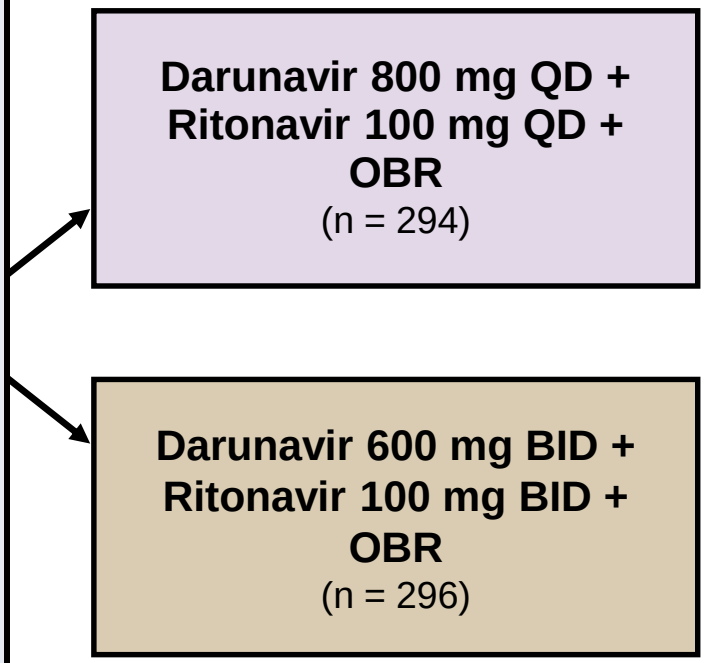
Darunavir/r Once Daily or Twice Daily in Treatment Experienced

ODIN Trial

Once-daily versus Twice-daily Darunavir in Treatment-Experienced
ODIN: Study Design

Study Design: ODIN

- **Background**: Randomized, open-label phase 3 trial to compare once daily versus twice-daily dosing of ritonavir-boosted darunavir in treatment-experienced patients with HIV infection
- **Inclusion Criteria (n = 590)**
  - Age ≥18
  - On stable antiretroviral regimen for >12 weeks
  - HIV RNA >1000 copies/mL
  - CD4 count >200 cells/mm^3
  - No darunavir resistance-associated mutations
- **Treatment Arms**
  - Darunavir 800 mg QD + RTV 100 mg QD + OBR*
  - Darunavir 600 mg BID + RTV 100 mg BID + OBR*



