The HIV Care Cascade: Identifying Gaps and the Role of the Pharmacist

Ninth Annual HIV Pharmacy Education Day – September 15, 2017

Introduction

Linda Robinson welcomed the day's participants with brief comments on the day's theme. With HIV care increasingly focused on monitoring and improving patient outcomes through the care cascade, she reflected on the role that pharmacists can play in addressing gaps in the care cascade, particularly through relationship building with vulnerable patients. The purpose of several of the day's sessions is to consider the perspectives and priorities of marginalized patient groups and for each participant to reflect on how they and their organizations might improve care experience for these communities.

Questions for reflection:

- *How can your organization better engage HIV patients at all points on the cascade?*
- *What additional services could you provide that would improve engagement at a specific point?*
- *Do you know where and how to refer people for quality care? How can you find out?*
- *Can you learn from what other agencies are doing? Could it be implemented in your agency?*
- *What initiatives and partnerships could you develop to better connect people with your services? With other relevant services in your community?*

Treating Poverty: Clinical Tools for Care Providers

Gary Bloch, MD, CCFP, FCFP; St. Michael's Hospital

Dr. Gary Bloch discussed the impact of poverty on front line care and what health care providers can do to treat poverty. He presented the case of an individual patient, stressing how the social and economic stresses on her made health outcome improvement unlikely. There is powerful evidence from many epidemiological studies of the link between poverty and the increased prevalence and mortality of many different diseases, including HIV. Income equality affects health across the spectrum, so that health outcomes decline with each declining quintile of income. Income inequality is associated with 40,000 Canadian deaths each year, the equivalent of a small to mid-sized commercial airliner falling out of the sky daily. In his comments and the discussion, Gary also stressed that some Canadians are disproportionately affected, such as racialized Canadians, the elderly and people with disabilities.

Poverty is such a strong predictor of poor health outcomes that Gary and his colleagues advocate that health care providers screen for it, just as they would other risk factors. The screening tool, *Poverty: A Clinical Tool for Primary Care Providers* (www.effectivepractice.org/poverty), has three components:

- **Ask and screen everyone** – "Do you ever have difficulty making ends meet at the end of the month?" This simple question has 98% sensitivity/40% specificity in identifying people at risk.
- **Assess risk and educate** – Integrate knowledge of poverty into risk assessment. For example, a physician should be quicker to suspect diabetes or order glucose testing for a low income patient.
- **Intervene and connect** – Ask questions and refer patients to resources that can improve income, such as, "Have you filled out and mailed your income tax this year?" and referring them to a tax clinic if they have not. (Some referral resources are provided at the end of this session report.)

Income interventions are effective and can have a rapid influence. Gary cited the outcomes of a *Manitoba Healthy Baby Prenatal Benefit* for low-income women which provided $81.41 a month of additional income during their pregnancy. This intervention had a positive impact on the health and birth weight of the babies. He also briefly described some of the interventions currently being implemented at his academic family health team at St. Michael's Hospital. This includes two income security counsellors who support patients in applications to improve income security, and a health justice intervention that partners with community legal clinics. Lastly, he touched on the systems level advocacy of health provider organizations.

Resources

Evidence:

- Current Evidence on Social Determinants of Health Affecting People Living with HIV/AIDS
- Income inequality is killing thousands of Canadians every year

Interventions:

- Poverty: A Clinical Tool for Primary Care Providers
- Primary Care Interventions in Poverty
- Unconditional Prenatal Income Supplement in Birth Outcomes (academic paper, Manitoba program)
- St. Michael's Academic Family Health Team – Social Determinants of Health Interventions

Referral Resources:

- Canada Benefits (federal and provincial income support programs)
- 2-1-1 (a listing of community support and social service organizations)
- Your Legal Rights (easy-to-find legal information for Ontario)

Health Provider Advocacy:

- Physicians and Health Equity: Opportunities in Practice – Canadian Medical Association
- Best Advice - Social Determinants of Health – College of Family Physicians of Canada

