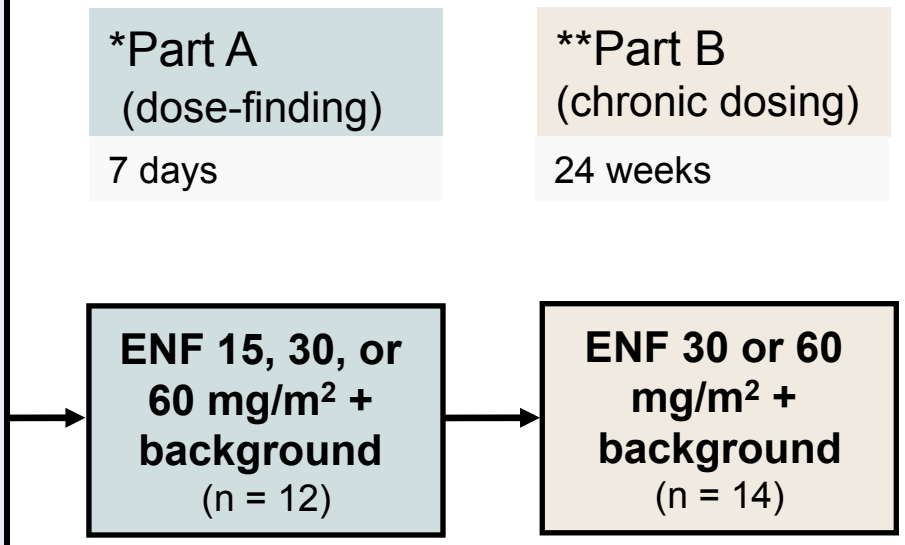
Enfuvirtide in Treatment-Experienced Pediatric Patients

PACTG P1005 Trial

Enfuvirtide (T-20) in Treatment-Experienced Children
PACTG P1005: Study Design

Study Design: PACTG P1005

- **Background**: Two-part, phase I/II open-label, dose-finding and chronic dosing study of enfuvirtide (ENF, T-20) in treatment-experienced children with HIV infection
- **Inclusion Criteria (n=26)**
  - Age 3 to 12 years old
  - On stable ART regimen with 2NRTIs +/- NNRTI or PI ≥16 weeks
  - HIV RNA >10,000 copies/mL
  - Limited exposure to NNRTIs and PIs
- **Treatment Arms**
  - Part A: Single injection of enfuvirtide 15 mg/m^2, 30 mg/m^2, or 60 mg/m^2 + background regimen
  - Part B: enfuvirtide 30 mg/m^2 or 60 mg/m^2 + background regimen



*Part A: 3 cohorts of 4 subjects received ENF at each dose. Subjects completing Part A were eligible to enroll in Part B (11 of 12 did so).

**Part B: 3 additional subjects enrolled in Part B. Background regimen changed at day 7 to include new agents

Source: Church JA, et al. Pediatr Infect Dis J. 2002;21:653-9.

Enfuvirtide (T-20) in Treatment-Experienced Children
PACTG P1005: Result (Part A)

Enfuvirtide Plasma Concentration 12 h after Single Subcutaneous Injection		
Enfuvirtide Dosage (mg/m^2)	Plasma Enfuvirtide Concentration (ng/mL)	No. of subjects ≥1000 ng/mL Plasma Enfuvirtide
15	322.6 +/- 323.1*	0
30	591.3 +/- 275.1	2
60	1809.8 +/- 391.7	4

*Mean +/- SD

Source: Church JA, et al. Pediatr Infect Dis J. 2002;21:653-9.

Enfuvirtide (T-20) in Treatment-Experienced Children
PACTG P1005: Result (Part A)

