BC Centre for Excellence in HIV/AIDS Pharmacovigilance Initiative

Annual Report: 2024

BRITISH COLUMBIA CENTRE *for* EXCELLENCE *in* HIV/AIDS

Providence Health Care

BRITISH COLUMBIA Ministry of Health

Disclaimer:
The British Columbia Centre for Excellence in HIV/AIDS (BC-CfE) Pharmacovigilance Initiative receives reports of suspected adverse drug reactions, drug interactions and other adverse drug-related events associated with the use of antiretroviral medications for HIV treatment and HIV Pre-exposure Prophylaxis (PrEP). The information provided in this report summarizes post-marketing experience with antiretroviral therapy in participants who receive HIV medications through the BC-CfE HIV Treatment Program or PrEP program. Reports of adverse drug-related events are voluntarily submitted by health care providers, program participants and caregivers and are not systematically evaluated for accuracy or for the strength of evidence regarding the causal relationship between drug exposure and observed effect.

Information from reports of adverse drug-related events is stored in the BC-CfE Registry, a secure, computerized database. This database is updated on a regular basis. Figures and tables provided in the Annual Report represent the best estimates available at the time this document was published.

Figures and graphs presented in this document are best viewed in colour.

Statement of Confidentiality:
The personal information of program participants and their health care providers is private and confidential. De-identified data are used for the purpose of drug safety surveillance in accordance with British Columbia Privacy legislation.

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Introduction

The BC-CfE Pharmacovigilance Initiative began as a demonstration project funded by the Canadian Patient Safety Institute in May 2007. Following a successful pilot study monitoring adverse drug-related events associated with antiretroviral medications, the Pharmacovigilance Initiative continued as an ongoing component of participant safety monitoring at the BC-CfE in June 2008.

The BC-CfE Pharmacovigilance Initiative collects, evaluates, and analyzes reports of suspected drug toxicity and other adverse drug-related events associated with antiretroviral medications in program participants, and uses this information to understand and prevent drug-related problems.

Antiretroviral medications have the potential for adverse drug reactions ("side-effects") or interactions with other medications that may result in health impacts and may interfere with treatment success. All drugs are tested for safety before they are approved for sale in Canada; however, pre-marketing clinical trials have limited scope to be able to detect adverse drug-related events that are rare, take a long time to develop, or occur more frequently in people with certain risk factors. These events may be discovered after a drug is used in the general population.

Ongoing monitoring of adverse drug-related events is required to detect unexpected toxicities as soon as possible, so that health care providers and clients can be warned of new safety concerns.

Acknowledgement

The Pharmacovigilance Initiative acknowledges with thanks the support provided by clerical staff, data analysts and programmers at the BC Centre for Excellence in HIV/AIDS, the staff of the St Paul's Hospital Ambulatory Pharmacy, and all those who report adverse drug-related events and HIV Treatment Program and PrEP program participants.

Conflict of Interest Declaration

The BC-CfE Pharmacovigilance Initiative does not receive pharmaceutical industry funding. The authors of this report have no conflicts of interest to declare within the past 3 years**.**

Definitions and abbreviations

The following definitions and abbreviations apply to terms used throughout this document. Terms that relate to a particular section of the report are defined within that section.

- **Adverse drug-related event:** Any untoward event associated with a medication. The BC Centre for Excellence captures events including (but not limited to) the following event categories:
    - **Adverse drug reaction (ADR):** A suspected adverse drug reaction (unintended, undesirable effect of an antiretroviral medication) attributed to one or more antiretroviral drugs. Includes events in which the medication is continued, dose adjusted or discontinued.
    - **ADR prevention (ADR/Pr):** Antiretroviral therapy is changed to **prevent** a potential adverse drug reaction (no ADR is reported to have occurred).
    - **Drug interaction, symptomatic (ADR/DI):** An adverse drug reaction resulting from a drug interaction between an antiretroviral medication and another drug.
    - **Drug interaction prevention (DI/Pr):** Antiretroviral medication is discontinued or the dose is adjusted to **prevent** a potentially harmful drug interaction with another medication (no ADR is reported to have occurred).
- **Adverse drug-related event information source:**
    - **Prescription:**
        - All requests for new antiretroviral regimens for HIV treatment or Pre-exposure Prophylaxis are reviewed and approved by the BC-CfE Drug Treatment Program. The 'Prescription Request' form for HIV treatment includes a section for reporting adverse drug-related events.
        - Prescribers may also document adverse drug-related events on refill prescriptions for ongoing regimens.
    - **Therapy interruption alert/ Late refill notification:** BC-CfE sends Therapy Interruption Alerts to prescribers if the participant's refill history suggests a >2-month gap in therapy for HIV treatment or >3-month gap for PrEP (>5-month gap for on-demand PrEP). Forms include a section for reporting adverse drug-related events.
    - **Spontaneous report:** A report voluntarily submitted directly to the BC-CfE Pharmacovigilance Initiative.
- **Antiretroviral drug (ARV):** Medications used to treat or prevent against Human Immunodeficiency Virus (HIV) infection.
- **Antiretroviral therapy (ART):** Combination of ARVs comprising the HIV treatment regimen.
- **Antiretroviral drug classes:**
    - NRTI: Nucleoside (-tide) reverse transcriptase inhibitor
    - NNRTI: Non-nucleoside reverse transcriptase inhibitor
    - PI: Protease inhibitor
    - INSTI: Integrase strand transfer inhibitor
    - PK enhancer: Pharmacokinetic enhancer ("booster"); does not have antiretroviral activity
- **BC-CfE:** BC Centre for Excellence in HIV/AIDS
- **HIV treatment (HIV-Tx):** Use of combination ART for the treatment of HIV infection (in HIV-positive persons).
- **Pre-exposure Prophylaxis (PrEP):** Use of certain ARVs to reduce the risk of acquiring new HIV infection (in HIV-negative persons).
- **Tenofovir AF (TAF):** Tenofovir alafenamide
- **Tenofovir DF (TDF)**: Tenofovir disoproxil fumarate

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Reports of adverse drug-related events associated with antiretroviral medications

Tables 1a-b and 2a-b summarize all reports of adverse drug-related events associated with antiretroviral use for Pre-exposure Prophylaxis (PrEP) and HIV treatment, respectively. Reports of adverse drug-related events related to PrEP medication remained stable in 2024. Overall reporting of events related to HIV treatment increased in 2024, related to an increase in preventative ART regimen changes (See also: Figure 12). Reports of adverse drug reactions related to HIV treatment continued to decline in 2024 despite an increase the total number of program participants

Table 1a. Adverse drug-related events associated with ARVs for PrEP – Five-year summary

Year	Number of participants receiving PrEP	Adverse drug-related event reports All categories, excluding duplicates	
		Total per year	Average per month
2020	5335	39	3
2021	5903	44	4
2022	7359	52	4
2023	8210	72	6
2024	**8907**	**74**	**6**

Table 1b. Adverse drug-related events associated with ARVs for PrEP –2024

Information category	Reports including duplicates N= 76 n (%)	Reports excluding duplicates N= 74 n (%)
Event Type		
Adverse Drug Reaction	72-76 (95-100)	70-74 (95-100)
Adverse Drug Reaction Prevention	<5 (0-5)	<5 (0-5)
Drug Interaction, Symptomatic	0 (0)	0 (0)
Information Source		
Prescription	67 (88)	*
PrEP Interruption Alert	9 (12)	*
Spontaneous Report	0 (0)	*
Reporter Type		
Physician	50 (65)	*
Pharmacist	<5 (0-5)	*
Other Healthcare professional	22-26 (29-35)	*

Small cell counts have been masked for privacy.
*Not applicable; multiple reporter or information source categories are possible for each event.

