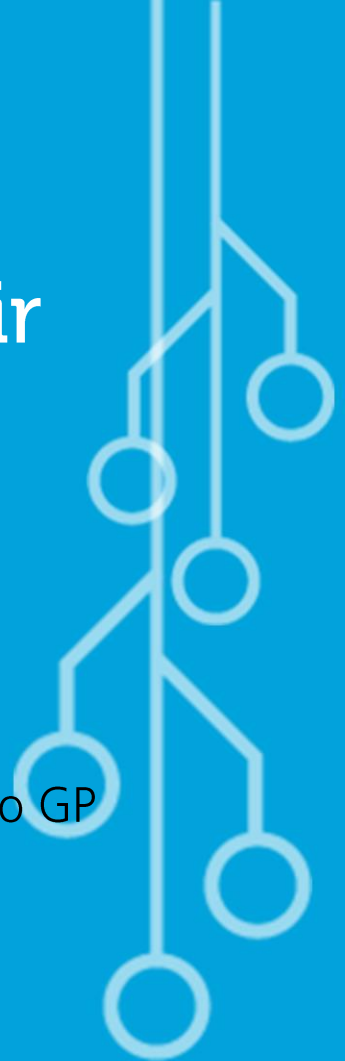


Suppressed Switch to Bictegravir/Emtricitabine/Tenofovir Alafenamide vs. Dolutegravir/Lamivudine

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Disclosures

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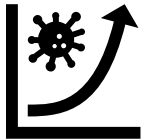
Background

	B/F/TAF	DTG/3TC
Uptake in US	Most prescribed regimen overall	Most prescribed 2-drug regimen
Once daily single tablet regimen	✓	✓
DHHS-recommended initial regimen for most	✓	If VL ≤500,000 copies/mL After resistance tests only
HIV-HBV co-infection	✓	✗
RCTs in virologically suppressed, ART-experienced individuals	Switch to B/F/TAF vs. remain on regimen Demonstrated efficacy, safety & tolerability	Switch to DTG/3TC vs. remain on regimen Demonstrated efficacy, safety & tolerability



Study Objectives

Among people with HIV switching from a prior regimen to B/F/TAF or DTG/3TC with a VL <200 copies/mL:



Compare the risk of confirmed virologic failure



Compare the risk of regimen discontinuation

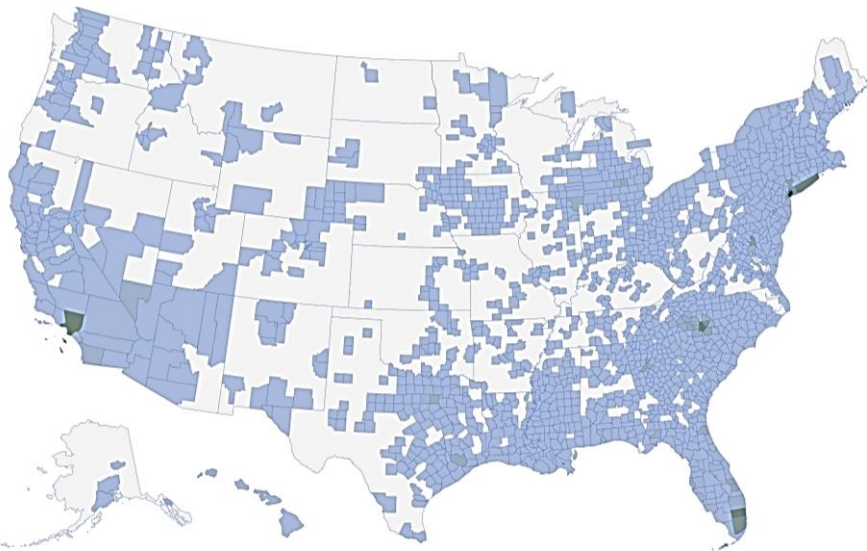
Methods





OPERA[®]

The Longitudinal Cohort



Observational **P**harmaco-
Epidemiology **R**esearch & **A**nalysis

>155K people with HIV in OPERA

~14% of people with HIV in the US



Study Design



Inclusion criteria

- ◆ ≥ 18 years old
- ◆ ART-experienced
- ◆ Viral load < 200 copies/mL
- ◆ ≥ 1 OPERA visit prior to index
- ◆ Switch to B/F/TAF or DTG/3TC between 01AUG2020 and 30JUN2022
- ◆ ≥ 1 viral load during follow-up



