

The official newsletter of the Pharmacy Association of Nova Scotia

The PHARMACIST

May 2017



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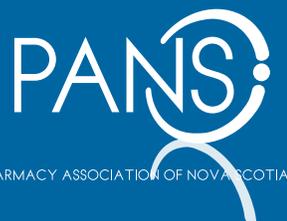
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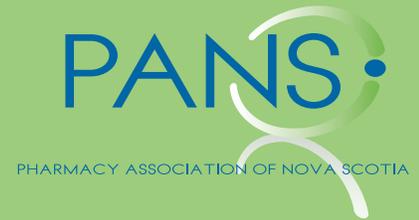
Have an interesting story idea or know of a pharmacist we should profile, we want to hear about it. Email amy@pans.ns.ca or call 422-9583, ext 4.



PHARMACY ASSOCIATION OF NOVA SCOTIA

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Message from the Chair and CEO

By: Rose Dipchnad, Chair of the Board
and Allison Bodnar, CEO



While conducting our Strategic Planning Process last year, a process which involved reaching out to PANS members and stakeholders, something we have believed for a long time was made crystal clear: The profession of pharmacy must be integrated into Nova Scotia's health care system. While this is clearly of benefit to you, our members, evidence continues to mount that this is absolutely necessary for the health care system as well.

This immediately became Strategic Priority 1 for the Association. Increased Integration of the Practice of Pharmacy into the Health Care System drives the work we do day in and day out. The focus of PANS work over the last year has been on improving awareness and utilization of pharmacy services, increasing scope and availability of services as well as fair and sustainable compensation for those services.

To do this there are a couple of things that must happen. The first is establishing demand by users of the service. By raising awareness through our marketing and public relations efforts, we are seeing that members of the public both want and need pharmacists to work to their full scope of practice. A recently conducted public opinion survey, conducted in partnership with PANS and CPhA, has shown this to be the case.

The second is demonstrate value for any

payor's investment into pharmacy services. Two recently released studies show that Nova Scotia cannot afford not to have pharmacists perform to their full scope of their practice.

The first study, released at the end of March and conducted by Dr. Carlo Marra (School of Pharmacy, University of Otago, New Zealand) Dr. Karissa Johnston (Memorial University, Newfoundland and Principal at Broadstreet HEOR), Dr. Valerie Santschi (School of Nursing Science, University of Applied Sciences Western Switzerland), and Dr. Ross T. Tsuyuki (Faculty of Medicine and Dentistry, University of Alberta) found that in cases where pharmacists were able to work to their full scope of practice (providing patient education and adjusting or prescribing medications) hypertension patients had fewer cardiovascular events (such as a stroke or heart attack) and lived longer. Over a period of 30 years, this would mean that in Nova Scotia there could be: 4,166 fewer strokes, 8,249 fewer heart attacks, 2,382 fewer cases of angina, 2,184 fewer instance of heart failure, and an additional 30,000 years lived. It would also save Nova Scotia's health care system \$490 million dollars.

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Message from the Chair and CEO

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The second study, released by Conference Board of Canada in April, showed similar cost savings and improved health outcomes. Their report, *The Value of Expanded Pharmacy Services*, provided the results of their economic modelling exercise which focused on the potential impact of greater uptake of three pharmacy services: smoking cessation programs, advanced medication reviews, and pneumococcal vaccine administration. It estimated that by 2035, Canada-wide implementation of just these three pharmacy services could yield total health care system efficiencies and increased labour force productivity valued between \$194 million and \$2.03 billion.

Additionally, PANS is currently working a number of initiatives to illustrate to the government the value of pharmacists working to their full scope of practice. Our Collaborative Care Demonstration Project will focus on the most common disease states in Nova Scotia: diabetes, heart disease and COPD/asthma. It is co-funded by Doctors Nova Scotia, PANS and the Nova Scotia Department of Health and Wellness. The interest in this project was overwhelming with more than 90 pharmacies and 60 physicians applying to participate in the program. An in depth online training program has been developed for participants and will be available for a fee to non-participating pharmacists this summer. The Chronic Disease Management Certification Program will be accredited for continuing education units and

will enable pharmacists who complete the program to register with Medavie Blue Cross and Green Shield to provide and bill for their chronic disease benefits programs.

Patient recruitment for the Collaborative Care Demonstration Program will take place over the second half of 2017 and patients will be followed for 12 months. The final report will be delivered to government three months after that.

There are a couple of other projects PANS is working on, such as the community pharmacist anti-coagulation project and we encourage you to read your Weekly Updates for more information as these projects progress.

We are confident that the results of the upcoming demonstration projects will be as remarkable as those that were released in March and April. It is our job at PANS to ensure that this information is shared with government decision makers, both elected and not. During this hectic election period, PANS has reached out to all three major political parties to ensure they are aware of the value pharmacists bring to the health care system and the positive outcomes they can have on their patients' health. Which ever party is elected to lead this province, a foundation has been laid to establish our goal of better integration of pharmacy practice into the health care system.

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2017 Nova Scotia Pharmacy Conference

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Role of Pharmacy Technician and Opioids
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Ask a Drug Information Pharmacist

Question:

Is Triple Antithrombotic Therapy Appropriate for Some Cardiovascular Patients?

Pharmacists commonly encounter patients who are on both antiplatelet and anticoagulant therapy. Approximately 21% of patients who have atrial fibrillation (AF) also have coronary artery disease (CAD) requiring either an acute coronary artery intervention (stent) or coronary artery bypass. Conversely, patients with acute coronary syndrome (ACS) also develop AF in 6 to 21% of cases or they have mechanical heart valves or venous thromboembolic disease that requires treatment with an oral anticoagulant (OAC).¹ Thus, there is a significant number of patients who may have both CAD and AF, each condition requiring different treatments.

The major healthcare burden in AF patients is the increased risk of stroke. OAC significantly reduces this risk by up to two-thirds compared with placebo, by 45% compared with aspirin, and is significantly better than dual antiplatelet therapy (DAPT) with clopidogrel and aspirin.^{3*} In patients

with established coronary artery disease who have had a drug-eluting stent, dual antiplatelet therapy is indicated for up to 12 months to prevent stroke, vascular events, and myocardial infarction. DAPT is superior to aspirin plus OAC in this patient population.³ Therefore, it is reasonable that despite an increased risk of bleeding, triple therapy (TT) will be required for many patients who have either AF or a mechanical heart valve, and CAD. However, it is important to note that a subset of these patients with a low risk of thromboembolism and a high risk of bleeding may not be candidates for triple therapy at the discretion of the prescriber.

Dosing and Drug Choices:

There is significantly more evidence to support warfarin as the agent of choice if OAC is required in a patient already taking DAPT. However, if non-vitamin K antagonist oral anticoagulation (NOAC) is preferred, it is better to start with a NOAC instead

of switching therapy from warfarin after DAPT is finished.^{4*} If taken with DAPT, NOACs should be prescribed at a lower dose: dabigatran 110 mg BID, rivaroxaban 15 mg QD, or apixaban 2.5 mg BID.¹ If warfarin will be combined with antiplatelet therapy, the target INR should be 2.0 to 2.5.¹ The optimal duration of TT is not known and depends on a number of patient factors as well as the type of stent. The INR target and NOAC doses are the same for AF patients who develop CAD or CAD patients who develop AF.⁴

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2. Briasoulis A et al. *Am J Cardiovasc Drugs.* 2016 Apr;16(2):103-10.
3. Asencio LA et al. *Am J Med.* 2014 Jul;127(7):579-85.
4. Rubboli A et al. *Int J Cardiol.* 2015 Oct 1;196:133-8

+ The P2Y12-inhibitors prasugrel and ticagrelor have not been studied as part of TT and should not be used in these patients.¹

* In patients with mechanical heart valves, warfarin is the drug of choice.³



Ask a Drug Information Pharmacist

Question:

Can Testosterone be used in Women?

Testosterone has been studied in the treatment of hypogonadotropic sexual desire disorder (HSDD) which is defined in the DSM-IV as “persistently or recurrently deficient (or absent) sexual fantasies and desire for sexual activity that causes marked distress or interpersonal difficulty.”^{1,2} During menopause, testosterone levels decline and women may experience symptoms of androgen deficiency such as sexual dysfunction³. There is no level of testosterone that can be used to diagnose HSDD as there is no association between levels of testosterone and sexual function.^{1,4,5}

Clinical trials of a testosterone 300ug patch have shown some improvement in symptoms of HSDD including increased libido and arousal; trials included women who have natural or surgically induced menopause with or without hormone therapy.⁴ A Cochrane review of 35 trials with a total of 4,768 participants showed that adding testosterone to hormone

therapy improves sexual function in post-menopausal women. The review could not make a recommendation for long term use; the median study duration was six months and longest duration was 24 months.⁶ However, one trial demonstrated safety of testosterone in over four years of use.²

Safety concerns have been raised with the use of testosterone therapy; however, most studies consider transdermal testosterone at a dose of 300ug daily to be relatively safe with only mild side effects reported such as acne and hirsutism.² Side effects such as liver toxicity and changes to lipids are minimized with the use of transdermal patches.²

The major drawback to using testosterone therapy in women is the lack of appropriate strengths in commercial products. Currently-marketed products contain too high a dose of testosterone; women typically need 1/10 the dose prescribed for men.⁵ One option is the

use of compounded topical preparations. Using a prepared, one per cent strength, a dose of 0.5 grams daily can be applied to the skin of the arms, legs, or abdomen⁵; however, there may be inconsistencies in delivered dose between different lots of the product.⁵

Testosterone therapy for HSDD is a therapeutically grey area despite some evidence of its efficacy and safety. However, if women want to try testosterone, they need to be informed of its benefits, potential side effects and monitoring requirements while on therapy.