Sanguen Community Health: A Mobile Outreach Program

Violet Umanetz; Outreach Coordinator

The Sanguen Health Centre is funded as a Hepatitis C (HCV) Team under the HCV Secretariat serving clients in Waterloo Region and Wellington-Dufferin-Guelph. They are funded to serve people who use drugs and experience a variety of other barriers: addictions, mental health challenges, homelessness, etc. When asked, clients said that being healthy was what they wanted, but often there were too many barriers. Sanguen tried referring clients to other agencies to address these barriers, but eventually discovered that the people they needed to reach the most couldn't access these referrals. They also began to document a variety of very practical concerns for their clients and for those that weren't yet their clients: food, seasonal clothing, menstrual supplies and fears that interactions with agencies would jeopardize relationships with their children or lead to arrest. Lastly, they noted the consistent reports of stigmatization that this population had experienced dealing with the health care system. Most health care professionals don't have training in supporting street-involved people who are using drugs; too often the expectation is for abstinence before treatment.

To meet the community "where they live," Sanguen bought a van to bring services to people. Although their funding mandate is HCV testing, they focused first on practical needs: food, clothing, hygiene products, and had the nurses travelling with the van to give out food. They had 91 visits to the community health van in the first month, none for health care provision.

Violet told the compelling story of the evolution of "the van" and its staff over time and the dramatic expansion of services as it gained community trust. Sanguen has worked hard to be driven by the needs people express, and to make the service open to everyone, not a stigmatized environment. The van now goes out three nights a week. In July in a single week (8 hours of service), it was visited by 1200 clients, dispensing 2272 food items, 848 syringes, 2283 hygiene items and providing HCV testing to seven people.

Challenges remain for the van program including a lack of primary care providers travelling with the van, and the space to provide medical care. It is challenging to provide continuity of care with this model, especially for complex issues. There are also the ongoing cost and logistic challenges of obtaining supplies – which is now supported by an army of donors and volunteers (although more are always needed)! The benefits of this approach are huge, particularly the value of going to people on their own turf and interacting with them in a more informal and equal way. Job satisfaction is high for the van staff. The van has also increased visits to the program's office and outreach locations as people with whom they have built trust seek out further care.

Resources

- Sanguen Health Centre
- The Community Health Van – Facebook Page

Cultural Competency: LGBT 101 / Trans Women and HIV

Yasmeen Persad; 519 Community Centre and CHIWOS Study Group

Yasmeen began the presentation with a discussion of common words used to express sexual orientation, gender identity and gender expression in Canada.

Sex- The medical classification of people as male or female, based on physical aspects of body.
Gender - How we perceive our identity as male, female, both or neither, regardless of our physical body.

Trans - An umbrella term referring to people with diverse gender identities and expressions that may differ from stereotypical gender norms. This is preferable to transgender or transgendered.
Cisgender – A person whose gender identity is aligned with their sex assignment at birth.

Two-Spirit - A cultural and spiritual identity used by some Indigenous peoples who have both masculine and feminine spirits.
Intersex - A person born with biological and/or physical characteristics that are not easily characterized by medical definitions of male or female.
Gender Queer/Gender Non-Conforming - Individuals who do not follow gender stereotypes based on the sex they were assigned at birth. They may or may not identify as trans.

Queer - An umbrella term used and reclaimed by some whose sexual orientations and/or gender identities defy the norm.

Bisexual - Someone emotionally, physically, spiritually, and/or sexually attracted to people of more than one gender.
Gay - Someone emotionally, physically, spiritually, and/or sexually attracted to people of the same gender.
Lesbian - A woman who is emotionally, physically, spiritually, and/or sexually attracted to women.

The Ontario Human Rights Code is a provincial law that gives everybody equal rights and opportunities without discrimination in areas such as jobs, housing and services. It aims to prevent discrimination on many grounds and includes gender identity, gender expression and sexual orientation.