Follow-up through

Regimen discontinuation, loss to follow-up, death or December 2022



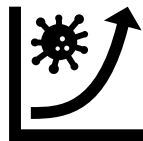
Outcomes

Confirmed Virologic Failure

2 consecutive VLs ≥ 200 copies/mL

or

1 VL ≥ 200 copies/mL + discontinuation




Discontinuation


Any regimen modification or treatment gap >45 days





Statistical Analyses

- 
- Incidence rates of virologic failure and discontinuation: **Poisson regression**
 - Association between regimen and time to virologic failure and discontinuation: **Cox proportional hazard models**
 - Statistical adjustment: **Inverse probability of treatment weights (IPTW)**
 - Race, payer type, baseline CD4 cell count, baseline eGFR



Sensitivity analysis: Confirmed virologic failure defined as
2 consecutive VLs ≥ 50 copies/mL or 1 VL ≥ 50 copies/mL + DC

Results





Study Population

Switch to B/F/TAF:
N = 3,512

Median follow-up:
16 months (IQR: 11, 22)

Switch to
DTG/3TC:
N = 2,327

Median follow-up:
15 months (IQR: 10, 21)



Baseline Demographic Characteristics

	Unweighted Population		d
	B/F/TAF (N=3,512)	DTG/3TC (N=2,327)	
Age, mean (sd)	45 (13)	46 (13)	0.02
Female sex, n (%)	609 (17)	430 (19)	0.06
Black race, n (%)	1,668 (47)	874 (39)	0.17
Medicaid or Ryan White/ADAP, n (%)	2,030 (58)	1,092 (49)	0.16

|d| represents the standardized mean difference between groups. A value of 0.1 or less is considered balanced.

Baseline Demographic Characteristics

	Unweighted Population			Weighted Population ^a		
	B/F/TAF (N=3,512)	DTG/3TC (N=2,327)	d	B/F/TAF (N=3,527)	DTG/3TC (N=2,213)	d
Age, mean (sd)	45 (13)	46 (13)	0.02	46 (13)	45 (13)	0.08
Female sex, n (%)	609 (17)	430 (19)	0.06	593 (17)	447 (20)	0.09
Black race, n (%)	1,668 (47)	874 (39)	0.17	1,562 (44)	980 (44)	0.00
Medicaid or Ryan White/ADAP, n (%)	2,030 (58)	1,092 (49)	0.16	1,921 (54)	1,208 (55)	0.00

|d| represents the standardized mean difference between groups. A value of 0.1 or less is considered balanced.

^a IPT weights adjusting for Black race, payer (Medicaid/Ryan White/ADAP), CD4 cell count, eGFR



Baseline Clinical Characteristics

	Unweighted Population		d
	B/F/TAF (N=3,512)	DTG/3TC (N=2,327)	
Failure of prior regimen, n (%) ^a	158 (5)	53 (2)	0.13
CD4 count, mean (sd)	705 (315)	748 (312)	0.14
BMI ≥30, n (%) ^b	1,013 (31)	743 (36)	0.10
eGFR, mean (sd)	90 (22)	86 (22)	0.18

|d| represents the standardized mean difference between groups. A value of 0.1 or less is considered balanced.

^a Missing: n=363 [unweighted]

^b Missing: n=251 [unweighted]

Baseline Clinical Characteristics

	Unweighted Population			Weighted Population ^c		
	B/F/TAF (N=3,512)	DTG/3TC (N=2,327)	d	B/F/TAF (N=3,527)	DTG/3TC (N=2,213)	d
Failure of prior regimen, n (%) ^a	158 (5)	53 (2)	0.13	148 (4)	59 (3)	0.09
CD4 count, mean (sd)	705 (315)	748 (312)	0.14	721 (315)	720 (313)	0.00
BMI ≥30, n (%) ^b	1,013 (31)	743 (36)	0.10	1,019 (31)	744 (36)	0.11
eGFR, mean (sd)	90 (22)	86 (22)	0.18	89 (22)	89 (22)	0.00

|d| represents the standardized mean difference between groups. A value of 0.1 or less is considered balanced.