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6. Somboonporn W et al. *Cochrane Database Syst Rev* 2005 Oct 19;(4):CD004509.

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by: Tanya Hamilton, RPhT

It's been four years since Pharmacy Technicians have become regulated professionals in Nova Scotia. As with any change, there can be many questions. Perhaps the biggest question in this stance is: "What can Pharmacy Technicians do for me?"

Under the Standards of Practice for Pharmacy Technicians and Nova Scotia's pharmacy regulations, Pharmacy Technicians can free up pharmacists' time and help with efficiencies by taking on a number of technical tasks. These include:

1. Demonstrating medical devices to patients. Such devices include puffers, aero chambers, nebulizers, peak flow meter, spirometer, diabetic meters, and blood pressure machines just to name a few.

2. Check the technical accuracy of prescription, including narcotics and benzodiazepines.

3. Transferring prescriptions and taking verbal orders from physicians. This will alleviate wait times on the phone for physicians or pharmacies waiting for the transfer.



Tip for Techs

There are more and more devices on the market all the time. If you are unsure as to how to demonstrate any of these devices your reps are a great resource to refresh your knowledge. Take advantage of their expertise!

Pharmacy Technicians are qualified and capable of adding significant value to your pharmacy team.

In conclusion, adding a Pharmacy Technician to your workflow will help alleviate wait times for patients, physicians and other pharmacies as well as give pharmacists much needed time to concentrate on their ever-expanding scope of practice.



FunFact

The title *Pharmacy Technician* is now a protected title. Not just anyone can call themselves a *Pharmacy Technician*. *Pharmacy Technicians* must go through a rigorous training and testing process to earn their certification - and they must continue to participate in education every year in order to maintain this certification. Much like *Pharmacists*, you have to go through a lot to become - and maintain your license as - a *Pharmacy Technician*.

by: Devin Covey, PhC



From the Front: Keeping It Under Our Hats

We pharmacists take pride in the many hats we wear on a daily basis. As with any collaborative health professional, we often are involved in patient cases that require much more than providing information about drug therapy.

A·poth·e·car·y (ə'pāTHə,kerē/) - a person who prepared and sold medicines and drugs.

At one time, this was our most recognizable hat. The physician diagnosed, put a plan together, and off you went to the chemist (British term for pharmacist) to receive an elixir or compounded salve to cure your ills. Providing the right medications and the proper doses is still a large part of a pharmacist's role, but as we evolve, so does our headgear.

Teach·er ('tēCHər/) - a person who helps others to acquire knowledge, competences or values.

As drug therapy becomes more complex, and monitoring vital to positive outcomes, pharmacists need to constantly be prepared to educate on all types of regimens. These range from over-the-counter drugs to specialized biologic treatments. We must include what to watch for in terms of side effects as well as any positive measures of surrogate endpoints (e.g., A1C, total cholesterol).

Assessor (ə'sesər/) - a person who evaluates the quality of a person or thing.

We put on this hat in the counseling room when we need to assess understanding. 'Please demonstrate how you are using

your inhaler'. 'Are you familiar with the term INR, and why frequent blood testing is necessary?' 'Explain when and how to use an Epipen or Naloxone Kit.' This will usually lead into further teaching moments over the course of many interactions.

Nav·i·ga·tor ('navə,gādər/) - a person who directs the route or course of a ship, aircraft, or other form of transportation, especially by using instruments and maps.



Image courtesy of the Computer Whisperer:
<http://www.thecomputerwhisperer.us>

This would look pretty sharp with a lab-coat, don't you think? You can thank my involvement with mental health initiatives for this one. The founders of the Bloom Program here in Nova Scotia realized that our mental health system featured a wealth of resources and community-based initiatives that were not being used to capacity or not expanding due to lack of awareness. One of the original tools developed was called, appropriately enough, The Navigator and aimed to collect all known programs, community groups, hot-lines and resources for each jurisdiction around the province. The goal was to empower community pharmacists to be more comfortable with

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The Celtic curse

Hereditary hemochromatosis and the pharmacist's role in helping identify sufferers

By Carlyn Volume-Smith, B.Sc.(Pharm.), M.Sc., PhD

Hereditary hemochromatosis (HHC) is an inherited disorder, which causes patients to absorb too much iron from their diet. This excess iron then accumulates in the patient's body, causing deposits in organs and joints. Individuals with HHC who are suffering from the effects of iron overload often remain undiagnosed until organ damage or other negative effects impact their longevity and quality of life. As one of the most accessible health-care providers, pharmacists can play a key role in identifying patients who may suffer from iron overload due to HHC.

HHC is a recessive disorder that is commonly seen in persons of Celtic and Northern European heritage. In Canada, it is estimated the disorder affects up to one in 300 people. Not all patients with the gene mutations suffer from iron overload, but for those that do, early intervention can prevent long-term consequences.

Patients usually present in mid-life, when body iron stores have accumulated and negative effects start to be felt. In some cases, a family history of severe liver disease (cirrhosis and/or liver cancer), arthritis and diabetes may be present. Onset in males is usually earlier than in females, who may be at lower risk due to pregnancies and menstrual blood losses which can deplete iron and prevent symptoms of iron overload.

The pharmacist's role

Community pharmacists are often among the first health-care providers approached by patients suffering from the diverse and non-specific symptoms of iron overload. Accordingly, pharmacists are positioned to intervene when they are suspicious of HHC

and can refer the patient to their family physician for assessment and diagnosis. In some cases, patients may seek the assistance of a pharmacist in an effort to self-treat before proceeding to their family physicians. Unfortunately, some remedies for iron overload symptoms can harm HHC sufferers over the long term. For example, advising regular dosing of acetaminophen could harm an already damaged liver. Similarly, recommending iron supplements or multivitamins containing iron can aggravate iron overload in an already dangerous situation.

The following are common indicators of iron overload that pharmacists may recognize in their patients:

- Arthritis and joint pain (in particular the first two joints of the first two fingers)
- General tiredness
- Changes in mood, anxiety or depression
- Chest pains and shortness of breath
- Impaired sexual function or infertility
- Loss of body hair
- Tanned or grey skin discolouration.

When presented with middle aged or older individuals (in particular males) seeking treatment for **two or more of the symptoms** outlined above, pharmacists should ask the following questions prior to recommending over-the-counter therapies:

- First, is the individual of Celtic or Northern European heritage?
- Is there a history of severe liver disease, arthritis and/or diabetes in the family?

If the answers to these questions are positive, there is merit in referring the

patient to their physician for additional testing to rule out HHC.

Once HHC and iron overload is diagnosed, the primary treatment is regular removal of blood (phlebotomy). Phlebotomies prompt the body to mobilize excess iron stored in joints and organs to make new red blood cells to replace those that were taken. Phlebotomies occur on a regular basis (e.g., weekly) until such time that serum ferritin and transferrin saturation reach reasonable levels. Though alterations in diet cannot treat iron overload, patients are also advised to avoid dietary iron which can negatively affect iron build-up. Once iron stores are normalized, HHC sufferers typically require phlebotomies every three to four months as maintenance therapy. Regular blood donation can be used in some cases as maintenance therapy.

Dr. Carlyn Volume-Smith is a licensed pharmacist and a Canadian Hemochromatosis Society board member. She believes that community pharmacists can play a vital role in patient health through their accessibility and the strong therapeutic relationships that they have with their patients.

The Canadian Hemochromatosis Society (www.toomuchiron.ca) is a registered non-profit society that works to promote early diagnosis of hemochromatosis through increased awareness of the disorder in both the medical community and public. The CHS is also an information resource for individuals and families affected by iron overload and helped develop the "Iron Tracker" app to assist patients in managing their condition.

Keeping It Under Our Hats

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being the first point of contact during crises and provide direction to patients and their families. This extends not just to specialist care, but financial aid, legal aid, counseling, and long-term care resources as well.

Coun se lor ('kouns(ə)lər/) - a person trained to give guidance on personal, social, or psychological problems.

I hesitated to list this one because pharmacists can not replace the skills and roles of trained counseling professionals. We do find ourselves in situations that require counseling ability in a more general sense. A supportive ear in the right place at the right time can sometimes make the difference in building trust and opening the door to a proper referral.

Ad-vo-cate ('advəkət/) - a person who publicly supports or recommends a particular cause or policy.

