17th Ontario HIV Pharmacy Education Day

The Latest and Greatest in HIV Prevention and Treatment

Friday, November 7, 2025
Novotel, 45 The Esplanade, Toronto (Champagne Room)

Introduction

The 17th annual HIV Pharmacy Education Day was centered on illustrating the growing roles of pharmacists in HIV care and prevention through experience sharing and clinical cases. For the first time, a social hour was offered to participants at the end of the day. This event was held as a stand-alone education event. The agenda included plenaries, a panel discussion, and case scenarios, with a focus on prevention in the morning and treatment in the afternoon. Brief summaries are provided in this report.

Linda opened the day by thanking all partners and sponsors:

- Support: Ministry of Long-Term Care, HIV and Hepatitis Programs, and The Ontario HIV Treatment Network
- Planning committee: Linda Robinson, Sue Gill, Deborah Yoong, Alice Tseng, Pierre Giguere, and Mikaela Klie
- Sponsors: Gilead, ViiV Healthcare, and Merck

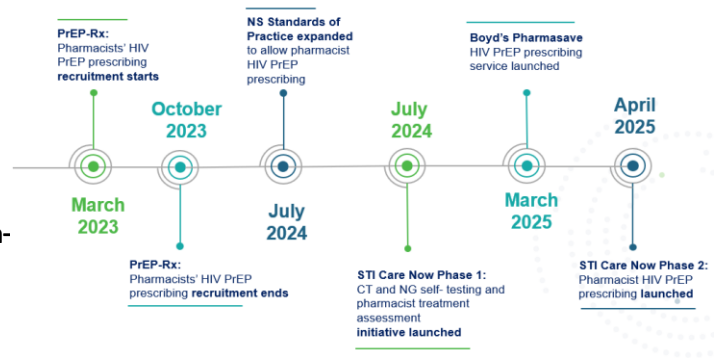
Next year will mark the 30th anniversary of the Ontario HIV Pharmacy Specialty group. For the occasion, participants were invited to vote for the new group logo, included at the top of this document.

First Plenary: Pharmacist-Driven HIV PrEP Programs

The Nova Scotia Experience

Speaker: *Tasha Ramsey (she/her) obtained her Bachelor of Science in Pharmacy degree in 2008 from Dalhousie University, her Pharmacy Residency diploma in 2009 from Kingston General Hospital and the University of Toronto, and her Post-Graduate Doctor of Pharmacy degree in 2013 from the University of British Columbia. Tasha is the Nova Scotia Health Clinical Therapeutics and Prophylactics Lead for Emerging and Re-Emerging Infections and an Assistant Professor at Dalhousie University's College of Pharmacy. She is a member of the Emerging and Re-emerging Infections Network, the co-chair of the Nova Scotia Emerging and Re-emerging Infections Therapeutics and Prophylactics Recommendation Group, and working group member of the Canadian HIV and Viral Hepatitis Pharmacists Network.*

PrEP-Rx Study (March-



- Primary health care shortage created challenging HIV PrEP access.
- Goal was to assess feasibility for pharmacists and acceptability from patients: lived experience to inform regulatory changes as findings provided evidence for scope expansion.
- Study was conducted in 10 community pharmacies with 45 participants enrolled (mostly white males who have sex with men or transwomen, majority between ages 25-35, and PrEP-naïve).
- Structured pharmacist appointments included eligibility assessment, lab requisitions, ongoing monitoring, and staged prescribing.
- Results showed: 82% remained engaged in care; 0 HIV seroconversions and 4 co-infections identified (HBV, syphilis, chlamydia, gonorrhea); and very high acceptability (97% comfortable with pharmacist care and 100% supported pharmacy-based PrEP access).

Nova Scotia Pharmacist Scope Expansion (July 2024)

- Pharmacists can prescribe oral HIV PrEP when using approved protocols and verifying laboratory testing (no POCT).
- Requirements include comprehensive counselling on PrEP, STBBI risk reduction, and appropriate referrals.
- Support documents included in EMR: 3 prescribing protocols (Initial Eligibility, Initial Prescribing, Refill), laboratory tests requisition forms, and Delivery and Infectious Disease Diagnosis resource.

Early Implementation Models

- STI Care Now: Province-wide virtual care service owned by Health Authority. It started with chlamydia and gonorrhea self-tests to now include HIV self-test, pharmacist PrEP prescribing and social-work support, with an emphasis on testing rather than PrEP prescribing. Patients report high accessibility, low stigma, and strong continuity of care.
- Boyd's Pharmasave: In-person and virtual appointment-based PrEP assessments to integrate into Community Pharmacy's workflow.