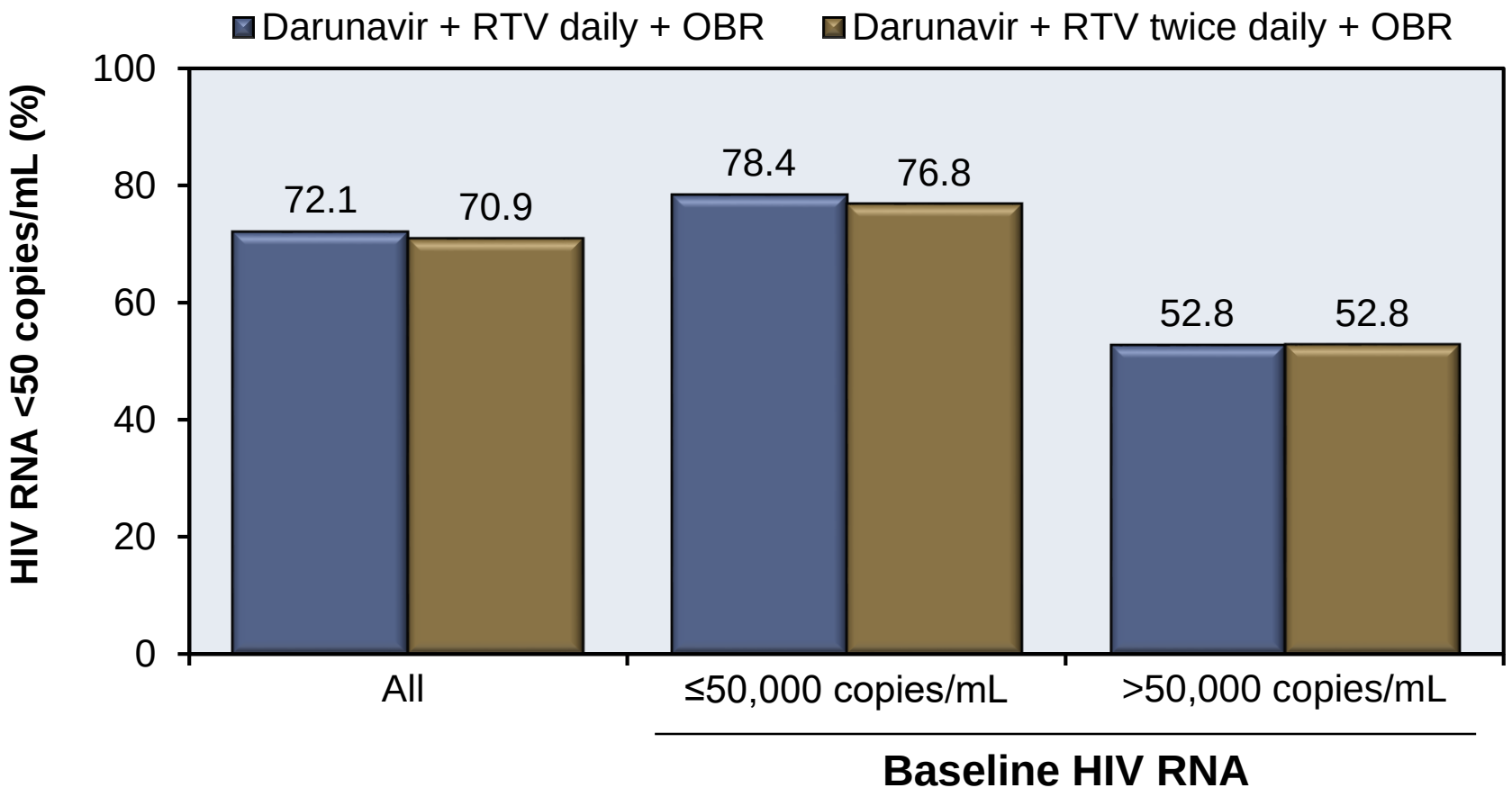
ODIN = Once-daily **D**arunavir **I**n treatment-experie**N**ced patients

*OBR = Optimized background regimen: ≥2 nucleoside reverse transcriptase inhibitors, investigator-selected

Source: Cahn P, et al. AIDS. 2011;25:929-39.

