

ABC-ZDV-3TC versus LPV-RTV + ZDV-3TC for PMTCT

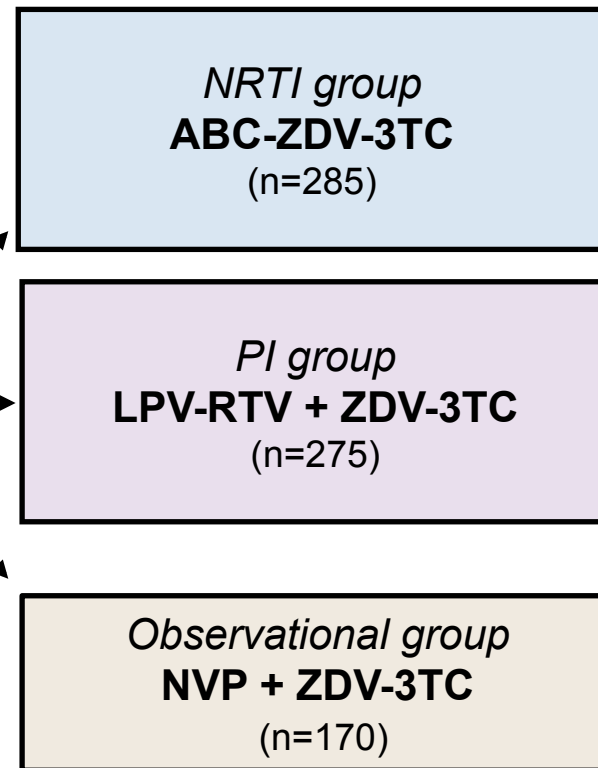
# **Mma Bana Trial**

# ABC-ZDV-3TC versus LPV-RTV + ZDV-3TC for PMTCT

## Mma Bana: Study Design

### Study Design: Mma Bana

- **Background:** Randomized, controlled trial comparing antiretroviral therapy regimens in pregnancy and breastfeeding to evaluate differences in efficacy, pregnancy outcomes, and toxic effects in mothers and infants
- **Inclusion Criteria (n=560 + 170 observational)**
  - HIV-infected pregnant women
  - Treatment-naïve
  - CD4  $\geq 200$  cells/mm<sup>3</sup> for randomized groups
  - CD4  $< 200$  cells/mm<sup>3</sup> for observational group
- **Treatment Arms**
  - *NRTI group*: ABC-ZDV-3TC 300-300-150 mg BID
  - *PI group*: LPV-RTV 400/100 mg BID + ABC-ZDV-3TC 300-300-150 mg BID
  - *Observational group*: NVP + ZDV-3TC 300-150 mg BID

