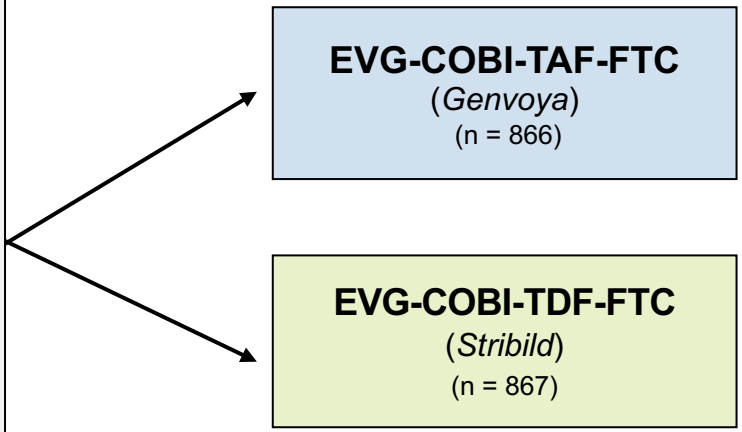
EVG-COBI-TAF-FTC versus EVG-COBI-TDF-FTC

Study 104 and Study 111

National HIV Curriculum

EVG-COBI-TAF-FTC versus EVG-COBI-TDF-FTC Study 104/111: Design

- **Background**: Randomized, double-blind, phase 3 trial comparing elvitegravir-cobicistat-tenofovir alafenamide-emtricitabine with elvitegravir-cobicistat-tenofovir DF-emtricitabine
- **Inclusion Criteria** (n = 1,733)
  - Antiretroviral-naïve patients
  - Age >18
  - HIV RNA ≥1000 copies/mL
  - Any CD4 count allowed
  - No AIDS conditions in prior 30 days
- **Treatment Arms**
  - Elvitegravir-Cobicistat-TAF-FTC
  - Elvitegravir-Cobicistat-TDF-FTC

