

HIV ADVANCED (YEAR 2) PHARMACY RESIDENCY

HIV AMBULATORY CARE ROTATION

TORONTO GENERAL HOSPITAL

SITE:

Immunodeficiency Clinic, Toronto General Hospital, University Health Network
585 University Avenue, Toronto, ON M5G 2N2
Location: 13th floor, Norman Urquart Building, room 1300
<https://hivclinic.ca>

The Immunodeficiency Clinic serves over 1500 patients a year, making it one of the largest outpatient clinics in Canada providing care to people living with or at risk of acquiring HIV. The clinic staff is comprised of HIV/infectious disease specialists and internists with expertise in HIV as well as various subspecialties, such as dermatology, nephrology. A comprehensive interdisciplinary approach (includes medicine, nursing, pharmacy, social work, nutrition) is utilized to provide patient care. The clinic is also a leading centre for HIV research; clinic is involved with over 35 ongoing trials, including phase II/III, pharmacokinetics, open-label/expanded access, and epidemiologic studies.

Examples of pharmacy-related consults include medication adherence assessment, support and monitoring, managing antiretroviral-associated toxicities, recommending new regimens for multi-class HIV drug resistance, optimizing antiretroviral therapy in pregnancy, utilization of therapeutic drug monitoring to optimize treatment response, and detecting, avoiding or managing interactions between antiretrovirals and medications for treating other co-morbidities such as cardiovascular disease, hepatitis, renal dysfunction, psychiatric illness, cancer, organ transplantation, and opportunistic infections.

Teaching will be provided by a variety of methods including self-directed learning, patient case discussions, resident-preceptor therapeutic discussions, multi-disciplinary teaching rounds, and pharmacy department rounds (e.g., clinical sharing sessions, clinical foundations, journal clubs, resident presentations, etc.).

Residents can expect to participate in peer to peer teaching and learning.

PRECEPTOR:

Alice Tseng, PharmD, FCSHP, AAHIVP
Immunodeficiency Clinic, Toronto General Hospital
Tel: (416) 340-4800, ext. 8763 Fax: (416) 340-4890
Alice.tseng@uhn.ca

DURATION:

10 weeks (two x 5 week rotation blocks)

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OUTCOMES:

The resident will develop the clinical knowledge, skills, and professional values to:

- A. provide direct patient care as a member of an inter-professional team
- B. provide medication and practice-related education
- C. manage one's own practice of pharmacy

for the ambulatory HIV-infected patient population seen in the Immunodeficiency clinic at Toronto General Hospital.

GOALS and OBJECTIVES:

Goals:

1. To acquire an appropriate degree of knowledge of various HIV-related topics in order to adequately and efficiently identify, resolve, and prevent drug-related problems in the HIV-infected ambulatory population.
2. To allow the resident to develop critical thinking skills, in order to analyze and integrate pertinent disease, drug and patient data and concepts for the purposes of being able to provide effective pharmaceutical care.
3. To develop an understanding and appreciation of the clinical role of the pharmacist in a specialty outpatient care setting.

Objectives:

1. The resident will acquire knowledge of the principles, strategies, and protocols for treating HIV infection, associated comorbidities and opportunistic infections (see Appendix 1).
2. The resident will acquire an understanding and appreciation of drug-related issues commonly encountered in the management of patients infected with HIV.
3. The resident will be able to develop strategies to manage patients with evolving medical conditions and complex drug-related issues on an ongoing basis.
4. The resident will be able to provide verbal and written therapeutic assessments, plans and recommendations.

Terminal Competencies:

By the end of the rotation, the resident is expected to be able to:

1. Describe the principles and goals of antiretroviral therapy based on HIV pathogenesis, natural history, and spectrum of disease.
2. Describe the pharmacology, pharmacokinetic characteristics, and place in therapy of available antiretroviral agents (Appendix 1), including indication, mechanism of action,

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absorption (food or gastric pH dependency), metabolism (cytochrome P450, UGT, P-glycoprotein or other transporters, inducing and/or inhibiting effects), common side effects, resistance, and drug cost/reimbursement status.