Table 2a. Adverse drug-related events associated with ART for HIV Treatment – Five-year summary

Year	Number of participants receiving antiretroviral treatment	Adverse Drug-Related Event reports All categories, excluding duplicates	
		Total per year	Average per month
2020	8111	1045	77
2021	8150	742	62
2022	8225	531	44
2023	8323	461	38
2024	**8431**	**514**	**43**

Table 2b. Adverse drug-related events associated with ART for HIV Treatment – 2024

Information category	Reports including duplicates N= 515 n (%)	Reports excluding duplicates N= 514 n (%)
Event Type		
Adverse Drug Reaction	238 (46)	237 (46)
Adverse Drug Reaction Prevention	209 (41)	209 (41)
Drug Interaction Prevention	68 (13)	68 (13)
Drug Interaction, Symptomatic	0 (0)	0 (0)
Information Source		
Prescription	511-515 (99-100)	*
Therapy Interruption Alert	<5 (<1)	*
Spontaneous Report	0 (0)	*
Reporter Type		
Physician	290 (56)	*
Pharmacist	221-225 (43-44)	*
Other Healthcare professional	<5 (<1)	*

Small cell counts have been masked for privacy.
*Not applicable; multiple reporter or information source categories are possible for each event.

Adverse drug reactions (ADRs) associated with ARVs for HIV treatment and PrEP

As shown in **Figure 1**, there was a sharp drop-off and subsequent rebound in reporting rates of ADRs related to ART for HIV treatment in 2020 (COVID-19 pandemic-related disruptions), followed by a gradual decline in ADR rates, ongoing in 2024. ADR rates related to ARVs for HIV Pre-exposure Prophylaxis have been relatively stable in the past five years.

Figure 1. Adverse drug reactions associated with ARVs for HIV treatment and PrEP (all drugs) – Five-year reporting patterns, by quarter

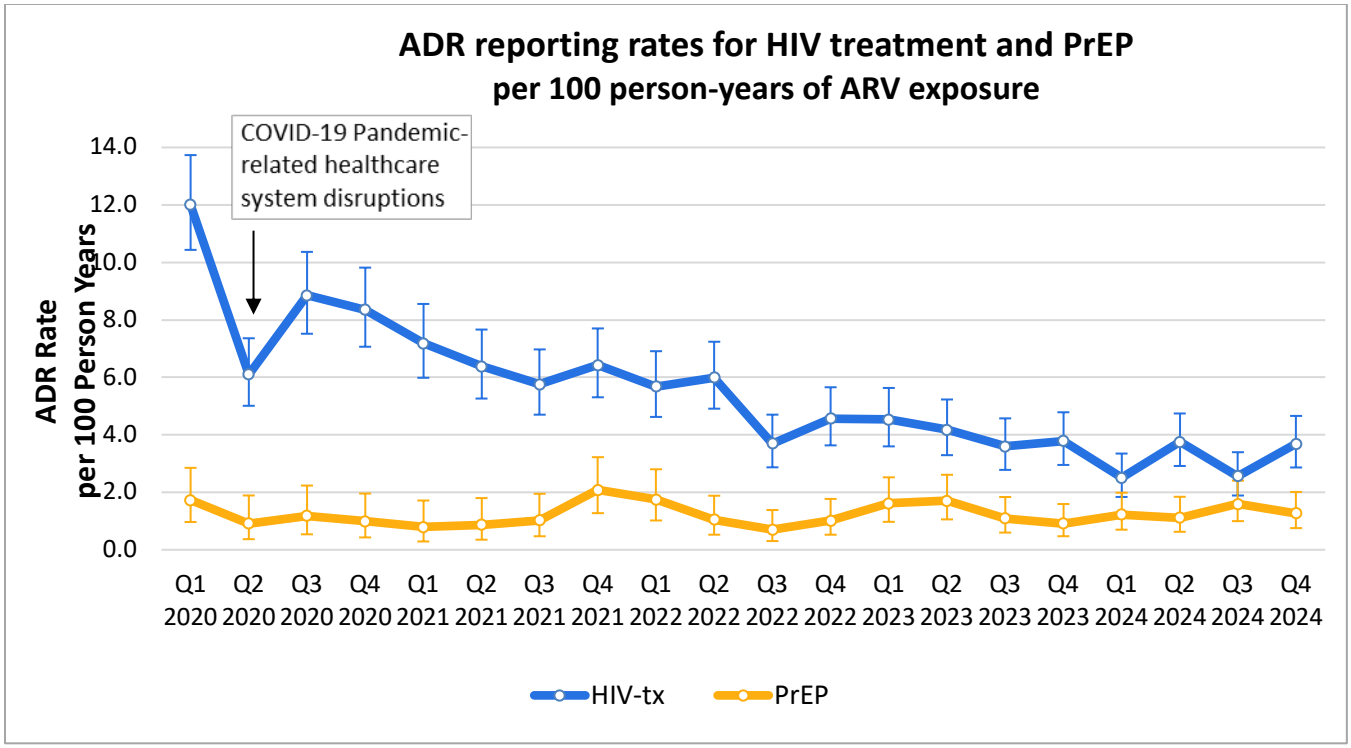


Figure 1 notes: Quarterly ADR rates in participants receiving ARVs for HIV treatment (HIV-tx) and pre-exposure prophylaxis (PrEP). Within each quarter (3-month period), the numerator is the number of ADR reports for participants (excluding duplicates, events with unlikely causality and ARV changes to prevent ADRs or drug interactions). The denominator is the total number of person-years of ARV exposure accrued during the quarter. Rates are expressed per 100 person-years of treatment. Error bars around each point display the 95% confidence interval, calculated by the Poisson method (using Byar approximation).

Adverse drug reaction (ADR) rates by antiretroviral drug class

Figures 2 to 5 display annual ADR rates over the past five years for the most commonly used ARVs. For each ARV, ADR rates are shown for all persons treated during the calendar year. See Appendix for details regarding calculation of rates.

2024 reporting year highlights:
Figure 2:
The rate of ADRs reported for tenofovir DF is lower for PrEP clients than HIV-tx clients. Similar to HIV-tx clients, ADRs related to renal health were commonly reported, however, the PrEP cohorts most commonly reported ADR for tenofovir DF was gastrointestinal side effects.

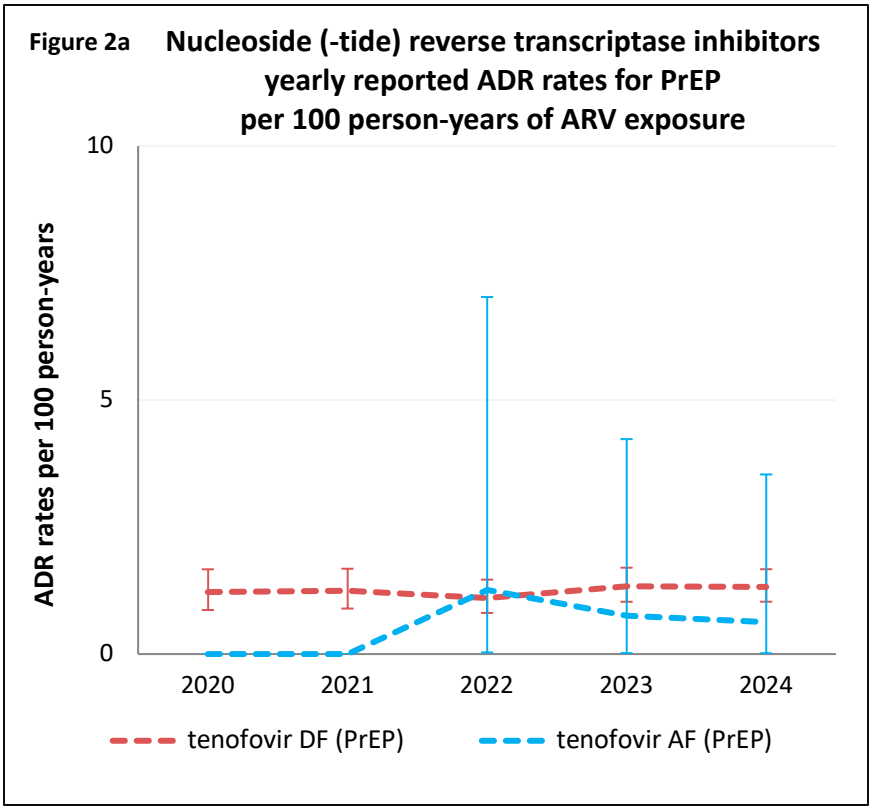
For HIV-tx clients, the shift in prescribing patterns from tenofovir DF to tenofovir AF, and decline in abacavir use continues, with tenofovir-related renal and bone health-related toxicities continuing to be the most commonly reported ADRs. Weight gain is increasingly reported with tenofovir AF, possibly influenced by co-formulation with the INSTI bictegravir.