Whether it's recommending an equally effective generic combo instead of a newfangled drug therapy or suggesting a suspension for someone unable to swallow large capsules, we aim to put the patients' health first. Pharmacists have called shelters to get those in need a place to stay, and are regularly contacting drug plans to wade through complex coverage policies. If we notice a patient's condition rapidly decline, we may alert family members in their circle of care or help connect them with specialized programs.

Men-tor ('men,tôr,'men,tər/) - an experienced and trusted adviser.

The pharmacy community is strong. As much as we coach patients to take responsibility for their health, we also take time to precept students, giving them real life experience and challenging their knowledge. This is invaluable to their development as leaders within the profession. These relationships often last throughout careers and beyond.

And lastly, the most important hat of all: You - the person behind the degree, under the lab coat.

As health care professionals, we possess a common set of trained skills, but our effectiveness is predicated on the passion that we bring to our work, our hobbies, our relationships, and our experiences. I wore a ball cap for many years of competitive baseball, and a felt cowboy hat for variety shows. Others don biking helmets for tours through Paris or Spain. Perhaps a hard-hat is worn for charitable works in impoverished countries, or simply a headband for another satisfying hour at the gym.

It's true that as a service provider, some consumers just want to see a pharmacist, but countless others want you. Your thoughts, your opinions, your advice matters greatly to all of those you aim to help. Develop your style, get comfortable with infusing your soul into whatever you do. Everyone will benefit.

So lift up that brim. We can't keep personalities under our hats.

Therapeutic Options

FOCUS ON COPD MANAGEMENT

Written by: Joanne Deshpande, BSc Phm, RPh

INTRODUCTION

Chronic obstructive pulmonary disease (COPD) affects at least 4% of Canadians and is a major cause of morbidity and mortality, adding substantial economic and social burden to our health care system.^{1,2} This article will review COPD in general with a greater focus on the therapeutic management, attempting to demonstrate how and when to implement current choices into individual patient care.

The latest evidence-based COPD guidelines, *Recommendations for Management of COPD*, was released by the Canadian Thoracic Society (CTS) in 2007.³ Although this report remains the cornerstone of COPD care, an updated guideline released in 2014, the *Prevention of Acute Exacerbation of COPD*, reflects the shift in management trends to a more preventative approach, which has influenced therapeutic choices.⁴ Other recognized international strategic reports such as the Global Initiative for Chronic Obstructive Lung Disease [GOLD]: *Global Strategy for the Diagnosis, Management, and Prevention of Chronic Obstructive Pulmonary Disease* and the National Institute for Health and Care Excellence [NICE] Quality standard: *Chronic obstructive pulmonary disease in adults* have also been updated this year to include similar information.^{1,5}

COPD OVERVIEW: PATHOPHYSIOLOGY AND RISK FACTORS

Airflow obstruction is the key characteristic of COPD and occurs in the large airways (via increased mucous production and decreased mucociliary clearance), the small airways (via increased mucous production and narrowing mechanisms) and in the lung parenchyma (via destruction of normal structure).^{1,6} Chronic inflammatory processes and the effect of repeated injury and repair can induce these various mechanisms.^{1,6} Destruction of lung parenchyma can damage alveolar attachments to airways and decrease elasticity, further affecting airway functioning.¹ With increasing obstruction, air becomes trapped in peripheral airways, producing “hyperinflation” which reduces inspiratory capacity and increases dyspnea, particularly during exercise.¹ Progressively, COPD can become a multisystem disease, causing right heart failure (“cor pulmonale”), peripheral muscle wasting and psychiatric disorders such as anxiety and depression.⁷

Cigarette smoking is still the most prevalent risk factor for COPD with tobacco smokers having a higher incidence of respiratory symptoms, lung function abnormalities and COPD mortality rates than non-smokers.^{1,6} Other types of tobacco smoking (pipe, cigar, water pipe)

and marijuana are also contributors to the disease.^{1,6} However, smoking does not seem to carry the same risk in all patients. For example, a genetic-environment interaction appears to be present as a significant familial risk has been seen in smoking siblings.¹ The most recognized genetic risk factor is alpha-1 antitrypsin deficiency, but other nucleotide polymorphisms and gene clusters are being studied.⁶ Factors such as personal microorganism balance and frequency of lower respiratory infections may also be involved.^{1,6} According to the American Thoracic Society, occupational exposure to dusts, chemicals and fumes can account for 10–20% of all cases.¹

SYMPTOMS, DIAGNOSIS AND STAGING

Dyspnea, chronic cough, and sputum production tend to be the triad of presenting symptoms leading to COPD diagnosis.⁶ Dyspnea is often described by patients as “a sensation of gasping for air” or “breathlessness”.^{1,6} It is usually persistent, progressive, worse with exercise and often the most distressing symptom for patients.^{1,6} Chronic cough, frequently the first symptom of COPD, is often overlooked as an expected consequence of smoking.⁶ Sputum production varies in quality and quantity, but any pattern can be indicative of COPD.¹ Physically, patients may present with minor

wheezing or a prolonged expiratory phase, chest tightness and demonstrate pursed-lip breathing.¹⁶ Past medical history will often reveal an insidious development of symptoms: childhood allergies, asthma, nasal polyps, multiple respiratory infections, increased avoidance of activities and missed work/social obligations.⁶ Feelings of depression or anxiety are often present as symptoms begin to impact and limit daily activities.¹⁶

Acute exacerbations (AE) are defined as “periodic escalations of symptoms” and are a major cause of worsening lung function, decline in quality of life and contribute to increased hospitalization and overall costs of managing COPD.⁴ For this reason, the trend to prevent AE has become a mandate of general COPD management rather than reactive treatment.¹⁴

The presence of any of the three cardinal symptoms in a patient older than 40 years, with a history of exposure to risk factors (tobacco smoking, occupational chemicals, family history of COPD), should prompt testing with spirometry.¹ Spirometry is the most widely available test of lung function, and specifically airflow limitation, and is essential to establish a diagnosis of COPD.¹ The test involves taking a deep breath in and then blowing it out forcibly and quickly into a spirometer, a device that measures volume and speed.⁸ Inhaled bronchodilation is often administered to assess the reversibility of the obstruction, a result more applicable in asthma diagnosis rather than in COPD.¹⁶

Forced expiratory volume in one second (FEV1) is the maximum amount of air that can be exhaled in one second (usually expressed as a percentage of the predicted value); forced vital capacity (FVC) is the total amount of air that can be forcibly exhaled after maximum inspiration; the ratio of FEV1/FVC measures the proportion of the total volume that can be exhaled in one second.¹⁸ Patients with airway narrowing and/or obstruction exhibit reduced FEV1 and FEV1/FVC.¹⁶ A post-bronchodilator FEV1/FVC < 0.7 is required for a diagnosis of COPD.¹ Previous GOLD guidelines used FEV1 results exclusively to stage disease severity (see Table 1) and was the

Table 1: COPD Severity Based on Post-Bronchodilator FEV1¹⁶

GOLD 1	Mild	FEV1 ≥ 80% predicted
GOLD 2	Moderate	50% ≤ FEV1 < 80% predicted
GOLD 3	Severe	30% ≤ FEV1 < 50% predicted
GOLD 4	Very severe	FEV1 < 30% predicted

FEV1: forced expiratory volume in one second; GOLD: Global Initiative for Chronic Obstructive Lung Disease strategy (2016)

basis for treatment decisions.¹⁶

However, a limitation of this classification system was that patients with the same FEV1 value but different symptom severity, exercise tolerance, comorbidities and risk of exacerbations may not respond as well to the same treatment plan.¹⁶ A revised assessment classification taking these factors into consideration was developed, better reflecting the complexity of COPD and the need for individualized management (see Table 2).¹

MANAGEMENT

Ideal management of COPD strives to improve symptoms and reduce the risk of AE while enhancing quality of life.⁹ An individualized treatment plan should combine both non-pharmacological

and pharmacological options as appropriate. Some non-pharmacological options that pharmacists can actively promote are (1) smoking cessation (considered the most important intervention) and (2) vaccination with influenza vaccine annually and at least one dose of 23-valent pneumococcal polysaccharide vaccine.^{14,6}

PHARMACOLOGIC CHOICES

Pharmacologic therapy is a major component of COPD management. Currently available medications can only control and stabilize symptoms; none are able to modify or reverse the decline in lung function.¹⁶ Although the types of medications used to manage COPD symptoms have not changed, the number of products, especially fixed-combination choices and delivery devices, has increased.

