Switch to RPV-TDF-FTC from Ritonavir-boosted PI Regimen

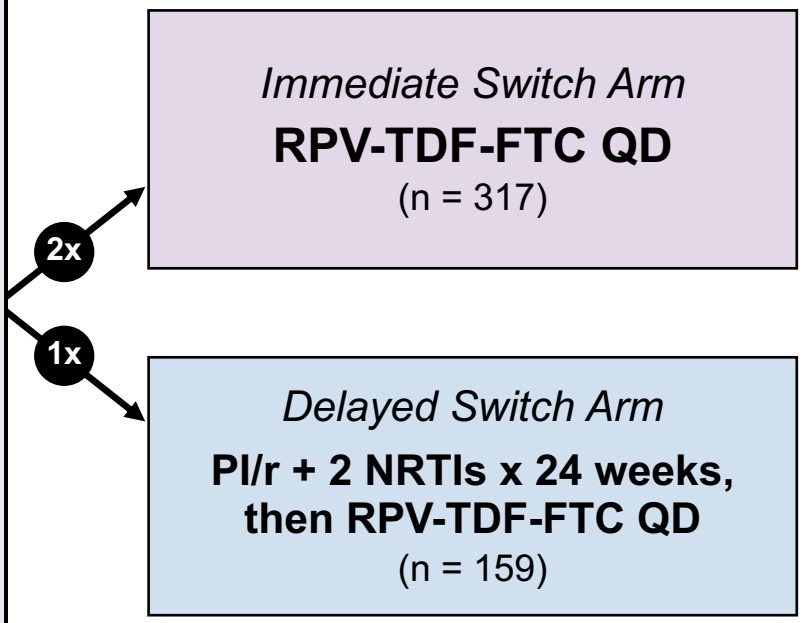
# SPIRIT STUDY

National HIV Curriculum

# Switch to RPV-TDF-FTC from Ritonavir-boosted PI Regimen
## Spirit: Study Design

### Study Design: SPIRIT STUDY

- **Background**: Open label, randomized phase 3b trial evaluating switching from ritonavir-boosted PI plus 2 NRTIs to single-tablet regimen of rilpivirine-tenofovir DF-emtricitabine once daily
- **Inclusion Criteria (n = 476)**
  - Age ≥18 years
  - HIV RNA <50 copies/mL for ≥6 months
  - On PI/r ≥6 months
  - No known resistance to study drugs
- **Treatment Arms**
  - Rilpivirine-tenofovir DF-emtricitabine
  - Ritonavir-boosted PI + 2 NRTIs x 24 weeks, then rilpivirine-tenofovir DF-emtricitabine




