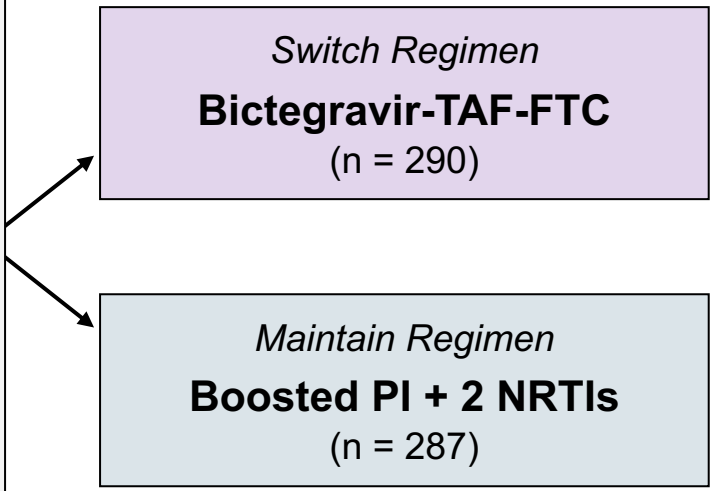
Switch from Boosted PI + 2 NRTIs to BIC-TAF-FTC with Viral Suppression

GS-380-1878

National HIV Curriculum

Switch from Boosted PI + 2 NRTIs to Bictegravir-TAF-FTC
GS-380-1878: Design

- **Background**
  - Randomized, phase 3, multicenter, open-label switch study evaluating the efficacy and safety of switching adults with viral suppression taking a boosted PI plus 2 NRTIs to BIC-TAF-FTC
- **Inclusion Criteria**
  - Age ≥18 years
  - HIV RNA <50 copies/mL for ≥6 months
  - Taking stable antiretroviral regimen for ≥6 months
  - No history of virologic failure
  - No prior treatment with an INSTI
  - eGFR ≥50 mL/min
  - HBV and HCV allowed
  - Taking atazanavir or darunavir (each boosted by ritonavir or cobicistat) + TDF-FTC or ABC-3TC



Source: Daar E, et al. Lancet HIV. 2018;5:e347-e356.

Switch from Boosted PI + 2 NRTIs to Bictegravir-TAF-FTC
GS-380-1878: Baseline Characteristics

Study GS-380-1878 Baseline Characteristics		
Characteristic	**BIC-TAF-FTC** (n = 290)	**Boosted PI + 2 NRTIs** (n = 287)
Median age, years (range)	48	47
Male, %	84	82
Black or African descent, %	27	25
Hispanic/Latino, %	21	16
Median CD4, cells/mL	617	626
HBV coinfection, %	8	6
HCV coinfection, %	5	5
Median eGFR, mL/min	107	105
Baseline TDF-FTC, ABC-3TC, %	84, 16	85, 15
Baseline DRV, ATV, %	57, 43	54, 46

Source: Daar E, et al. Lancet HIV. 2018;5:e347-e356.