Figure 3:
For HIV-tx clients, the use of PIs is declining. Gastrointestinal adverse effects continue to be the most commonly reported ADRs for darunavir. ADR rates for atazanavir remained low and spanned a broad variety of symptom categories.

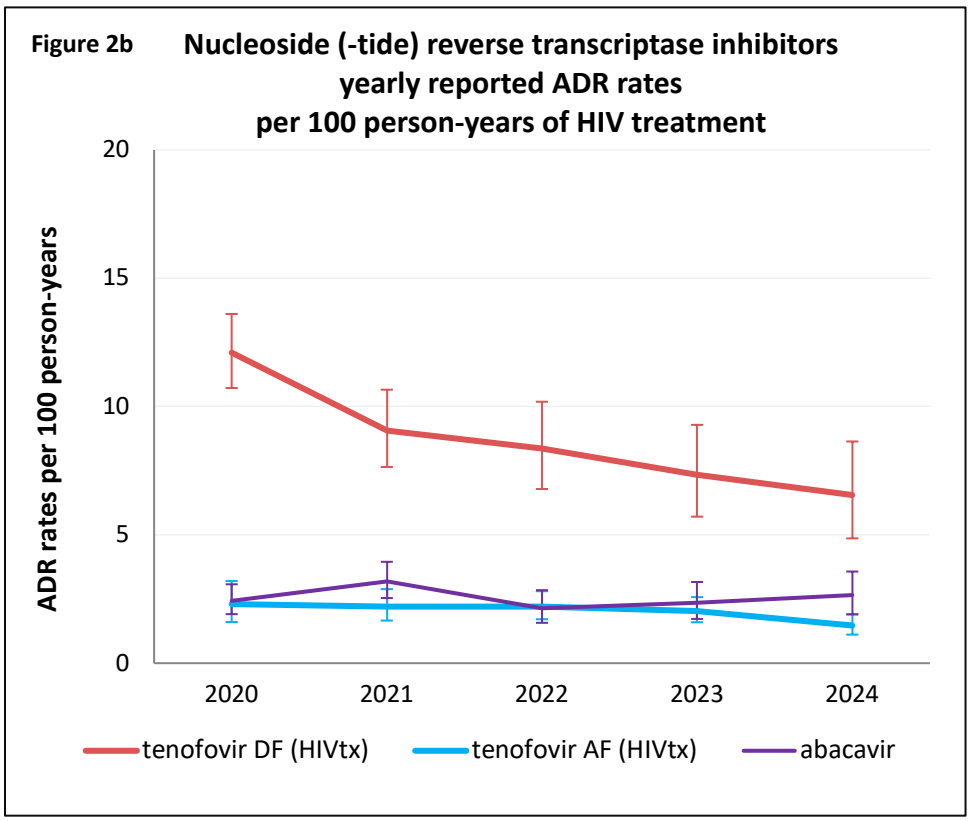
Figure 4:
For HIV-tx clients, the use of NNRTIs other than doravirine is declining. Neuropsychiatric and gastrointestinal effects continue to be the most commonly reported NNRTI ADRs.

Figure 5:
For HIV-tx clients, the second generation INSTIs dolutegravir and bictegravir, account for the majority of INSTI usage. Neuropsychiatric effects, gastrointestinal upset and unintentional weight gain remain the most commonly reported ADRs with these newer INSTIs.

Figure 2a-b. Nucleoside (-tide) reverse transcriptase inhibitor ADR rates associated with ARVs for PrEP and HIV treatment

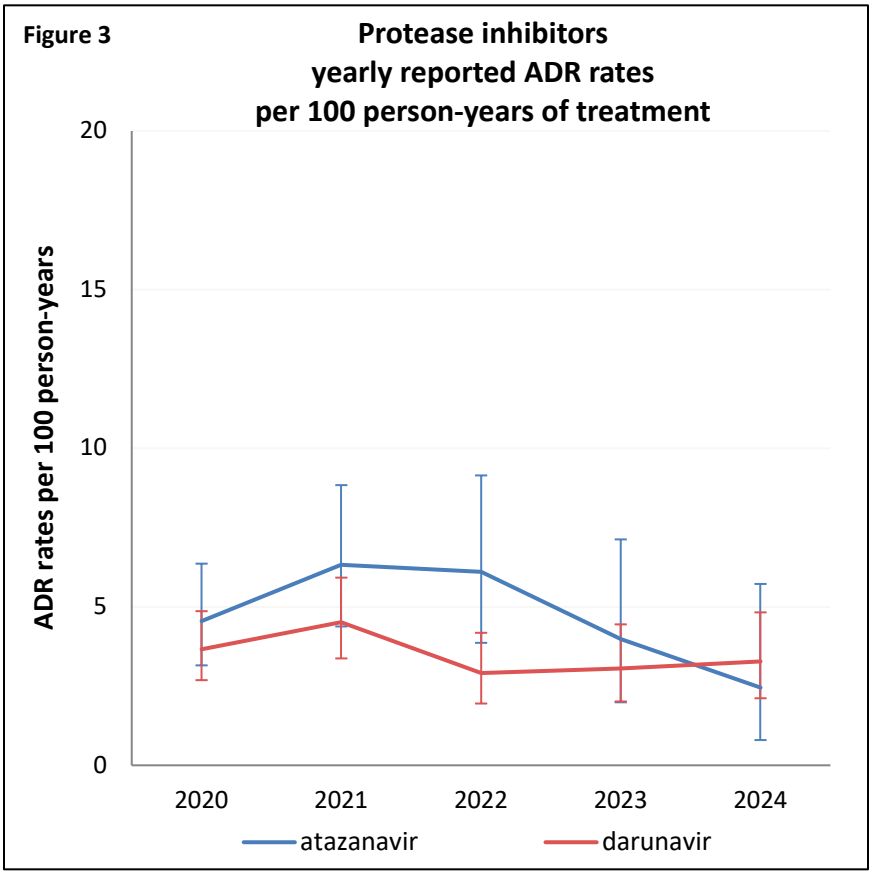


Number of adverse drug reaction (ADR) reports / Total person-years drug exposure					
	2020	**2021**	**2022**	**2023**	**2024**
tenofovir DF	33/ 3194	37/ 3379	46/ 4263	63/4871	70/5291
tenofovir AF	Limited data				



