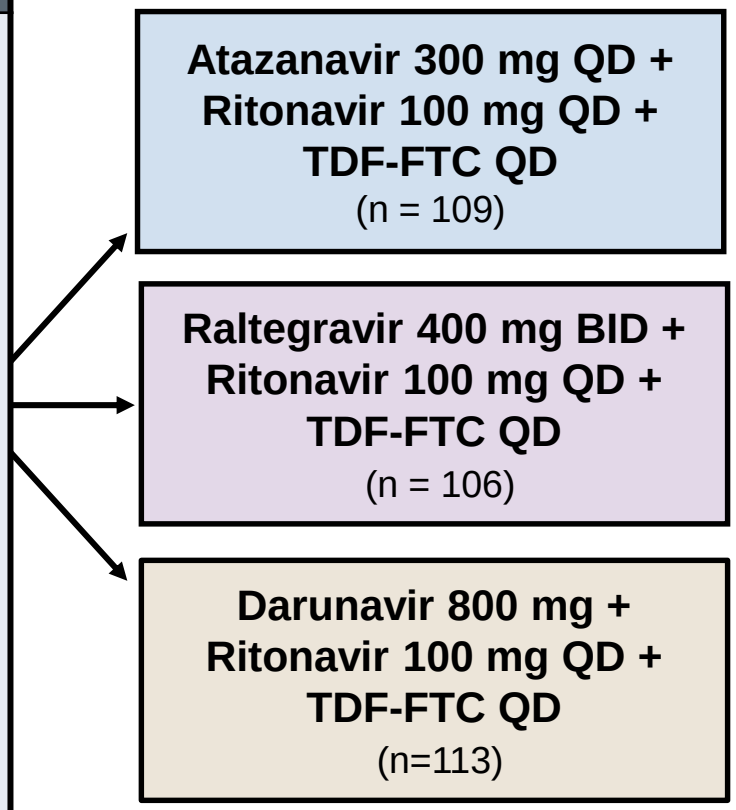
TDF/FTC + [Atazanavir/r or Darunavir/r or Raltegravir]

ACTG 5260s (Substudy of 5257)

Raltegravir vs Darunavir/r vs Atazanavir/r
ACTG 5260s (substudy of ACTG 5257): Study Design