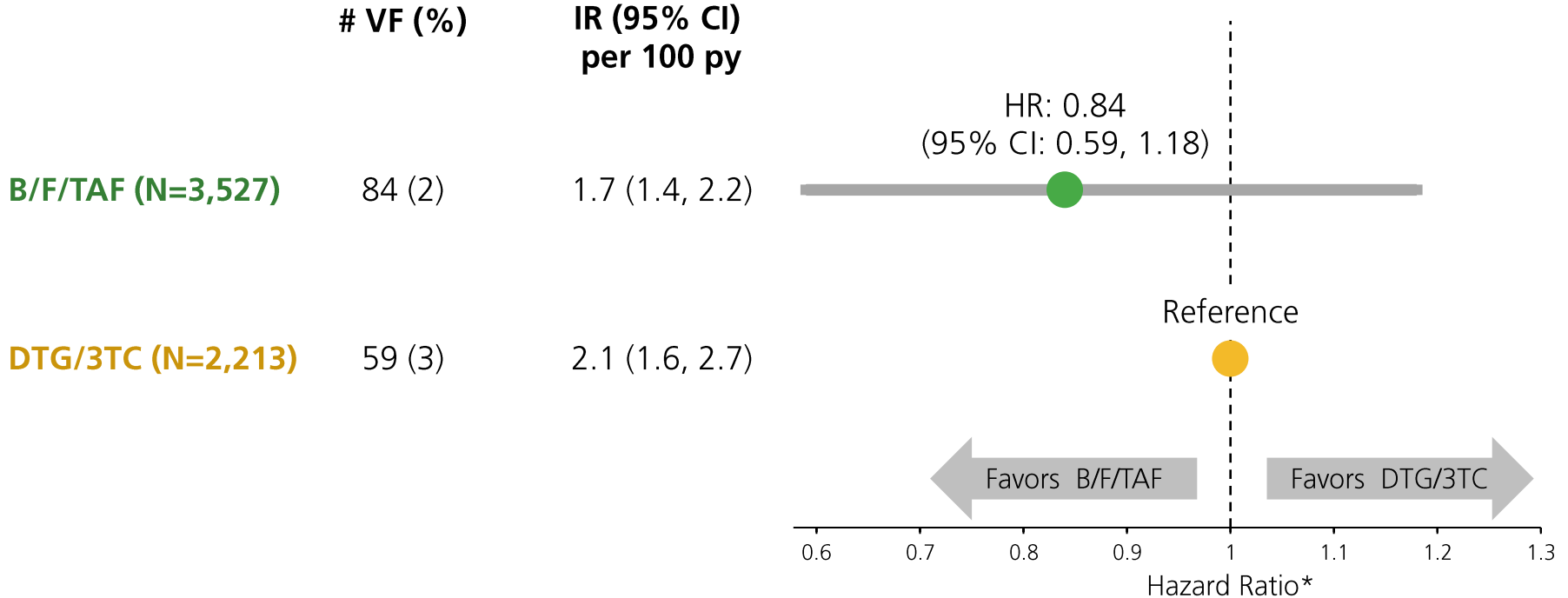
^a Missing: n=363 [unweighted]; n=365 [IPTW]

^b Missing: n=251 [unweighted]; n=250 [IPTW]

^c IPT weights adjusting for Black race, payer (Medicaid/Ryan White/ADAP), CD4 cell count, eGFR