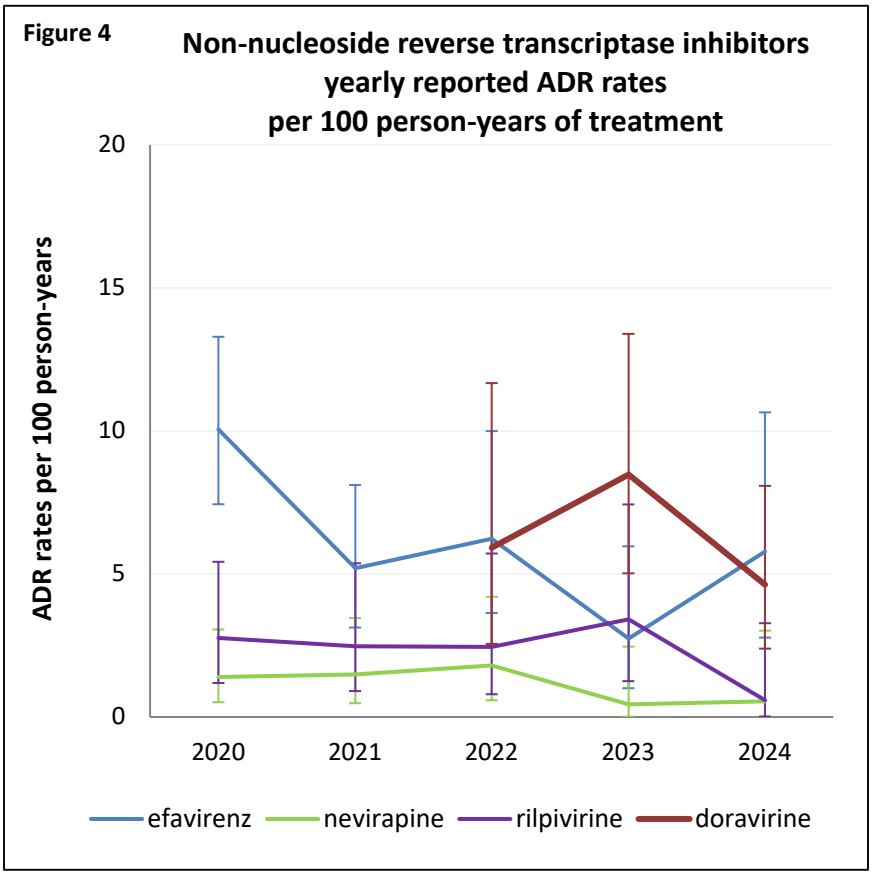
Number of adverse drug reaction (ADR) reports / Total person-years drug exposure					
	2020	**2021**	**2022**	**2023**	**2024**
abacavir	71/ 2951	82/ 2605	47/ 2196	45/1903	42/1589
tenofovir DF	279/ 2307	146/ 1601	98/ 1172	70/940	50/763
tenofovir AF	35/ 1523	54/ 2442	67/ 3034	70/3479	57/3881

Figure 3. Protease inhibitor ADR rates associated with ART for HIV treatment



Number of adverse drug reaction (ADR) reports / Total person-years drug exposure					
	2020	**2021**	**2022**	**2023**	**2024**
atazanavir	34/ 747	34/ 538	23/ 378	11/276	5/204
darunavir	47/ 1286	52/ 1152	29/ 997	27/884	25/765

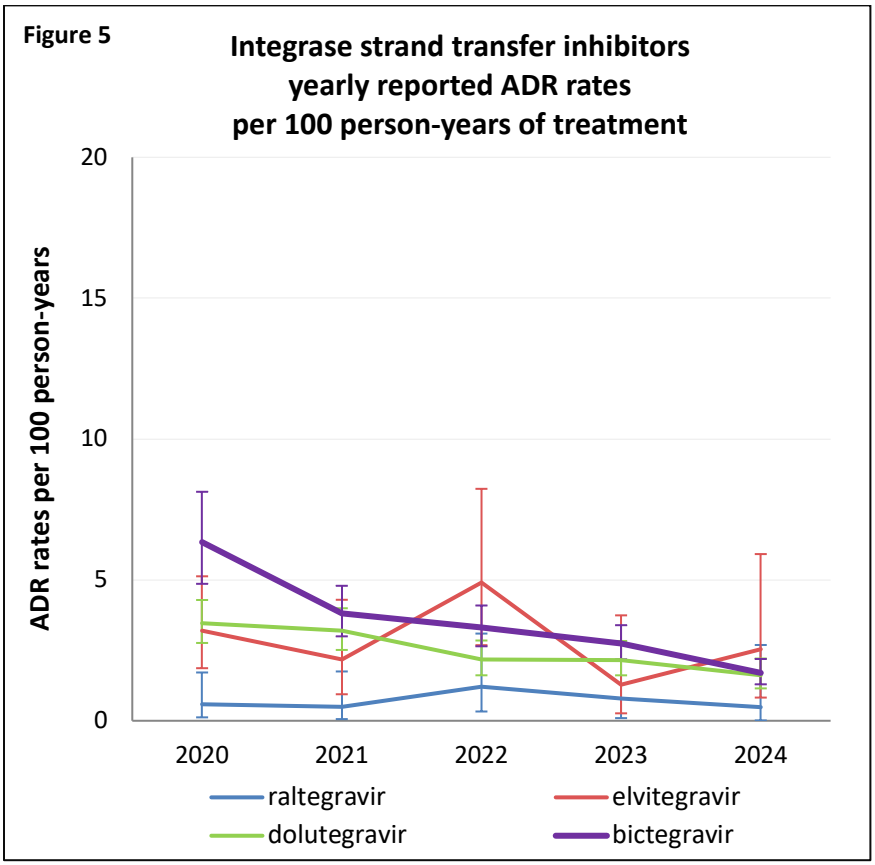
Figure 4. Non-nucleoside reverse transcriptase inhibitor ADR rates associated with ART for HIV treatment



Number of adverse drug reaction (ADR) reports / Total person-years drug exposure					
	2020	**2021**	**2022**	**2023**	**2024**
doravirine	Limited data	6/ 43	8/ 135	18/213	12/259
efavirenz	49/ 487	19/ 366	17/ 272	7/219	10/173
etravirine	<5/ 177	<5/ 145	<5/ 115	<5/91	<5/75
nevirapine	6/ 427	5/ 337	5/ 278	<5/226	<5/185
rilpivirine*	8/ 291	6/ 243	5/ 204	6/176	<5/170

*Rilpivirine includes both oral and injectable forms.
Etravirine is not displayed in the figure due to low ADR rates.
Small cell counts have been masked for privacy

Figure 5. Integrase strand transfer inhibitor ADR rates associated with ART for HIV treatment



Number of adverse drug reaction (ADR) reports / Total person-years drug exposure					
	2020	**2021**	**2022**	**2023**	**2024**
raltegravir	<5/ 511	<5/ 413	<5/ 331	<5/256	<5/207
elvitegravir	17/ 531	8/ 367	14/ 285	<5/234	5/197
dolutegravir	84/ 2426	76/ 2381	51/ 2353	53/2408	39/2414
bictegravir	62/ 978	74/ 1939	85/ 2569	83/3033	59/3470

Cabotegravir (oral and injectable) became available in BC in 2023. Not displayed due to limited data.
Small cell counts have been masked for privacy.

Adverse Drug Reaction Rates by Symptom Category, associated with ART for HIV treatment

