

Switching from TDF/FTC to TAF/FTC
Study 311-1089

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Study 311: Design

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- **Background:** Open-label, randomized Phase 3 trial to evaluate switch to tenofovir alafenamide-emtricitabine in patients with virologic suppression on a regimen containing tenofovir DF-emtricitabine.
- **Inclusion Criteria (n = 668 enrolled)**
 - Adults with HIV infection
 - HIV RNA <50 copies/mL
 - Regimen contains tenofovir DF-emtricitabine
 - eGFR >50 mL/min
- **Treatment Arms**
 - Tenofovir alafenamide-emtricitabine (Switch)
 - Tenofovir DF-emtricitabine (Continue)

Switch to TAF/FTC*
(n = 333)

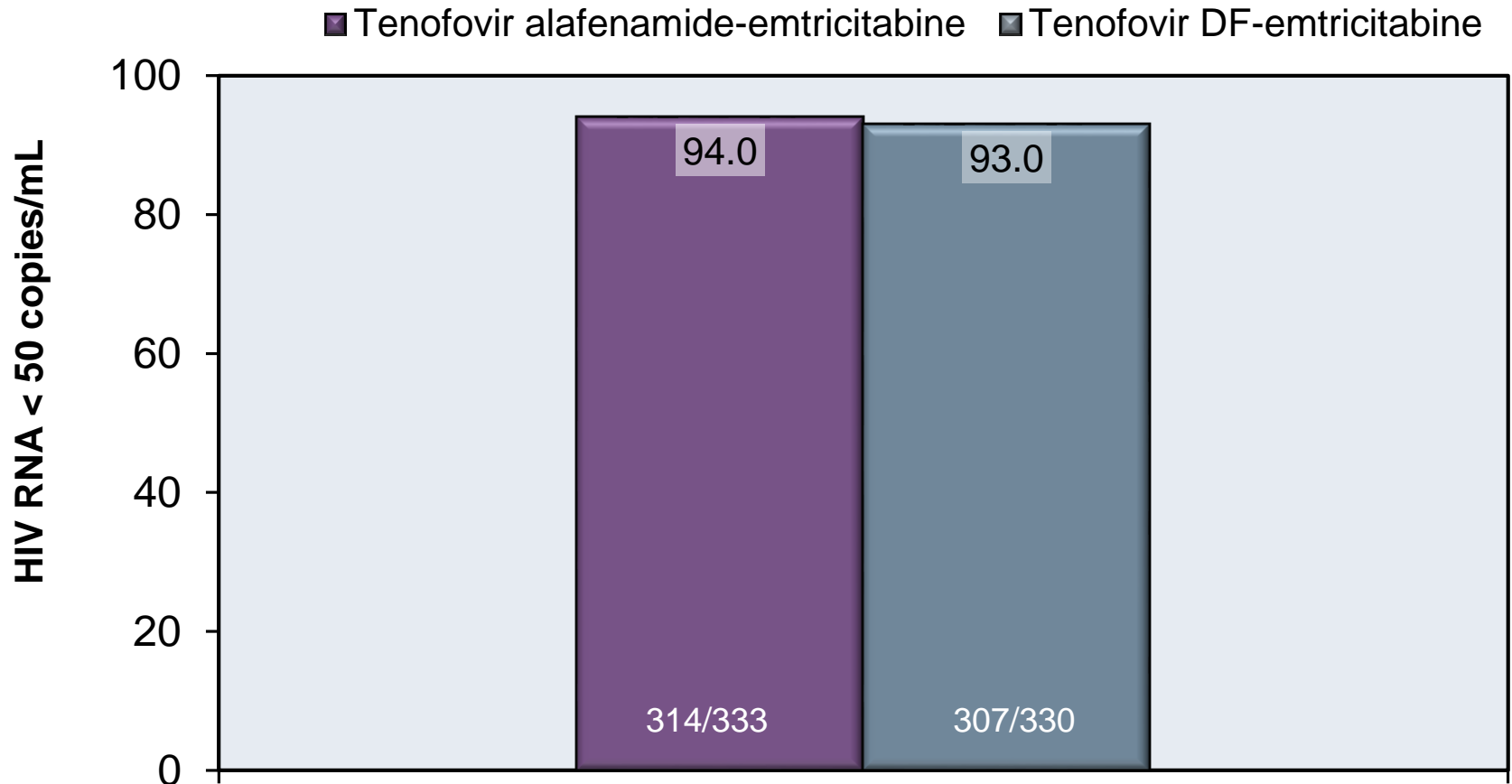
Continue TDF/FTC
(n = 330)

*Patients on a pharmacokinetic booster (ritonavir) received tenofovir alafenamide-emtricitabine 10/200 mg
Patients those not on a booster received tenofovir alafenamide-emtricitabine 25/200 mg