Risk of Confirmed Virologic Failure

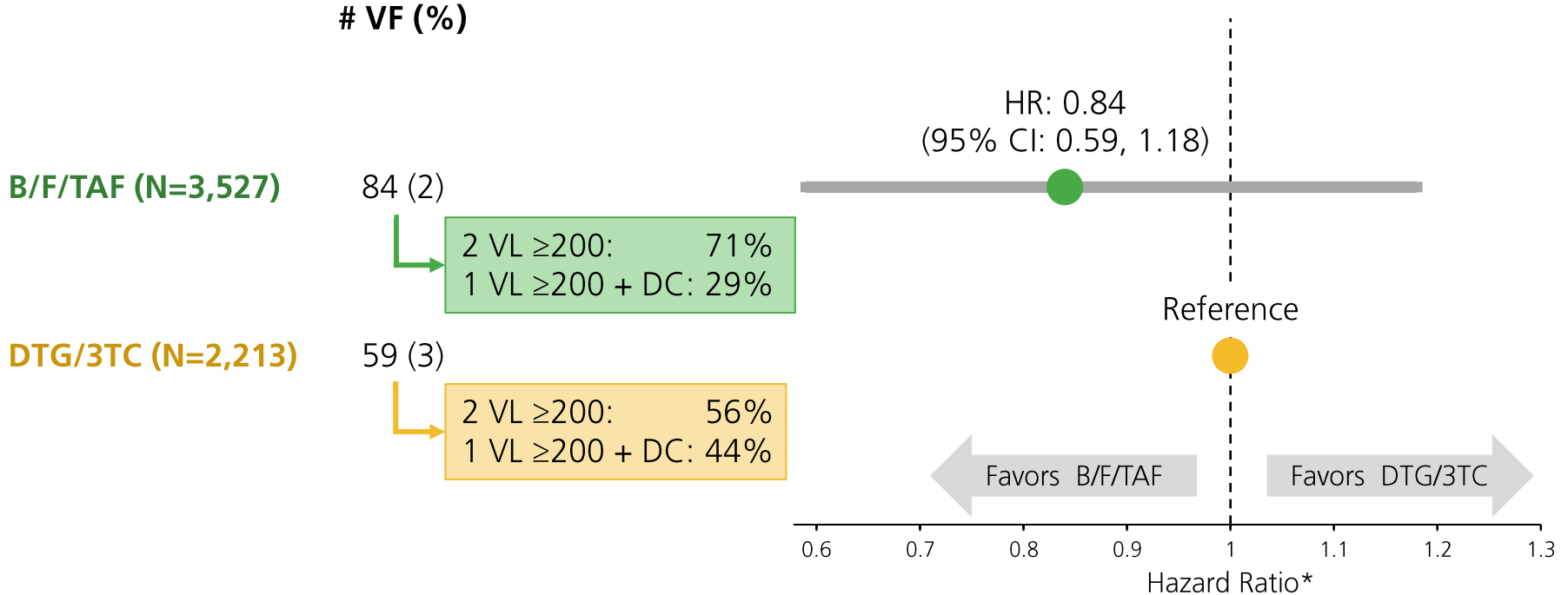
Main Analysis (≥ 200 copies/mL)



*Adjusted for Black race, payer, CD4 cell count, eGFR

Risk of Confirmed Virologic Failure

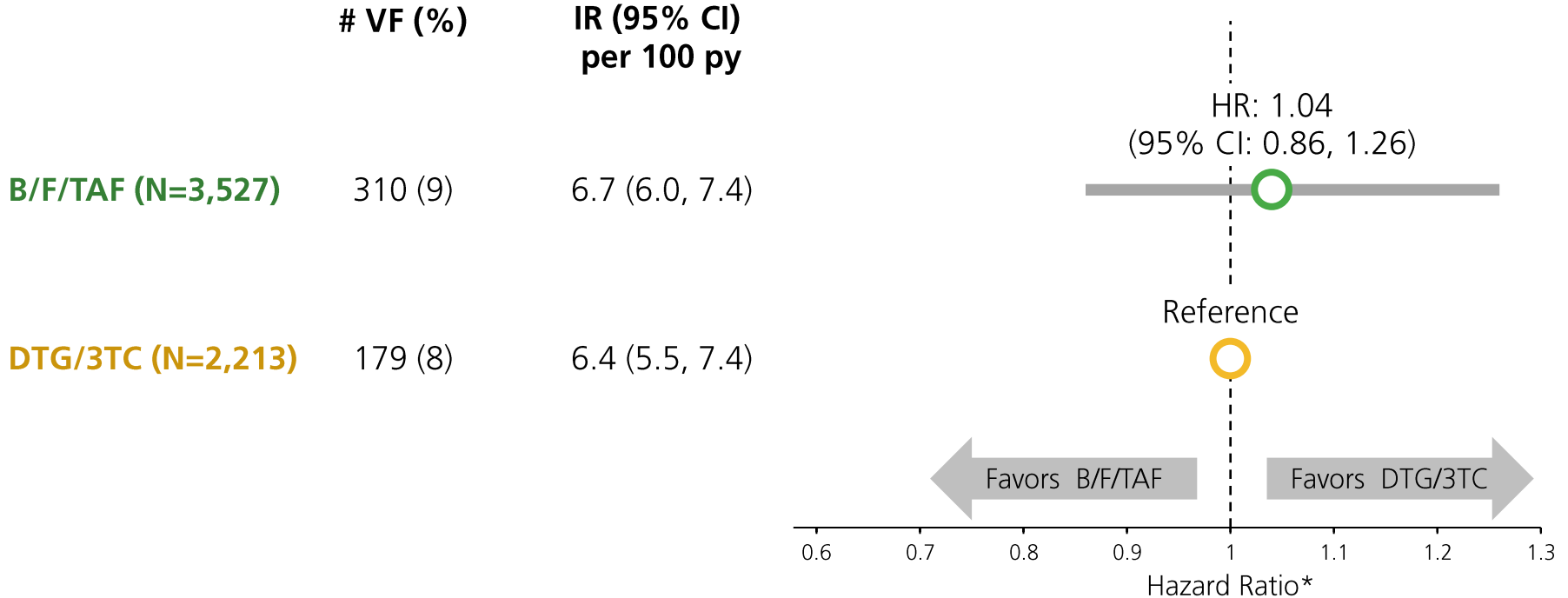
Main Analysis (≥ 200 copies/mL)