Very little is known about how social and structural inequities affect the lives of trans women living with HIV. However, a recent analysis from the Canadian HIV Women's Sexual & Reproductive Health Cohort Study (CHIWOS) provides some insights. It compared socio-economic factors and treatment outcomes for 53 trans women with 1360 cisgender women in the cohort. It found that:

- More trans women were living in the lowest income bracket, over 90% earn less than $20,000/year
- Over 77 percent receive social assistance, few trans women were employed (11.3%) and 9.4% reported sex work as a source of income (compared to 1.7% of cisgender women)
- 26% of trans women reported unstable housing (compared to 10% of cisgender women); about a third of both groups reported food insecurity
- 88% of trans women report experiencing violence in childhood (compared to 68% of cisgender women); over 80% trans women experience ongoing harassment (being called names or abnormal)
- 8.2% of trans women have NEVER accessed HIV-related care (compared to 2.5% of cisgender women)
- 68% of trans women are currently on ART; 77% of those have undetectable viral load
- 28% of trans women say their doctor has not discussed potential interactions between HIV medications and hormones; although 87% say they are comfortable discussing trans-specific health care with their HIV doctor

Trans women are predominantly living in poverty, experience high rates of violence and stigma and have many unmet service needs.

Resources

- Ontario Human Rights Code
- The Canadian HIV Women's Sexual & Reproductive Health Cohort Study (CHIWOS)

Cultural Competency: Culturally Diverse Populations

Marvelous Muchenje; Women's Health in Women's Hands

Culture is the values, beliefs, language, thinking patterns, behavioural norms, and communication styles shared by a group of people. It is the filter through which people process their experiences including their health care experiences. Culture is a powerful determinant of health-related behaviour.

In health care work places, we can strive to be **culturally sensitive** (open to learning about and accepting of different cultural groups, and willing to adapt our communications and behaviours) and aim to become **culturally competent** (having an understanding of the diverse attitudes, beliefs, behaviours, practices, and communication patterns of another culture[s]). Cultural competency requires many skills including: self awareness, cultural understanding and the ability to consider multiple perspectives, intercultural communications, relationship building and conflict resolution skills. There is no recipe for cultural competency, it is a process of adaptation and evolution.

Culture is not fixed. African women entering HIV care have cultural ideas from the communities they were born into, cultural ideas formed in transition from those communities and concepts adapted from Canadian host communities. When they return to their homeland, they may also encounter new cultural ideas.

Culture affects people's health seeking behaviours, how they perceive the cause of illness and how they make treatment decisions. For example, many African women to do not perceive themselves as having mental health challenges, regardless of the stresses they encounter or experiences of depression. In their

home countries, the concept of mental illness applies only to people who are socially disenfranchised due to extreme behaviour.

Culture also shapes socially acceptable forms of behaviour and communication such as making eye contact or "getting down to business immediately." These two ways of communicating are often inappropriate in other cultures.

Marvelous suggested several strategies to strengthen access to information and services for culturally diverse populations:

- Build rapport and trust.
- Explain why you must ask personal or sensitive questions.
- Watch for patient's verbal and non-verbal cues.
- Allow patient to ask questions at frequent intervals.
- Have posters on the wall that depict people of different racial/ethnic groups
- Avoid local jargon and phrases.
- Learn to appreciate that your way of doing is not always the best and that your social position influences how you interact with patients.
- Work to ensure that patients understand your messages; use the cultural expertise of translators as well as their language expertise, when it is available to you. (One example around messaging is the word undetectable, this does not mean cured!)
- Take into consideration the context of people's lives (their experiences as newcomers or women).
- Hire staff that reflect the client population.

Be creative in communicating and in finding opportunities for community input. Cultural competency doesn't mean never making mistakes, it means being flexible and adaptive to what you learn from those mistakes and from the communities you serve.

PrEP: Questions and Controversies

Linda Robinson; Deborah Yoong; Pierre Giguère; Andrea Sharp, MSW

This session began with an anecdote from Linda about "PrEP gone bad" which illustrates some of the challenges in the current PrEP environment, when many people, including health care providers, are uninformed about PrEP. Increasingly, pharmacists must navigate how and where to intervene in this prescribing environment. Deborah Yoong presented several vignettes to consider during the PrEP presentations; appropriate responses in each of these scenarios were discussed at the end of the session.