Study Design: ACTG 5260s

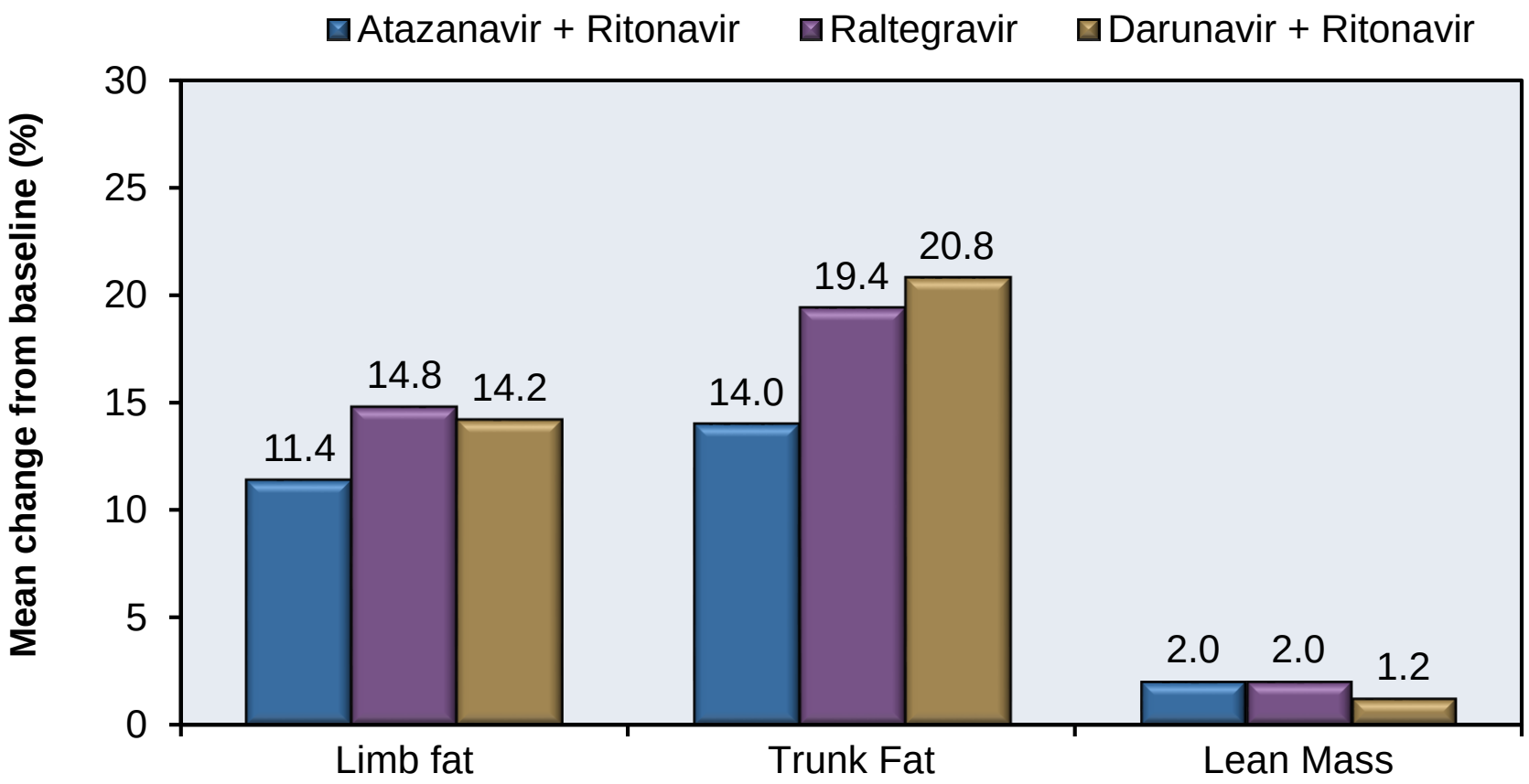
- **Background**: Substudy of an open-label, randomized, phase 3 trial with objectives of comparing cardiovascular markers, changes in immune activation, and effects on body composition of 3 NNRTI-sparing antiretroviral regimens
- **Inclusion Criteria (n = 328)**
  - Substudy of ACTG 5257
  - Exclusions:
    DM, or
    Uncontrolled thyroid disease, or
    Use of lipid lowering therapy
- **Treatment Arms**
  - ATV 300 mg + RTV 100 mg + TDF-FTC QD
  - RAL 400 mg BID + TDF-FTC QD
  - DRV 800 mg QD + RTV 100 mg QD+ TDF-FTC QD



Source: McComsey GA, et al. Clin Infect Dis. 2016;62:853-62.

Raltegravir vs Darunavir/r vs Atazanavir/r
ACTG 5260s (substudy of ACTG 5257): Result

Week 96: Changes in Measures of Body Composition



Source: McComsey GA, et al. Clin Infect Dis. 2016;62:853-62.