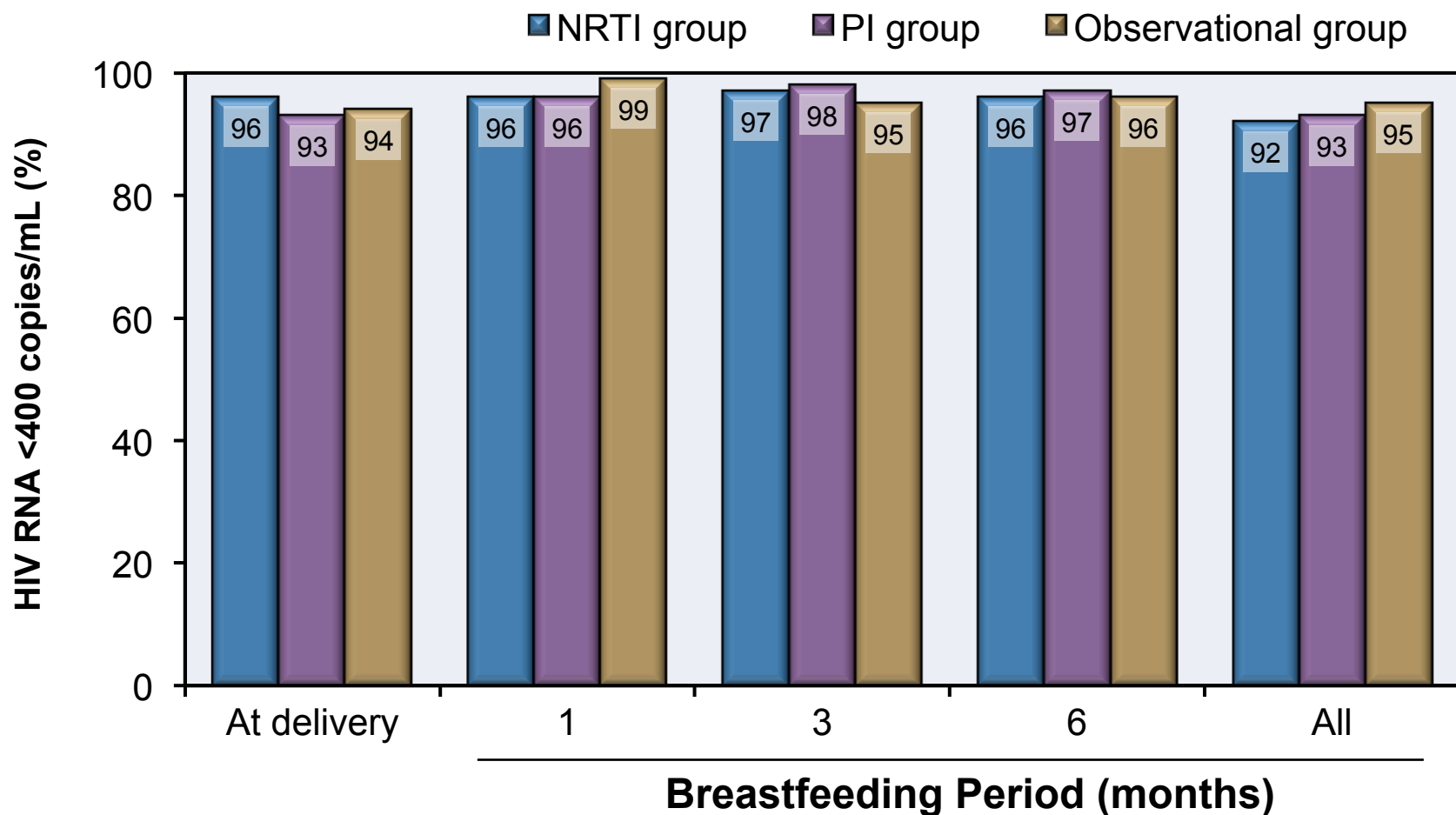


\*Women in NRTI and PI groups treated from 26-34 weeks' gestation through 6 months.  
All infants received single-dose NVP + 4 weeks AZT