Pierre Giguère is part of the national team, which is drafting Canadian National Guidelines on HIV nPEP and PrEP. This multidisciplinary team anticipates publication of the guidelines in *CMAJ* in the next few months, however they are currently under-review; **some recommendations may be amended**. The guidelines will describe **who** should receive PrEP, **what** regimen is recommended, **how** PrEP should be dispensed and **when** to follow-up.

> **What** – The guidelines will describe two acceptable regimens: ***continuous PrEP*** taken daily OR ***on demand PrEP*** (two pills together 2-24 hours before the first sexual exposure, followed by daily pills until 48 hours after the last exposure).
>
> **How** – The guidelines suggest PrEP be dispensed for a duration of three months with no refills (not just no renewal) to ensure ongoing evaluation.

Who - The guidelines will recommend PrEP use for:

- Men who have sex with men and trans people who had condomless anal sex in the last six months AND who have had:
    - a sexually transmitted infection (STI) in the last 12 months, OR
    - Have been prescribed nPEP more than once, OR
    - have an ongoing sexual relationship with an HIV-positive partner(s) where there is a significant risk of transmission
- Heterosexual people who are having condomless vaginal and and/or anal sex in a serodiscordant relationship where there is a significant risk of transmission

The guidelines suggest considering PrEP prescribing for people who use injection drugs and are at risk of HIV infection, or for heterosexual people in serodiscordant relationships with non-negligible risk.

The different levels of risk are an important element. The risk of a sexual relationship is considered:

- ***Significant*** if the person's partner is HIV-positive and viremic (has a viral load > 40 copies/ml); OR if their HIV status is unknown and they are from a priority population, which is at high-risk
- ***Low*** if the person's partner is HIV-positive and they are believed (but not confirmed to the standard below) to be undetectable

A person's sexual risk is thought to be ***negligible/none*** if their partner is confirmed HIV negative, OR HIV-positive with a viral load < 40 copies/ml (undetectable) and no sexually transmitted infections at the time of exposure. Sexual contact with people of unknown HIV status from the general population is also considered a negligible risk.

When (Evaluation and follow-up) - Prior to beginning PrEP, confirmation is needed of the person's HIV-negative status including both an HIV test and a review of the person's recent medical history for signs and symptoms of acute HIV disease. Renal function should be assessed (CrCl > 60 ml/min) and screening for STI should be done. Viral hepatitis screening and immunization should be updated. Counselling around adherence and risk reduction as well as assessment for potential drug-drug interactions. Routine bone monitoring is not recommended.

Follow-up should be done 30 days after PrEP initiation and every three months thereafter. Follow-up visits should include STI screening, renal screening and assessment of changing risk patterns as well as adherence counselling as needed.

A presentation from Andrea Sharp, a social worker at UHN where the HIV Prevention Clinic operates, focused on strategies for PrEP payment. They currently have about 300 active PrEP patients. Although PrEP payment options continue to be limited, the social workers have had good success helping people explore private insurance options; they estimate that for any household making $50,000 a year or more, the private coverage route is more cost effective than Trillium. Private coverage must be sought before commencing the drug.

Formulary coverage of generic forms of PrEP in Ontario is anticipated "imminently," as several generic versions received notices of compliance over the summer. It is anticipated that for these drugs the formulary will include a prevention indication, not just a treatment indication. [Note: The Sept 28th summary of formulary changes lists the new drugs; in addition, Truveda and the Teva drug have an indication for pre-exposure prophylaxis.] Having these drugs in the marketplace will substantially change the cost equation for many people, and may make private drug coverage (which often pays 80-90% of drug costs) a more feasible option for many. The new Apotex is priced as low as $400-500, with new products from Mylan and Teva potentially even lower.

