulatory and community settings is advancing quickly and is here to stay. POCT has the potential to provide significant value to individuals, pharmacy professionals, and to the health system at large.

Information obtained from POCT is essential to managing drug use and disease status in individuals and it is critical that pharmacy professionals take a proactive approach to implementing new POCT technologies into practice.

A pharmacist's role in POCT spans the continuum of providing education to individuals performing home tests, through to performing POCT in pharmacies for disease screening, therapeutic monitoring for drug efficacy and disease status, pharmacogenomic testing for drug responses, and diagnosis of disease.

Guided by the principles of person-centered care and the need for appropriate, effective and safe testing that contributes to the health of individuals, and to fully realize pharmacists' roles as drug and disease management experts, this environmental scan brings to bear several pertinent considerations for implementing POCT into pharmacy practice. These are captured in the following six (6) principles:

1. Person-centered care: Person-centered care is foundational to good pharmacist practice. Being one of the most accessible of all healthcare professionals, pharmacists are uniquely positioned to engage with, educate and support individuals to manage their health needs. POCT is a tool that enables pharmacists to better deliver on the value that they bring to patients and to the health system via their application of knowledge and expertise about drugs, drug therapy and disease in response to individual's health needs. In keeping with the principles of person-centered care, the public's health and safety is of the highest importance in the delivery of POCT by pharmacists. Pharmacists have a responsibility to identify and confirm the clinical need for testing, the frequency of testing and the benefits of testing for each individual. Pharmacists also have a duty to interpret and report test results and to follow-up with individuals tested, to discuss results and next steps if any. Reporting of test results can involve adding data to individuals' pharmacy record, uploading data to Netcare, informing other members of the

individuals' health team (as appropriate), and/or notifying health authorities if the disease is considered notifiable.

2. Quality management systems that support POCT: In offering POCT, high quality accurate test results must be guaranteed and prevention of harm to individuals being tested and pharmacy personnel ensured. Quality management systems that minimize risk to individuals and to the facility need to be developed and implemented. Such programs must address concerns that have been identified in the pre-test, test, and post-test phases of POCT delivery (refer to **Table 2**) and should be consistent with programs that have been developed elsewhere (e.g., in the USA for CLIA-waived testing).

3. Training and competency evaluation programs that support POCT: To provide optimal care that uses new POCT technologies, it is imperative that pharmacists and pharmacy personnel are fully knowledgeable about the equipment they are using and the diseases that they are actively managing. Training in POCT and its applications and ongoing competency evaluation is essential.

4. Professional oversight: To ensure consistent high-quality POCT services are delivered across Alberta and to support the advancement of POCT in pharmacy practice, it is the responsibility of the Alberta College of Pharmacists to define standards and guidelines that support the safe and effective use of new POCT in pharmacies. The rigor of standards and guidelines will vary depending upon who was performing the test (individual/consumer, pharmacist), the purpose of the test (screening, therapeutic monitoring), and the risk associated with test results. The College will also require appropriate mechanisms to monitor pharmacies that they govern for compliance. The Alberta Pharmacists' Association has a key role in providing training that optimally prepares pharmacists for delivering new POCT services in pharmacies.

5. Partnership: The scale and scope of POCT is broad and expanding. Inter-professional collaboration with stakeholders and partners having interest, experience and expertise in this area can inform the development of a meaningful and effective framework for POCT practices in pharmacy. Partners may include CPSA, AHS Laboratory Services - and other health professional colleges and associations that are facing similar evolutions in the adoption of POCT into their practices.

6. Research, innovation and evaluation: POCT is a quickly emerging opportunity. As the field progresses and as the Alberta College of Pharmacists and the Alberta Pharmacists' Association move forward to develop professional standards, guidelines, and programs in this area it will be essential to self-monitor and evaluate activities. Rigorous self-monitoring, research and evaluation strategies can contribute to Alberta becoming professional leaders in the delivery of POCT.