This section focuses on ART for HIV treatment**.**

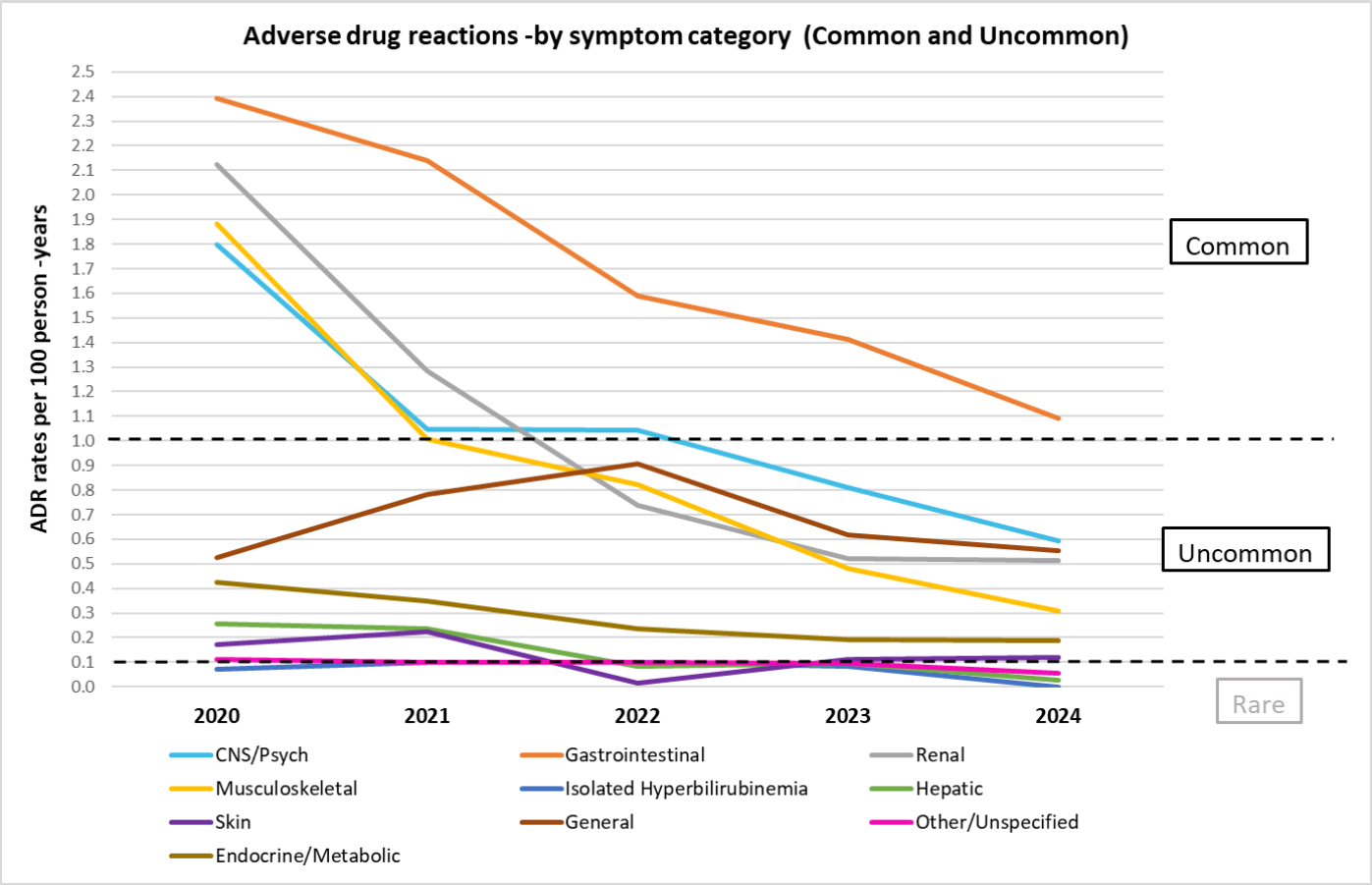
Figure 6 displays annual ADR rates over the past five years, by symptom category.

For each symptom category, ADR rates are reported per 100 person-years of ARV exposure for each calendar year. ADRs are counted in the year in which they are reported and consider the total number of ADR reports related to each symptom category across all ARVs, excluding duplicate reports of the same event. The denominator is the total person-years of ART exposure for all ART-treated persons accrued during each calendar year. The reported ADR rates exclude ADRs with causality assessment deemed "unlikely" to be associated with the ARV(s). Reports of ART regimen changes to **prevent** the occurrence of ADRs or drug interactions are excluded from this section.

Symptom categories are organized by body system. For visual clarity, symptom categories are grouped into common (>1), uncommon (0.1-1.0) and rare (<0.1) ADR events per 100 person-years of ART exposure. Common and uncommon events are displayed in **Figure 6**. Some rates of symptoms reported in the common and uncommon categories have declined over the past 5 years leading to a new classification. Symptoms that were previously charted as common and uncommon are still displayed despite falling into the rare category in 2024.

2024 reporting year highlights: Although gastrointestinal, central nervous system, renal and musculoskeletal (bone health) concerns continue to be the most commonly reported ARV-associated ADRs (Figure 6), ADR rates of these symptoms are declining, consistent with the overall decline in ADR rates. "General" side effects (Figure 6) include unintentional weight gain. Consistent with the literature, second generation INSTIs and tenofovir AF are most commonly implicated in reports of unintentional weight gain.

Figure 6. Adverse drug reaction rates by symptom category, associated with ART for HIV treatment



CNS/Psych:	Insomnia/ sleep disorder, nightmares/vivid dreams, headache, altered mood, altered mental status
Gastrointestinal:	GI upset/ discomfort, nausea and/or vomiting, difficulty swallowing medication (“pill size”), diarrhea
Musculoskeletal:	Bone mineral loss (osteopenia, osteoporosis), myalgia, arthralgia
Renal:	Serum creatinine elevated/GFR low, proteinuria, nephrolithiasis, renal impairment (unspecified)
Endocrine/ Metabolic:	Lipid abnormalities (e.g. elevated cholesterol), low serum phosphorus
General:	Unintentional weight gain/loss, fatigue/malaise/low energy, general allergic reaction
Hepatic:	Hepatic transaminases (AST/ALT) elevated, cholelithiasis, abnormal liver function tests (unspecified)
Isolated Hyperbilirubinemia:	Hyperbilirubinemia ± jaundice
Skin:	Rash/hives, itching (no lesions)
Other/ Unspecified:	Other/ unspecified adverse reactions

Adverse drug reactions associated with ARVs for HIV treatment and PrEP in specific populations

PrEP (see Figure 7)
By assigned sex at birth
2% of the total ARV-treated population were persons assigned female sex at birth (AFAB). The proportion of participants AFAB with a reported ARV ADR was higher than for participants assigned male at birth, however this was not statistically significant (p= 0.08). ADR reports for PrEP participants AFAB were too infrequent to report on most common symptoms

ADR rates amongst gender diverse PrEP participants were low and not statistically significant

By age category
≥50 years: 18% of participants receiving ARVs for PrEP were adults age ≥50 years. The proportion of participants age ≥50 years with a reported ADR was higher than the proportion of participants age <50 years with ADRs (1.3% vs. 0.7%, respectively), which was statistically significant (p =0.017). ADRs related to renal function were the most commonly reported ADRs for participants age ≥50 years.

≥65 years: 3% of participants receiving ARVs for PrEP were adults age ≥65 years. The proportion of participants age ≥65 years with a reported ARV ADR was higher than the proportion of participants age <65years with ADRs (1.7% vs. 0.7%, respectively), which was not statistically significant (p =0.07). ADR reports for PrEP participants age ≥65 years were too infrequent to report on most common symptoms

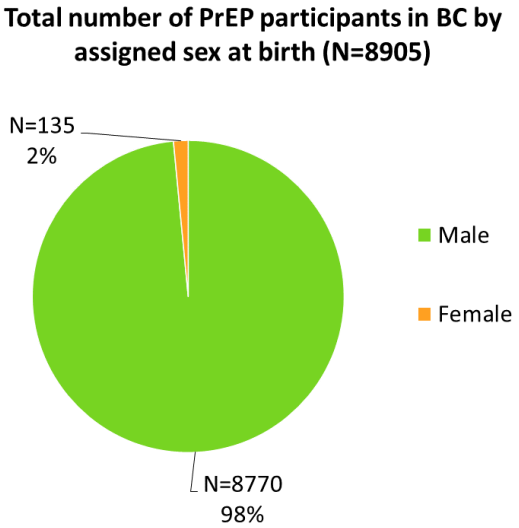
HIV treatment (see Figure 8)
By assigned sex at birth
17% of the total ART-treated population were persons AFAB. The proportion of participants AFAB with a reported ARV ADR was higher than for participants assigned male at birth (4.1% and 2.3%, respectively), which was statistically significant (p< 0.001). ADRs most commonly reported in AFAB were similar to ADRs reported in participants assigned male at birth, with gastrointestinal, general (weight gain, fatigue), renal, and musculoskeletal (bone health) symptoms accounting for the majority of reports (listed in declining order of frequency).

ADR rates amongst gender diverse HIV-Tx participants were low and not statistically significant.