Clinical Vignettes and Discussion

Vignette	Discussion
Amy is asking for a refill of her monthly prescription of Truvada, atazanavir, and ritonavir. You notice that a claim was submitted 2 ½ weeks ago but she tells you that she has run out already. You notice there are many occasions where the prescription is filled early. You know she is hoping to become pregnant with her partner who is HIV-negative.	Suspect that Amy is sharing her HIV medications as an informal form of PrEP with her partner as they try to get pregnant. Requires education: • PrEP use needs to be more regimented than sporadic ARV use • Risks for partner since he has had no screening (renal, etc.) • If Amy is undetectable, his risk is negligible
James calls to ask to refill his prescription: Truvada, 1 tablet daily; 3-month supply; no repeats/extension He explains that although he picked up his supply a week ago, he had it in his bag and the bag got stolen. He's asking if you can refill the prescription.	Suspect that sharing may be happening • Talk about the risks of unmonitored sharing with the patient • Most would also contact the physician about re-filling this prescription and about your suspicions
Matthew hands you his prescription: Truvada, 1 tablet daily; 3-month supply; no repeats/extension Because of his finances, he asks to fill 1 month at a time. Four months later, he returns to pick up another 1-month supply. You inquire about the gap and he tells you that he hasn't really needed it lately and takes it "when he needs it".	• On demand dosing will be part of the PrEP and nPEP clinical guidelines however a conversation is needed with the patient about how they are using PrEP • Need to ensure appropriate risk perception, since studies show risk perception is not always appropriate
You receive a new prescription: Truvada, 1 tablet daily; 3-month supply; no repeats/extension You notice that it is dated June 30, 2017 but today is September 15 2017.	• Need to talk about why this gap has occurred (have there been risk encounters since June, maybe it is an issue of travel?) • Would be a useful circumstance for POC testing in pharmacy • If patient assures you there have been no high risk encounters since June, many would fill, but need to document this conversation with as much detail as possible
Daniel comes to your pharmacy with a prescription from the emergency department: Truvada, 1 tablet daily; Tivicay 50mg daily; 27-day supply His medication profile shows previous prescriptions for sertraline and escitalopram. You also notice that he filled a prescription for Truvada and raltegravir x 28 days about 9 months ago.	• Repeated nPEP will be an indication for PrEP in new guidelines • Have a conversation about possible transition to PrEP, advise on how to start that process with referral to sexual health clinic (referral info below) • Discussion of a pharmacist-led PrEP clinic in Seattle presented at CROI

Resources

- How more Ontarians could gain access to a '99.9%' effective HIV-prevention drug (CBC News)
- Sexual Health Ontario (Use find a clinic feature for referral)
- Feasibility of a Pharmacist-Run HIV PrEP Clinic in a Community Pharmacy Setting (CROI abstract and video)
- Ontario Drug Benefit Formulary – Summary of Changes September 2017

Hepatitis C: Treatment Update and Ontario Coverage

Pierre Giguère; Alice Tseng

Pierre began these presentations with remarks about the rapidly changing HCV treatment environment in Ontario with significant new drugs approved in both February and September of this year. Alice's presentation provided further details about these therapies.

Access

DAA (direct acting antiretroviral) medications for HCV are exceedingly costly; few patients can consider paying $60,000 out-of-pocket for three months of treatment. People must rely on good private plans (100% coverage) or ODB coverage. All of the major companies also have patient assistance programs. They may cover up to 50% of costs and they try to coordinate with insurance plans (ODB or private):

- Momentum
- AbbVie Care
- Claire
- Merck Care
- Ibavyr Patient support

Prior to February of this year, there were many people for whom ODB did not have much to offer. If they had a liver fibrosis scores < 2, they had a mixed genotype, or were treatment experienced, there was nothing available for them on ODB, and most of the patients served were accessing private coverage sometimes in combination with the patient assistance programs above. When attempts were made to access drugs through the Exceptional Access Program (EAP) the process was cumbersome, and SLOW (weeks or months). The process requires declaring a treatment start and stop date, but if the process was delayed, the stop date would frequently be passed, and re-application would be necessary.