3. Describe typical antiretroviral regimens in treatment-naïve and treatment-experienced patients which includes:
 - a. summarizing the US Department of Health and Human Services (DHHS) Guidelines on preferred and alternative antiretroviral agents for use in treatment-naïve patients.
 - b. explaining the factors involved in antiretroviral drug selection
 - c. ability to state the appropriate indications for the use each agent.
 - d. devise regimens for treatment-experienced patients, which may include use of non-standard combinations or drug doses
 - e. Explain the conditions and criteria for modifying, intensifying, or simplifying antiretroviral therapy in patients taking treatment on a chronic basis, including treatment-experienced patients who are virally suppressed
4. Discuss concepts of antiretroviral resistance, including:
 - a. Mechanisms of antiretroviral resistance (including transmitted and acquired)
 - b. Within-class cross-resistance mutations
 - c. Impact of M184V mutation on viral fitness
 - d. Genetic barrier to resistance for different antiretroviral classes and agents within each class
 - e. Difference between genotypic and phenotypic resistance testing
 - f. Interpreting resistance test results
5. Explain the signs and symptoms, epidemiology, risk factors, pathophysiology, clinical course and treatment options of diseases and complications commonly encountered in patients with HIV infection including:
 - a. treatment, primary and secondary prophylaxis of opportunistic infections, including but not limited to:
 - i. pneumocystis carinii pneumonia (PCP)
 - ii. mycobacterial infections (tuberculosis and M. avium complex)
 - iii. oropharyngeal and esophageal candidiasis.
 - b. management of hepatitis C/HIV co-infected patients
 - c. complications associated with antiretroviral therapy including:
 - i. lipodystrophy/weight gain
 - ii. hyperlipidemia
 - iii. hyperglycemia
 - iv. osteopenia
 - v. increased cardiovascular risk
 - vi. hepatotoxicity
 - vii. nephrotoxicity
 - viii. gastrointestinal intolerance
 - ix. central nervous system complications
 - d. Managing aging patients with HIV and associated concerns including:
 - i. Treating comorbidities such as cardiovascular disease, metabolic disease, osteoporosis, cancer diagnosis, etc.
 - ii. Minimizing polypharmacy

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- iii. Medication deprescribing and treatment simplification
 - e. prevention of HIV in specific populations:
 - i. prevention of mother-to-child-transmission (MTCT) in pregnancy
 - ii. post-exposure prophylaxis, occupational and non-occupational (PEP, nPEP)
 - iii. pre-exposure prophylaxis (PrEP)
 - iv. treatment as prevention (TasP)
6. Demonstrate sufficient knowledge of common diseases and drugs encountered in this population in order to provide pharmaceutical care to patients attending an ambulatory HIV clinic.
- a. To be able to collect relevant drug, disease, and patient information in an effective and concise manner. This may be done via: chart review, patient interview, utilizing resources (including standard textbooks, published medical literature, conference abstracts, unpublished data from manufacturers and investigators, and reliable Internet sites), and communication with other health professionals (including community/hospital pharmacists, family physicians, nurses, etc.).
 - b. To analyze and integrate pertinent data in order to identify actual and potential drug-related issues for individual patients, in an accurate and efficient manner.
 - c. To be able to prioritize drug-related issues through discussions with the patient and health care team.
 - d. To be able to develop and provide appropriate recommendations on the management or prevention of each drug-related problem in a timely manner. The resident should be able to provide rationale for his/her pharmacy care plans, and be able to modify recommendations based on individual patient factors.
 - e. To communicate care plans, recommendations, and drug-related information effectively with patients, family members, and members of the health care team. This may be done in person, over the telephone, chart documentation, or through written consult letters.
 - f. To effectively provide follow-up care by determining desired therapeutic outcomes and developing monitoring plans that incorporate efficacy and toxicity endpoints.
 - g. To demonstrate an awareness of how various psycho-social, ethical, cultural, and economic factors are involved in the management of individuals living with HIV.
7. Contribute to the improvement of medication-use systems and pharmacy services within the clinic.
- a. Identify and report adverse drug reactions, incidents, accidents, and near misses, according to institutional requirements. The resident will be able to recommend modifications to medication-use systems and pharmacy services, if applicable, to prevent future occurrences and improve patient safety.
 - b. Prepare tools such as protocols, checklists, Dear Doctor letters, etc. in order to improve consistency and/or quality of care.
8. Provide appropriate, timely and concise drug information to the team upon request. This may be in the form of answering brief queries, researching in-depth issues, and/or making informal or formal presentations.
- a. Identify the issues that need to be researched in order to provide comprehensive, complete drug information.