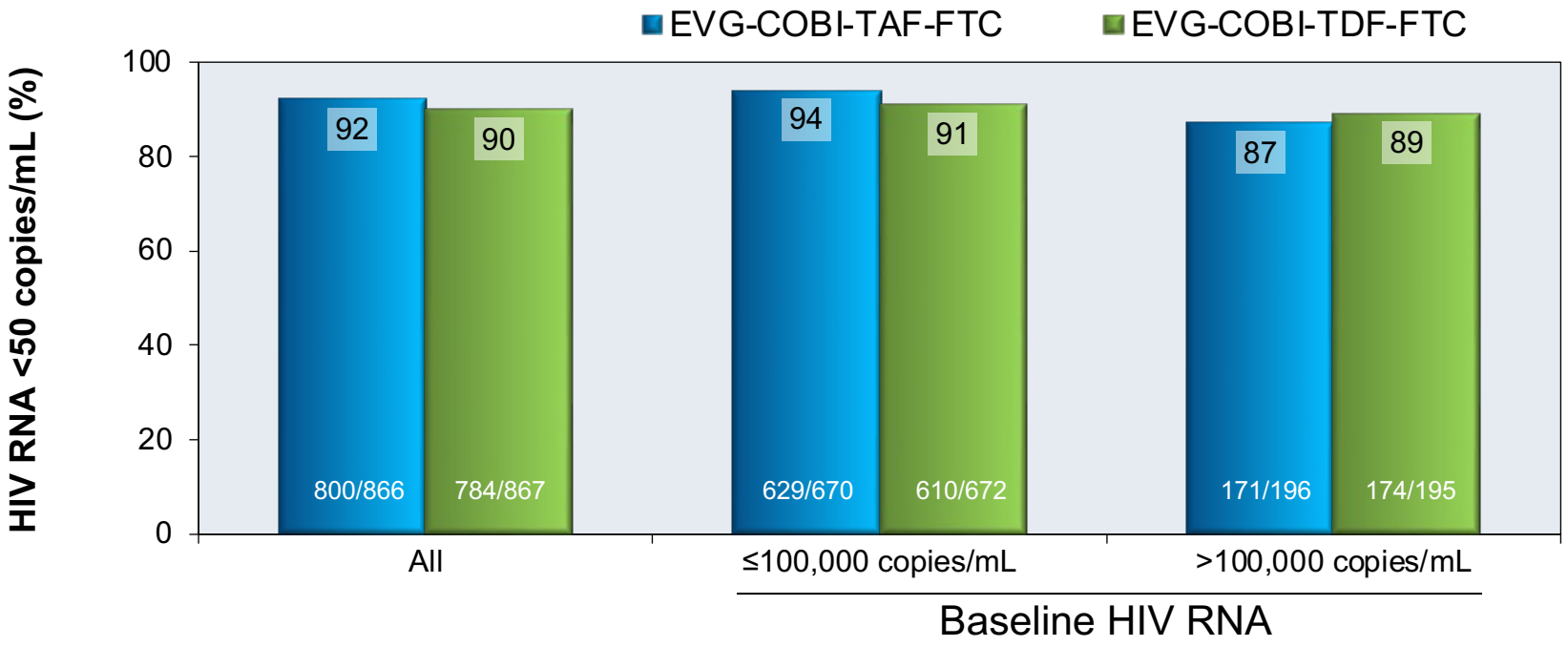


Source: Sax PE, et al. Lancet. 2015;385:2606-15.

National HIV Curriculum

EVG-COBI-TAF-FTC versus EVG-COBI-TDF-FTC
Study 104/111: Result

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

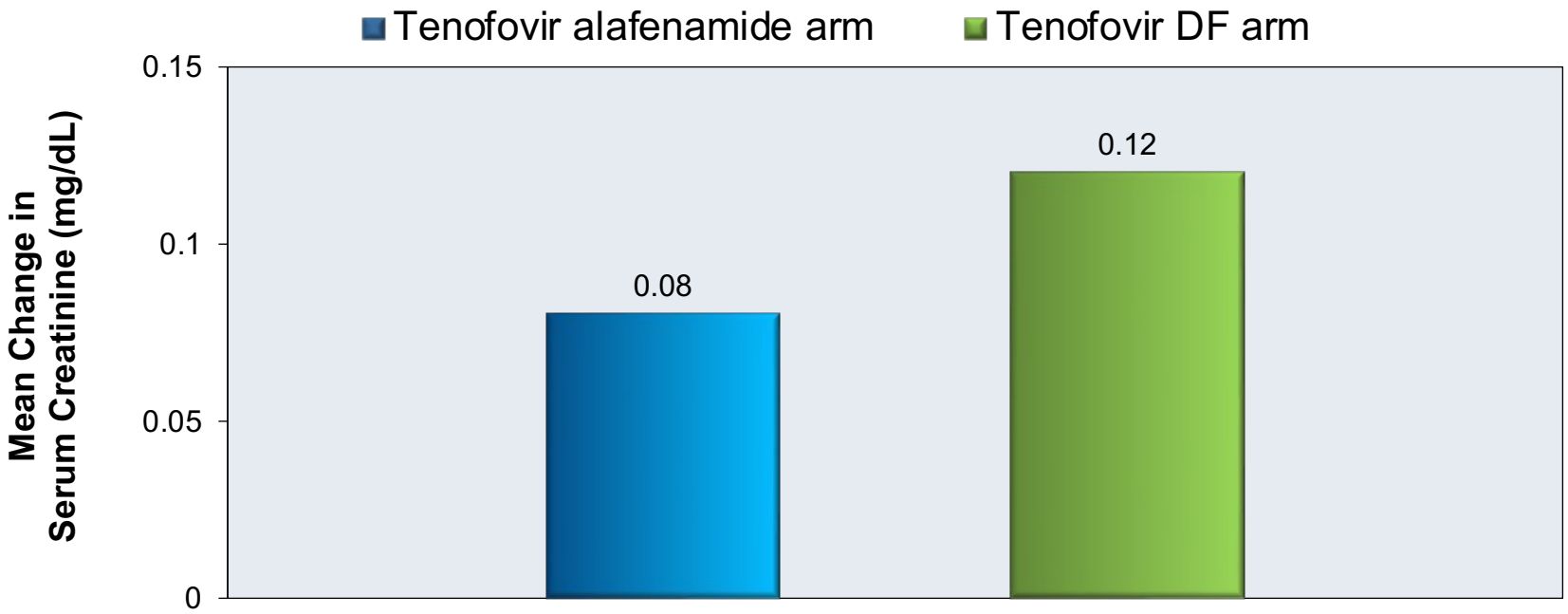


Source: Sax PE, et al. Lancet. 2015;385:2606-15.