**Source: Palella FJ, et al. AIDS. 2014;28:335-44.**

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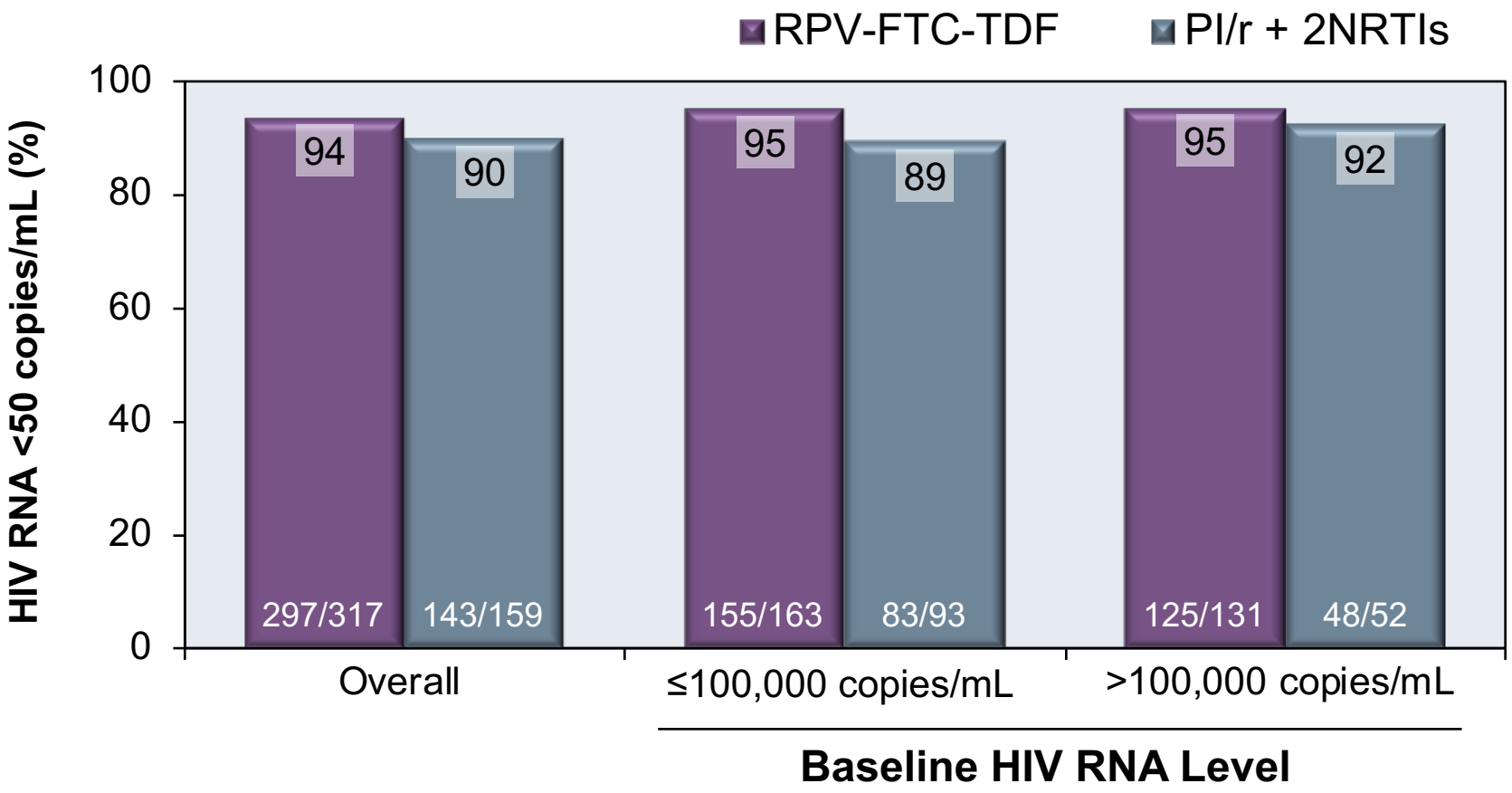
## Spirit: Study Design

| Baseline Antiretroviral Regimens | | |
|---|---|---|
| | **Immediate Switch Arm** (n = 317) | **Delayed Switch Arm** (n= 159) |
| **NRTI at Screening** | | |
| TDF-FTC | 80.4% | 81.8% |
| ABC-3TC | 13.2% | 13.2% |
| **Ritonavir-Boosted PI at Screening** | | |
| Atazanavir | 38.5% | 34.0% |
| Lopinavir | 30.6% | 36.5% |
| Darunavir | 19.9% | 20.8% |
| Fosamprenavir | 7.9% | 7.5% |
| Saquinavir | 1.9% | 1.3% |

**Source: Palella FJ, et al. AIDS. 2014;28:335-44.**

# Switch to RPV-TDF-FTC from Ritonavir-boosted PI Regimen
# Spirit: Result

## Week 24 Virologic Response (Intent-to-Treat Analysis)




Source: Palella FJ, et al. AIDS. 2014;28:335-44.

