

CLINICAL TRIALS NETWORK

**Continuing
Buprenorphine/Naloxone With
Counseling Is More Effective Than
Detoxification With Counseling for
15-21 Year Old Opioid Addicts**

**University of Pennsylvania
And the
National Institute on Drug Abuse**

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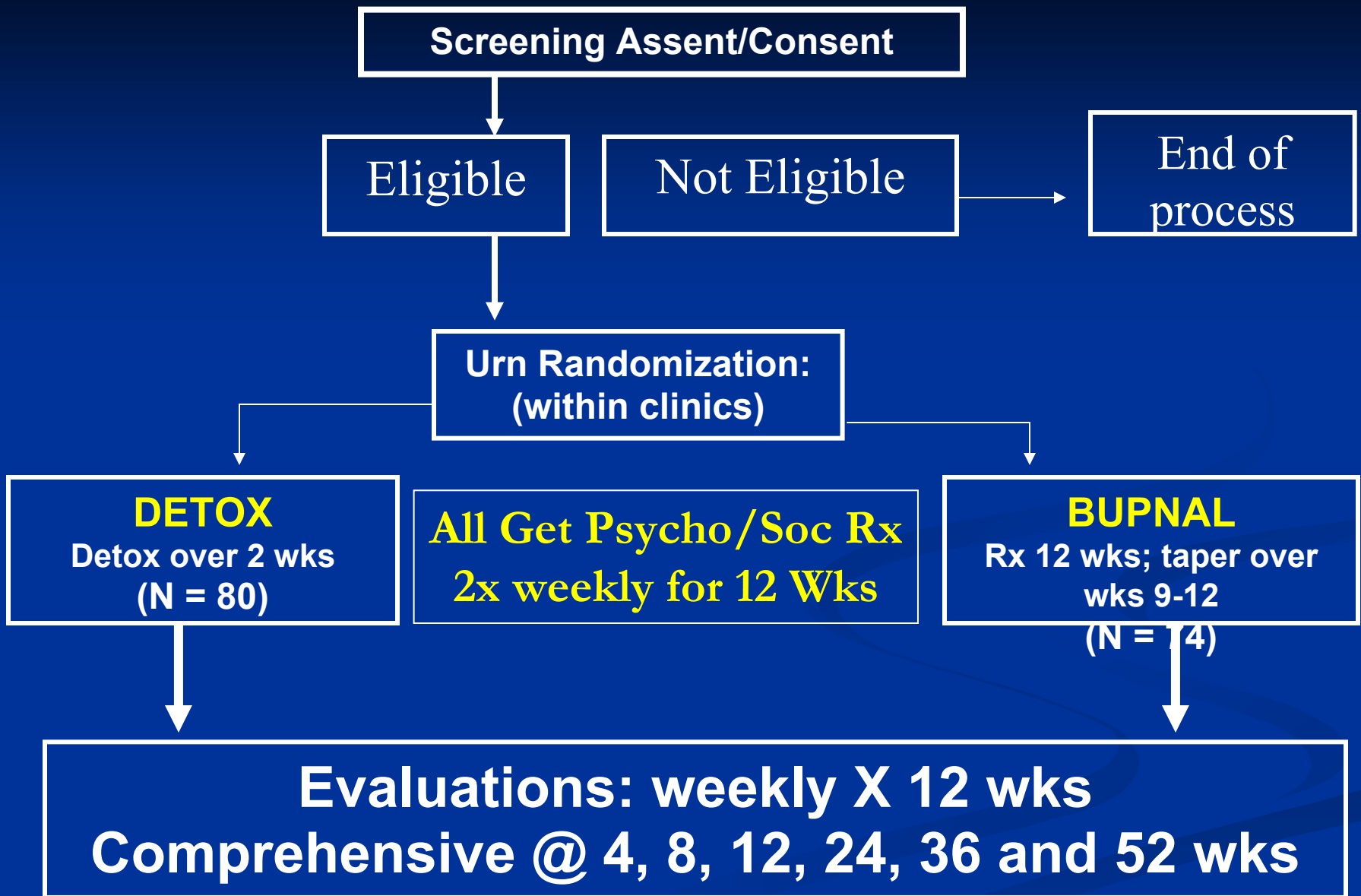
Pennsylvania

Site Investigators

- **Mountain Manor:** Geetha Subramaniam, MD
- **Duke Addictions Program:** Len Handlesman, MD/Ashwin Patkar, MD
- **University of New Mexico:** Michael Bogenschutz, MD (2 sites: Albuquerque & Ayundantes)
- **Brandywine Counseling:** Joseph Glick, MD
- **Mercy Hospital/Portland ME:** Marc Publicker, MD

Background

- Increase in adolescent/young adult opioid use and addiction
- 2006 national survey showed Rx opioids first drugs used illicitly, followed by marijuana
- Most rx options for young, recently-addicted patients are abstinence-oriented (including abstinence from prescribed meds)
 - Entire rx system shifted to outpatient
 - Little availability of residential care



