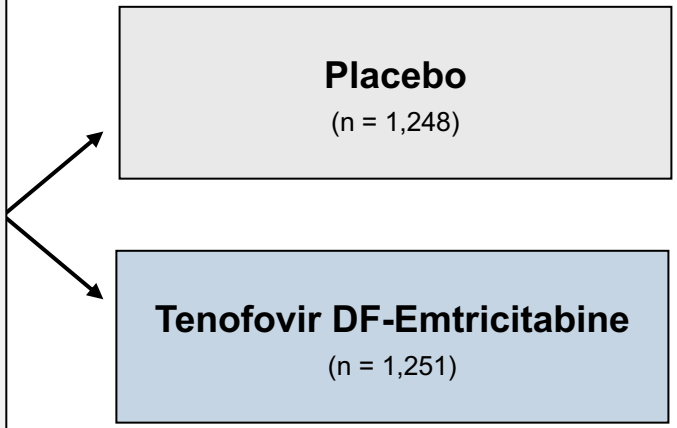
TDF-FTC versus Placebo as HIV PrEP for MSM and TGW

iPrEx Trial

TDF-FTC versus Placebo as HIV PrEP for MSM and TGW
iPrEx Trial: Study Design

- **Background**: Randomized, placebo-controlled trial that examined efficacy and safety of tenofovir DF-emtricitabine as preexposure prophylaxis for HIV-seronegative men (or transgender women) who have sex with men
- **Inclusion Criteria** (2,499 enrolled)
  - 18 years of age or older
  - HIV-seronegative
  - Men (or transgender women) who have sex with men
  - Evidence of high-risk for HIV acquisition
- **Treatment Arms**
  - Placebo: 1 pill daily
  - Tenofovir DF-emtricitabine: 1 pill daily

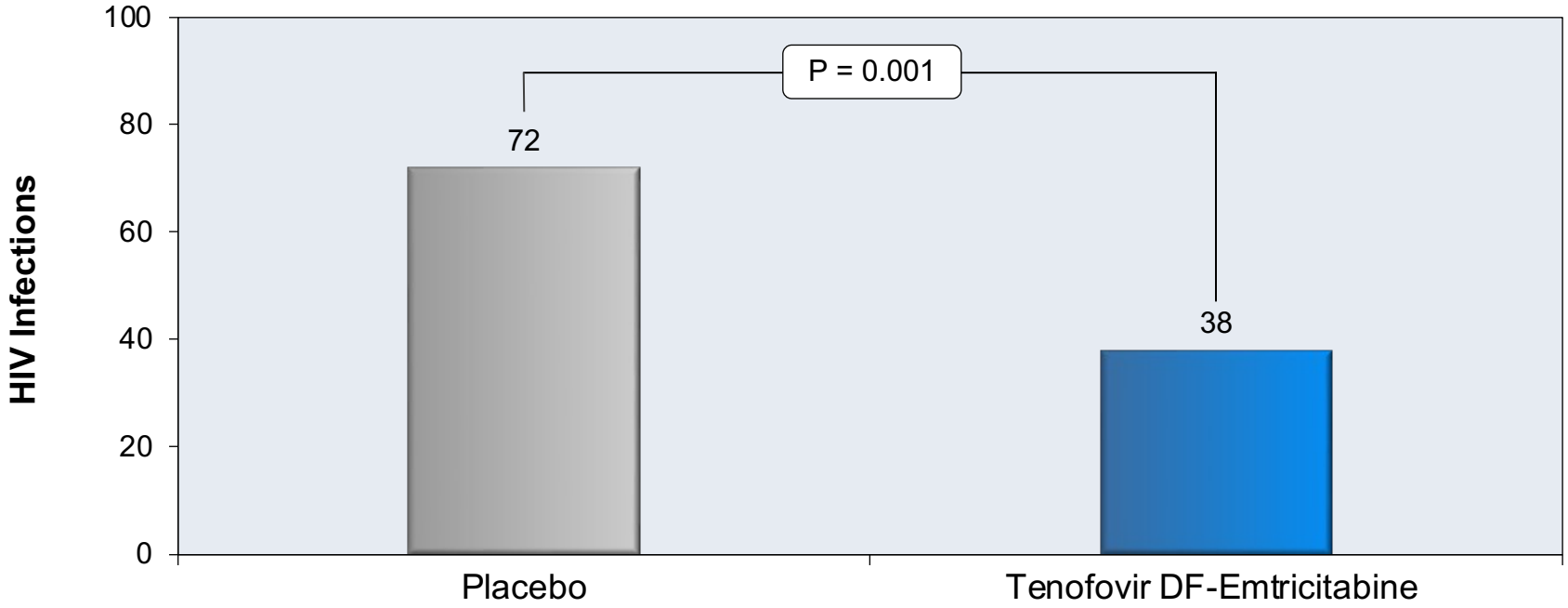


Note: 10 subjects had HIV infection at onset of study

Source: Grant RM, et al. N Engl J Med. 2010;363:2587-99.