Lessons Learned

- Structured protocols, appointment-based models and pre-populated lab requisitions improve workflow.
- Community partnerships enhance reach and cultural safety.
- All actors should be engaged.
- "One-stop" sexual-health services increase engagement.
- Facilitators: inclusion, advocacy, collaboration.
- Barriers: no remuneration for pharmacists, PrEP cost, lab access.

In summary, Pharmacist-led PrEP is clinically effective, acceptable, and scalable, with virtual and hybrid models expanding access for rural and underserved populations. However, system-level funding and testing infrastructure remain major constraints to broader rollout. It is important to engage the regulators early in the process (e.g. as part of the research team) to ensure all their questions will be answered. In addition, also have proactive conversation with nearby partners as resistance usually comes from confusion.

The Ontario Experience

Speaker: *Kishan Rana is a pharmacist and the designated manager at the PrEP Clinic, Canada's first online PrEP provider. He is certified to provide HIV care and promotes queer-competency in pharmacy. His passion is to bridge care to marginalized individuals in his local community as a queer brown health care provider.*

The PrEP Clinic in Toronto specializes in PrEP. It grew from being the first online PrEP provider in Canada to clinics in Toronto, Ottawa, Brampton, with the goal of making PrEP affordable. It started as a pharmacy and expanded to a clinic with a multi-professional team.

PrEP Access Considerations

- Provide stigma free care: safe, affirming and inclusive spaces; trained staff; accessible conversations; anonymous testing.
- Interprofessional team: NPs, RNs, RPNs, RPh, RPhT; accepting and supporting non-insured clients.
- Consider PrEP cost: pharmacists provide financial navigation to pay for PrEP.
- Adjust to clients' time: remote and in-person services available.

Rapid Start

Pharmacists support the PrEP care cascade by using their specific skills: medication reconciliation; counselling (side-effects, interactions, dosage, follow-up); navigating coverage; dispense prescriptions and offer vaccinations as needed.

Key Takeaways

By having an interprofessional team with a patient-centered approach, the PrEP clinic really takes advantage of the pharmacists' skills, including their knowledge of the financial support available. Ontario has many coverage solutions available, but applications can be tricky/time consuming. Community pharmacists know how to advocate for their clients for coverage – there is always a way to be found.

The Quebec Experience

Speaker: *A community pharmacist-owner in downtown Montréal, Emmanuel G.-Thibaudeau has been involved for over ten years in pharmaceutical care related to HIV, STBBIs, hepatitis, and substance use treatment. At his pharmacy, he developed innovative prevention services, including PrEP prescribing and*

sexual health screening. He shares his experience to illustrate how pharmacy practice can improve access to preventive care.

Quebec context

- New HIV diagnoses rising post-pandemic, disproportionately impacting newcomers and GbMSM, with Montréal accounting for 71% of cases, with a 120% increase vs 2020.
- Conservative regulations in Quebec compared to other provinces, which limit innovation.
- Historically no prescribing rights for pharmacists.
- Ownership rules: pharmacist only/no external investor, professional fees to be shared amongst pharmacists only/no collaborative project.
- Code of ethics: no client referral system/no external partnership, strict solicitation rules.

PrEP Clinic – Pilot to Platform

- Used to work in a pharmacy close to biggest sexual health clinic in Montréal: saw people struggling to access prevention services (GoFreddie left Quebec, no virtual option for people out of the city).
- No need to establish diagnosis to prescribe PrEP so made sense for pharmacists to do it.
- Concept established within a small independent pharmacy located in the Village, in collaboration with STI screening center (MD signing prescription for patients seeing pharmacists).
- Initially in-person and then expanded through telepharmacy for wider reach across the province: platform integrating PrEP consultations, follow-up, and medication management.
- Demand increased so added STI testing and injections, with dedicated exam room.
- Now Clinic activities are embedded in routine community pharmacy practice and deliver medications all over Quebec, but pharmacists are not compensated for it (no prescription fee).

Challenges

- Structural & Operational: stretching resources to manage pharmacy and clinic; activity not compensated financially; Canada Post unreliable; no software to support PrEP clinic in pharmacy.
- System Barriers: want one-stop-shop but Pharmacist cannot have a license for public labs, only private (15$ Vs. 200$ for testing, 2 weeks wait time), so care remains fragmented; no training available for pharmacists to start prescribing PrEP.
- Equity & Reach: cannot advertise or get referrals so rely on word-to-mouth/be found online; still hard to reach marginalized populations.