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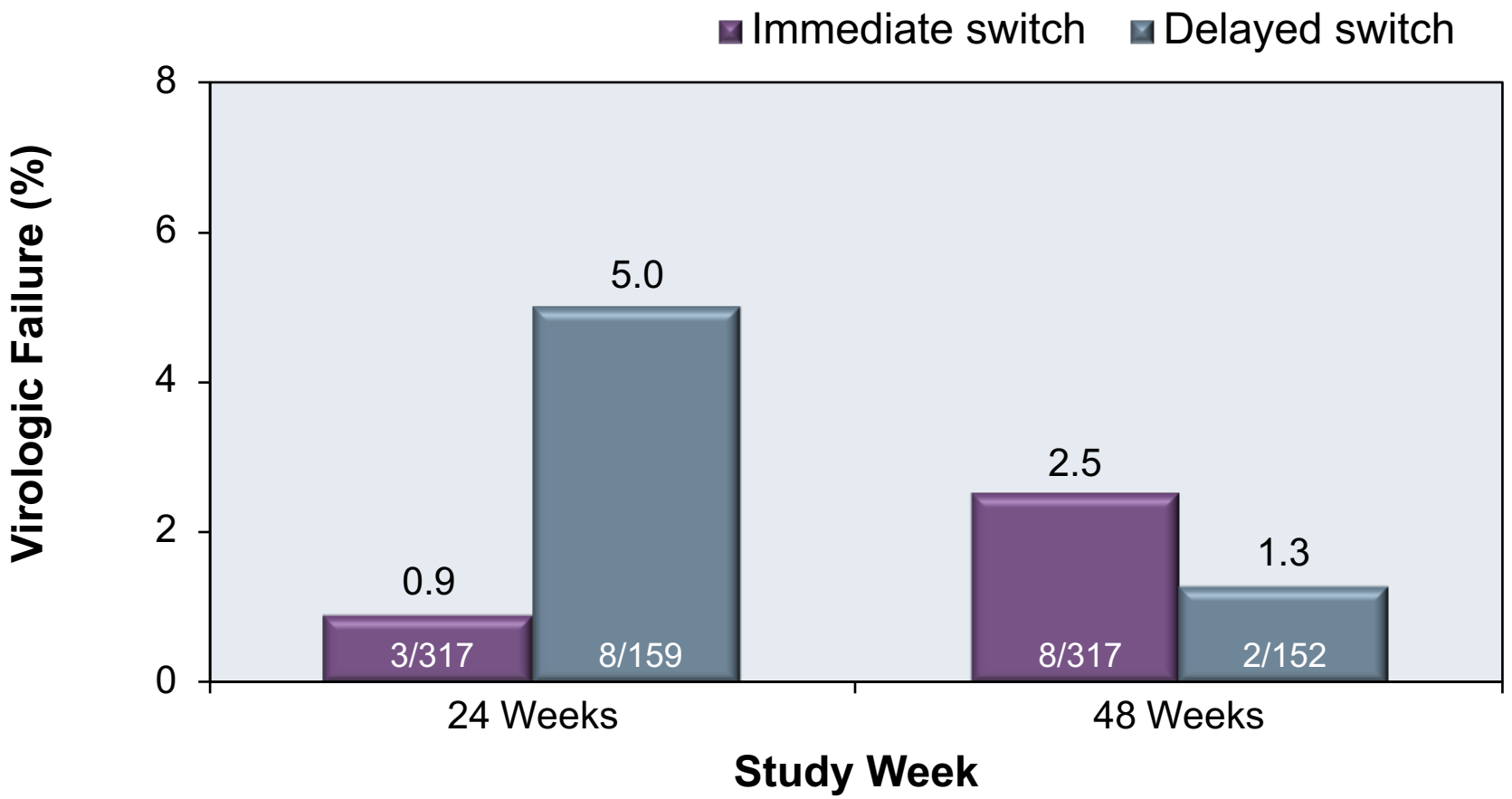
## Spirit: Result

### Virologic Failure (HIV RNA ≥50 copies/mL) at Weeks 24 and 48




Source: Palella FJ, et al. AIDS. 2014;28:335-44.