By age category
≥50 years: 61% of participants receiving ART for HIV treatment were adults age ≥50 years. The proportion of participants age ≥50 years with a reported ARV ADR was higher than the proportion of participants age <50 years with ADRs (3.0% vs. 1.9%, respectively), which was statistically significant (p =0.0016). ADRs most commonly reported in adults ≥50 years were similar to other participants, with gastrointestinal, renal, neuropsychiatric (sleep disturbances, dizziness), and general (predominantly weight gain), symptoms accounting for the majority of reports (listed in declining order of frequency).

≥65 years: 18% of participants receiving ART for HIV treatment were adults age ≥65 years. The proportion of participants age ≥65 years with a reported ARV ADR was higher than the proportion of participants age <65 years with ADRs (3.4% vs. 2.4%, respectively), which was statistically significant (p =0.026). ADRs most commonly reported in adults ≥65 years were similar to other participants, with gastrointestinal, renal, musculoskeletal (bone health), and neuropsychiatric (sleep disturbances, dizziness) symptoms accounting for the majority of reports (listed in declining order of frequency).

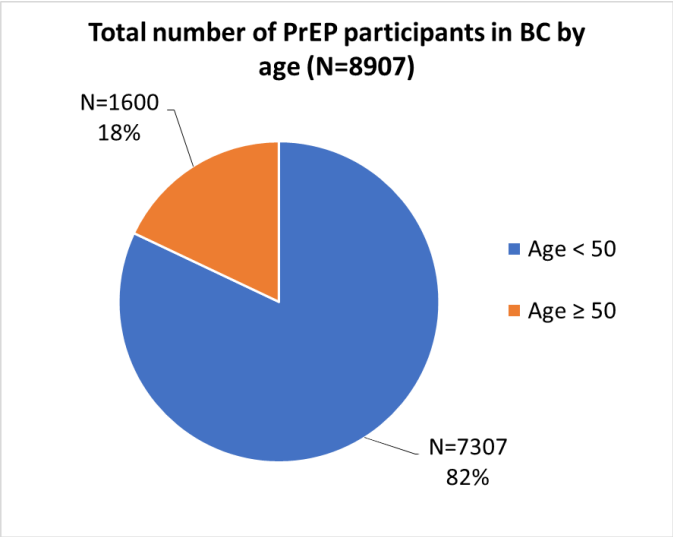
Figure 7. Adverse drug reactions associated with ARVs for PrEP

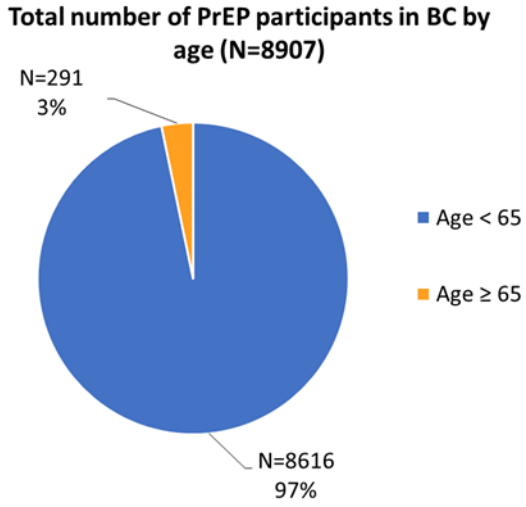


Distribution of ADR reports in ARV-treated persons by assigned sex at birth

ADR category	Female	Male	p-value*
Any ADR	<5	66	0.08
No ADR	131-135	8704	

Small cell counts have been masked for privacy





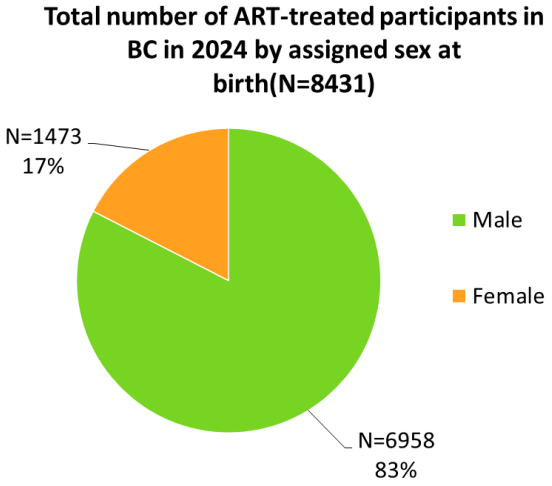
Distribution of ADR reports in ARV-treated persons by age

ADR category	Age < 50	Age ≥ 50	p-value†
Any ADR	49	20	0.017
No ADR	7258	1580	

ADR category	Age < 65	Age ≥ 65	p-value*
Any ADR	64	5	0.07
No ADR	8552	286	

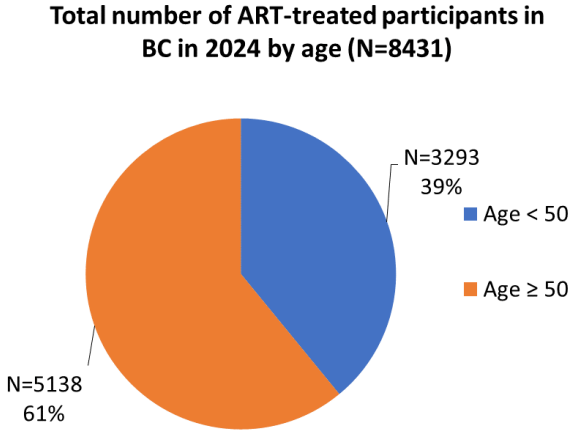
** Statistical comparisons between groups are calculated using Fisher's Exact*
†Statistical comparisons between groups are calculated using Pearson's Chi-squared

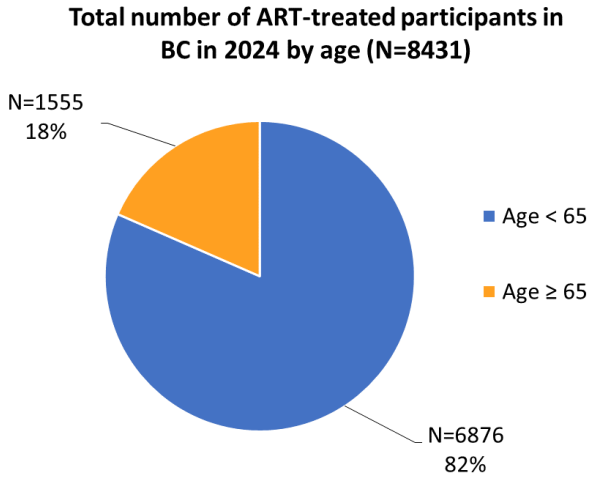
Figure 8: Adverse drug reactions associated with ART for HIV Treatment



Distribution of ADR reports in ARV-treated persons by assigned sex at birth

ADR category	Female	Male	p-value†
Any ADR	61	158	<0.001
No ADR	1412	6800	





Distribution of ADR reports in ARV-treated persons by age

ADR category	Age < 50	Age ≥ 50	p-value†
Any ADR	63	156	0.0016
No ADR	3230	4982	

ADR category	Age < 65	Age ≥ 65	p-value†
Any ADR	166	53	0.026
No ADR	6712	1502	

†Statistical comparisons between groups are calculated using Pearson's Chi-squared

Serious or unexpected adverse drug reactions associated with ARVs for HIV treatment or PrEP

In support of national and international drug safety monitoring programs, the BC-CfE Pharmacovigilance Initiative reports serious or unexpected adverse drug reactions to the Health Canada Vigilance Program, which in turn submits reports to the World Health Organization. Serious adverse drug reactions include those of grade IV severity (potentially life-threatening) and/or those resulting in hospital admission, prolongation of hospital stay or death. Unexpected reactions include clinically important events associated with newly marketed drugs, or rare adverse reactions associated with established drugs.