What's to come

- Bill 67 will open pharmacists' prescribing scope for minor ailments and disease prevention: will be able to initiate prescription and supervise nurses.
- College of Pharmacists gave Guidelines: need for "appropriate expertise to be demonstrated" but no training to be provided.
- Next steps for the Clinic: hire full-time nurse and admin support, implement EMR, use AI for note-taking, develop compliant marketing strategy.
- Lessons learned: need for training and mentorship, importance of fitting new activities in community pharmacy workflow, advocate for fair remuneration, build community partnership, work on equity and inclusion of marginalized population, and normalize sexual health discussions at the pharmacy.

A Panel Discussion on PrEP Implementation for Ontario Pharmacists

Moderator: *Sue Gill*
Panelists: *Tasha Ramsey, Kishan Rana, Deborah Yoong, Emmanuel Thibaudeau*

Sue: The new PrEP and PEP Guidelines are coming out for World AIDS Day on December 1st in the CMAJ. The panel included pharmacists, as well as nurses, doctors, ASO workers, representing the Sector across Canada (including QC). The Guidelines really encourage pharmacists to be key promotors of PrEP and deliver PrEP to the communities, which make them a great document to advocate for pharmacists to be driven in the field.
Educational resources will be created to put Guidelines recommendations from the pharmacist's lens, along with some information on how to connect with pharmacists who are experienced in PrEP. These will be made available through CHAP and the Ontario HIV Pharmacy Specialty Group.

Tasha/NS: How did you find founders/people from the College to get involved in your projects?
- Used relationships built during COVID.
- Made sure to understand what they needed (metrics, etc.) from the get-go.
- People also hesitant to ask for more when they get involved at the beginning.

Tasha/NS: What were the concerns of patients NOT happy with pharmacists prescribing PrEP?
- 10% only and inherently tied to study design: desire for virtual care/one-stop-shop.

ALL: What are the pharmacist's responsibilities when a patient tests positive?
- In NS, provincial labs automatically report reflexively to Public Health. However, currently many chlamydia cases and Public Health is overwhelmed, so for past 2Y, whoever ordered the test is responsible for talking to the patient about contact tracing. If there are barriers, case can be referred to Public Health for anonymous contact tracing.
- In QC, pharmacists must report to Public Health and contact patient. Lots of work and hard to integrate in community pharmacy workflow. Need for tools/forms and training for pharmacists newly taking on PrEP activity.
- In ON, varies depending on PHU (contact patient, contact tracing).

ALL: Is there also a need to report treatment to Public Health?
- In NS, apart from chlamydia, Public health will get involved after positive result: contact the provider who ordered to test to know what's been done so far and take over if the patient is lost to follow-up.
- In QC, Public Health can check electronic archive network to see if patient receive treatment. Will call if something is missing.
- In ON, prescriber to report treatment and if patient is lost to follow-up.

ALL: Can you prescribe medications for other STIs?
- In NS, hospital pharmacists already prescribing for gonorrhea and chlamydia as they get diagnosis through the hospital. Expected to come soon for community pharmacists. Along with prescribing, responsibilities include delivering diagnosis, walking through contact tracing and linking to care to best of their ability (i.e. in primary care, ER as last resource).
- In QC, Bill 67 will allow pharmacists to do it, but only when there are no symptoms and a positive lab test (patients with symptoms need to be examined by doctor).
- In ON, pharmacists can only prescribe for minor illnesses, but not for STIs (or test for them). But can identify risky situations during conversations.

ALL: How will Long-Acting options be implemented?

- In the QC project, LA is listed as an option for patients to pick. Can get injected at the pharmacy in Montréal, or through PSP elsewhere (e.g. rural areas). Covered by public insurance, so private forced to cover as well: if add PSP, makes injectable PrEP the only free option available.
- In ON, the PrEP Clinic has been implementing LA over the past year. Pivotal thing is getting coverage set up before injections start (Trillium, slow uptake with private insurances), otherwise start with oral option in the meantime. Always pair patients with PSP as bridge support for continuous care in case there is loss/changes in coverage. Also necessary to have multidisciplinary team: nurses do injections.
- In NS, only oral options can be prescribed by pharmacists. Experts not supporting using CAB routinely, and it only got provincial coverage 1 month ago.