National HIV Curriculum

EVG-COBI-TAF-FTC versus EVG-COBI-TDF-FTC
Study 104/111: Adverse Effects

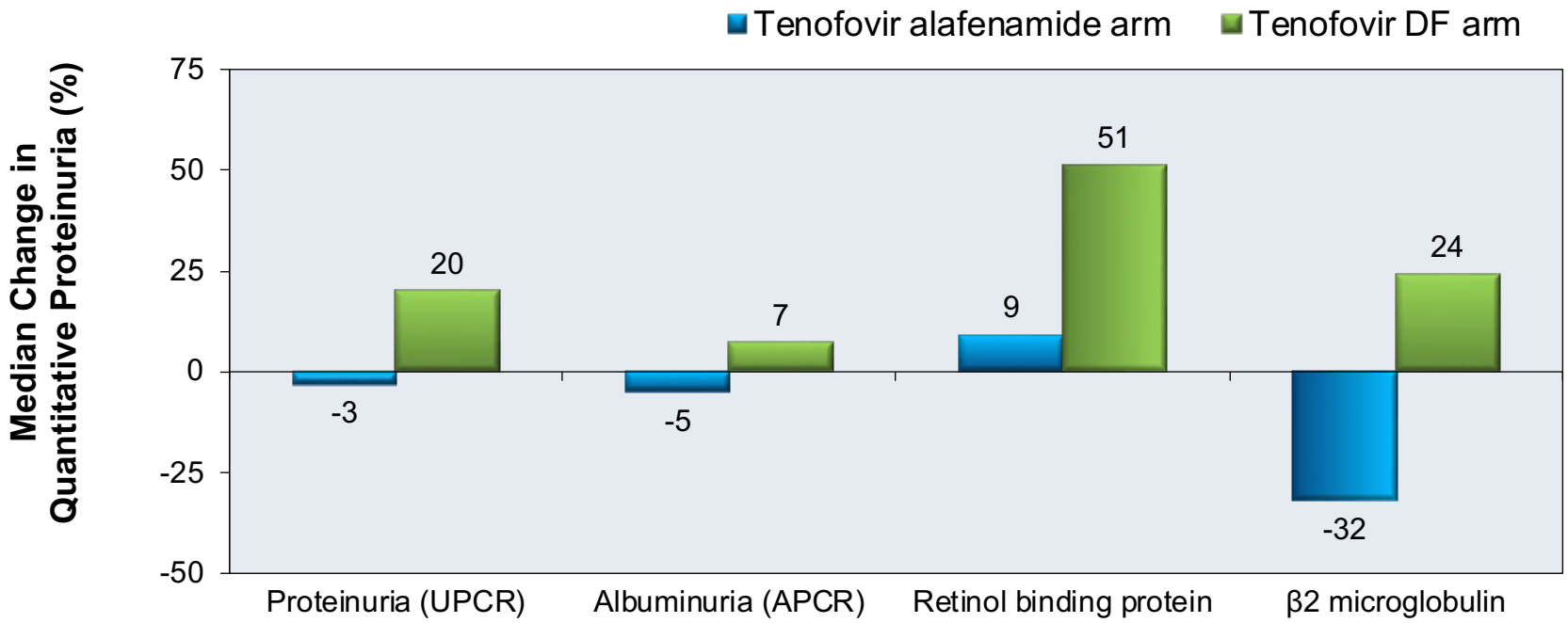
Week 48: Change in Serum Creatinine from Baseline



Source: Sax PE, et al. Lancet. 2015;385:2606-15.