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- b. Independently utilize the available drug information resources to research the pertinent literature.
 - c. Use critical appraisal skills to assess the quality, clinical significance, and relevance of information in the area of HIV/infectious diseases.
 - d. Is able to synthesize pertinent material and prepare a concise presentation.
 - e. Effectively and efficiently present the information to the team.
 - f. Answer questions with appropriate terminology, conclusions, recommendations and references.
9. As applicable, demonstrate effective methods of practice-based teaching (direct instruction, role modelling, coaching, and facilitation) with undergraduate students, APPE students, Year 1 residents, and other medical or allied health learners.
 - a.
10. Function as a mature, responsible, professional member of the health care team.
 - a. To be able to identify and prioritize learning objectives, and to continually expand and modify these objectives as required throughout the rotation.
 - b. Is able to gather and process information in a self-directed manner, by utilizing available resources and identifying when assistance or feedback is required from the preceptor.
 - c. Has the ability to problem-solve in a systematic, logical manner.
 - d. Is able to respond positively to constructive feedback.

RESIDENT RESPONSIBILITIES:

The resident will:

1. provide previous rotation assessment, longitudinal knowledge tracking, and rotation specific objectives to preceptor at start of rotation.
2. complete required and suggested readings in a timely manner.
3. provide pharmaceutical care to patients selected by the resident and preceptor according to the rotation objectives and the resident's experience and interest. The number of patients selected varies from resident to resident, but an estimate of the expectation is 2-4 new patients/week.
4. use an appropriate pharmaceutical care framework to complete work-ups on assigned patients, identify and prioritize drug-therapy problems/issues, develop pharmacy care plans, and document patient's progress and follow-up. The resident will be the primary pharmacy care-giver responsible for providing pharmaceutical care to these patients.
5. document all pharmacy interventions/activities on the patient's medical chart and electronic patient record (EPR), with the preceptor's co-signature.
6. meet regularly with preceptor to review and discuss patient issues. Specific meetings may include:
 - pharmaceutical care patient work up

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- pre-selected therapeutic discussion
7. identify, resolve and prevent drug therapy problems and be able to discuss well thought-out plans for the prevention and resolution of these problems with other members of the patient care team.
 8. develop and present at least one presentation (case presentation/journal club/evidence-based medicine) to staff pharmacists. Additional presentations to nursing, physician or allied health staff (as determined by preceptor) and/or a teaching session to pharmacy students or technicians may be assigned at preceptor discretion.
 9. attend the following educational rounds:
 - pharmacy education (clinical sharing or clinical foundations)
 - pharmacy resident presentations (as applicable)
 - HIV rounds (Mondays at noon)
 - ID rounds (optional)
 - ID journal club (optional)
 10. complete the following assessments:
 - written midpoint and final self-assessment
 - verbal and written self-assessment after each presentation
 - written assessment of the rotation and preceptor at the end of the rotation
 - longitudinal knowledge tracking

RESIDENT ASSESSMENT:

Residents will be assessed in the following manner:

- verbal formative feedback provided on a daily basis.
- mid-point meeting and review of resident self-assessment (Clinical Rotation Assessment form)
- written final rotation assessment completed by preceptor (Clinical Rotation Assessment form).

Assessments will be based on patient care work-ups, therapeutic interventions, participation in inter-professional rounds, resident-preceptor therapeutic discussions, case presentations, teaching activities and professional conduct.

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Appendix 1: Antiretroviral Therapy

1. Reverse Transcriptase Inhibitors
 - a) Primary: abacavir, tenofovir disoproxil (TDF), tenofovir alafenamide (TAF), lamivudine (3TC), emtricitabine (FTC)
 - b) Secondary (less commonly used): didanosine (ddI), stavudine (d4T), zidovudine (AZT)
2. Non-Nucleoside Reverse Transcriptase Inhibitors
 - a) Primary: doravirine, etravirine, rilpivirine
 - b) Secondary: nevirapine, efavirenz
3. Protease Inhibitors
 - a) Primary: atazanavir, darunavir
 - b) Secondary: fosamprenavir, lopinavir, nelfinavir, saquinavir, tipranavir
4. Integrase Inhibitors
 - a) Bictegravir, raltegravir, elvitegravir, dolutegravir, cabotegravir (investigational)
5. Attachment inhibitor
 - a) Fostemsavir
6. Entry inhibitor
 - a) Ibalizumab
7. Pharmacokinetic enhancers
 - a) Cobicistat, ritonavir
8. CCR5 antagonists
 - a) Maraviroc
9. Fusion Inhibitor
 - a) Enfuvirtide
10. Complementary/Herbal remedies

Direct acting Antiviral (DAA) therapy for hepatitis C:

1. Glecaprevir/pibrentasvir
2. Elbasvir/grazoprevir
3. Sofosbuvir/ledipasvir



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4. Sofosbuvir/velpatasvir
5. Sofosbuvir/velpatasvir/voxilaprevir