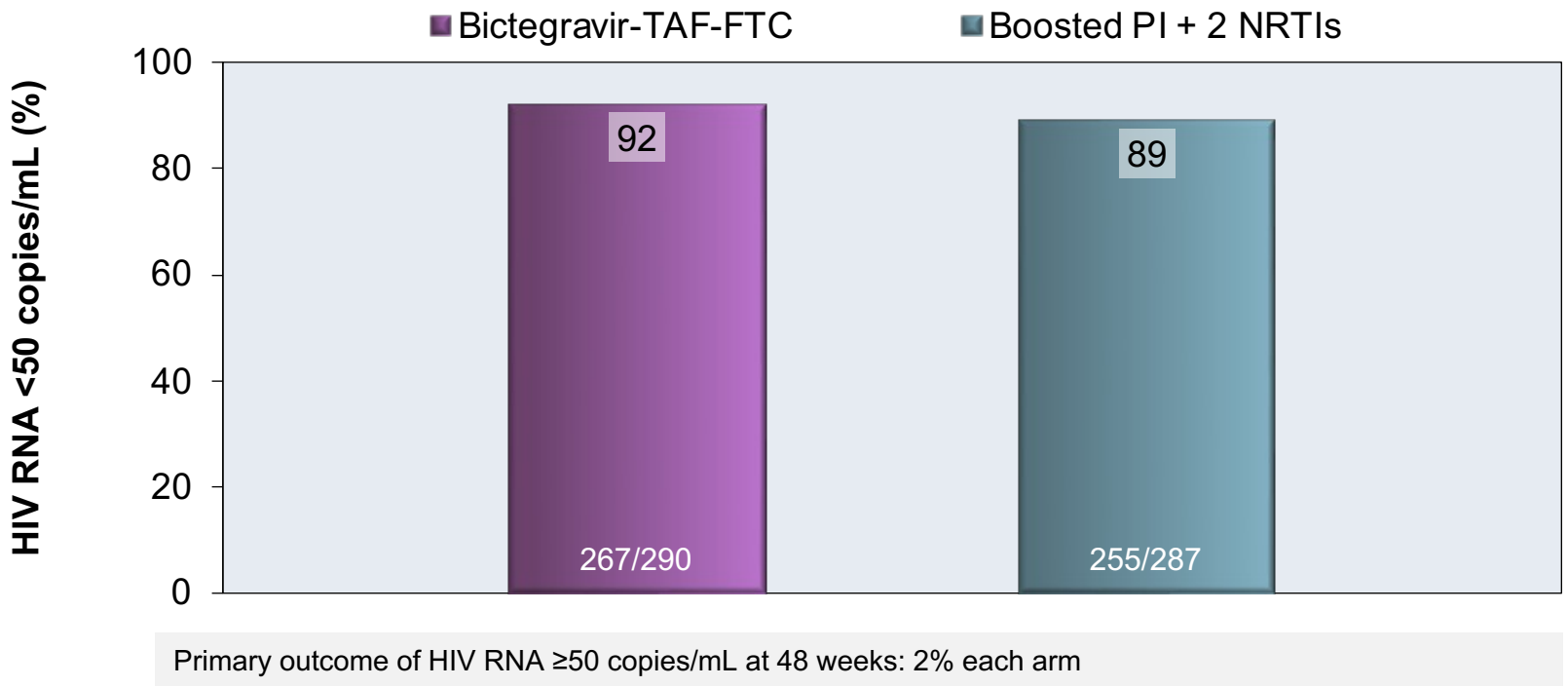
Switch from Boosted PI + 2 NRTIs to Bictegravir-TAF-FTC GS-380-1878: Baseline Characteristics

Study GS-380-1878 Baseline Antiretroviral Regimen		
Baseline Antiretroviral Medications	**BIC-TAF-FTC** (n = 290)	**Boosted PI + 2 NRTIs** (n = 287)
NRTI		
Tenofovir DF-emtricitabine, %	84	85
Abacavir-lamivudine, %	16	15
Protease Inhibitor	21	16
Darunavir, %	57	54
Atazanavir, %	43	46

Source: Daar E, et al. Lancet HIV. 2018;5:e347-e356.

Switch from Boosted PI + 2 NRTIs to Bictegravir-TAF-FTC GS-380-1878: Results

Week 48 Virologic Response (Intention-to-Treat Analysis)



Primary outcome of HIV RNA ≥50 copies/mL at 48 weeks: 2% each arm

Source: Daar E, et al. Lancet HIV. 2018;5:e347-e356.

Switch from Boosted PI + 2 NRTIs to Bictegravir-TAF-FTC GS-380-1878: Adverse Events

Most Common Treatment-Related Adverse Events (AE's) Through 48 Weeks		
	BIC-TAF-FTC (n = 290)	**Boosted PI + 2 NRTI's** (n = 287)
Headache, %	12	4
Diarrhea, %	8	8
Nasopharyngitis, %	7	12
URI, %	7	8
Back pain, %	5	6
Arthralgia, %	4	5
Change in eGFR	-4.3 mL/min	0.2 mL/min

Abbreviations: eGFR = estimated glomerular filtration

Source: Daar E, et al. Lancet HIV. 2018;5:e347-e356.