TDF-FTC versus Placebo as HIV PrEP for MSM and TGW
iPrEx Trial: Results

Number of HIV Infections: Intent-to-Treat Analysis



Source: Grant RM, et al. N Engl J Med. 2010;363:2587-99.

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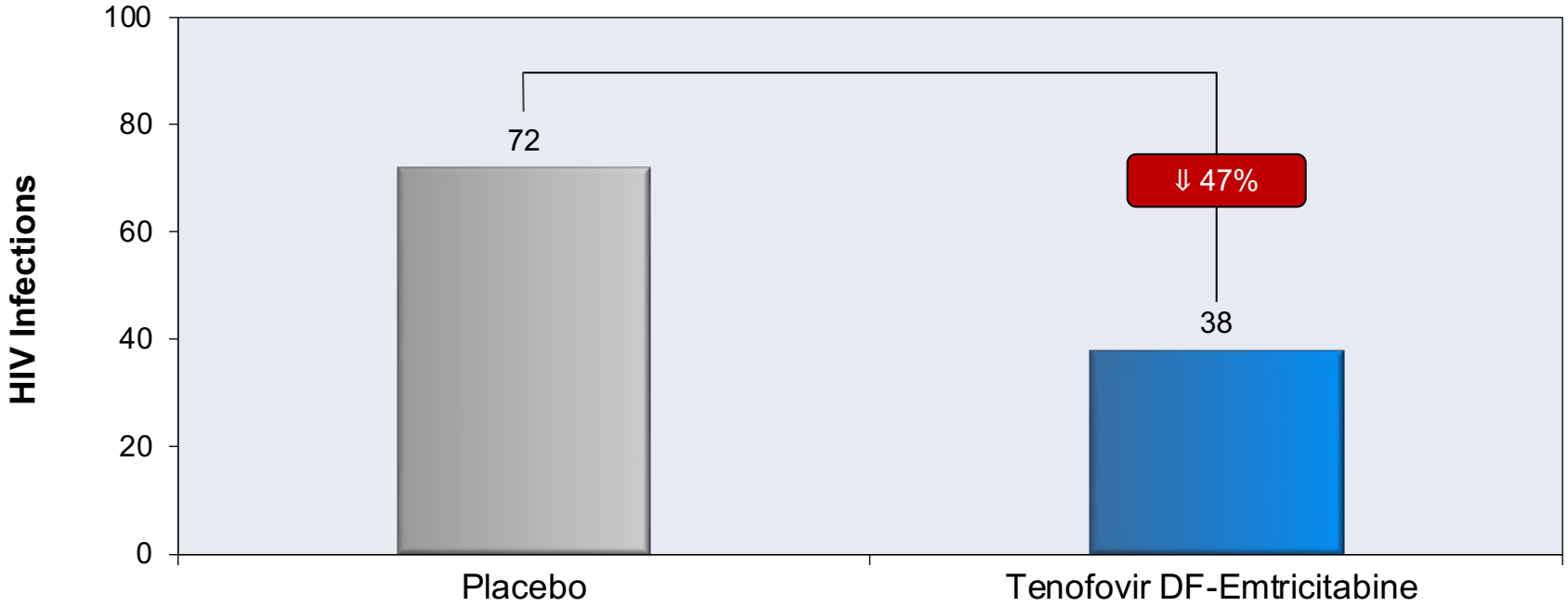
iPrEx Trial: Results

Risk Reduction Compared with Placebo: Intent-to-Treat Analysis



Source: Grant RM, et al. N Engl J Med. 2010;363:2587-99.