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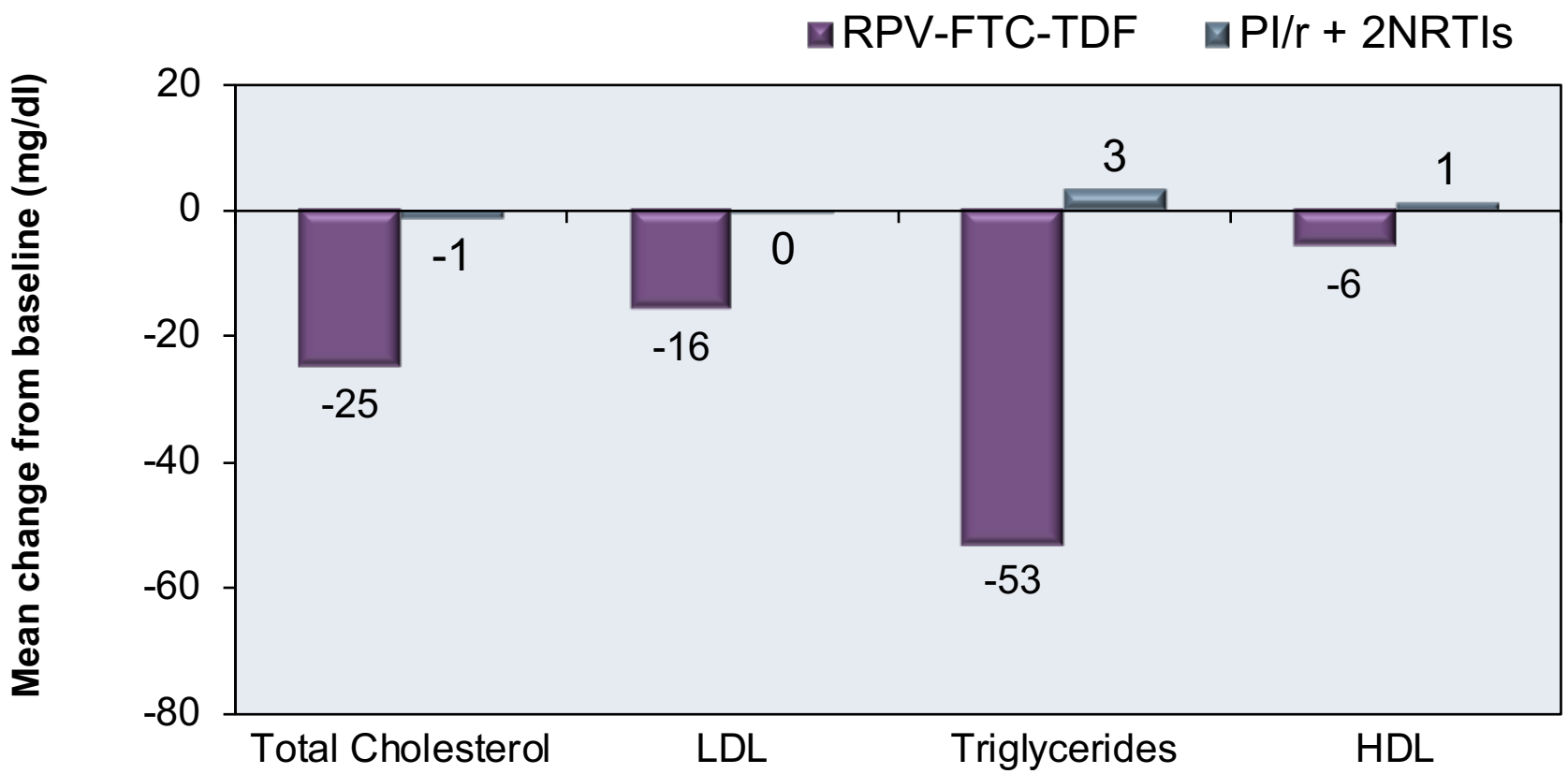
## Spirit: Result

### Week 24: Change in Plasma Lipids from Baseline




Source: Palella FJ, et al. AIDS. 2014;28:335-44.