ALL: Can you prescribe PrEP for all genders?

- All research done in one particular subgroup, but PrEP for women has changed a lot recently.
- LEN not included in new Guidelines so TAF/FTC and CAB are recommended for vaginal exposure - no restriction other than on-demand.

Emmanuel/Qc: Could Marvin chatbot (developed by Dr B. Lebouché) help with appointment reminders?

- Hard to find time for following up with patients but need a tool that could do appointment reminders AND allow communication with patients - none available that would store data in Canada.
- Suggestion to use Ocean MD: run in background of EMR; patient can provide cellphone number and email to then send and receive messages; send email reminders.

Deborah/ON: Can the learning modules be used to advocate to OCP for pharmacists to prescribe PrEP?

- Modules to be created by Doctors – might need another one from pharmacist's lens, or could use ones created in QC once the Bill is passed and translate in English.
- College in QC not planning to train pharmacists: onus will be on pharmacists to have sufficient experience and knowledge, and know their limits.
- OPA (largest pharmacists association in Canada) could be that advocating voice. Also important to support groups like CHAP and this one.
- Pharmacy students in QC created advocacy poster to push for PrEP access to government – just needs to be translated in English.
- Also flagged that primary care sexual health modules were created with pharmacist's lens: available in EN and FR, and cover PrEP, DoxyPEP, STBBIs testing, etc. Application for CIHR grant was put for implementation of additional pharmacist's roles and how to reach marginalized communities. Great opportunity for collaboration but ON specific.

ALL: How to get medical associations on board?

- Lots of resistance in ON from OMA every time pharmacists try to expand their scope – acting very protective of their prescribing rights and tends to be discouraging.
- In ON, physicians part of the panel to create modules.
- in QC, given the needs and gaps in access, Public Health opened the door out of emergency.
- in NS, had to fight to keep the rights gained during COVID - conversations had directly with regulators - no need for physicians blessing. One physician was very vocally against and so invited him on the project: was onboard by the end.
- NPs are also progressively taking on a bigger role in HIV care and might resist pharmacists taking on more responsibilities in the future.

Kishan/ON = How to use Registered Pharmacy Technicians to their full potential?

- The PrEP Clinic employs pharmacy assistants and techs: at first doing dispensing services, but slowly expanded their roles to retrieving laboratory results, having conversations with patients and helping with support programs communications.
- If you have an assistant with the drive to move beyond their role, leverage it! Teach them additional skills to incorporate new services at the pharmacy and free some time for pharmacists to prescribe and do consultations.
- Now have a fully functioning team, distributing the work, and people feel like they are contributing: great for team moral!

Second Plenary: HIV Treatment and Prevention Update 2025

Speaker: *Dr. Sharon Walmsley is the Director of the Immunodeficiency Clinic, Toronto Hospital, University Health Network and a Professor, University of Toronto Department of Medicine. She is a Senior Scientist at the Toronto General Hospital Research Institute and the Co-Director of the CIHR- Canadian HIV Trials Plus Network.*

The Canadian HIV landscape has been pretty stable for the past 2 decades. A post-pandemic rebound in diagnoses was observed, due to lack of testing during COVID. To reach the 95/95/95 UNAIDS goals, Canada needs to increase testing and engagement in care, in particular in women.

Treatment Options

Rapid ART Initiation

A note that most studies were conducted in resource-limited environments. In Canada, goals and coverage should be discussed before starting therapy, hence the importance of the pharmacist's role. Given the very limited risk of transmission right after diagnosis, treatment can be started in 2 to 4 weeks.

As guidance, all is needed is: patient interest; physical exam to rule out TB, meningitis or other AIDS-defining conditions; adherence counsel; and 3 drugs therapy to limit resistance-related issues.

DHHS[1]
Recommended Regimens
BIC/FTC/TAF
DTG + (TAF or TDF) + (3TC or FTC)
(DRV/RTV or DRV/COBI) + (TAF or TDF) + (3TC or FTC)
Regimens Not Recommended
NNRTI-based regimens or DTG/3TC due higher rate of transmitted NNRTI and NTRI drug resistance
Regimens requiring ABC until HLA-B*5701 test results received

IAS-USA[2]
Recommended Regimens
DTG + (FTC or 3TC)/(TAF or TDF)
BIC/FTC/TAF
DRV/RTV + (FTC or 3TC)/(TAF or TDF)
Regimens Not Recommended
NNRTI-based regimens due to concerns over transmitted drug resistance (K103N)
Regimens requiring ABC until HLA-B*5701 test results received

Same-day ART initiation is resource intensive and requires multidisciplinary coordination of care.