Table 2: COPD Staging Assessment^{1,6}

	CHARACTERISTIC*	SPIROMETRY CLASSIFICATION	EXACERBATIONS PER YEAR	SYMPTOM RATINGS**
GROUP A	Low risk, Less symptoms	GOLD 1 or GOLD 2 Mild or moderate airflow limitation (FEV1 ≥ 50%)	0-1	mMRC grade 0-1 or CAT score < 10
GROUP B	Low risk, More symptoms	GOLD 1 or GOLD 2 Mild or moderate airflow limitation (FEV1 ≥ 50%)	0-1	mMRC grade ≥ 2 or CAT score ≥ 10
GROUP C	High risk, Less symptoms	GOLD 3 or GOLD 4 Severe or very severe airflow limitation (FEV1 < 50%)	≥ 2	mMRC grade 0-1 or CAT score < 10
GROUP D	High risk, More symptoms	GOLD 3 or GOLD 4 Severe or very severe airflow limitation (FEV1 < 50%)	≥ 2	mMRC grade ≥ 2 or CAT score ≥ 10

CAT: COPD assessment test (questionnaire); FEV1: forced expiratory volume in one second; GOLD: Global Initiative for Chronic Obstructive Lung Disease strategy (2016); mMRC: modified British Medical Research Council questionnaire

*Risk is determined by highest risk according to GOLD grade (spirometry classification) or exacerbation history

**Symptoms can be assessed using two simple questionnaires.

-mMRC -self-rating scale (0-4) of breathlessness^{1,6}

-CAT- questionnaire measuring the impact of COPD on daily life; eight questions each graded on a five-point scale (maximum total score of 40); (<http://www.catestonline.org>)⁶

BRONCHODILATORS

Bronchodilators continue to be the mainstay of COPD therapy.⁶ By relaxing the smooth muscles of the airway, these medications effectively clear the “obstructive component”, reduce the hyperinflation of trapped air and improve emptying of the lungs.⁶ Three types, with different mechanisms, are used: beta₂-agonists, muscarinic antagonists (also referred to as anticholinergics) and methylxanthines.¹ Choice of agent and dosing will depend on assessment and response (see Table 3).

Short-acting bronchodilators are initiated on an as-needed (prn) basis for intermittent symptom relief.¹ As symptoms persist or exacerbations develop, long-acting agents are added on a regular scheduled basis to improve baseline functioning and maintain symptom control.^{1,10} The use of long-acting bronchodilators has been shown to be more effective than short-acting agents in the prevention of exacerbations in moderate to severe stages of COPD.⁴ Once long-acting monotherapy becomes ineffective, combining bronchodilators of different mechanisms can provide greater improvement in FEV1 and symptoms than either agent alone, while limiting adverse effects.¹ **A short-acting bronchodilator, on a prn basis, should always be available for acutely worsening symptoms.**⁶

Short-acting beta₂-agonists (SABAs) and short-acting muscarinic antagonists (SAMAs) are felt to be very similar in efficacy and symptom relief.⁴ One comparison between SABAs and ipratropium showed no difference in post-bronchodilator FEV1 measurements; however, a slight borderline statistically significant increase in FVC and pre-bronchodilator FEV1 was seen with ipratropium, indicating that possible lung function benefits may exist for SAMAs.⁴ A meta-analysis of four studies also found that significantly fewer patients on SAMAs required additions or increases in oral steroids compared to those on SABAs, suggesting an advantage in preventing mild to moderate AE.⁴ Ultimately, differences in onset, duration and side effect profiles may influence choice. SABAs are

preferred because of their rapid onset of action; however, SAMAs tend to last longer (up to 8 hours vs. 4–6 hours with SABAs).¹¹

Long-acting beta₂-agonists (LABAs) and long-acting muscarinic antagonists (LAMAs) are both considered efficacious in symptom control.⁴ Recent systematic reviews found that tiotropium (LAMA) may be advantageous over LABAs in preventing acute exacerbations in patients with moderate to severe COPD.^{4,12,13} Whether this is specific for tiotropium or a class effect remains to be studied.¹³ Both long-acting groups have durations of 12–24 hours, depending on the agent used.¹¹ Newer LABAs (indacaterol and olodaterol) have 24-hour durations and more rapid onset than salmeterol and formoterol.¹¹ Most of the LAMA agents, tiotropium, glycopyrronium and umeclidinium have 24-hour durations, making them convenient choices.¹¹

Inhaled muscarinic antagonists are not well absorbed; hence, tend to be well tolerated with side effects related to the topical effects: dry mouth, sore throat, bitter/metallic taste, and potentially precipitation of glaucoma when given as a solution with a face mask.¹ Side effects with beta₂-agonists are typically seen with higher or excessive doses or in older patients: tachycardia, palpitation, tremor and hypokalemia with concomitant thiazide use.¹⁶

Theophylline, an oral methylxanthine, causes bronchodilation by general inhibition of phosphodiesterase.⁶ Due to a narrow therapeutic window, drug interactions potential and intolerance in elderly patients, this agent is limited to use only when other agents are not effective or tolerated in patients.¹⁶

CORTICOSTEROIDS

Inhaled corticosteroids (ICS) reduce the airway inflammatory component of COPD, slowing the progression of symptoms and decreasing the risk/severity of exacerbations.¹⁰ An ICS is recommended for use in patients with increased risk of exacerbations despite being on optimal bronchodilation regimens.¹⁰ Monotherapy with ICS is not recommended as it

offers no advantage efficacy-wise and it may be associated with increased adverse effects.^{4,10} Side effects commonly seen with ICS include oral candidiasis, hoarse voice, skin bruising and increased risk of pneumonia, occurring more frequently with higher and/or cumulative dosing.¹⁰

PHOSPHODIESTERASE-4 INHIBITORS

Roflumilast, an oral phosphodiesterase-4 inhibitor (PDE4I), is the first of a new category of medications to manage COPD.⁶ Unlike theophylline, a general inhibitor of phosphodiesterase that causes bronchodilation, the selective inhibition of PDE4 by roflumilast decreases inflammatory cell activity in the lung, but the exact mechanism of action is not fully understood.^{6,14} Although it has been shown to improve FEV1 when used in combination with other medications, its main benefit is in reducing the frequency of exacerbations.¹⁶ Currently, it is recommended as “add-on” therapy in Group C or D patients with continued exacerbations despite maximally tolerated inhalers.^{16,10} (see Table 3). Common side effects include nausea, diarrhea, weight loss, and headache, which tend to occur early in treatment but subside with continued use.¹⁶

SELECTION OF PHARMACOTHERAPY

Choice of pharmacotherapy is based on the level of symptoms and exacerbation risks (Table 2).¹ Initial therapy can vary for each group, even though some groups share similar characteristics. For example, Group A and Group C patients both experience low levels of symptoms; however, because their exacerbation risks differ (based on previous number of AEs or hospitalizations), the management regimens are quite different. Improper technique with inhalers remains a problem in at least 50% of patients, therefore, regular re-evaluation by pharmacists can impact efficacy.¹⁵

Table 3: Initial Pharmacologic Management of COPD¹

CLASSIFICATION	FIRST CHOICE ¹ / ²	ALTERNATE CHOICE ¹ / ³	RATIONALE FOR USE
Group A ↓ Symptoms ↓ Risk of exacerbations	SABA prn or SAMA prn	SABA + SAMA or LABA or LAMA	<ul style="list-style-type: none"> Evidence for efficacy of medications in patients with FEV1 > 80% predicted is not available as most studies use a lower FEV1 entry criteria¹ SABAs are used prn initially to limit the sympathomimetic exposure in patients with mild symptoms¹⁰ Few studies used combined SABDs; however, the degree of bronchodilation achieved with SABA SAMA is additive, increasing the mean peak FEV1 more than either agent alone;^{1,10} five studies found combined use was preferred over SABA in the prevention of AE⁴
Group B ↑ Symptoms ↓ Risk of exacerbations	LABA or LAMA	LABA + LAMA	<ul style="list-style-type: none"> LABDs are superior to SABDs⁴ A LAMA may provide benefit over a LABA in the reduction of AE (see Bronchodilators section)⁴ For symptoms of severe breathlessness, combination LABA + LAMA is suggested¹
Group C ↓ Symptoms ↑ Risk of exacerbations	ICS + LABA or LAMA	LABA + LAMA or LABA + PDE4I or LAMA + PDE4I	<ul style="list-style-type: none"> Evidence supporting first-line choices is limited to one study comparing fluticasone propionate/salmeterol to tiotropium in 1,323 patients over 2 years; no difference in exacerbation rates was found between the groups.^{1,16} PDE4I used in combination with a LABD is recommended in patients with concurrent chronic bronchitis and/or continued exacerbations.¹ The use of dual LABDs may provide similar positive outcomes to ICS + LABA without the risk of pneumonia associated with ICS; further study is needed.^{4,10}
Group D ↑ Symptoms ↑ Risk of exacerbations	ICS + LABA and/or LAMA	ICS + LABA + LAMA or ICS + LABA + PDE4I or LABA + LAMA or LAMA + PDE4I	<ul style="list-style-type: none"> Long-term treatment with ICS is recommended for patients with severe symptoms and frequent exacerbations that are not adequately controlled with LABDs¹ Add-on therapy with PDE4I is recommended when chronic bronchitis, severe symptoms or frequent exacerbations are present and not adequately controlled with LABDs¹ The use of dual LABDs may provide similar positive outcomes to ICS + LABA without the risk of pneumonia associated with ICS; further study is needed.¹⁰