After February 2017, new drugs became available on the formulary for more indications, and the indications for existing drugs were changed, so that there are several options for treatment-experienced patients. The two drugs approved were appropriate for people with mixed genotypes: Epclusa (1-4) and Zepatier (1 and 4). These changes have released drug approvals from the cumbersome EAP process, as the drugs are now limited use. As well the treatment criteria changed, so that more people were eligible. The current eligibility criteria for DAA medications are: Fibrosis criteria: ≥ F2 …. OR

- Co-infection with HIV or hepatitis B.
- Co-existent liver disease with diagnostic evidence of fatty liver disease (e.g. non-alcoholic steatohepatitis)
- Post organ transplant (liver and/or non-liver transplant)
- Extra-hepatic manifestations (such as symptomatic vasculitis associated with HCV, or HCV immune-complex-related neuropathy or a number of others)
- Chronic kidney disease stage 3, 4 or 5
- Diabetes receiving treatment with anti-diabetic drugs
- Woman of childbearing age planning pregnancy within the next 12 months

This has greatly expanded access so that 60-70% of patients now have access to treatment. The province has said that these eligibility criteria will continue to expand over time, presumably until all of the people with chronic HCV are eligible. Initially, ODP required manual claiming for these treatments, which would require the patient to pay for the initial prescription ($20,000) and then be reimbursed, fortunately this barrier appears to have been resolved.

On August 16, 2017, Health Canada approved two new drugs (also just approved in the US):

- Maviret (glecaprevir/pibrentasvir)
- Vosevi (sofosbuvir/velpatasvir/voxilaprevir)

Maviret (glecaprevir/pibrentasvir) has the potential of an eight-week dosing schedule for some patients, including some treatment-experienced patients. It can be used to treat all six HCV genotypes and may be given to patients with any degree of renal impairment. It is taken as three tablets once a day with food.

Vosevi (sofosbuvir/velpatasvir/voxilaprevir) is a single tablet drug approved for treating treatment-experienced patients and can also be used for all six genotypes. It requires no dose adjustments for mild to moderate renal impairments, or for mild hepatic impairment, although it is not recommended for those with more severe liver damage.

The arrival of these additional drugs may change the recommendations for HCV treatments. Alice speculated about some of these changes and recommended close attention to the AASLD/IDSA joint HCV Guidelines, as updates have been promised in the near future (see resources). It may also begin to have a positive impact on pricing; Alice noted reports that an 8-week course of Mavyret (US spelling) will be priced at $26,400 in the USA, and recommended the NATAP (National AIDS Treatment Advocacy Project) web site as a good early warning source of such information in the US.

Alice also briefly reviewed the drug-drug interactions associated with modern DAA therapies, and then looked specifically at interactions with both HIV antiretroviral therapies and statins. She recommended the HIV/HCV Drug Therapy Guide, as a resource on drug interactions.

Category	**Impact**	**Examples**
Acid-reducing agents	↓ DAA absorption	Ledipasvir, velpatasvir
Potent P-gp inducers, moderate-potent CYP inducers	↓ DAA concentrations	Anticonvulsants, rifamycins, St. John's wort
Inhibitors of P-gp, BCRP, OATP	↑ DAA concentrations	Certain ARVs
Substrates of P-gp, BCRP, OATP1B1/3	↑ substrate exposures	Statins, dabigatran, certain ARVs

Resources

- OPDP Bulletin: Funding of Hepatitis C drug products under the Ontario Drug Benefit Program – February 22-28, 2017
- HCV Guidance: Recommendations for Testing, Managing, and Treating Hepatitis C – AASLD/IDSA
- NATAP – specifically FDA Approves Abbvie G/P, Mavyret, List Price, FDA Package Insert
- HIV/HCV Drug Therapy Guide (web app, also downloadable from Apple and Google Play)

Closing Remarks

Sue Gill

The last scheduled section on the expanded scope of Ontario pharmacists working in HIV and HCV had to be cancelled due to a family emergency. Sue suggested that a discussion about people's expanding roles be an item at next year's Education Day, encouraging people to share the innovative programs they are part of that are expanding their impact in HIV and HCV care.

Sue observed that the day's sessions highlight opportunities to improve care for our patients. It is all about respect, and this is something we need to stress particularly with students we work with.