Preferred First-Line Regimens

Current compounds available are safe, effective and have a high barrier to resistance. In all Guidelines, INSTI-based therapy remains recommended as first line: TAF/FTC/BIC or TXF/XTC+DTG or DTG/3TC (if VL<500,000, no HBV, no resistance, no rapid start). In most clinical trials, INSTI-based regimens are either noninferior or better, with fewer side-effects and less drug interaction, resulting in better adherence.

Nowadays, new diagnoses will get either Biktarvy (TAF/FTC/BIC) or Dovato (DTG/3TC). While no trials compared them to each other, both have been shown to be noninferior to Triumeq (ABC/DTG/3TC). In switch study PASO-DOBLE, no difference was observed whether patients were switched to Biktary or Dovato. But switching isn't always the same as starting naïve patient on therapy.

184V mutation: common mutation to 3CT so it makes sense to avoid Dovato. But emerging evidence show that in patients who are suppressed and have an old 184V mutation that can't be found in current genotypes, it might be possible to switch them to Dovato.

High viral load (VL): GEMINI studied DTG+3TC in ART-naïve adults but limited to VL<500,000, which informed the label and explains the concern of used 2 drugs regimen in high VL cases. However, DOLCE studied ART-naïve patients with CD4≤200 and high VL, and both regimens had comparable results. Finally, another study compared Biktarvy and Dovato in ART-naïve patients with VL>500,000 and CD4≥200 and also got similar results (even though the sample was small).

Long-Acting ART

First option available is Cabenuva (injectable CAB/RPV). FLAIR switch study showed efficiency compared to Triumeq for suppressed patients, with injection every 4weeks. ATLAS-2M then showed the same efficiency with the Q2M/every 8weeks schedule, the only concern being for those missing their injection, leaving more time for the virus to grow and therefore a risk of resistance to both CAB and RPV. In general, women are doing better and stay suppressed longer than men.

Oral lead-in: not done in clinical practice anymore as FLAIR extension study showed similar efficacy.

Risk of failure: occurs in 1% of cases in clinical trials without reason so it is important to advise patients. Associated factors identified are: RPV resistance; subtype A6; BMI≥30 but can use bigger needle to access the muscle and go through the fat (but if butt implant, would need to do a very painful SC injection). The more of these factors a patient will have, the less likely Cabenuva is likely to work. In real life, it is also 1% and mostly in the case of viremic patients switching therapy.

Switch for unsuppressed patients: originally worried about resistance development, but study from WARD 86 in SF showed positive results. However, even patients with 50<VL<200 were included, who will do fine no matter what. Guidelines now state that Cabenuva can be used in viremic patients in the absence of another option. Alternatively, it can be negotiated with a patient for them to start on Biktarvy and Cabenuva at the same time at first. Main challenge is to get coverage for both drugs. No toxicity expected as studies have been done on patients switching from Biktarvy to Cabenuva (i.e. both drugs in their system at the same time at one point).

Existing resistance: CARES study from Africa assessed the necessity of genotyping in low-income settings. Patients were switched to Cabenuva without prior resistance test and had good results, even when having low-level resistance to either CAB or RPV. The ones that failed were suppressed when switching to oral therapy.

K103N mutation: main mutation to NNRTIs, found in many patients. In low-income settings, many people received Atripla as first therapy, failed and developed K103N mutation and 3CT resistance. While there was hesitation to use RPV with K103N mutation, studies have shown positive results.

Discontinuation: main reason for patients to discontinued Cabenuva as per RELATIVTY cohort is pregnancy. While Guidelines used to not recommend Cabenuva use during pregnancy, it has now changed and the recommendation is to keep suppressed women on their treatment. The other reason is transfer to another hospital, as patients need to secure a place to receive their injection. This cohort also showed 11% of virologic failure, which is very high and probably linked to adherence issues.

Underlying HBV: Cabenuva offers no hepatitis B coverage and studies have shown acute hep B in non-immune patients, so it is important to vaccinate patients. Similarly, hep B can reactivate in patients with underlying hepatitis B core antibody positive. Finally, hep B can flare up when switching from Truvada, which was suppressing it.