In 2024, there were a total of 308 adverse drug reaction reports received for HIV treatment and PrEP participants combined (excluding duplicates). <5/308 (0-1%) ADR reports were submitted to Health Canada, all reports were for HIV treatment clients and none were classified as serious.

Drug interactions associated with ART for HIV treatment

This section focuses on ART for HIV treatment.

Antiretroviral therapy changes for the purpose of preventing a potentially harmful drug interaction with another medication are documented as "drug interaction prevention" and are monitored separately from symptomatic ADRs resulting from a drug interaction (documented as "ADR/DI").

Figures 9 and 10 summarize antiretroviral drug interaction reporting patterns in 2024

In 2024 there was a decrease in drug interaction prevention reports and no reports of symptomatic ADRs resulting from a drug interaction. As shown in Figures 10 a-b, the pharmacokinetic enhancers cobicistat and ritonavir accounted for the majority of ART therapy changes related to drug interactions between HIV medications and other drugs.

As summarized in Figures 11 a-b, Drug interactions with corticosteroids (e.g. inhalers and intra-articular injections), cardiovascular drugs (e.g. anticoagulant and antiplatelet medications), anti-infective drugs (e.g. for treatment of tuberculosis, hepatitis C) and gastrointestinal drugs (e.g. drugs that suppress gastric acid, such as proton pump inhibitors) are among the most common interacting medications

Figure 9. Antiretroviral drug interactions by ARV class

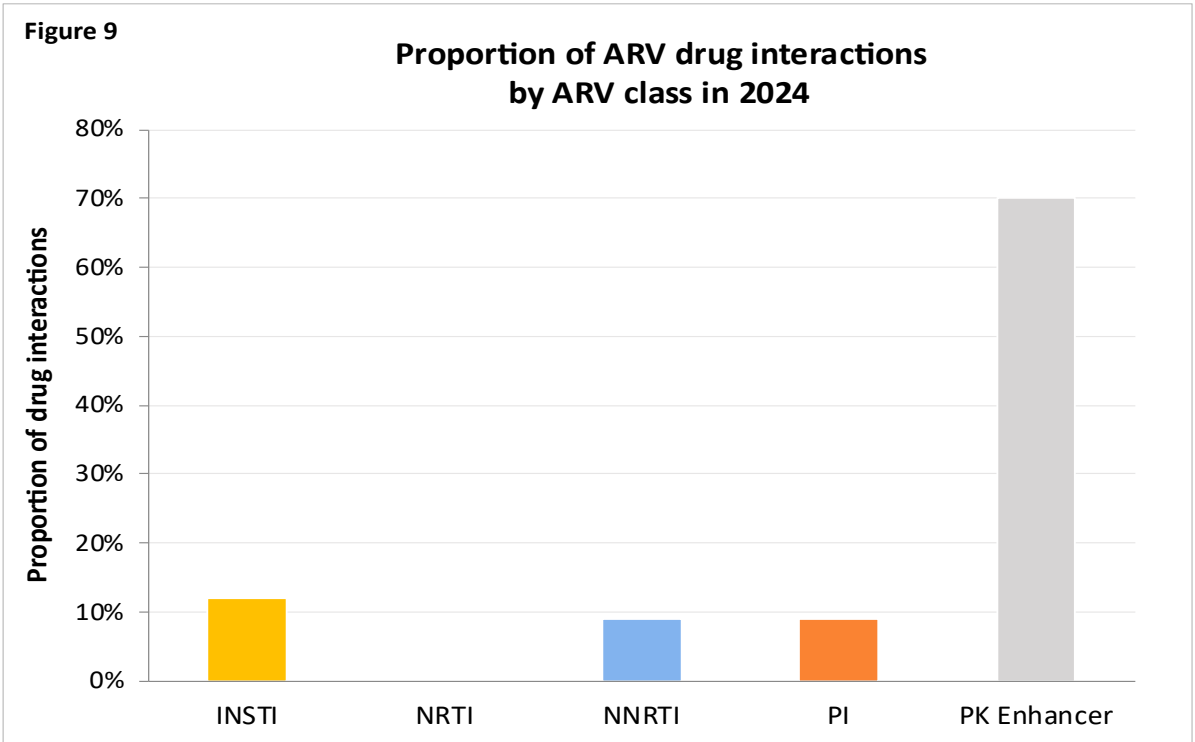
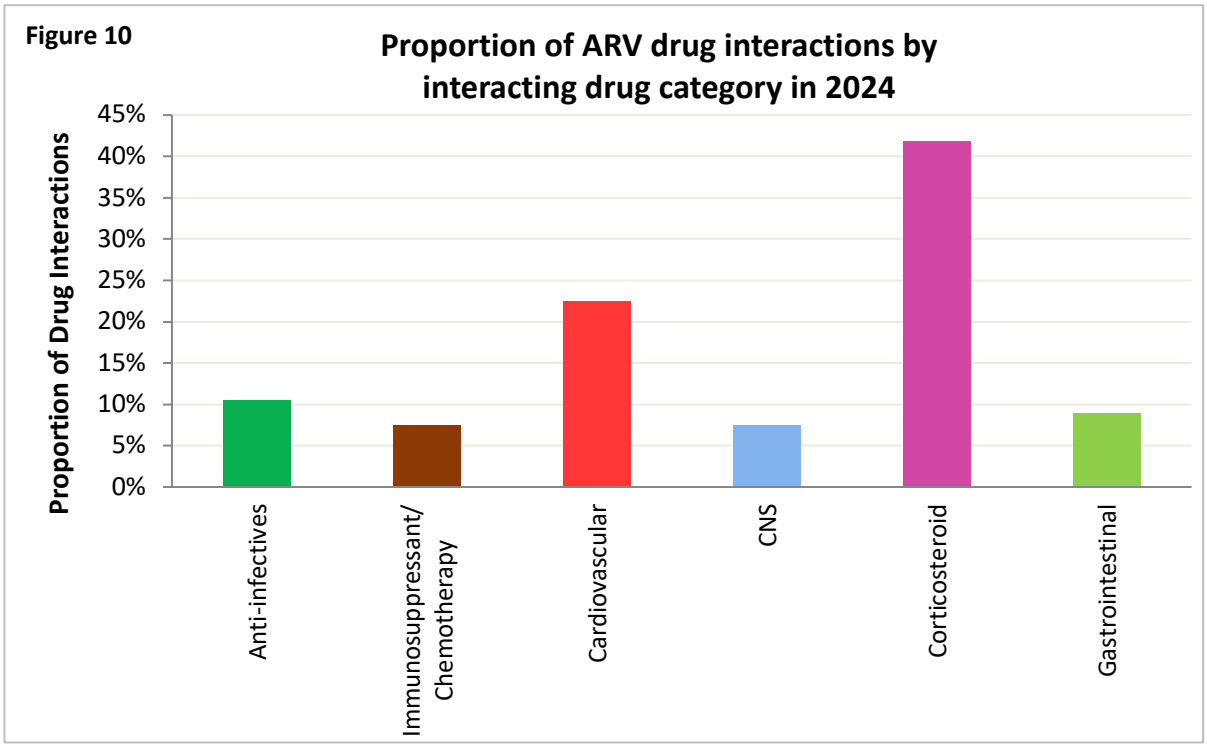


Figure 10. Antiretroviral drug interactions by interacting drug category



Figures 9 and 10 notes: PK enhancer, Pharmacokinetic enhancer ("booster") ritonavir or cobicistat; CNS, Central nervous system.