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Study 311: Results

Week 48 Virologic Response (Overall)

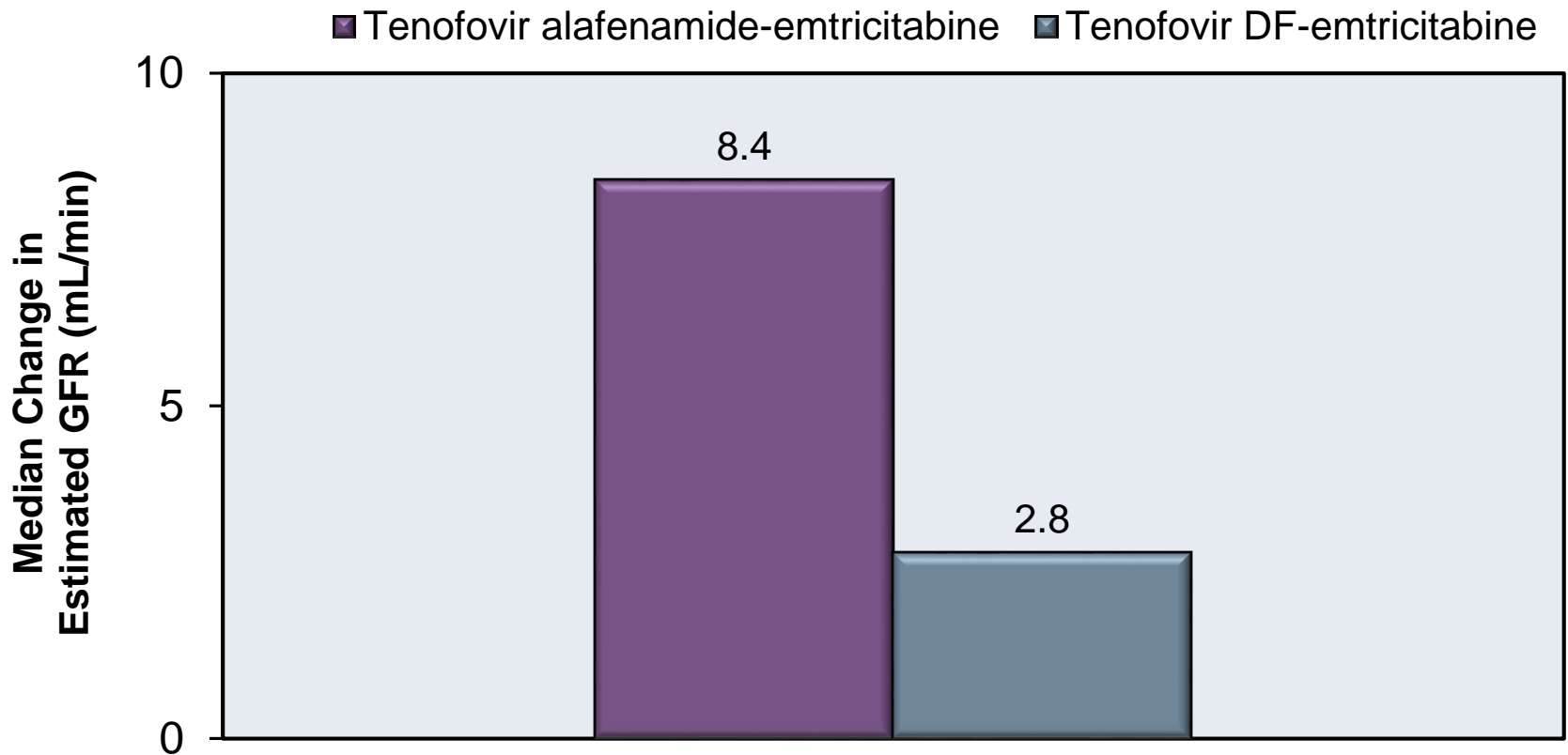


Source: Gallant JE, et al. Lancet HIV. 2016;3:e158-65.

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Study 311: Results

Week 48 Median Change in Estimated GFR



Source: Gallant JE, et al. Lancet HIV. 2016;3:e158-65.

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Study 311: Conclusions

Interpretation: “In patients switching from emtricitabine with tenofovir disoproxil fumarate to emtricitabine with tenofovir alafenamide, high rates of virological suppression were maintained. With its safety advantages, fixed-dose emtricitabine with tenofovir alafenamide has the potential to become an important NRTI backbone.”

Acknowledgment

The **National HIV Curriculum** is an AIDS Education and Training Center (AETC) Program resource funded by the United States Health Resources and Services Administration. The project is led by the University of Washington and the AETC National Coordinating Resource Center.

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