*Adjusted for Black race, payer, CD4 cell count, eGFR

Risk of Confirmed Virologic Failure

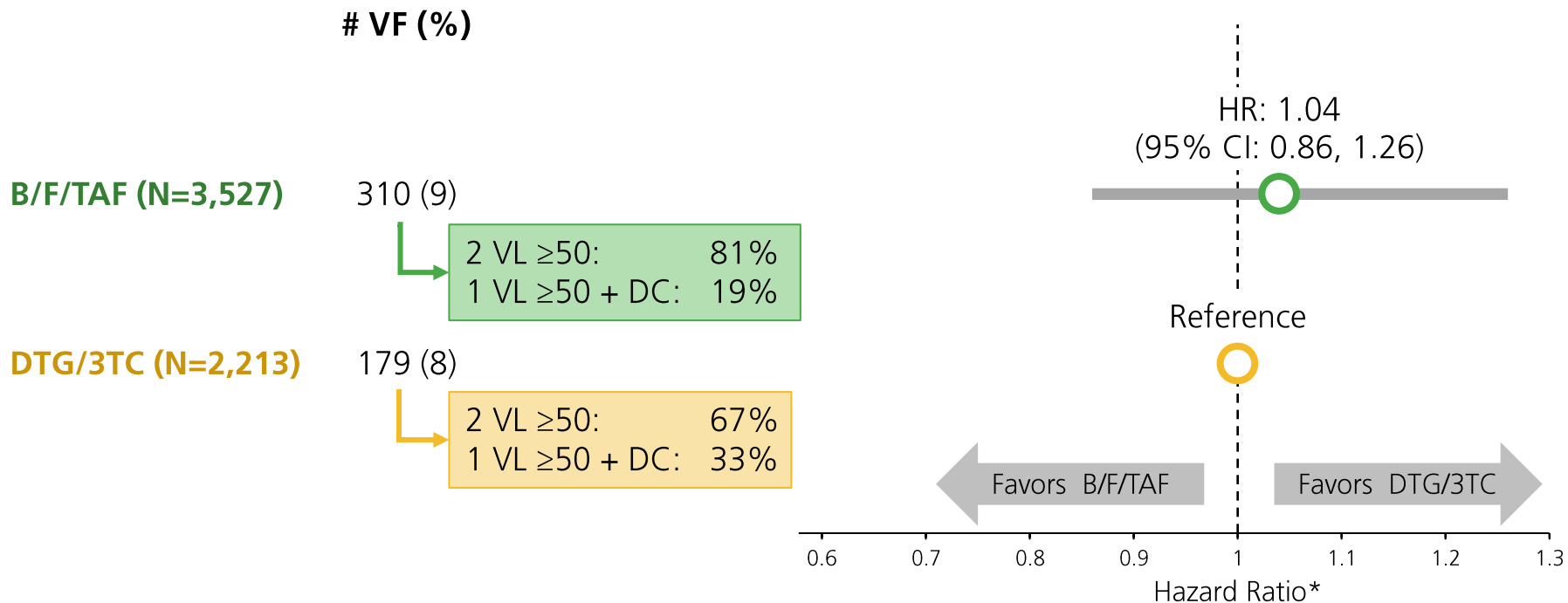
Sensitivity Analysis (≥ 50 copies/mL)