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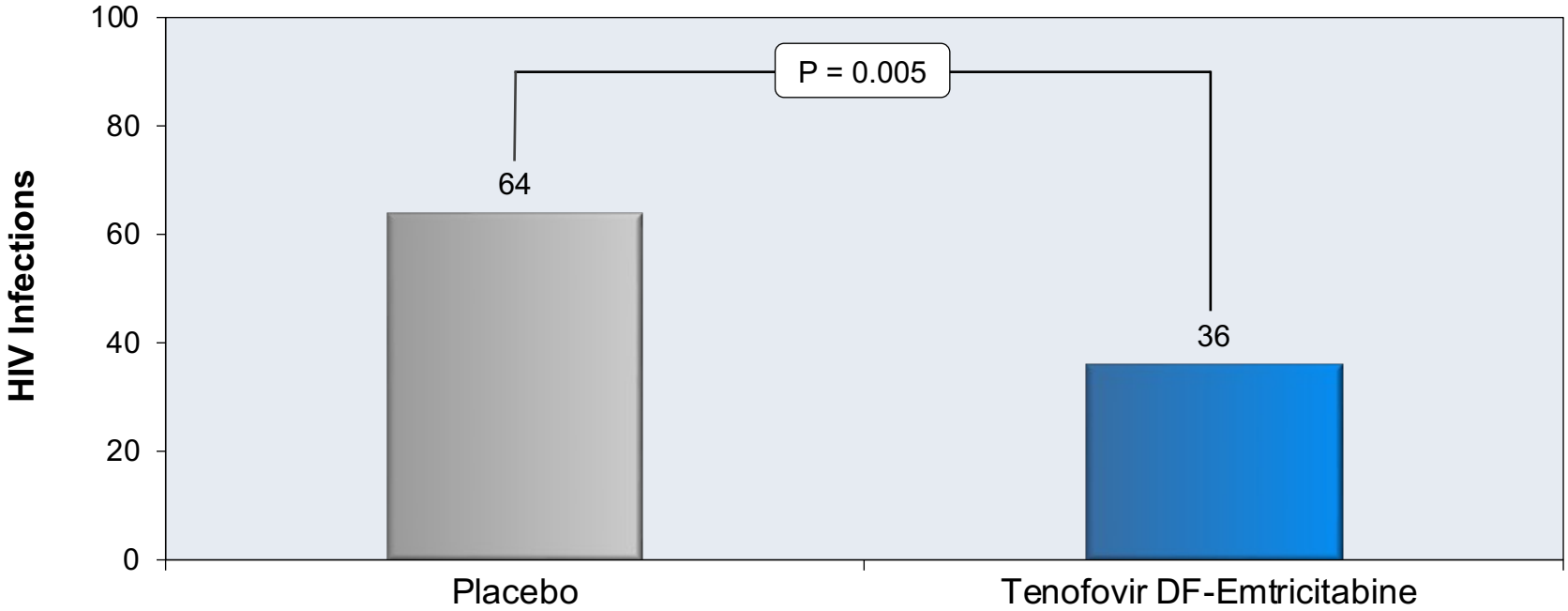
iPrEx Trial: Results

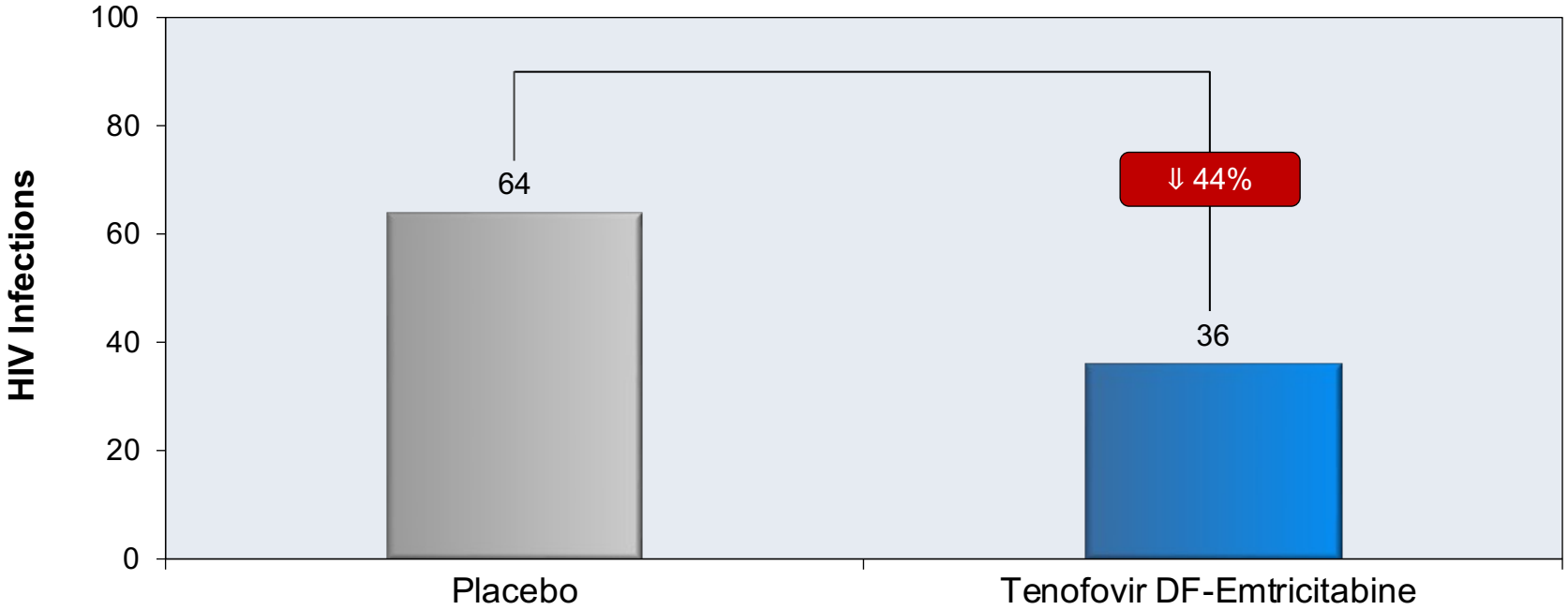
Number of HIV Infections: Modified Intent-to-Treat Analysis



Source: Grant RM, et al. N Engl J Med. 2010;363:2587-99.