Once Daily versus Twice Daily Darunavir in ARV-Experienced ODIN: Result

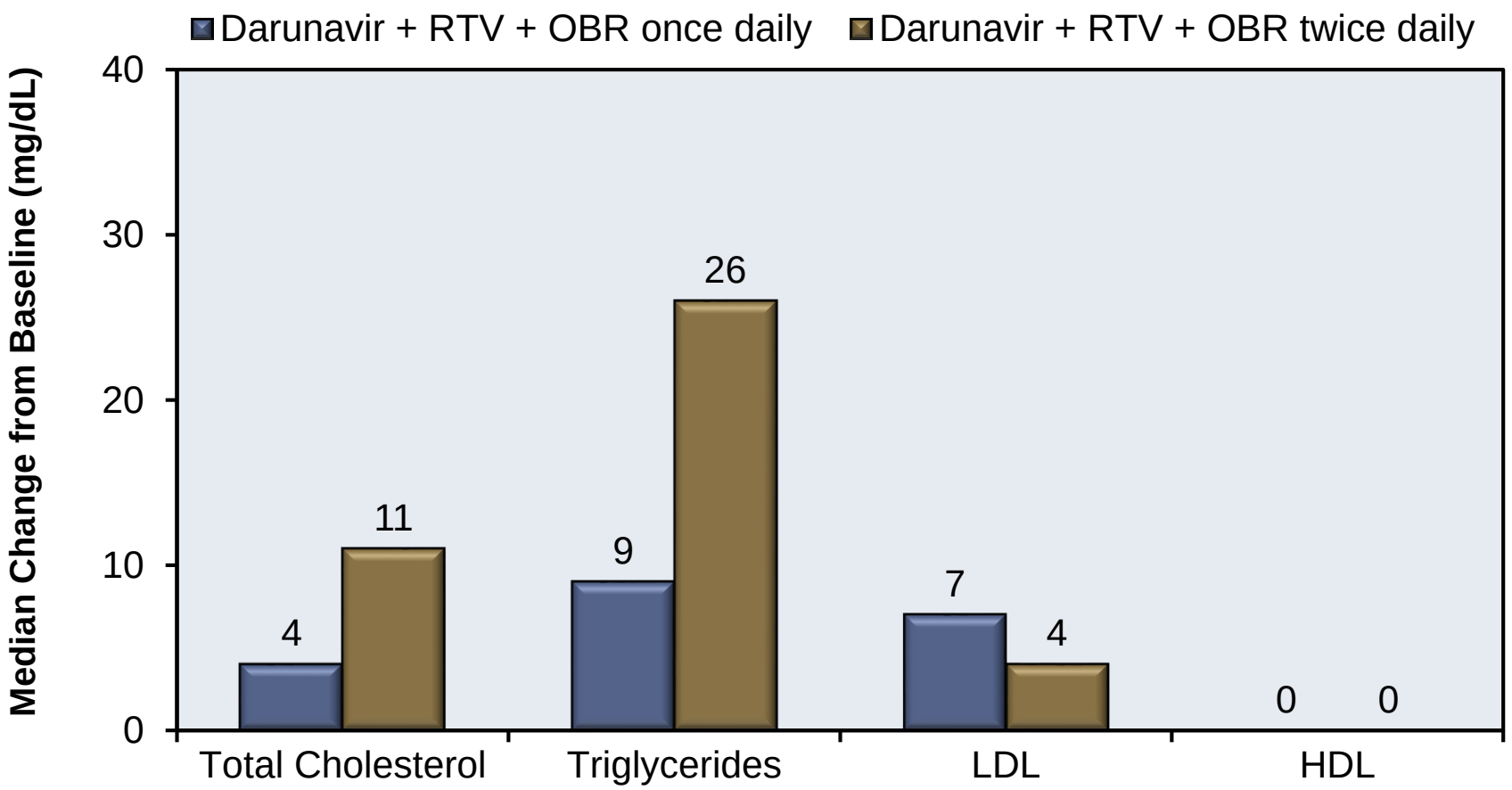
Week 48: Virologic Response (ITT-TLOVR)



Source: Cahn P, et al. AIDS. 2011;25:929-39.

Once Daily versus Twice Daily Darunavir in ARV-Experienced ODIN: Result

Week 48: Changes in Lipids from Baseline



Source: Cahn P, et al. AIDS. 2011;25:929-39.

Once Daily versus Twice Daily Darunavir in ARV-Experienced
ODIN: Result

Adverse Events Possibly Related to Darunavir + Ritonavir (≥ 2% incidence in either arm)		
Symptom	**DRV + RTV + OBR once daily** (n = 294)	**DRV + RTV + OBR twice daily** (n = 296)
Nausea	10.9%	10.5%
Vomiting	9.9%	15.2%
Diarrhea	3.1%	5.4%
Rash	2.7%	2.7%
Headache	1.4%	2.0%

Source: Cahn P, et al. AIDS. 2011;25:929-39.

Once Daily versus Twice Daily Darunavir in ARV-Experienced
ODIN: Conclusions

Conclusion: “Once-daily DRV/r 800/100 mg was non-inferior in virologic response to twice-daily DRV/r 600/100 mg at 48 weeks in treatment-experienced patients with no DRV RAMs, and with a more favorable lipid profile. These findings support use of once-daily DRV/r in this population.”

Source: Cahn P, et al. AIDS. 2011;25:929-39.

Acknowledgment

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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