*Adjusted for Black race, payer, CD4 cell count, eGFR

Risk of Confirmed Virologic Failure

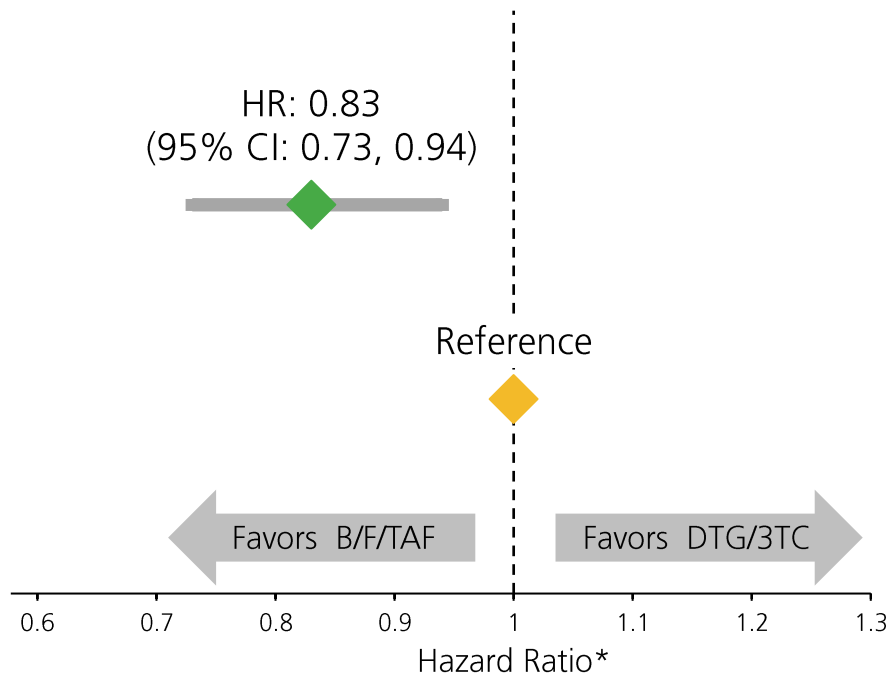
Sensitivity Analysis (≥ 50 copies/mL)



*Adjusted for Black race, payer, CD4 cell count, eGFR

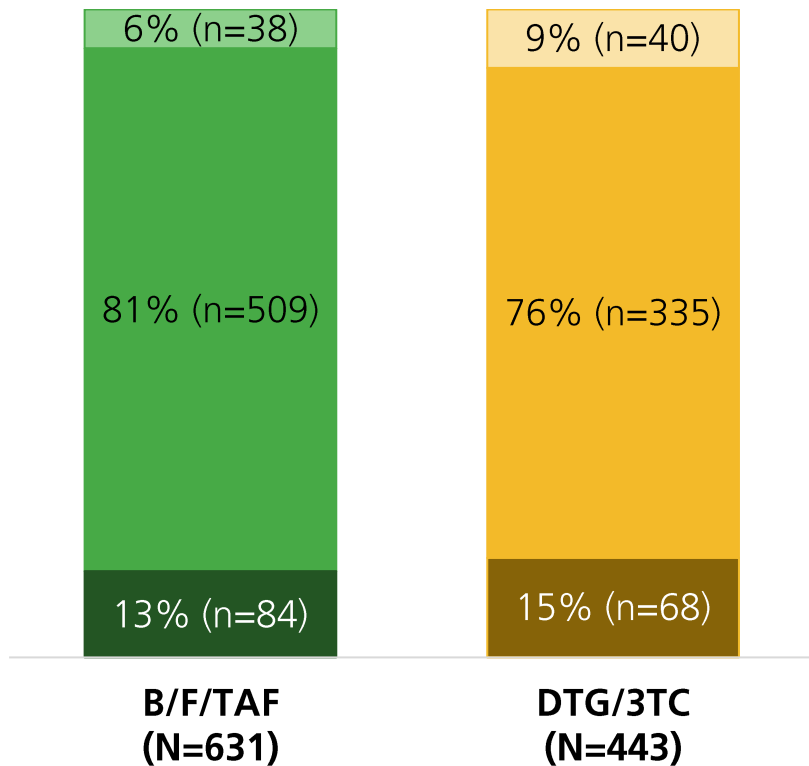
Risk of Regimen Discontinuation

	# DC (%)	IR (95% CI) per 100 py
B/F/TAF (N=3,527)	599 (17)	12.4 (11.4, 13.4)
DTG/3TC (N=2,213)	425 (19)	14.8 (13.4, 16.3)