AE: acute exacerbations; FEV1: forced expiratory volume in one second; ICS: inhaled corticosteroid; LABA: long-acting beta₂-agonist; LABD: long-acting bronchodilator; LAMA: long-acting muscarinic antagonist; PDE4I: phosphodiesterase-4 inhibitor; prn: as needed; SABA: short-acting beta₂-agonist; SABD: short-acting bronchodilator; SAMA: short-acting muscarinic antagonist. Choices are listed in alphabetical order as there is not usually an order of preference # A short-acting bronchodilator, on a prn basis. should always be available for worsening symptoms

¹In addition to alternative choices, other treatments are possible but have not been included

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Therapeutic Options

FOCUS ON SGLT2 INHIBITORS FOR TYPE 2 DIABETES MELLITUS

By Christine Elliott, BScPhm, RPh and Tiffany Barker, BScPhm, RPh

BACKGROUND

Diabetes is a major metabolic disease that affects more than 300 million people globally, and this number is growing.^{1,2} Type 2 diabetes mellitus (T2DM) accounts for 90 to 95% of diagnosed diabetes cases.² Currently there is a large armamentarium of medications (Table 1) to treat T2DM, yet many patients do not achieve therapeutic targets.³ Many antihyperglycemic drugs are associated with adverse effects including hypoglycemia or weight gain.⁴ These effects negatively impact compliance. Furthermore, patients may continue to experience poor control of blood sugars, even with combination therapy. Sodium-glucose co-transporter 2 (SGLT2) inhibitors, with a novel mechanism of action, offer patients an additional option to attain treatment goals. Canagliflozin, dapagliflozin and empagliflozin work by inhibiting the reabsorption of glucose in the kidneys, resulting in increased glucose excretion in the urine.^{4,5} They are associated with a low risk of hypoglycemia and a potential benefit of weight loss.^{4,5} The average expected reduction in A1C from the SGLT2 inhibitors, along with other established therapies, is listed in Table 1.^{3,6}

INDICATIONS⁷⁻⁹

Canagliflozin, dapagliflozin and empagliflozin are approved for treatment of T2DM in adult (≥18 years) patients:

- As monotherapy in patients who have a contraindication to metformin
- In combination therapy with some antihyperglycemic medications (see Table 2)

PHARMACOLOGY¹⁰

The kidneys play a major role in glucose homeostasis, in part by reabsorbing glucose in the proximal convoluted tubules. Two sodium-

glucose transport carrier proteins (SGLT1 and SGLT2) facilitate glucose reabsorption in the proximal tubules. SGLT2 facilitates 90% of the reabsorption. In healthy adults, >99% of the glucose filtered by the glomeruli is returned to the circulation via reabsorption in the tubules. At plasma glucose concentrations beyond the resorptive threshold, glucose will spill into the urine. In T2DM patients, renal glucose

TABLE 1: Antidiabetic agents available in Canada^{3,6}

Drug name	Medication class	Expected decrease in A1C*
Acarbose	Alpha-glucosidase inhibitor	0.6%
Sitagliptin Saxagliptin Linagliptin Alogliptin	DPP-4 inhibitor	0.7%
Dulaglutide Exenatide Liraglutide	GLP-1 receptor agonist	1.0%
Insulin	Insulin	0.9-1.1%
Gliclazide Glimepiride Glyburide Chlorpropamide Tolbutamide	Sulfonylurea	0.8%
Repaglinide	Meglitinide	0.7%
Metformin	Biguanide	1.0-1.5%
Rosiglitazone Pioglitazone	Thiazolidinedione	0.8%
Canagliflozin Dapagliflozin Empagliflozin	SGLT2 inhibitor	0.7-1.0%

* Expected decrease in A1C when added to metformin, with the exception of metformin where the expected decrease is with monotherapy.

TABLE 2: Approved combination therapies with SGLT2 inhibitors⁷⁻⁹

	MET	SU	SU + MET	PIO + MET	PIO (± MET)	SIT (± MET)	INSULIN (± MET)
Canagliflozin	✓	✓	✓	✓			✓
Dapagliflozin	✓	✓	✓			✓	✓
Empagliflozin	✓		✓		✓		✓ (basal or prandial insulin*)

MET: metformin; PIO: pioglitazone; SIT: sitagliptin; SU: sulfonylurea
 ✓ Represents an approved combination.
 * Empagliflozin has not been studied in combination with regular or analogue insulin mix; therefore, empagliflozin should not be used in combination with insulin mix.

reabsorption is increased, contributing to elevated plasma glucose levels even in the presence of hyperglycemia. SGLT2 inhibitors decrease the amount of glucose reabsorbed through the proximal tubule, resulting in less glucose in the circulation. The excess glucose that is not reabsorbed is excreted in the urine.

PHARMACOKINETICS

Canagliflozin is rapidly absorbed with peak plasma concentrations occurring 1 to 2 hours after oral administration. The terminal half-life ($t_{1/2}$) is 10 to 13 hours. Steady state is reached after 4 to 5 days of dosing. Canagliflozin is metabolized to two inactive metabolites via O-glucuronidation (UGT1A9 and UGT2B4 pathways). CYP metabolic pathways are minimal for canagliflozin. Canagliflozin and its metabolites are excreted 52% in the faeces and 33% in the urine.⁷

Dapagliflozin is rapidly and well absorbed with peak plasma concentrations occurring within 2 hours after oral administration in the fasting state. The terminal half-life ($t_{1/2}$) is 13 hours. Dapagliflozin is metabolized to one primary inactive metabolite via O-glucuronidation (UGT1A9 pathway). CYP metabolic pathways are minimal for dapagliflozin. Dapagliflozin and its metabolite are eliminated 21% in the faeces and 75% in the urine.⁸

Empagliflozin is rapidly absorbed with peak plasma concentrations occurring 1.5 hours after oral administration. The terminal elimination half-life ($t_{1/2}$) is approximately 12 hours. Steady state is reached by the 5th day of dosing. Empagliflozin is metabolized to mainly three metabolites via glucuronidation (UGT2B7, UGT1A3, UGT1A8 and UGT1A9 pathways). Empagliflozin does not inhibit or induce, or inactivate major CYP450 isoforms. Empagliflozin is eliminated 41% in the faeces (majority as

unchanged parent drug) and 54% in the urine (approximately half as unchanged parent drug).⁹

EFFICACY

Canagliflozin, dapagliflozin and empagliflozin have been evaluated in T2DM patients as monotherapy and in combination with some oral antihyperglycemic agents and insulin. The efficacy of these SGLT2 inhibitors has also been studied in head-to-head clinical trials against some glucose-lowering medications.⁴

The primary endpoint of these trials was usually change in HbA1C from baseline; however, other endpoints, including the percentage of patients achieving target HbA1C (e.g., <7%) and changes in body weight, fasting plasma glucose and blood pressure, were also evaluated.^{4,5,11-13} Trials have consistently demonstrated that SGLT2 inhibitors reduce HbA1C when used both as monotherapy or add-on therapy in patients who are uncontrolled on various antihyperglycemic agents or combinations.^{4,12} HbA1C is lowered by approximately 0.5 to 1% by SGLT2 inhibitors.¹² The efficacy of this class may be affected by the degree of hyperglycemia as higher blood glucose levels lead to greater urinary glucose excretion, resulting in greater antihyperglycemic effect.⁴ Since the glucose-lowering mechanism of SGLT2 inhibitors is independent of insulin, their effectiveness is maintained regardless of a patient's insulin secretion capacity or insulin resistance (i.e., with T2DM progression).⁴ The antihyperglycemic durability of SGLT2 inhibitors is still being investigated in long-term trials.⁴ Head-to-head trials evaluating the comparative efficacy of SGLT2 inhibitors are currently lacking.⁴

Both osmotic and glucosuric effects of SGLT2 inhibitors account for observed weight loss in clinical

trials.⁵ Approximately 200 to 300 kcal were excreted daily and weight loss of approximately 1 to 5 kg was maintained up to 52 weeks.¹² Weight loss attributed to SGLT2 inhibitors is predominantly from loss of fat mass, not lean body mass, and this is advantageous for T2DM patients.^{4,12}

Modest lowering of systolic and diastolic blood pressures has been observed when SGLT2 inhibitors are used as monotherapy or in combination with other antihyperglycemic agents. This is likely due to the osmotic diuretic effect of these drugs.¹²

Efficacy of SGLT2 inhibitors is influenced by renal function. Glucose-lowering ability of this class is expected to be reduced in patients with lower GFRs, as this results in decreased urinary glucose excretion⁴ (see "Dosage & Administration" below for renal dosing information).