New NNRTIs: DOR/ISL

Doravirine (DOR), once a day pill and well tolerated (no rash or busy head). Switch studies showed non-inferiority of DOR/ISL compared to BIC/FTC/TAF. However, it is only recommended as first-line therapy in Europe because of cost.

A note that islatravir (ISL) is not yet available in Canada as it was first studied as PrEP in high dose and showed a killing effect of T cells. However, recent clinical trials for HIV treatment at lower dose are showing good results.

Similarly to Cabenuva, they do not have hepatitis B coverage so it is important to check patient's status.

There was hope that DOR will help with INSTIs-related weigh gain as studies did not show weigh gain when starting DOR. However, studies did not show weigh improvement in patient with BMI>30 when switching from INSTIs based therapy to DOR, either associated to TAF or TDF (which is believed to be a weigh suppressant). Would be interesting to do more studies enrolling patients who gained weight with HIV treatment/were not obese before starting therapy.

Agents for Treatment Experienced Patients

Fostemsavir (FOS) and Lenacapavir (LEN) studied in patients with advanced HIV disease who were failing and had limited treatment options. Both showed good results. Some patients failed but no real understanding of why/how it correlates to resistance.

Two types of patients who develop multidrug-resistant virus over time: those with adherence issues, and those who develop resistances because of inadequate viral suppression in the early days of ART.

Whether in clinical trials or in real-world studies, got better results when combining FOS and LEN with another active agent. In people with adherence issues, combining 2 injectable (CAB and LEN) seem to show positive results.

Upcoming LA drugs

More schedule options will be available: ISL and UOL once a week, which is not an easy schedule to maintain; LEN prodrug; ultralong Cabenuva every 4 months; bnabs every 6months in IV or SC.

Preliminary study on once-weekly ISL+LEN in suppressed patients showed good results. However, studies on bnabs revealed that a third to half of the patients have resistance before even starting therapy. In addition, patients can also develop resistance over time. It'll be about the tradeoff.

The future of HIV Care
What will be the place of AI to determine treatment?
RNA monitor is currently in development to keep VL under control.
What will be the place of the clinics? Probably limited to complex cases and lots of things will happen at the pharmacy. At home care and virtual care will also take up more space.

Prevention Options

PrEP works when taken. Which explains why studies showed that it worked well on MSM and not as well on women: women do not like to take pills.
Current options available include oral PrEP available both continuous and on-demand (for men); CAB injectable every 2months. Studies showed that choice is important and will help with adherence.

Future option under study is LEN in IM injection every 6months and once yearly. Would have to work around to screen for STIs, and determine how long someone would stay in sub-therapeutic level after stopping and the impact on resistance development.
Multipurpose prevention products are in development such as CAB/MPA implants (progesterone to prevent pregnancy), ISL biodegradable implants and rings.

More importantly, we should be looking at people who are currently not on PrEP and how to reach out to them: Indigenous communities, immigrants, people using substances. What settings will make the products available to them?

3 Current Case Scenarios

Moderator: *Linda Robinson*

Lessons from an HIV Novice Pharmacist

Speaker: *Mikaela Klie*

Patient Profile:

- 53-year-old cisgender female
- diagnosed with HIV in 1996
- viral load undetectable since March 2007
- severe allergy to nevirapine
- private insurance coverage
- currently on Genvoya (FTC/TAF/EVG/c) + darunavir 800 mg daily
- other medications: estradiol, progesterone and recently discontinued rosuvastatin 10mg daily
- 2 genotyping tests on file, including one older and harder to interpret

Request for regimen simplification assessment.

Key Clinical Concepts:
Importance of ARV History

- Extensive ARV history is essential before attempting regimen changes.
- Lots of work but key part of the pharmaceutical consultation.

Understanding Genotypes & Resistance

- Genotypic testing detects resistance mutations to help identify reduced ARV susceptibility.
- VL≥250 copies/mL required.
- VL sample sent to PHO who uses British Columbia Centre for Excellence for genotyping.
- Stanford HIV Drug Resistance Database used for interpretation.

Use your Community

- Get advice on your assessment and recommendations from more experienced pharmacists.
- Consult CHAP Google group and use observer ship opportunities.
- Contact Medical Liaisons if you have questions.

Outcome

Patient demonstrated high-level NRTI class resistance and concern for potential cross-sensitivity with NNRTIs so offered 3 PI-based alternatives: BIC/FTC/TAF + DRV/c (modernization but still 2 tablets) or BIC/FTC/TAF (TAF off-label use and risk of virologic rebound) or DTG/3TC+DRV/c (modernization but still 2 tablets as well).