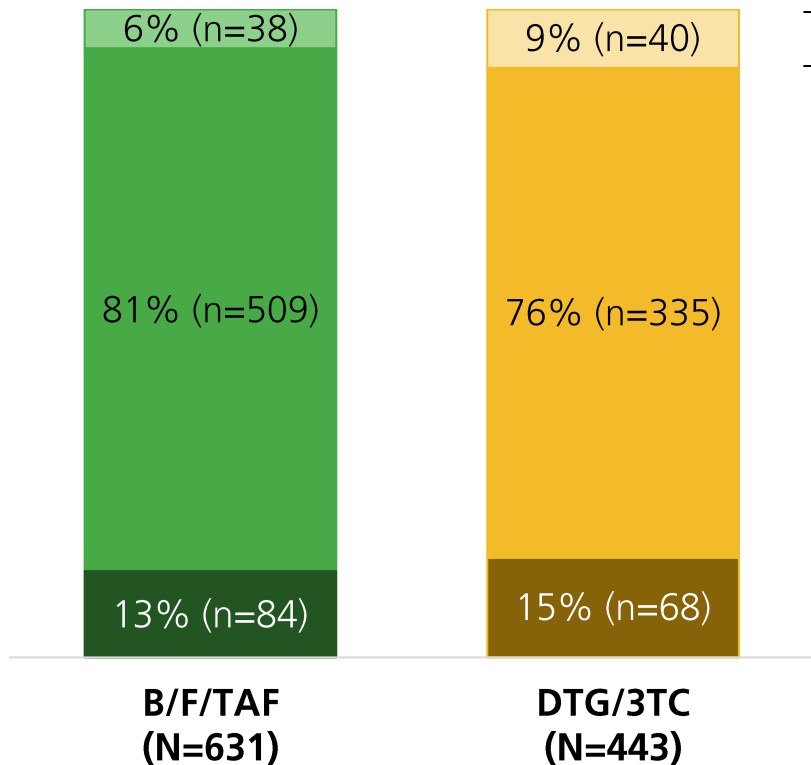


*Adjusted for Black race, payer, CD4 cell count, eGFR

Reasons for Discontinuation



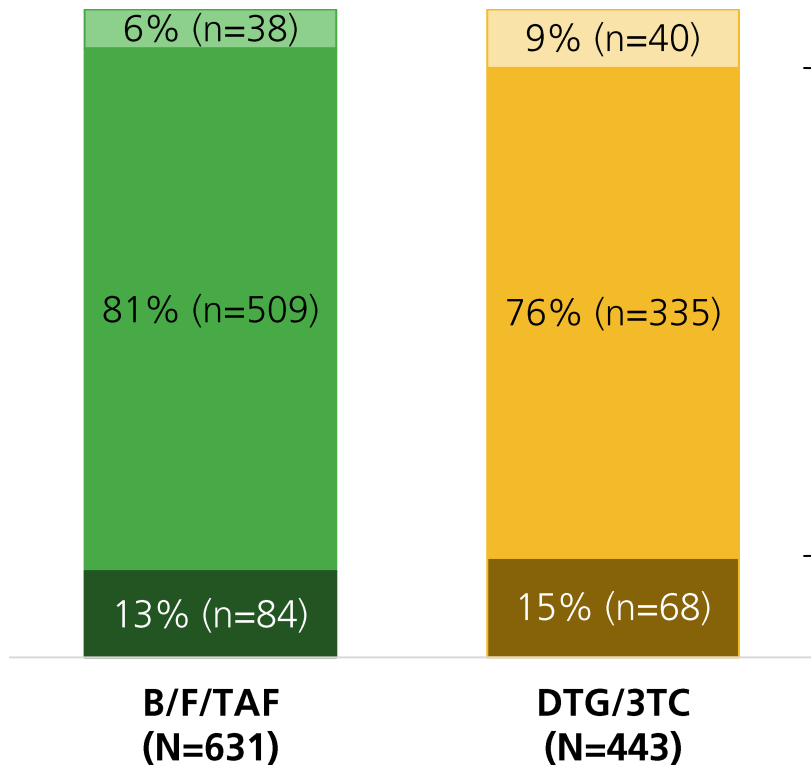
Reasons for Discontinuation



Treatment-related reasons (not mutually exclusive)

- Last VL ≥ 200 copies/mL (3% vs. 5%)
- Adverse diagnosis/Side Effect (3% vs. 4%)
- Lab abnormality ($\leq 1\%$ vs. $\leq 1\%$)