WARNINGS, PRECAUTIONS & ADVERSE EFFECTS⁷⁻⁹

Warnings and precautions for SGLT2 inhibitors include:

- Not indicated for use in patients with type 1 diabetes or for treatment of diabetic ketoacidosis.
- May cause volume depletion via osmotic diuresis; should be used with caution in patients at risk of volume depletion or those who may experience a drop in blood pressure (e.g., concurrent diuretic use, elderly patients, known cardiovascular disease, low systolic blood pressure or patients with renal impairment). Use is not recommended in patients who are volume depleted.
- Hypoglycemia occurred more frequently in combination with insulin or a sulfonylurea.
- May increase hemoglobin or hematocrit. Use with caution in patients with elevated hematocrit.
- May modestly elevate LDL-C in a dose-related manner by an unknown mechanism (an increase in HDL-C and decrease in triglycerides have also been reported); clinical significance of these effects is currently unknown¹². LDL-C levels should be monitored.
- Increases in serum creatinine and impairments to the glomerular filtration rate are possible in a dose-dependent manner. Renal function monitoring is recommended.

The most common adverse effects (≥5%) observed in SGLT2 clinical trials were:

- Vulvovaginal candidiasis, urinary tract infection (UTI) and polyuria or pollakiuria with canagliflozin.⁷
- Female genital mycotic infections, nasopharyngitis and urinary tract infections with dapagliflozin.⁸
- Hypoglycemia (dependent upon background therapy) and urinary tract infection with empagliflozin.⁹

The US FDA has revised SGLT2 inhibitor labeling to include a warning about serious urinary tract infections due to 19 cases of pyelonephritis/urosepsis requiring hospitalization reported with SGLT2 inhibitors. Patients should be aware of UTI signs/symptoms and contact a health care professional if any of these occur.¹⁴

Notable differences between the three drugs include:

- An imbalance in the incidence of bladder cancers was observed in clinical trials; the effect of dapagliflozin on pre-existing bladder cancer is unknown. Patients with active bladder cancer should not take dapagliflozin, and it should be used with caution in patients with a previous history of bladder cancer.⁸ Dapagliflozin should not be used in patients taking pioglitazone,⁸ which independently has also been associated with an increased incidence of bladder cancer.¹⁵
- The US FDA has revised the canagliflozin labeling to reflect new data confirming an increased incidence of fractures with canagliflozin compared to placebo as well as the risk of decreased bone mineral density at the hip and lower spine (also as compared to placebo). Continued evaluation of dapagliflozin and empagliflozin for fracture risk and any need for labeling changes is underway.¹⁶

Health Canada has issued important safety information regarding serious (sometimes life-threatening or fatal) cases of diabetic ketoacidosis (DKA) occurring in patients taking SGLT2 inhibitors for both type 1 and type 2 diabetes. A number of cases were atypical and occurred in patients with only moderately elevated blood glucose levels. In some cases, SGLT2 inhibitors were used in patients with type 1 diabetes; this advisory reiterates that SGLT2 inhibitors are not indicated for, and should not be used in, type 1 diabetes. SGLT2 inhibitors should not be used in patients with a history of DKA and should be used cautiously in patients with risk factors for DKA (temporary discontinuation

should be considered in situations that predispose to DKA). Patients should be informed of ketoacidosis signs and symptoms and to seek immediate medical attention if these occur. SGLT2 inhibitors should be discontinued immediately if DKA is suspected or diagnosed. More information about this topic can be found on the Health Canada website.¹⁷

For a complete list and explanation of warnings, precautions and adverse effects, refer to the respective product monographs.⁷⁻⁹

DRUG INTERACTIONS

Pharmacokinetic studies with various other medications, including cardiovascular and antidiabetic agents, suggest that SGLT2 inhibitors generally have very few clinically relevant drug-drug interactions.⁴

Individuals may require the maximum daily dose of canagliflozin (300 mg) when combined with UDP-glucuronosyl transferase enzyme inducers such as rifampin, phenytoin, phenobarbital, barbiturates, St. John's Wort, carbamazepine, ritonavir and efavirenz.⁷

The digoxin C_{max} and AUC values were increased by 36% and 20%, respectively, when taken with canagliflozin. Digoxin monitoring is recommended with combined therapy.^{7,11}

Pharmacokinetic studies with dapagliflozin and empagliflozin did not demonstrate a clinically relevant interaction with rifampin/rifampicin or digoxin.^{8,9}

Potential pharmacodynamic interactions include the risk of hypoglycemia when combined with other antidiabetic agents such as sulfonylureas or insulin, or hypotension when administered with antihypertensive agents such as diuretics, especially loop diuretics. There may be a risk of hyperkalemia (reported with canagliflozin) in patients with some renal impairment who are taking potassium sparing diuretics, drugs that interfere with the renin-angiotensin system, or other medications that may cause volume depletion.^{4,7-9}

DOSAGE & ADMINISTRATION

The recommended starting dose for **canagliflozin** is 100 mg daily and can be increased to 300 mg daily if required. It can be taken with or without food but is recommended before the first meal of the day. No dosage adjustment is required in patients with mild renal impairment ($eGFR \geq 60$ mL/min/1.73m²). Canagliflozin should

not be initiated with $eGFR < 60$ mL/min/1.73m². Patients established on canagliflozin whose $eGFR$ falls below 60 mL/min/1.73m² can continue on a dose of 100 mg daily. If the $eGFR$ falls below 45 mL/min/1.73m² canagliflozin should be discontinued. Dosage adjustment is not required for mild to moderate hepatic impairment. Safety has not been established in severe hepatic impairment and use is not recommended in this population.⁷

The recommended starting dose for **dapagliflozin** is 5 mg daily and can be increased to 10 mg daily if required. It can be taken any time of day, with or without food. No dosage adjustment is required in patients with mild renal impairment ($eGFR \geq 60$ mL/min/1.73m²). Dapagliflozin should not be used in individuals with $eGFR < 60$ mL/min/1.73m². Dosage adjustments are not required for patients with mild to moderate hepatic impairment or in the geriatric population. Use of dapagliflozin is not recommended in patients with severe hepatic impairment.⁸

The recommended starting dose for **empagliflozin** is 10 mg daily and can be increased to 25 mg daily if required. It can be taken any time of the day, with or without food. No dosage adjustment is required in patients with mild renal impairment ($eGFR \geq 60$ mL/min/1.73m²). Empagliflozin should not be initiated with $eGFR < 60$ mL/min/1.73m². If the $eGFR$ falls below 45 mL/min/1.73m² empagliflozin should be discontinued. Dosage adjustment is not required for mild to moderate hepatic impairment and empagliflozin use is not recommended in patients with severe hepatic impairment. No dose adjustment is required in the geriatric population, however, initiation of empagliflozin is not recommended in patients ≥ 85 years of age due to limited experience in this age group.⁹

DISCUSSION

The Canadian Diabetes Association has published a 2016 interim update to their guideline on pharmacologic management of T2DM, which includes SGLT2 inhibitors.¹⁸ SGLT2 inhibitors may be added to metformin or used in combination with other antihyperglycemic agents (while accounting for other therapeutic considerations) if glycemic targets are not met. Additions to the previous recommendations include that an SGLT2 inhibitor with demonstrated cardiovascular outcome benefit should be added to therapy to reduce cardiovascular and all-cause mortality risk in patients

with clinical cardiovascular disease and unmet glycemic targets. Currently, empagliflozin is the only SGLT2 inhibitor shown to have superior cardiovascular outcomes over placebo; it is unknown whether canagliflozin and dapagliflozin provide the same cardiovascular benefits, as these trials are ongoing.¹⁸ Other classes of add-on antihyperglycemic agents have not yet demonstrated superiority in randomized controlled trials of cardiovascular outcomes¹⁹ (metformin has shown cardiovascular benefits in overweight patients³). The presence or risk of cardiovascular disease is an important characteristic to consider when choosing add-on therapy to metformin in patients with T2DM.¹⁹

The American Diabetes Association Standards of Medical Care in Diabetes 2016 recommends SGLT2 inhibitors for T2DM as add-on therapy to metformin, or as part of triple therapy with metformin and one of the following: sulfonylurea, thiazolidinedione, DPP-4 inhibitor or insulin (usually a basal insulin).¹⁹ The National Institute for Health and Care Excellence (NICE) guidelines recommend the use of canagliflozin or empagliflozin with metformin if a sulfonylurea cannot be taken or there is a risk of hypoglycemia; in triple therapy with metformin and either a sulfonylurea or thiazolidinedione; and with insulin, with or without other diabetic medications.^{20,21} The NICE guidelines also recommend use of dapagliflozin in combination with metformin if a sulfonylurea cannot be taken or there is a risk of hypoglycemia; or, in combination with insulin, with or without other antihyperglycemic agents.²² However, the guidelines do not recommend dapagliflozin use with metformin and a sulfonylurea (except as part of a clinical trial).²² The treatment algorithm from the American Association of Clinical Endocrinologists recommends SGLT2 inhibitors as monotherapy if metformin is contraindicated or not tolerated, as add-on to metformin, or as part of triple-therapy.²³ Refer to the respective practice guidelines for further information regarding SGLT2 inhibitors' place in T2DM therapy.