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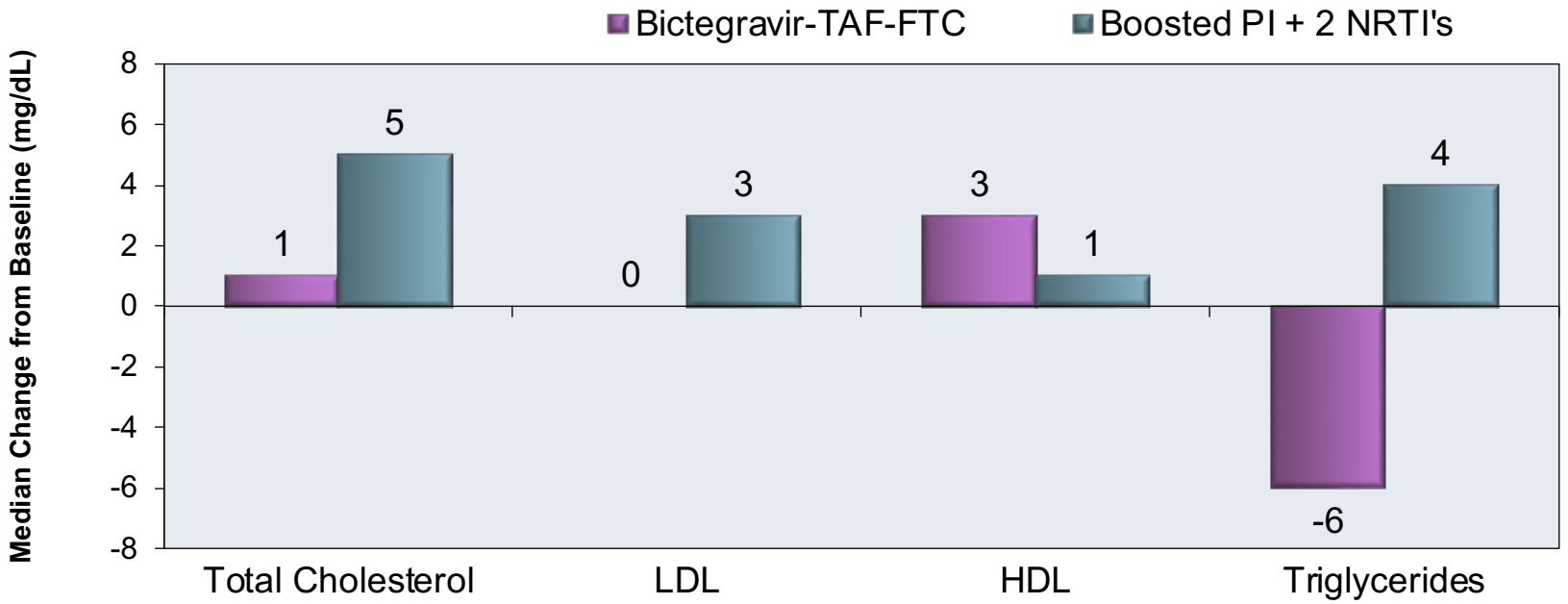
Change in Lipids at 48 Weeks



Source: Daar E, et al. Lancet HIV. 2018;5:e347-e356.

Switch from Boosted PI + 2 NRTIs to Bictegravir-TAF-FTC GS-380-1878: Conclusions

Interpretation: “Fixed-dose bictegravir, emtricitabine, and tenofovir alafenamide might be a safe and efficacious alternative to continued boosted protease inhibitor therapy in adults with HIV-1 infection.”

Source: Daar E, et al. Lancet HIV. 2018;5:e347-e356.

Acknowledgments

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National HIV Curriculum

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