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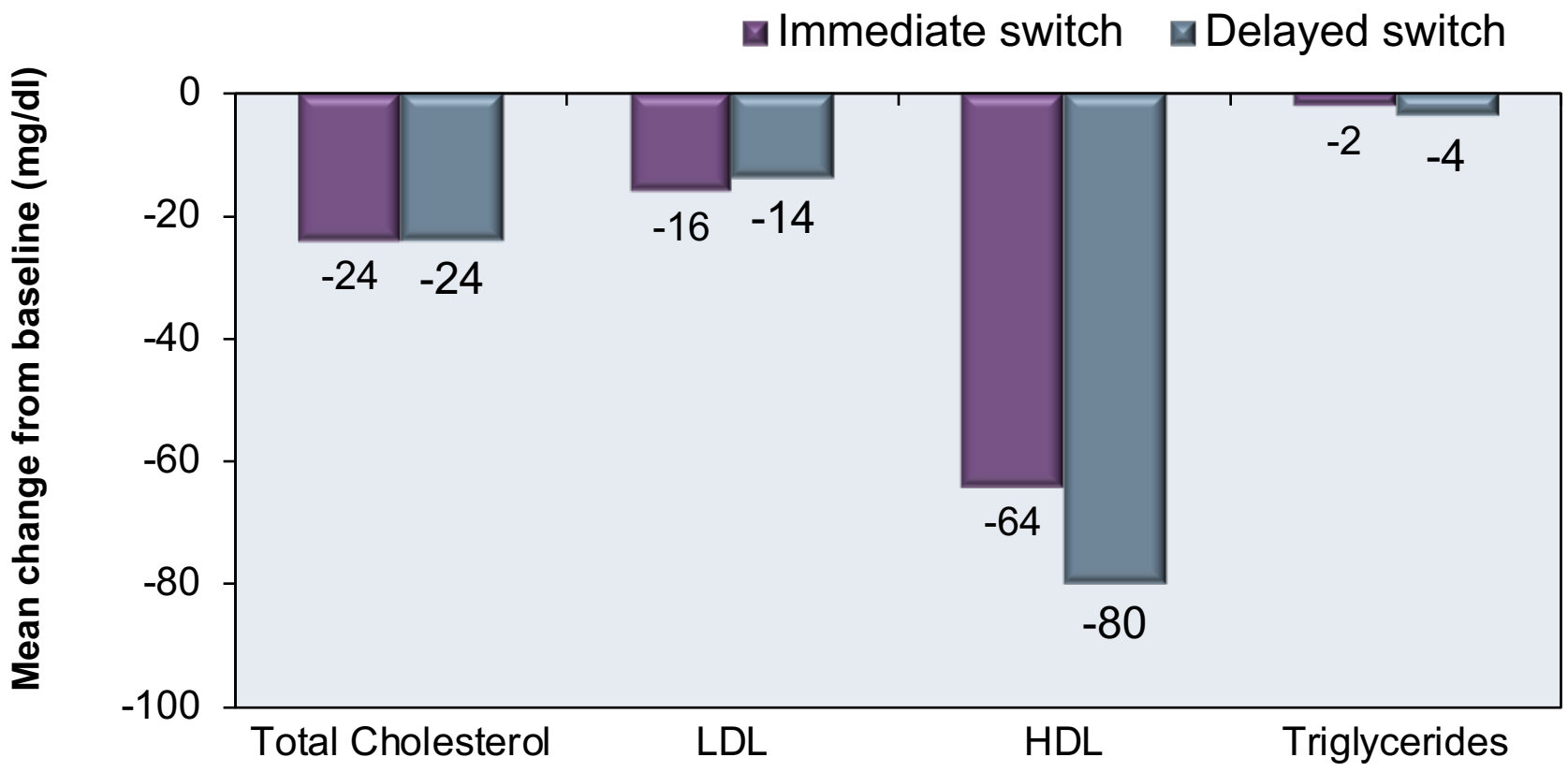
## Spirit: Result

### Week 48: Change in Plasma Lipids from Baseline




Source: Palella FJ, et al. AIDS. 2014;28(3):335-44.