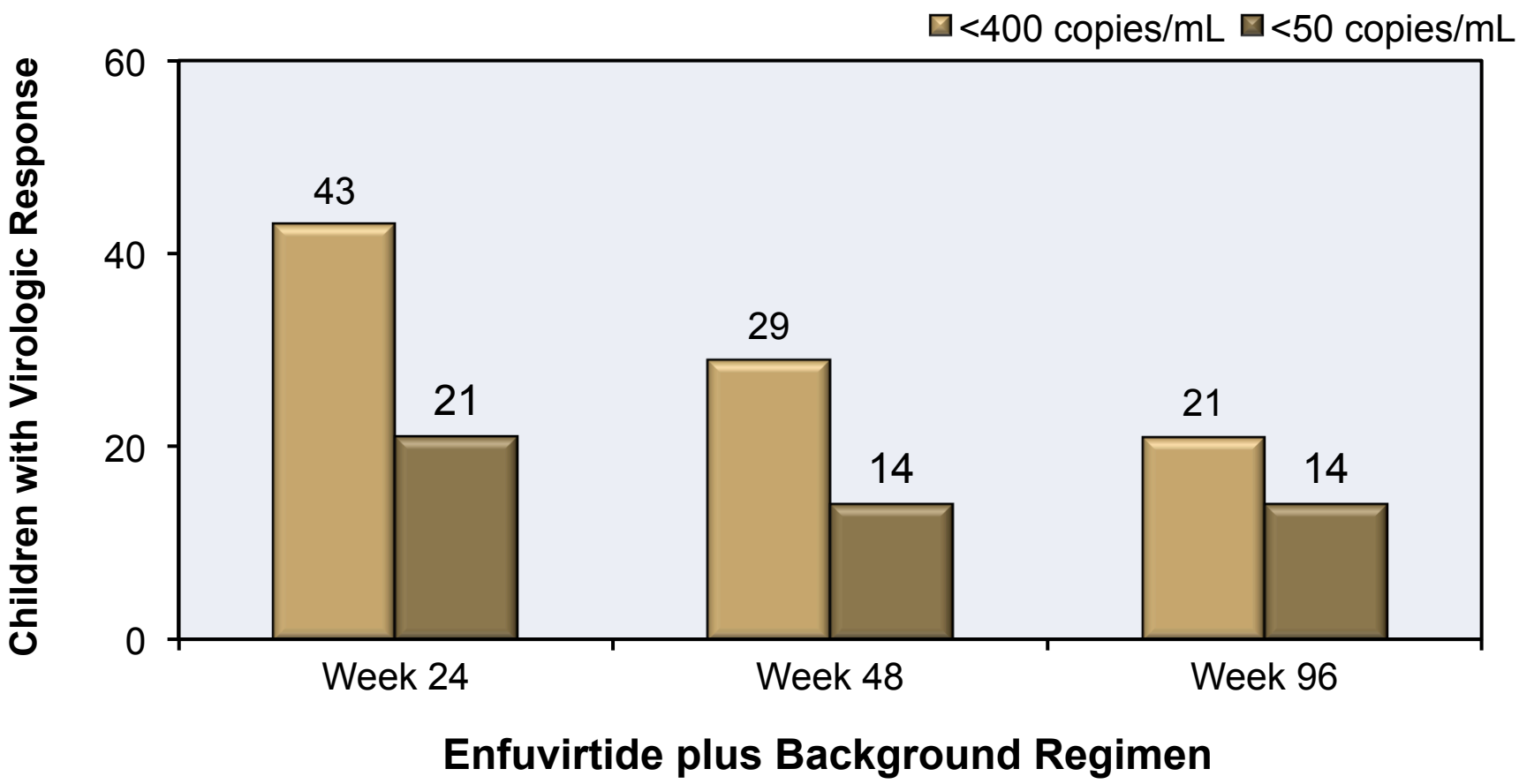
T-20 Trough Plasma Concentrations 12 h after 7 Days of BID SC Dosing

T-20 Dosage (mg/m^2)	No. of subjects	Concentration (ng/mL)		No. of subjects with T-20 >1000 ng/mL
		Mean +/- SD	Range	
30	4	870+/- 306	470-1323	1/4
60	6	2363 +/- 1597	268-4875	6/8

Source: Church JA, et al. Pediatr Infect Dis J. 2002;21:653-9.

Enfuvirtide (T-20) in Treatment-Experienced Children
PACTG P1005: Result (Part B)

Week 96: Virologic Response (ITT Analysis)



Source: Church JA, et al. Pediatr Infect Dis J. 2002;21:653-9.

Enfuvirtide (T-20) in Treatment-Experienced Children
PACTG P1005: Result (Part B)

Number of Children with Local Injection Site Reactions					
Worst Grade	Erythema	Induration	Pain	Lymph Node Swelling	All Reactions
Grade 1	1	5	4	2	5
Grade 2	4	2	4	0	5
Grade 3	1	0	0	0	1
All grades	6	7	8	2	11

Source: Church JA, et al. Pediatr Infect Dis J. 2002;21:653-9.

Enfuvirtide in Treatment-Experienced Pediatric Patients
PACTG P1005: Conclusions

Conclusions: “These results indicate that a 24-week regimen of twice daily s.c. dosing of T-20 in HIV-1-infected children is safe and tolerable and that it is associated with suppression of HIV-1 replication during 24 weeks of administration.”

Source: Church JA, et al. Pediatr Infect Dis J. 2002;21:653-9.

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