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## Mma Bana: Result

Delivery and Breastfeeding Virologic Outcomes, by Study Group

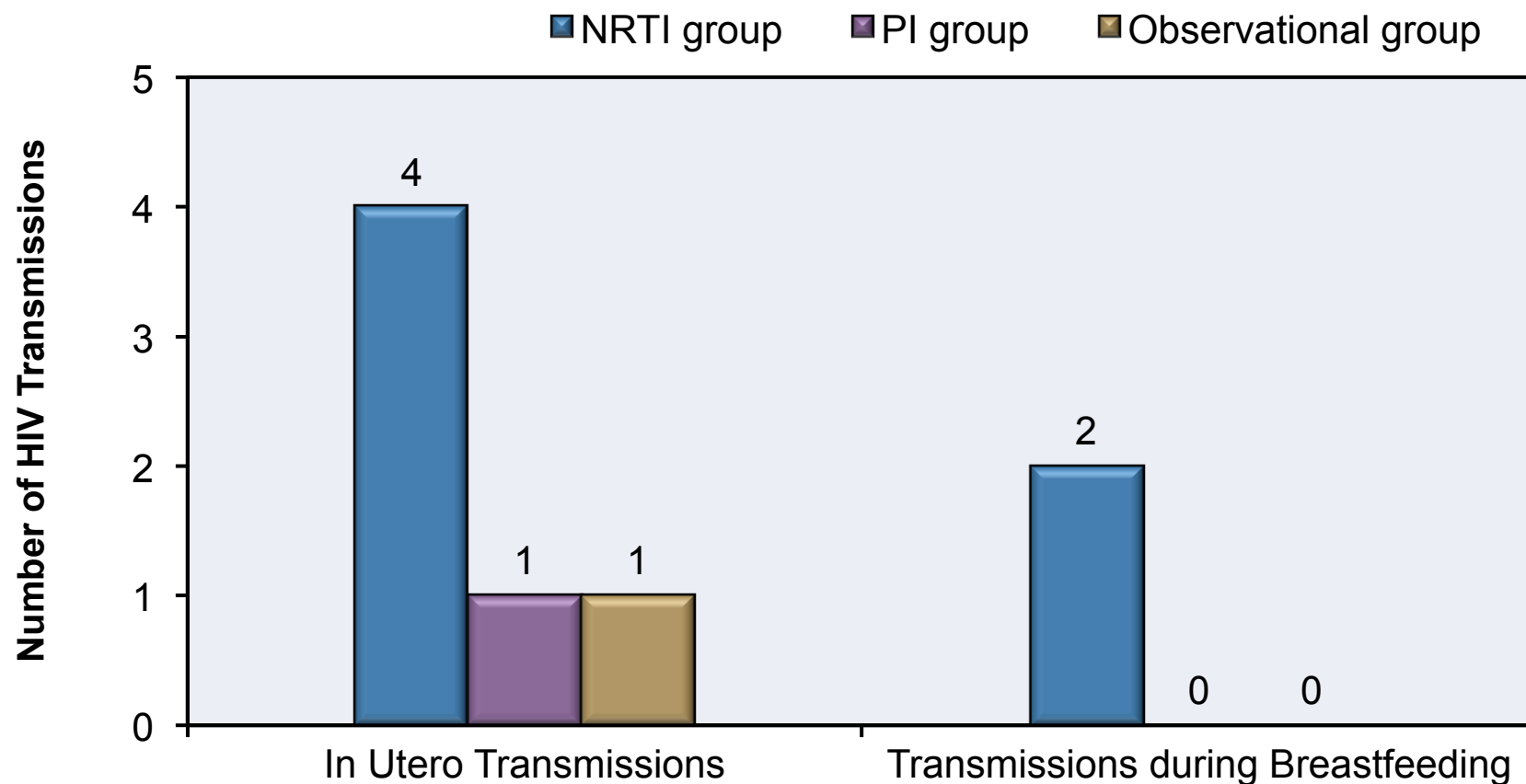


Source: Shapiro RL, et al. N Engl J Med. 2010;362:2282-94.

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## Mma Bana: Result

Through 6 Months Post-Partum: Mother-to-Child HIV Transmissions



# ABC/ZDV/3TC versus LPV-RTV + ZDV/3TC for PMTCT

## Mma Bana: Results

Mma Bana: Adverse Events at 6 Months			
Events in Mothers	NRTI group (n = 285)	PI group (n = 275)	Control group (n = 170)
Death	<1	0	2
≥1 grade 3 or 4 diagnosis	6	6	15
Any grade 3 or 4 laboratory event	15	12	18
Common grade 3 or laboratory event			
Anemia	5	4	11
Neutropenia	6	2	11
Elevated ALT, AST, or total bilirubin	1	1	1
Elevated level of amylase or lipase	2	3	8
Treatment-modifying adverse event	2	2	11

# ABC/ZDV/3TC versus LPV-RTV + ZDV/3TC for PMTCT

## Mma Bana: Results

Mma Bana: Adverse Events at 6 Months			
Events in Infants	NRTI group (n = 283)	PI group (n = 270)	Control group (n = 156)
Death	2	3	4
≥1 grade 3 or 4 diagnosis	10	6	8
Any grade 3 or 4 laboratory event	41	46	41
Common grade 3 or laboratory event			
Anemia	13	16	20
Neutropenia	15	18	22
Elevated ALT, AST, or total bilirubin	12	16	3

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## Mma Bana: Conclusions

**Conclusions:** “All regimens of HAART from pregnancy through 6 months post partum resulted in high rates of virologic suppression, with an overall rate of mother-to-child transmission of 1.1%.”

# 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.*