Patient ended up declining any change: feels great on her current therapy and worried about tolerating switches.

Salvaging cabotegravir/rilpivirine failures with bictegravir

Speaker: *Pierre Giguere*

Definition of virologic failure as per DHHS Guidelines is the inability to achieve or maintain VL<200. However, it varies between studies. For the TOH Cohort, virologic failure is defined as: genotypic resistance and need for treatment change (no VL cutoff).

Patient #1:

- Multiple treatment switch due to intolerance/side-effects and ran out of oral options
- 103N mutation: EFV resistance
- CAB/RPV started in 09/2023 and patient achieved viral suppression
- VL=44 in 12/2024 then VL=373 in 04/2025

Not liking the trend but is it still a blip or a failure?

- Genotype test revealed Clad B wild type (i.e. no mutation) – so not a failure as per Cohort definition
- K103N mutation shown in RELATIVITY study to not have impact on CAB/RPV response
- Study showed that viral blip is not predictive of treatment failure

Very important to differentiate between viral blip and failure before making treatment changes.

The Ottawa Hospital (TOH) Cohort:

- About 310 patients received CAB/RPV prescription (most using PSP), including on/off-label use
- 9 treatment failures observed, i.e. 3-4% (7 on-label + 1 unconfirmed, 2 off-label)

- Off-label failures included patients with existing INSTI resistance and ongoing viral replication – went on injectable because patients ran out of options/refused oral options
- Close to 2 years median follow-up
- Risk factors: BMI>30 only for 44%; AG clade rather than A6
- Only 2 failed with high VL
- All patients had double class mutations, i.e. dual class regimen resistance (NNRTI and InSTI) – some studies showed lower stats but 100% of drug-related mutations observed in this cohort

	Patient	Clade	BMI	Treatment prior to CAB/RPV	Viral load at CAB/RPV start	Viral load at CAB/RPV failure	RAM at CAB/RPV failure		BIC Resistance	Follow-up on BIC/FTC/TAF	
							NNRTI	InSTI		VL	Duration of therapy
On Label Use	1	C	37	RPV/FTC/TAF	<20	3120	101E	148R	Low	<20	28 months
	2	AG	30	DTG/ABC/3TC	<20	91300	138G, 230L	74I, 138E/K, 140A/G, 148K/Q/R, 230R/S	High	<20	28 months
	3	C	25	BIC/FTC/TAF	<20	9340	181C, 221Y	138K 148R	Int	54	23 months
	4	A	31	DTG/RPV*	32.5	1290	90I 103N	138K, 148K	Int	<20	15 months
	5	D	29	DTG/ABC/3TC	<20	1280	98G, 101E, 181C, 190A	118R	Int	<20	16 months
	6	AG	25	DTG/ABC/3TC	<40	1100	103N, 188L	138K 140A 148K	High	<20	3 months
	7	AG	38	DOR/3TC/TDF	<20	87300	106A, 221Y, 227L	74I, 97A, 138K, 148R	High	NA	Started Aug 11
		NA	<30	DTG/3TC	<20	912	unconfirmed failure				
Off Label	8	AG		DTG/ABC/3TC	98900	1490	101E, 103K/R, 181C, 221Y	66I, 74M, 118R	High		Started 3 weeks ago
	9	C	28	BIC/FTC/TAF	3170*	446	74I, 155H, 263K	90I, 100I, 138K, 227Y	High	started LEN + BIC/FTC/TAF	

- Most switch to BIC/FTC/TAF and one to BIC/FTC/TAF + LEN (failed on BIC in the past, probably because of adherence issue but did not want to take the risk)
- Despite intermediate to high BIC resistance, almost everyone achieved suppression with BIC/FTC/TAF

Treatment Options Post-CAB/RPV Failure:

- Literature review showed good predicted genotypic susceptibility to DOR, ETR and DTG or BIC
- Studies showed BIC/FTC/TAF effectiveness with NRTI resistance
- Studies showed minimal impact on BIC and DTG from 1 InSTI resistance associated mutation, however 2 or 3 mutations will have greater impact, which will vary depending on mutations involved
- Growing evidence of suppression achieved with DTG or BIC after CAB/RPV or PrEP CAB failure in patients with InSTI resistance associated mutations (SOLAR, CARES, BRAAVE, Impala, HPTN 083)

While Guidelines suggest picking treatment based on genotypic susceptibility, evidence shows that it is not necessarily true. More data is needed to better understand options after treatment failure and determine if a boosted PI regimen can be delayed (usually preferred option after failure).