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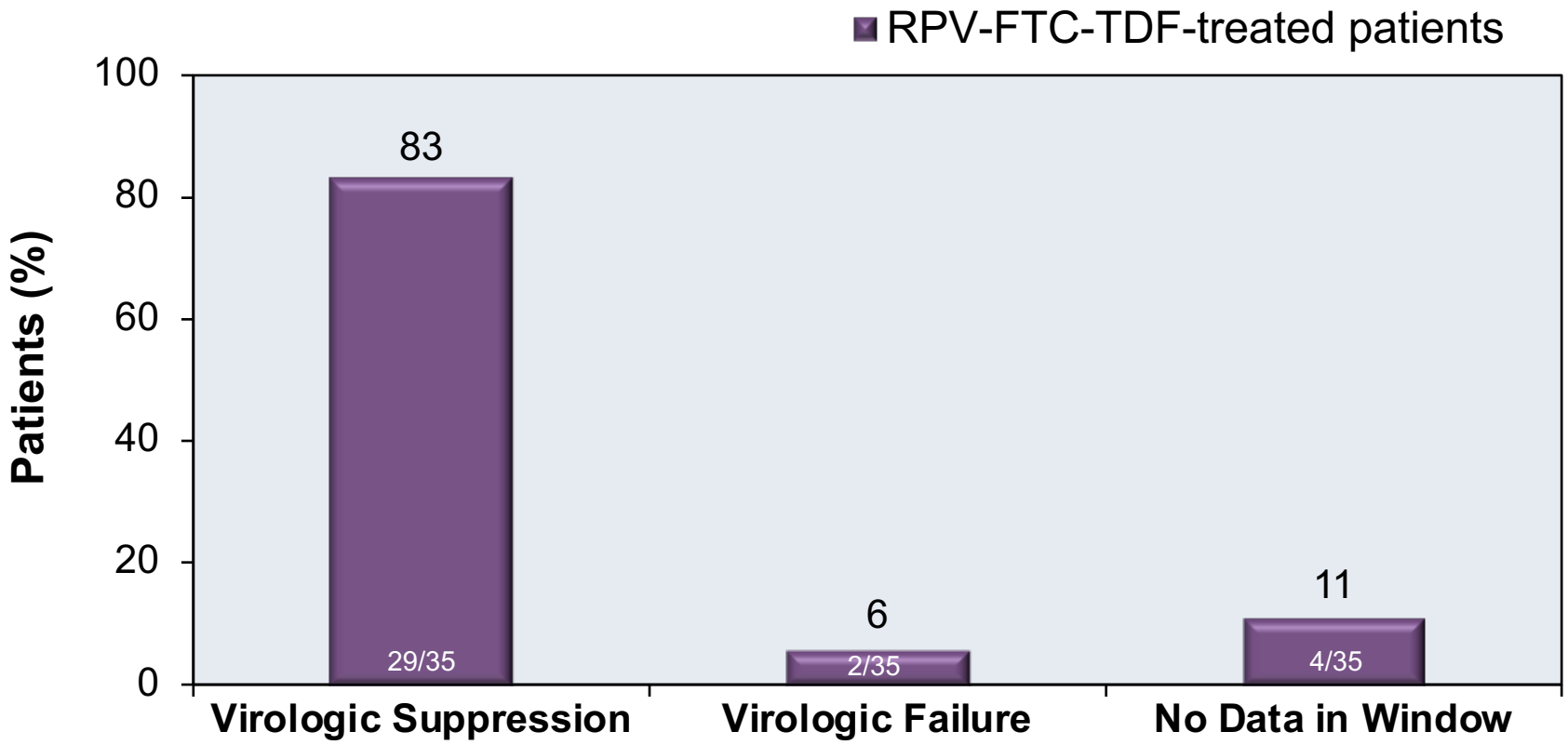
# Spirit: Result

## Week 48 Virologic Outcomes in Patients with Resistance Mutations*




*Pre-existing NRTI or NNRTI resistance mutations by baseline proviral DNA or historical RNA genotype

**Source: Porter DP, et al. HIV Clin Trials. 2016;17:29-37.**

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# Switch to RPV-TDF-FTC from Ritonavir-boosted PI Regimen
## Spirit: Conclusions

**Conclusion**: "Switching to the STR RPV/FTC/TDF from an RTV-boosted protease inhibitor regimen in virologically suppressed, HIV-1-infected participants maintained virologic suppression with a low risk of virologic failure, while improving total cholesterol, LDL, and triglycerides."