SGLT2 inhibitors offer an additional

treatment option for adult patients with T2DM. Potential advantages of this class include convenient dosing, few drug interactions to date, generally mild to moderate side effect profile, mild blood pressure reduction and modest weight loss, as well as ability to modify beta cell function and insulin resistance.⁴ Antihyperglycemic efficacy has been demonstrated when these agents are used as monotherapy or in combination with other diabetes medications. Cost and the need for longer-term efficacy and safety data are potential disadvantages. Currently, empagliflozin is the only agent in its class to demonstrate cardiovascular benefits, with trials of canagliflozin and dapagliflozin underway. Additional studies are needed to further evaluate the impact of SGLT2 inhibitors on macrovascular and microvascular outcomes.⁴

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Employee and Family Assistance Plans (EFAPs)

By: Chris Matthews, CJM Solutions+

What are they?

24 hour per day confidential counselling service for an employee, employer or their family members to help manage their work and personal life. These plans allow for communications by email, phone or in person depending on the need. All EFAP plans have a team of professional counsellors in various disciplines

The key areas that advice and information can be provided include:

Parenting and Child Care - please note they provide advice not parenting or childcare

Education - advice on what is needed to assist in career choices, etc.

Dealing with Older Adults – I had many questions when dealing with my elderly parents and it can be very challenging, I found the advice given very helpful. I am sure my children will use this service, hopefully later rather than sooner

Mid-life and Retirement Issues – whether it is financial, emotional or career oriented

Disability – counseling help for employees who are disabled

Financial – helping employees plan their financial future or dealing with immediate financial needs

Legal – providing legal clarity; helping employees understand what their legal obligations are and what needs to be done

Work Issues – dealing with work life balance

Managing People - can include getting advice on how to deal with difficult employee situations

Health - counselling to help managing health situations

Emotional Wellbeing – helping an employee who needs to know how to manage their life

Grief and Loss – helping an employee or family member deal with a death of a loved one

Addiction & Recovery – providing advice on the resources available to assist someone in their struggle

In addition there is an abundance of resources and tools including booklets, recordings and wellness articles available to the employee and dependents on- line.

Many employers have Employee and Family Assistance Plans and most of them are under-utilized because the employee does not know or think about the service, or they do not trust the confidentiality of the service. The employee should be aware that the service has to be kept confidential because the counselor is subject to the same constraints as any Health Professional.

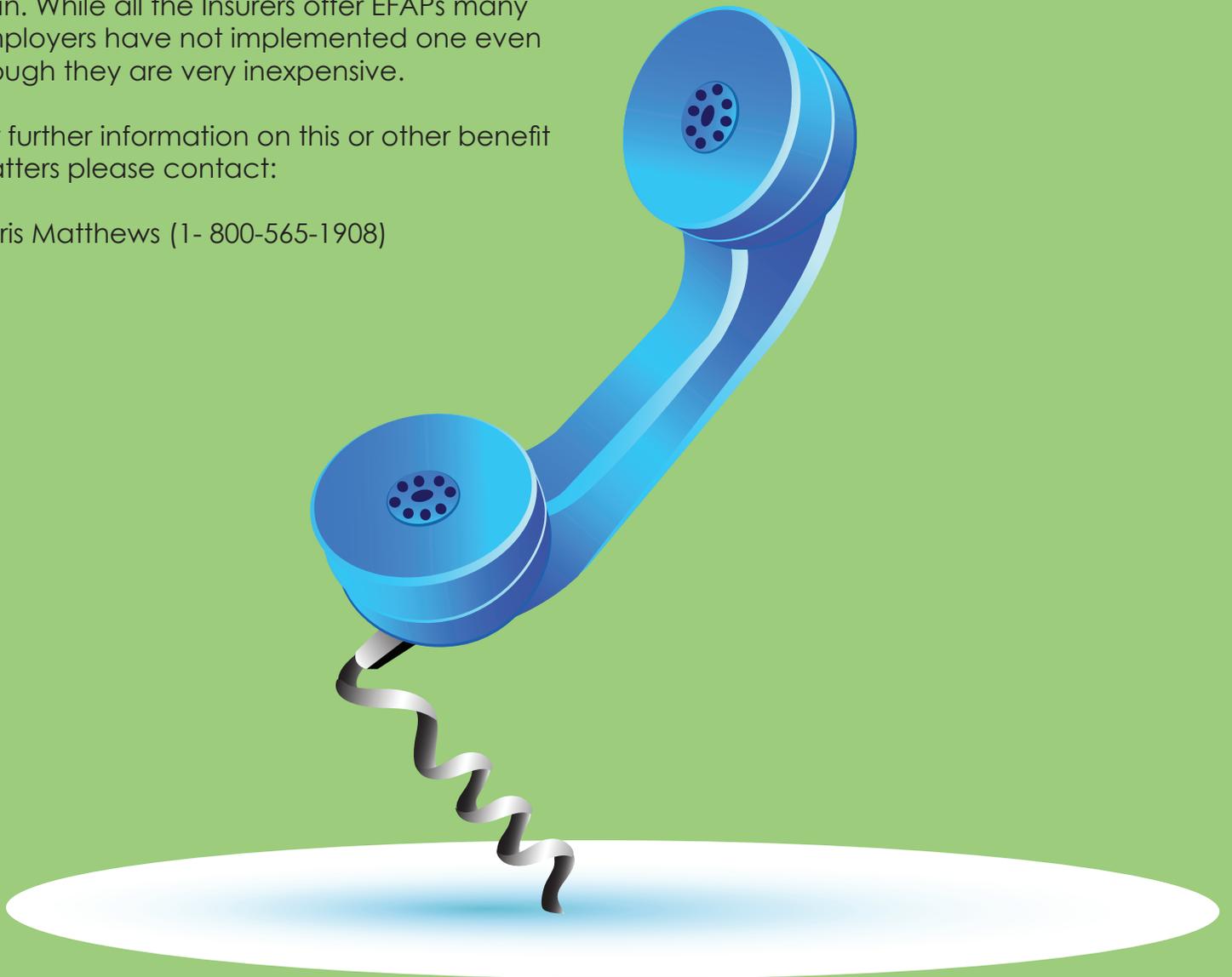
As an employee or dependent this is a great addition to a health plan and can alleviate a number of stressful situations. If you are an employer it is a great management tool, to assist you with

employees with whom you may have challenges. This is a very inexpensive way to help you as the employer and your employees.

The Pharmacy Association group insurance plan has an Employee and Family Assistance Plan built in for all employees covered by this plan. While all the Insurers offer EFAPs many employers have not implemented one even though they are very inexpensive.

For further information on this or other benefit matters please contact:

Chris Matthews (1- 800-565-1908)



Understanding Professional Liability

By: Jonathan Hines, BBA, CAIB, CRM
Partner, Wilson Insurance Ltd.

In almost every profession, professionals are held to high standards; to be informed, to be knowledgeable, to act with care and due diligence, to act in the best interests of the patient or client.

The question is, are the risks of practicing a professional service or activity changing?

Almost certainly. With the inception of social media, issues and/or circumstances can easily be communicated to large audiences with damaging results, even when professionals are not negligent or at fault. Information technology and large data are creating more informed consumers who have easy access to information to challenge opinions. Technology and products are evolving at exponential rates creating an environment where even the most informed professionals are challenged to maintain current information about their practice. Society is becoming more litigious, with litigation broadly discussed on public forums, including social media.

Within the pharmacy industry, risks are changing and evolving. More services are being offered such as injections, electronic information is fully integrated into pharmacy services and services like compounding and holistic and natural supplements are becoming commonplace. New and emerging risks such as abuse allegations from procedures conducted in private spaces, and in some cases with vulnerable persons are occurring more frequently. The propensity of patients or clients to bring allegations of negligence or wrongful acts seem to be on the increase. Product recall, once products have been changed, altered

or repackaged, can draw in and name multiple parties liable including the individual pharmacy practitioner and the pharmacy business. Like many other professions, it is important to understand and manage these risks.



Are all insurance policies created equal?

The short answer is no. There can be significant differences between how insurance policies address claims, allegations and the cost associated to investigate and defend against them. The intent of purchasing insurance is to “transfer” or assign risk to the insurance company. Understanding how insurance policies are structured and written defines how they will respond. The significant differences are found in two key areas within the insurance contract; definitions, and exclusions. How the insurance policies define a “wrongful act” has significant bearing on if and how coverage will apply and respond. A “wrongful act” definition defines what elements of professional negligence are considered by the insurance policy. The policy exclusions specifically limit coverage

for certain types of claims, damages or circumstances. Unfortunately, if not carefully considered, these coverage limitations and exclusions may result in denial of a claim and costs to the insured.

What factors should be considered when purchasing insurance for pharmacy professional liability?

Why is the scope of coverage for “allegations of a wrongful act” or professional negligence? Remember, even if the allegations or claim is frivolous or groundless, there still are almost always costs to investigate and defend the claim. If the allegations of a “wrongful act” are not covered within the definition, or are excluded, the insurance policy will not respond to these costs. Often, disciplinary proceedings outside of a court of law are excluded. Other common exclusions could be allegations of abuse, damage to “your product” or “your work”, possibly resulting in product recall concerns, loss of data or release of electronic information, or allegations of criminal or illegal acts. The good news is that these exposures can either be covered under the employer's policy, or the individual practitioner's policy. For those purchasing individual practitioners coverage through an employer, it is critical any limitations of these policies and common restrictions, such as those limiting coverage to work completed on behalf of the employer only. Understanding the risks and coverage covered under the employers' policy can make it clear to individuals where coverage is limited and what coverage they need to seek under their own policy.