TDF-FTC versus Placebo as HIV PrEP for MSM and TGW
iPrEx Trial: Results

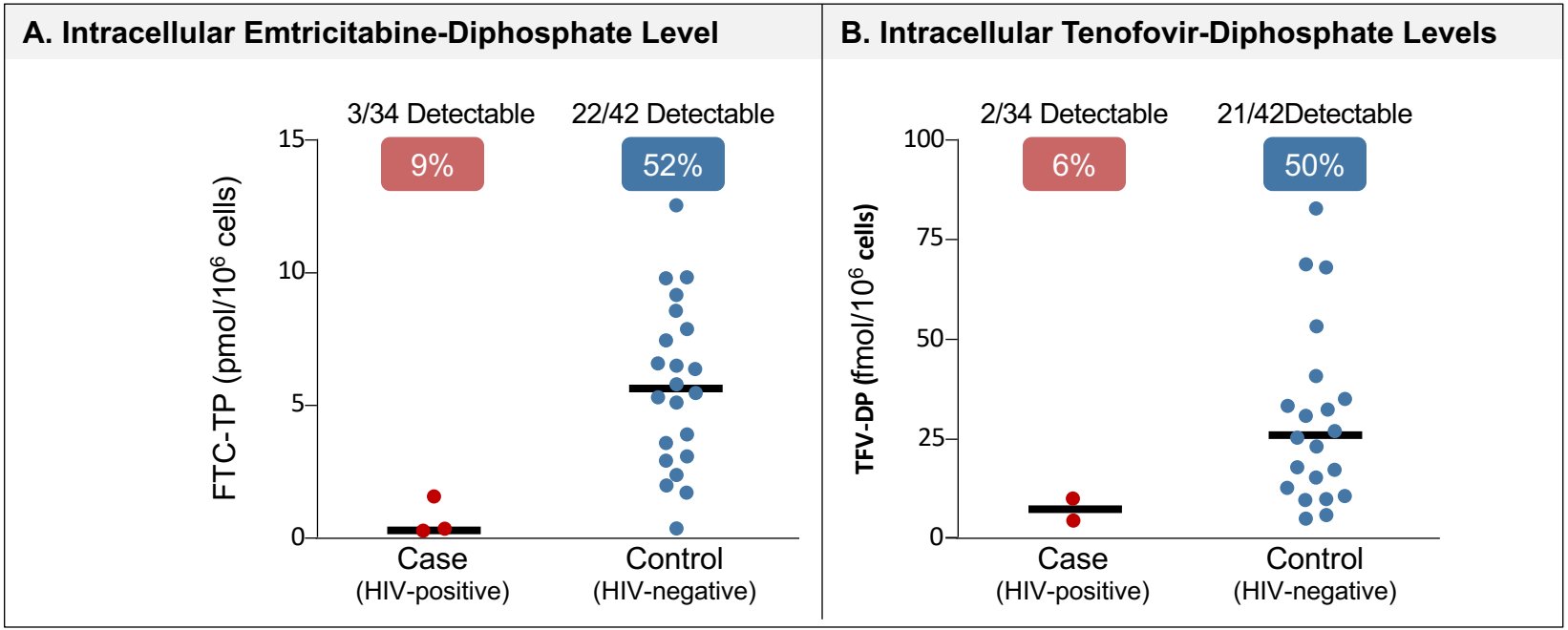
Risk Reduction Compared with Placebo: Modified Intent-to-Treat Analysis



Source: Grant RM, et al. N Engl J Med. 2010;363:2587-99.

TDF-FTC versus Placebo as HIV PrEP for MSM and TGW iPrEx Trial: Results

Detectable Drug Levels in Patients on Tenofovir DF-Emtricitabine



Adjusted relative risk reduction (any detectable level) = 95%

Source: Grant RM, et al. N Engl J Med. 2010;363:2587-99.

TDF-FTC versus Placebo as HIV PrEP for MSM and TGW iPrEx Trial: Conclusions

Conclusions: “Oral tenofovir DF-emtricitabine provided protection against the acquisition of HIV infection among the subjects. Detectable blood levels strongly correlated with the prophylactic effect.”

Source: Grant RM, et al. N Engl J Med. 2010;363:2587-99.

Acknowledgments

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National HIV Curriculum

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