EVG-COBI-TAF-FTC versus EVG-COBI-TDF-FTC
Study 104/111: Adverse Effects

Week 48: Changes in Quantitative Proteinuria from Baseline

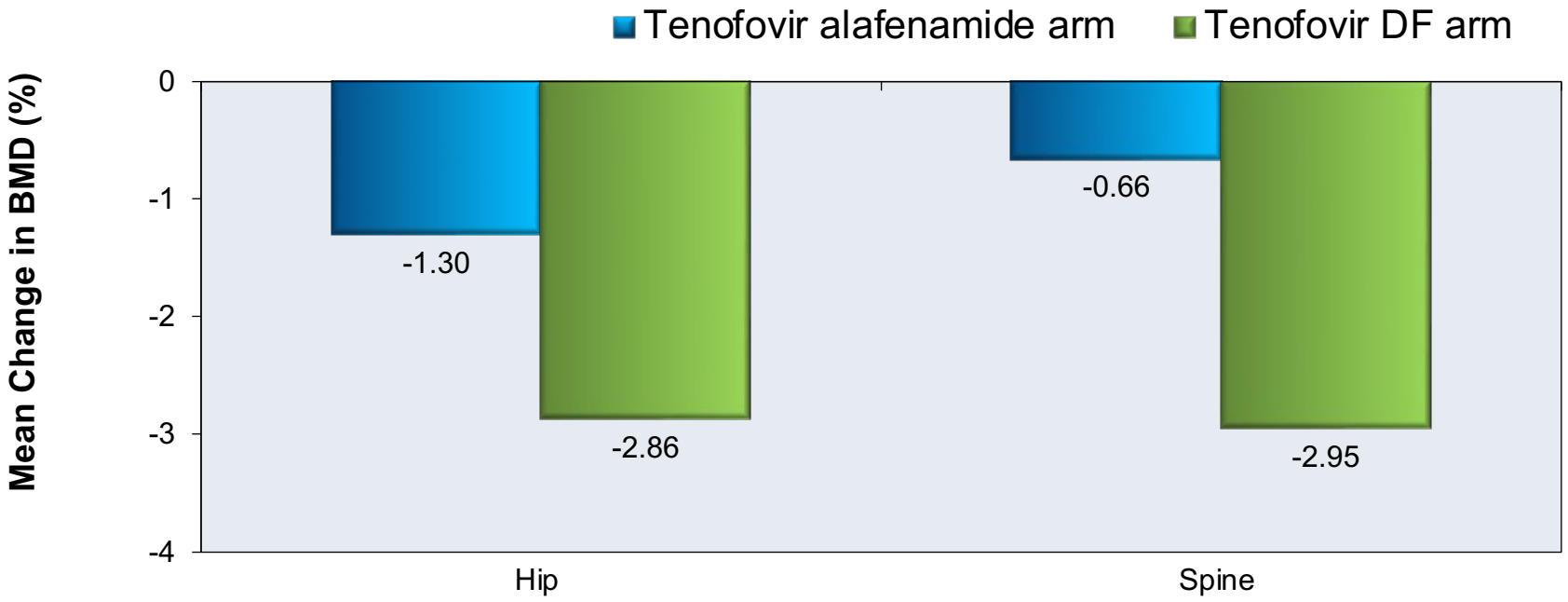


Source: Sax PE, et al. Lancet. 2015;385:2606-15.

National HIV Curriculum

EVG-COBI-TAF-FTC versus EVG-COBI-TDF-FTC
Study 104/111: Adverse Effects

Week 48: Changes in Spine and Hip Bone Mineral Density (BMD)



Source: Sax PE, et al. Lancet. 2015;385:2606-15.

EVG-COBI-TAF-FTC versus EVG-COBI-TDF-FTC
Study 104/111: Adverse Effects

Week 48: Changes in Lipid Parameters

Median Change from Baseline to Week 48	EVG/COBI/TAF/FTC (n = 866)	EVG/COBI/TDF/FTC (n = 867)	P Value
Total cholesterol	+29	+14	<0.001
LDL	+14	+5	<0.001
HDL	+8	+4	<0.001
Triglycerides	+19	+8	0.027
Total cholesterol:HDL ratio	+0.1	+0.1	0.84

Source: Sax PE, et al. Lancet. 2015;385:2606-15.

EVG-COBI-TAF-FTC versus EVG-COBI-TDF-FTC
Study 104/111: Conclusions

Interpretation: “Through 48 weeks, more than 90% of patients given E/C/F/tenofovir alafenamide or E/C/F/tenofovir disoproxil fumarate had virological success. Renal and bone effects were significantly reduced in patients given E/C/F/tenofovir alafenamide. Although these studies do not have the power to assess clinical safety events such as renal failure and fractures, our data suggest that E/C/F/tenofovir alafenamide will have a favourable long-term renal and bone safety profile.”

Source: Sax PE, et al. Lancet. 2015;385:2606-15.

Acknowledgments

The **National HIV Curriculum** is supported by the Health Resources and Services Administration (HRSA) of the U.S. Department of Health and Human Services (HHS) as part of a financial assistance award totaling $1,021,448 with 0% financed with non-governmental sources. The contents are those of the author(s) and do not necessarily represent the official views of, nor an endorsement, by HRSA, HHS, or the U.S. Government. For more information, please visit HRSA.gov. This project is led by the University of Washington's Infectious Diseases Education and Assessment (IDEA) Program.

AETC AIDS Education & Training Center Program

National HIV Curriculum

IDEA INFECTIOUS DISEASES EDUCATION & ASSESSMENT