**Source: Palella FJ, et al. AIDS. 2014;28:335-44.**

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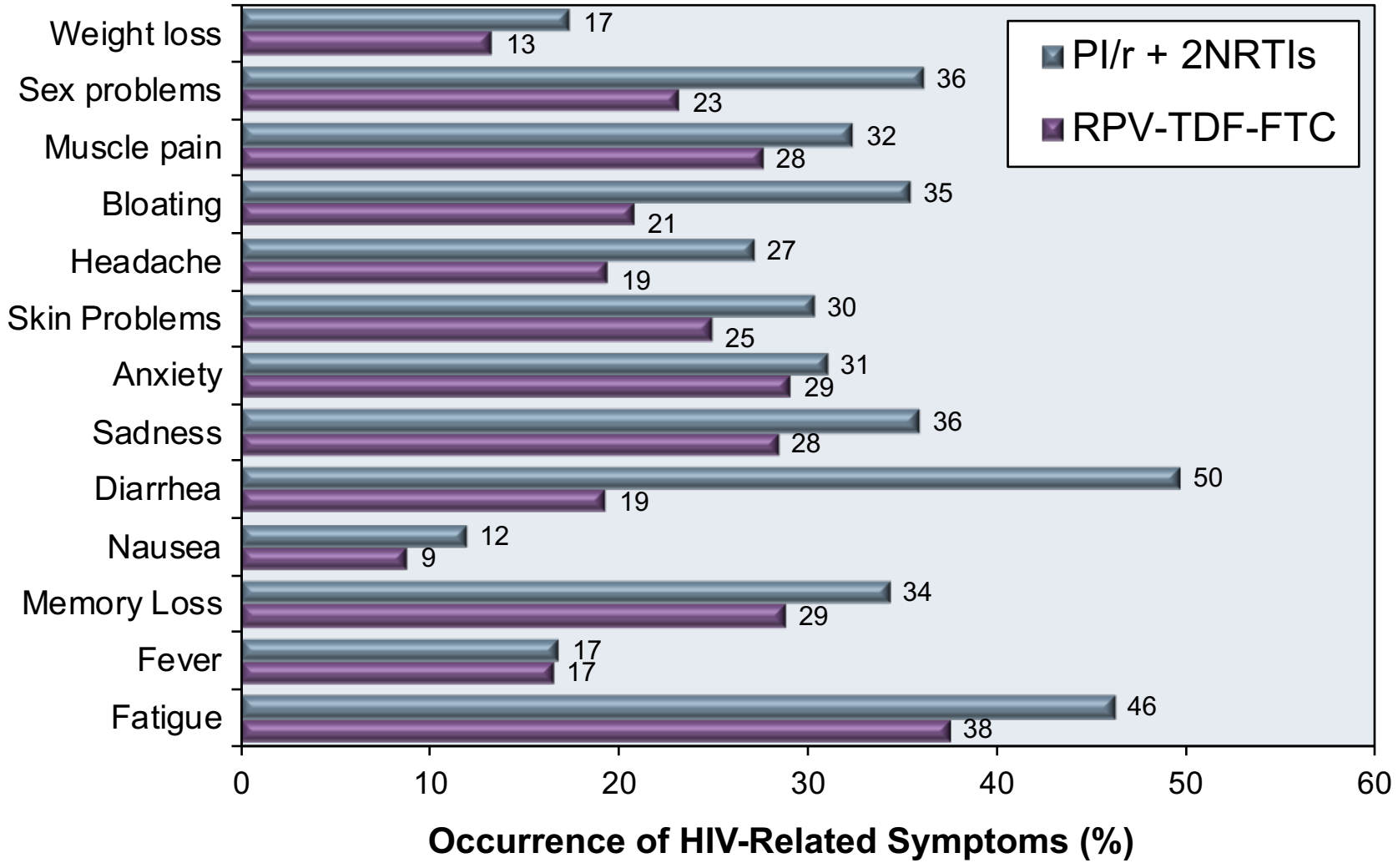
## Spirit: Patient-Reported Outcomes




Source: Brunetta J, et al. Patient. 2015;8:257-67.

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# Switch to RPV-TDF-FTC from Ritonavir-boosted PI Regimen
## Spirit: Conclusions

**Conclusions**: “These data suggest that switching to the STR RPV/FTC/TDF from a PI-based multi-pill regimen is associated with greater patient-reported treatment satisfaction and improved tolerability in HIV-1-infected, virologically suppressed individuals.”

**Source: Brunetta J, et al. Patient. 2015;8:257-67.**

# Acknowledgment

The **National HIV Curriculum** is an AIDS Education and Training Center (AETC) Program supported by the Health Resources and Services Administration (HRSA) of the U.S. Department of Health and Human Services (HHS) as part of an award totaling $800,000 with 0% financed with non-governmental sources. This project is led by the University of Washington's Infectious Diseases Education and Assessment (IDEA) Program.

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