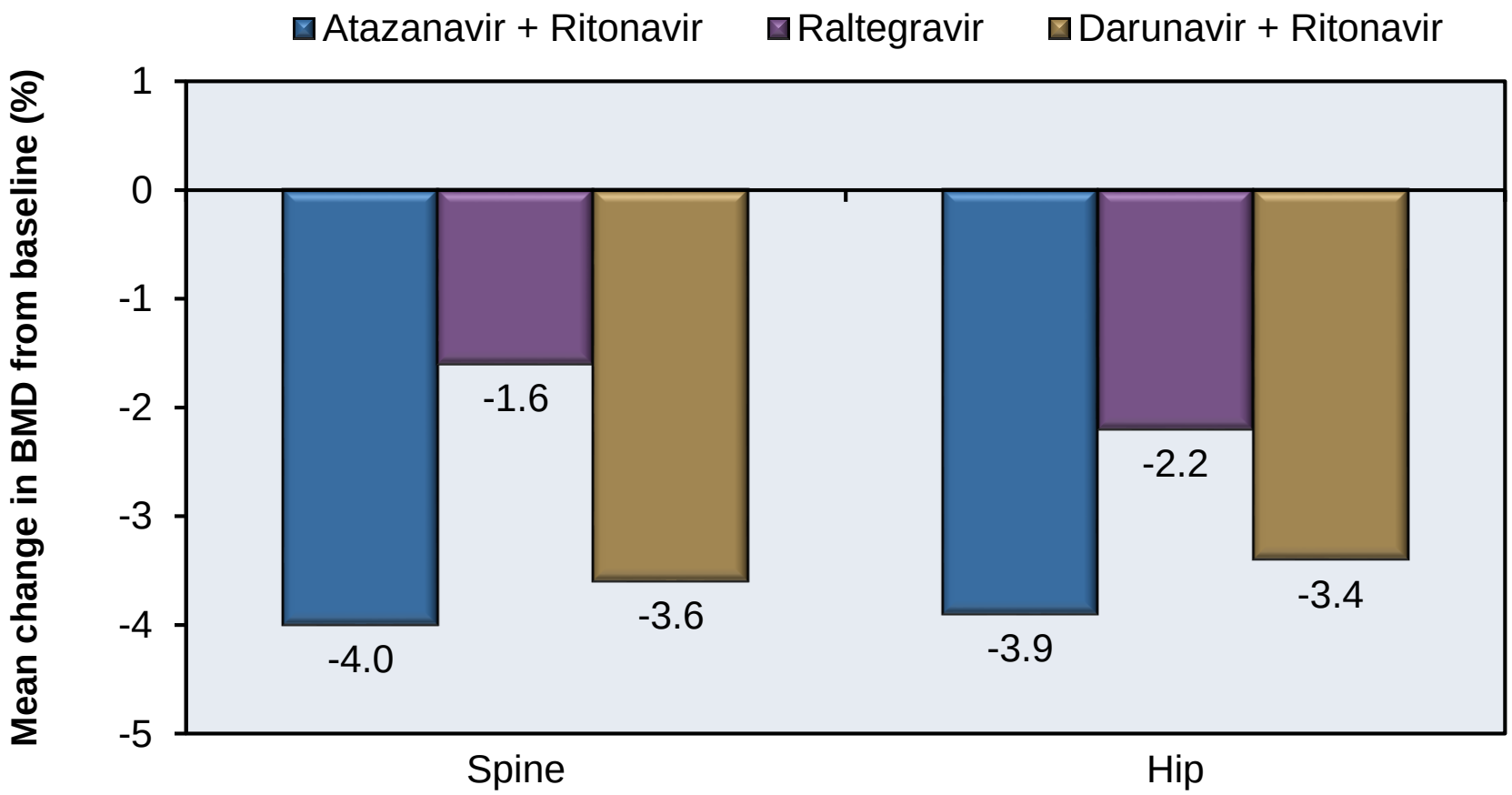
Raltegravir vs Darunavir/r vs Atazanavir/r
ACTG 5260s (substudy of ACTG 5257): Conclusions

Conclusions: "In treatment-naive participants initiating ART with TDF/FTC, no differences in lean mass and regional fat were found with RAL when compared with ATV/r or DRV/r over 96 weeks."

Source: McComsey GA, et al. Clin Infect Dis. 2016;62:853-62.

Raltegravir vs Darunavir/r vs Atazanavir/r
ACTG 5260s (substudy of ACTG 5257): Result

Week 96: Changes in Bone Mineral Density



Source: Brown TT, et al. J Infect Dis. 2015;212:1241-9.