ART changes for Prevention of Adverse Drug Reactions in persons receiving HIV treatment

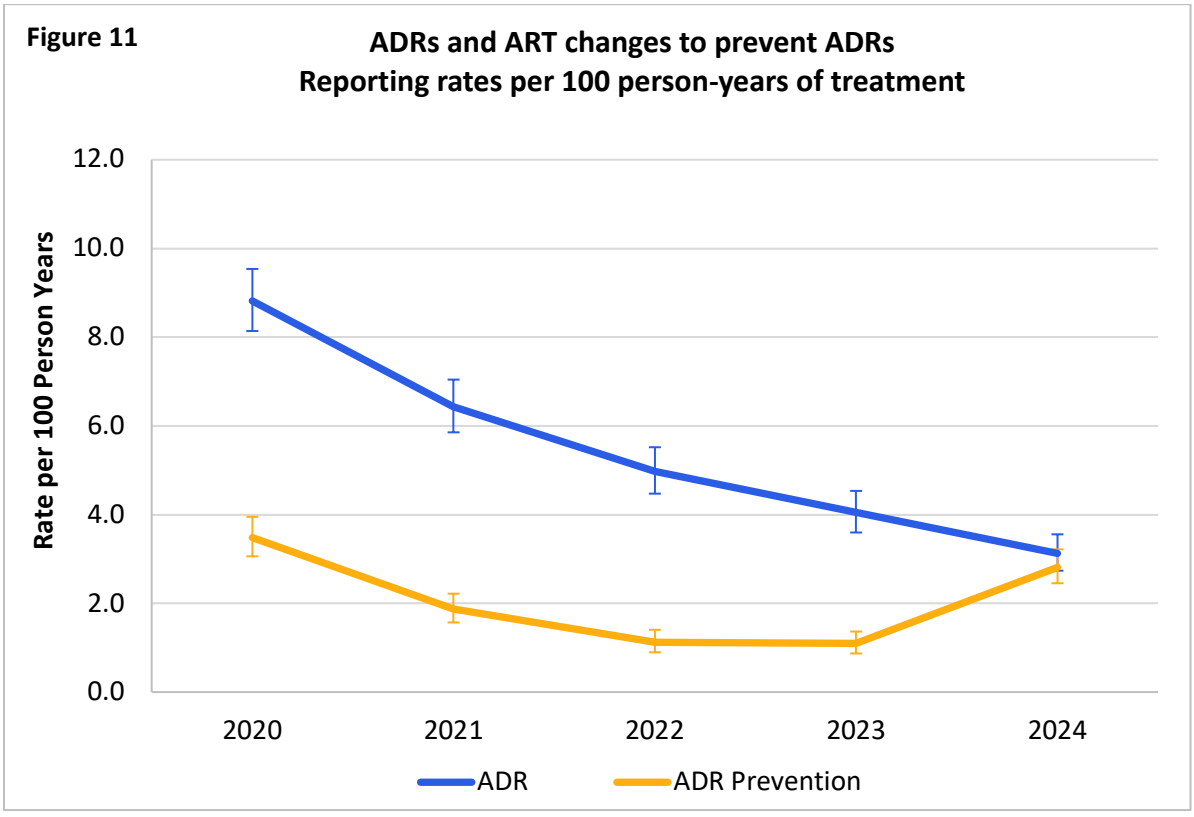
This section focuses on ART for HIV treatment.

Antiretroviral therapy changes for the purpose of preventing a potential ADR, such as reducing the long-term risk of renal injury, are documented as "ADR prevention" (where no ADR is reported to have occurred) and are monitored separately from symptomatic ADRs. Reports of ADR prevention are captured when the prescriber documents this intention on a request for ARV regimen change.

Figure 11 shows the pattern of ART changes for ADR prevention in relation to reports of ADRs. In 2020 there was an increase in preventative ARV regimen changes, associated with a shift to newer ARVs. In 2024 there was an increase in preventative ARV regimen changes, associated with emerging evidence regarding potential safety signals.

In 2024, the ARVs most commonly implicated in preventative changes are tenofovir DF (long term renal and bone health concerns) and abacavir (cardiovascular risk reduction).

Figure 11. Five-year reporting rates for ADRs and ART changes to prevent ADRs associated with ART for HIV treatment (all drugs)



How to report an Adverse Drug Reaction to BC-CfE Pharmacovigilance

Reports of suspected ADRs may be submitted to the BC-CfE Pharmacovigilance Initiative in several ways:

Any health care provider or person taking antiretroviral medication for HIV treatment or pre-exposure prophylaxis (PrEP) may report an antiretroviral ADR by completing an Antiretroviral Adverse Drug Reaction Report form. Click for ADR report form. Fax or mail the completed report to the address shown on the form.

Alternately, health care providers may choose to report suspected ADRs to the BC-CfE Pharmacovigilance Initiative in the following ways, instead of completing the ADR Report form:

Report on the HIV Treatment Program or PrEP Program Prescription Form:

For HIV treatment program clients, describe the suspected drugs and reaction in the "Reason(s) for medication change" section of the prescription request form.

For PrEP program clients, describe the suspected drugs and reaction on the prescription request or refill prescription form.

Report on the HIV Treatment Program or PrEP Program Therapy Interruption/Adherence Alert:

If an HIV treatment program client does not refill their prescribed ARV medications for more than two to three months after the expected refill date, a Therapy Interruption/Adherence Alert is mailed to the client's health care provider to support continuity of care.
If an HIV pre-exposure prophylaxis (PrEP) program client does not refill their prescribed ARV medications for more than three months after the expected refill date (more than five months for on-demand PrEP), a Therapy Interruption/Adherence Alert is mailed to the client's health care provider to support continuity of care.
The Alerts include the opportunity for healthcare providers to provide an update regarding the client's current treatment status, including an opportunity to report ADRs.

Report by telephone:

To submit a confidential adverse drug reaction report by telephone, contact the BC-CfE Pharmacovigilance Initiative at 604-806-8663 (weekdays).

APPENDIX: Technical information

Analytical methods used in the preparation of this report are summarized below:

Unless otherwise specified, the inclusion and exclusion criteria for all Adverse Drug Reaction (ADR) analyses are as follows:
Include: Events categorized as ADR (including ADRs resulting from drug interactions), see Definitions.
Exclude: Duplicate reports of the same event, ADRs with a causality assessment of "unlikely" to be associated with ARV(s), and reports of therapy change to prevent ADRs or drug interactions.
ADR rates are reported without consideration for the duration of drug therapy prior to the ADR report, or the duration of symptoms prior to the ADR report date.

Figure 1: Calculation of overall ADR rates for HIV-treatment and PrEP participants. Within each quarter (3-month period), the numerator is the number of ADR reports for ARV-treated persons. The denominator is the total number of person-years of ARV exposure accrued during the quarter. The resulting ADR rate is multiplied by 100 to give events per 100 person-years of treatment. Error bars around each point display the 95% confidence interval, calculated by the Poisson method.

Figure 2-5: **Calculation of ADR rates, by antiretroviral drug.** Within each calendar year, the numerator is the number of ADR reports specifying an adverse reaction attributed to the drug of interest. The denominator is the total number of person years exposure to the drug, accrued during the time period. The resulting ADR rate is multiplied by 100 to give events per 100 person-years of treatment. Error bars around each point display the 95% confidence interval calculated by the Poisson method.

Figures 6: **Calculation of ADR Rates by symptom category**. ADR reports contribute data for each relevant clinical category once per person in the calendar year the ADR was reported.

ADR rates are calculated as follows: In each calendar year, the numerator is the number of ADR reports specifying an adverse reaction for the symptom class of interest. The denominator is the total number of person-years exposure to antiretroviral therapy for treatment of HIV during the calendar year. The resulting rate is multiplied by 100 to give events per 100 person-years of treatment. Error bars around each point display the 95% confidence interval calculated by the Poisson method.

Adverse drug reactions associated with ART for HIV treatment in specific populations
Statistical comparisons between groups are calculated using Pearson's Chi-squared test or Fisher's exact test where required.

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Established in 2008, the BC-CfE Pharmacovigilance Initiative collects, evaluates, and analyzes reports of drug toxicity to understand and prevent drug-related problems. The Pharmacovigilance Initiative continues as an ongoing component of participant safety monitoring at the BC-CfE and does not receive pharmaceutical industry funding.

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