Using fostemsavir and lenacapavir in clinical practice

Speaker: *Alice Tseng*

Case #1 - Mr. K

- 70-year-old male, HIV+ since 1990, MDR-HIV
- Virally suppressed since 2001 with DTG + DRV/c
- Various comorbidities and lots of co-medications, including DOAC
- Admission for falls/upper GI bleed led to switch DOAC to apixaban half dose because of renal insufficiency

Apixaban is counter-indicated with DRV/c because of significant interaction. They can be prescribed together but apixaban dose should be reduced by 50% in normal renal function, and is to be avoided if already at low dose. What change can be made to the ARV therapy?

Lenacapavir (LEN) and fostemsavir (FTR) are both indicated in treatment-experienced patients with multidrug-resistant HIV but have different dosing schedules, side-effect profiles and drug interactions.

	Lenacapavir	Fostemsavir
Dosing	SC q6 months	PO 600 mg BID
Side effects	nodules	QT (++ doses)
DDIs	Moderate CYP3A4 inhibitor	Inhibits OATP1B1/3, BCRP
Contraindications	Strong CYP3A4 inducers	Strong CYP3A4 inducers
Coverage	Compassionate access	Compassionate access
Other	Still need other ARVs which are dosed more frequently	CD4 boosting effect?

Switched DRV/c to FTR because of interaction concern with LEN and DOAC, and for FTR CD4 recovery boosting effect (observed when adding FTR to existing therapy in virally suppressed patients).

- After 2months, nephrologist observed severe hypertension: attributed to FTR (last medication added) and recommended switching back to previous regimen
- Hypertension not mentioned in FTR product monograph and determined to be from loss of DRV/c-boosting effect on Ca channel blocker (diltiazem)

Explained situation to nephrologist, reinstated FTR and titrated diltiazem appropriately to stabilize blood pressure.

Case #2 - Mr. A

- 55-year-old male, HIV+ since 1992, several mutations and extensive resistance across classes
- Virally suppressed on DTG/RPV and became detectable during COVID

Running out of options so decided to try something new and initiated LEN + DRV/c: maintaining viral suppression and good adherence.

Case #3 - Mr. G

- 85-year-old male, HIV+ since 1994, MDR-HIV, numerous adverse drug reactions
- Virally suppressed since 2006 but swallowing difficulty since 2019 lead to intermittent non-adherence

- Stopped taking DRV/c in 2021 and became detectable
- Restarted DRV/c (crushed) + DTG (small tablet) and achieved viral suppression again
- In 2023, not able to tolerate crushed DRV/c anymore because of its bitter taste

Genotypic analysis showed susceptibility to all PIs and INSTIs, but due to tolerability issues patient was switched to LEN + DTG. Achieved viral suppression and received his injections at home up until he moved to assisted living facility.

Note: In this situation, patient was able to get compassionate access to LEN outside of standard criteria (resistance to at least 3 drug classes – very limited treatment options) and was able to swallow oral lead-in (allow to get to therapeutic level by day 2 compared to week 5 or 6 with injections).

TGH Case Series in the making

	Age	Time on ART (yrs)	VL at switch	Co-morbidities	Comeds	Reasons for switch	OBR	Follow-up/ viral suppression
Fostemsavir (n=6) 5 M/1 F	66	32.5	• N=4 TND/<20 • n=2 @ 60 c/mL	6	7.5	DDI (n=6)	• B/F/TAF, DOR (n=3) • B/F/TAF DTG BID, DOR • DTG, MVC	• 29 months (9-33) • 100%
Lenacapavir (n=4) 3 M/1 F	60	30	• N=1 <20 • 6650-114,000	1.5	3	intolerance (n=1), viremia (n=3)	• DTG • DTG/3TC, DRV/c • DRV/c • CAB	• 18 months (11-32) • 100%

Different patient profiles:

- FTR: older people; VL<100; lots of comorbidities and comedications so switch because of drug-drug interactions with PI (CYP3A4 inhibiting effect)
- LEN: most patients had high viral load and switched because of treatment resistance; less comorbidities and less comedication (LEN also has CYP3A4 inhibiting effect)

All patients achieved and maintained viral suppression for more than 1 year, which makes both LEN and FTR good options for patients with multi-resistant HIV: PK properties, dosing schedules and interactions profiles impact choice.