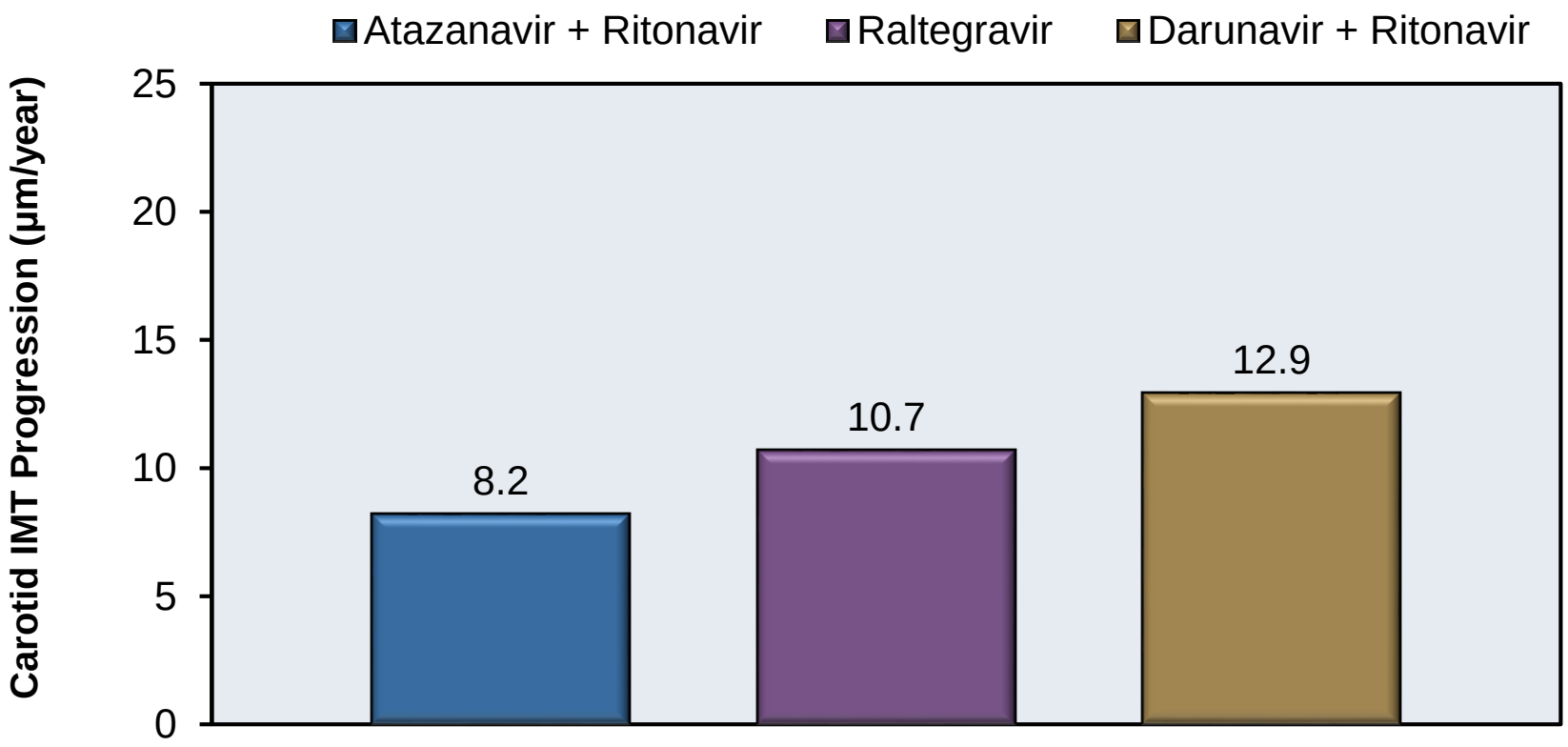
Raltegravir vs Darunavir/r vs Atazanavir/r
ACTG 5260s (substudy of ACTG 5257): Conclusions

Conclusions: "BMD losses 96 weeks after ART initiation were similar in magnitude among patients receiving PIs, ATV/r, or DRV/r but lowest among those receiving RAL. Inflammation and immune activation/senescence before ART initiation independently predicted subsequent BMD loss."

Source: Brown TT, et al. J Infect Dis. 2015;212:1241-9.

Raltegravir vs Darunavir/r vs Atazanavir/r
ACTG 5260s (substudy of ACTG 5257): Result

After Week 112: Progression in Carotid Intimal Media Thickness (IMT)



Source: Stein JH, et al. AIDS. 2015;29:1775-83.

Raltegravir vs Darunavir/r vs Atazanavir/r
ACTG 5260s (substudy of ACTG 5257): Conclusions

Conclusion: "In ART-naive HIV-infected individuals at low cardiovascular disease risk, carotid IMT progressed more slowly in participants initiating ATV/r than those initiating DRV/r, with intermediate changes associated with RAL. This effect may be due, in part, to hyperbilirubinemia."

Source: Stein JH, et al. AIDS. 2015;29:1775-83.

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.

The content in this slide set does not represent the official views of the U.S. Department of Health and Human Services, Health Resources & Services Administration.

National HIV Curriculum

AETC AIDS Education & Training Center Program
National Coordinating Resource Center