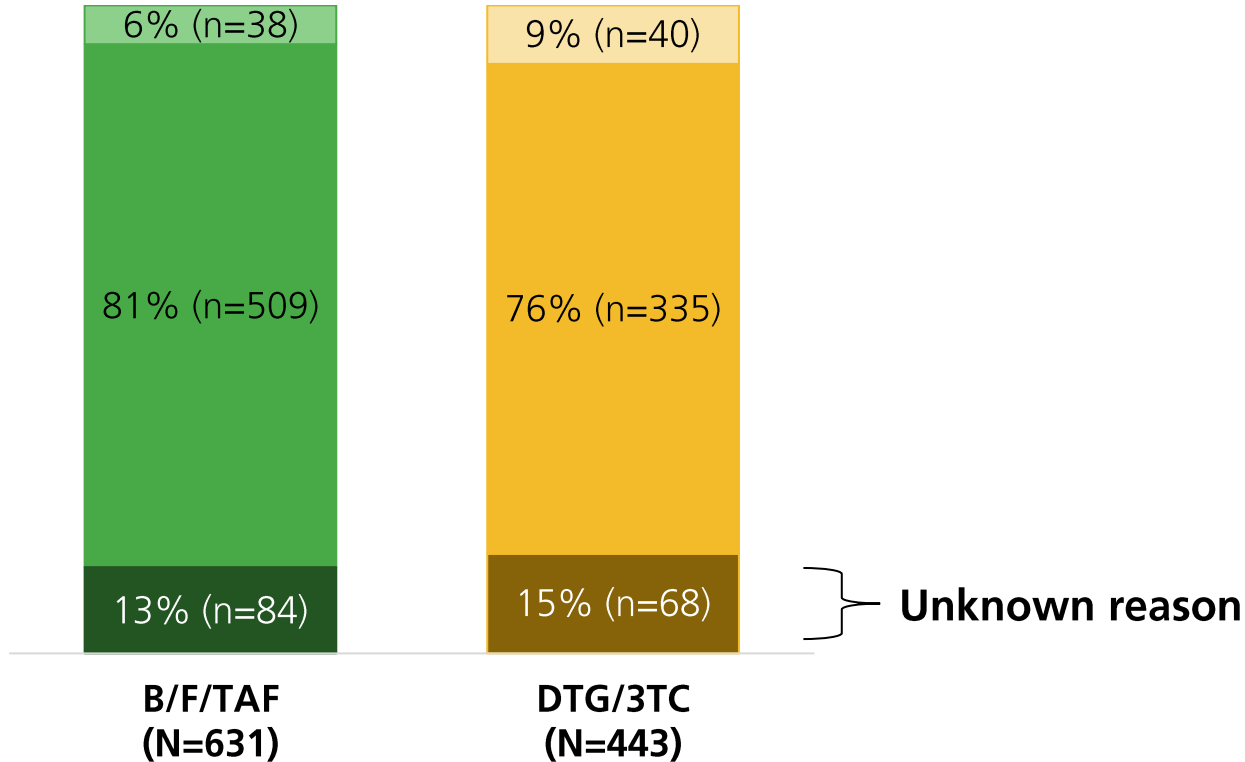
Reasons for Discontinuation



Other reasons (not mutually exclusive)

- Switch to long-acting regimen (**10%** vs. **15%**)
- Pregnancy (**1%** vs. **≤1%**)
- Access issues (**≤1%** vs. **0%**)
- ≥45 days without ART (**55%** vs. **37%**)
- Patient's choice (**≤1%** vs. **≤1%**)
- Provider's choice (**21%** vs. **32%**)

Reasons for Discontinuation



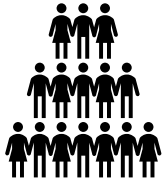
Key Findings

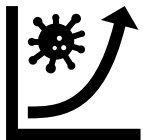




Large real-world US cohort


- 3,713 virologically suppressed adults switching to B/F/TAF (61%)
- 2,327 virologically suppressed adults switching to DTG/3TC (39%)
- B/F/TAF was more likely to be prescribed to:
 - Black individuals
 - On Medicaid or Ryan White/ADAP
 - Who had experienced virologic failure on their prior regimen
 - With lower CD4 cell counts
 - With higher eGFR
- Balance was achieved with IPTW






Both regimens were virologically effective

- Infrequent virologic failure
- No statistically significant difference between B/F/TAF and DTG/3TC



Regimen discontinuation occurred statistically earlier with DTG/3TC than B/F/TAF

- 
- More treatment-related discontinuations were noted with DTG/3TC than B/F/TAF
 - In both groups, most discontinuations seemed unrelated to treatment effectiveness or to safety/tolerability events severe enough to be noted in the EHR
 - Switch to long-acting ART more frequent from DTG/3TC than B/F/TAF

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