While there is a significant range in cost of insurance through different policies and programs, coverage differences can be

critical and complex.

How can individuals manage this risk?

Be Informed...

Ask Questions...

Look Beyond Pricing...

Insurance policies and coverages change and evolve to meet the changing needs of the pharmacy industry. Industry and professional programs designed and trusted through professional associations are one way to take advantage of the information collected by the association and used to lobby for better solutions for members. Association insurance plans can be specifically designed to respond to changing issues and risks through collaborative consultation with the association and provider of the program. While not all insurance policies are created equal, innovation and adaption does exist within the insurance industry when the focus is on value and partnership.

~~RISK~~

INSURANCE

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Message from the Chair and CEO

continued from page 4

Additionally, PANS has been working on an education program for employers in Nova Scotia about the value of pharmacy services and the importance of their inclusion in employee benefits packages. The feedback from these employers has been very positive and some employers have already added pharmacy services to their benefits plans as a result of these meetings. PANS has developed materials to help employers and pharmacy team members explain the value of these services and electronic versions will be available on the PANS website for your use. We encourage all members to meet with employers that they know have health plans and using the materials available, explain to them the value of adding these services to their plans.

At PANS, we are seeking every avenue we can to get our message out to every decision maker in the province. Nothing however, replaces the value of message that you, our members, deliver every day to your patients across the province. Working together, we will achieve our goals and we will see pharmacy integrated into the health care system.



Not performing your best?

Pharmacists can provide consultations to help you prevent medication side effects or manage them if they occur.

Pharmacy Services are now covered by your employee health plan. Check your plan for details.

Don't go without your medications

Pharmacists can provide up to a 90-day renewal on many medications.

Pharmacy Services are now covered by your employee health plan. Check your plan for details.

Still sneaking that smoke?

Pharmacists can provide many services to help you quit, including prescribing medication.

Pharmacy Services are now covered by your employee health plan. Check your plan for details.

Feeling older than your years?

Pharmacists can provide many consultation services to help you meet your health goals.

Pharmacy Services are now covered by your employee health plan. Check your plan for details.

Too old to look like a teenager?

Pharmacists can assess and prescribe for many conditions, including acne.

Pharmacy Services are now covered by your employee health plan. Check your plan for details.

Is your heavy breathing not sexy anymore?

Lung problems don't have to control your life. Pharmacists can provide many consultation services to help you get back on track!

Pharmacy Services are now covered by your employee health plan. Check your plan for details.

Sick and tired of being sick and tired?

Pharmacists can provide many consultation services to help you meet your health goals.

Pharmacy Services are now covered by your employee health plan. Check your plan for details.

Every day, pharmacists help people by recommending changes to their medications that make them feel better. Pharmacists can also provide health and lifestyle coaching to better manage illness and disease.

Pharmacy Health Care Services

PANS
PHARMACY ASSOCIATION OF NOVA SCOTIA
110 Conroy Drive, Suite 225
Dartmouth, Nova Scotia
Canada B3B 0G1
Phone: 1-800-422-9683
Fax: 1-902-422-2619
Email: pans@pans.ns.ca
www.pans.ns.ca

Your health condition doesn't have to weigh you down.

PHARMACY HEALTH CARE SERVICES

Links of Interest

Alzheimer's Society - Canada

<http://www.alzheimer.ca/en>

Asthma Society of Canada

<http://www.asthma.ca/>

Canadian Celiac Association

<http://www.celiac.ca/>

Canadian Dermatology Association

<http://www.dermatology.ca/>

Diabetes Canada

<http://www.diabetes.ca/>

Canadian Lung Association

<http://www.lung.ca/>

Canadian Paediatric Society

<http://www.cps.ca/en/>

Canadian Pharmacist's Association (CPhA)

<http://www.pharmacists.ca>

Cancer Care Nova Scotia

<http://www.cancercare.ns.ca/en/home/healthprofessionals/stp/default.aspx>

Crohn's and Colitis Canada

<http://www.crohnsandcolitis.ca/site/c.dtJRL9NUJmL4H/b.9012407/k.BE24/Home.htm>

Health Canada - Advisories and Warning

<http://www.hc-sc.gc.ca/ahc-asc/media/advisories-avis/index-eng.php>

Health Canada - Tobacco Information

<http://www.hc-sc.gc.ca/hc-ps/tobac-tabac/index-eng.php>

Mayo Clinic

<http://www.mayoclinic.org/>

Medication InfoShare

<http://medicationinfoshare.com/>

Medline Plus (U.S. National Library of Medicine)

https://www.nlm.nih.gov/medlineplus/druginfo/herb_All.html

Mother Risk (Hospital for Sick Children, Toronto)

<http://www.motherrisk.org/>

National Center for Complementary and Integrative Health (U.S. Dept. of Health & Human Services)

<https://nccih.nih.gov/>

Osteoporosis Canada

<http://www.osteoporosis.ca/>

Sleepwell Nova Scotia

<http://sleepwellns.ca/>



www.pans.ns.ca



facebook.com/PharmacyNS



twitter.com/PharmacyNS



youtube.com/pharmacyassocns

Pharmacy Services Update

by: Chris Matthews, CJM Solutions+

Unlike Quebec, Nova Scotia employers are not required to cover Pharmacy Services. This creates a bit of a challenge for us.

In order to promote pharmacy services in Nova Scotia there are number of steps that need to take place. Insurers will never add anything to their Health Insurance plans unless they are pushed by employers and Insurance brokers/consultants.

The first step is to show employers the value of pharmacy services. Given the amount of evidence that supports the benefits of pharmacy services, once in front of employers, persuasion is not difficult. If it can be proven that pharmacies can provide employees and their families' easier access to health professionals and better health outcomes as the result of adherence etc., it should be an easy sell particularly since there is strong evidence of the positive financial impact of pharmacy services.

These are achieved through:

1. **Better Health Outcomes**

This equates to healthier employees and their families and lower health and disability insurance premiums as a result of fewer claims.

2. **Less Absenteeism**

If an employee can go to a pharmacy to renew a prescription or be diagnosed a minor ailment rather than have to take time off work to go to a doctor this will help improve workplace productivity.

It is like Wellness Programs, however many

employers who may be persuaded by the positive evidence of pharmacy services, the initial insurance company charge to include this service may discourage many employers from adding it to their plans. They may not want to add another "cost" to their health plan. Insurers do not know how to price pharmacy services because they have no history with it. The other issue that arises is that adding pharmacy services to their employees' benefits plan is not necessarily a high priority for the employer. While the employer may be enthused initially about pharmacy services, unless it is a strong follow-up takes place, end result is the idea of adding pharmacy services to an employer's benefit plan can be shelved.

Even though various studies show that it is financially worthwhile for an employer to add pharmacy services to their employees' benefits place, because of reduced overall healthcare claims, adding such service can result in increases in overall health care premiums. The insurers do not have history with Pharmacy Services and when they are in doubt they tend to price high.

As benefit consultants, we have been successful in implementing pharmacy services in a number of group health plans. The most successful plans are when the insurer (e.g. Medavie Blue Cross) allows the service to be coded as a "pseudo" DIN and can be processed as if it were a drug claim. Less successful plans are those where the employee has to send the claim in for reimbursement - although this is getting easier with insurer mobile apps where employees just has to photocopy the receipt

Pharmacy Services Update

and send it in to the insurer for payment.

Some employers have set up Health Spending Accounts for their employees. This is similar to a bank account where an employee can choose which health service they wish to have their plan pay for - up to a certain dollar maximum - usually set up instead of/or in addition to a dental plan, glasses and physiotherapy, etc. These Health Spending Accounts allow payment of pharmacy services but, once again, this is done on a reimbursement basis (the employee pays up front and then gets reimbursed by the insurer).

So what needs to be done?

Step 1: Employers need to see the advantage of the work done by pharmacy. There have been a number of approaches to major employers by PANS, with some successes, this is very much a work in progress. Most employers require more than one visit or discussion and need to be prodded.

Step 2: Insurers need to add it in to their plans. Ideally all the Insurers should offer pharmacy services on the gold standard i.e. paid through the Drug Card. So far, only one insurer (Medavie Blue Cross) has agreed to this. Great West Life and Sun Life (Telus) will provide the benefit on a reimbursement basis only. Most of the major

insurers and broker/consultants in the Atlantic Region have been approached by PANS with some success.

Step 3: Prompting the employees to use pharmacy services once the program is in place. Employee meetings are useful. At the very least, there should be some kind of announcement to the employees.

As pharmacists and pharmacy owners you can help this process by promoting your services to employers, employees, and their dependents.



Insuring Your Financial Health



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