Outcomes

- **Primary: opioid + urines at weeks 4, 8, 12**
- **Secondary:**
 - Dropout from assigned rx condition
 - Received methadone, bup, detoxification or rehab outside assigned rx condition
 - HIV risk reduction
 - Opioid + urines at 6, 9 & 12 months
 - Other drug use; overall adjustment

Number Consented/Number Randomized

- Consented: 229
- Randomized: 154; Analysis 152
- 2 ss dropped (WPW & screen failure)

Notes:

- Approximately 7 <18 yrs of age interested but declined when told parents had to consent
- Others could not arrange transportation for 5-7 days/week dosing

Demographics: No Sig Grp Dffs

- Male 90 (58%)
- Race
 - Caucasian 114 (74%)
 - African-American 3 (2%)
 - Hispanic 38 (25%)
- Empl/School (Past 6 months)
 - School 28%
 - Working/worked 72%
- Hepatitis C + 29 (19%)

Demographics (overall/cont.)

■ Major problem

■ Heroin	84 (55%)
■ Opiates/analgesics	53 (35%)
■ Polydrug	16 (10%)

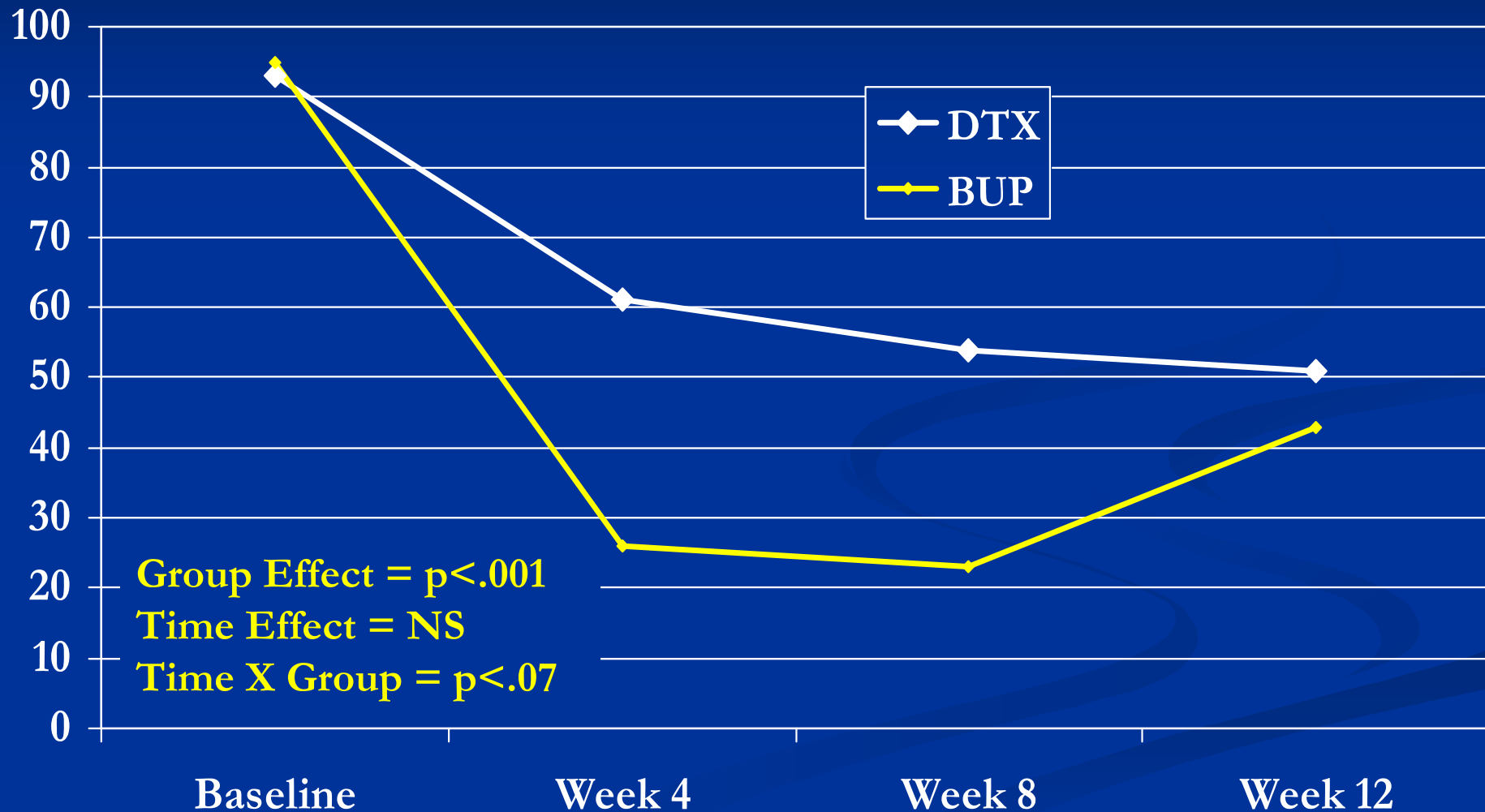
■ Average Years Addicted 2

■ Mean age 19.1 (SD: 1.49)

■ <18 yrs: 27 ss (1 was 15)

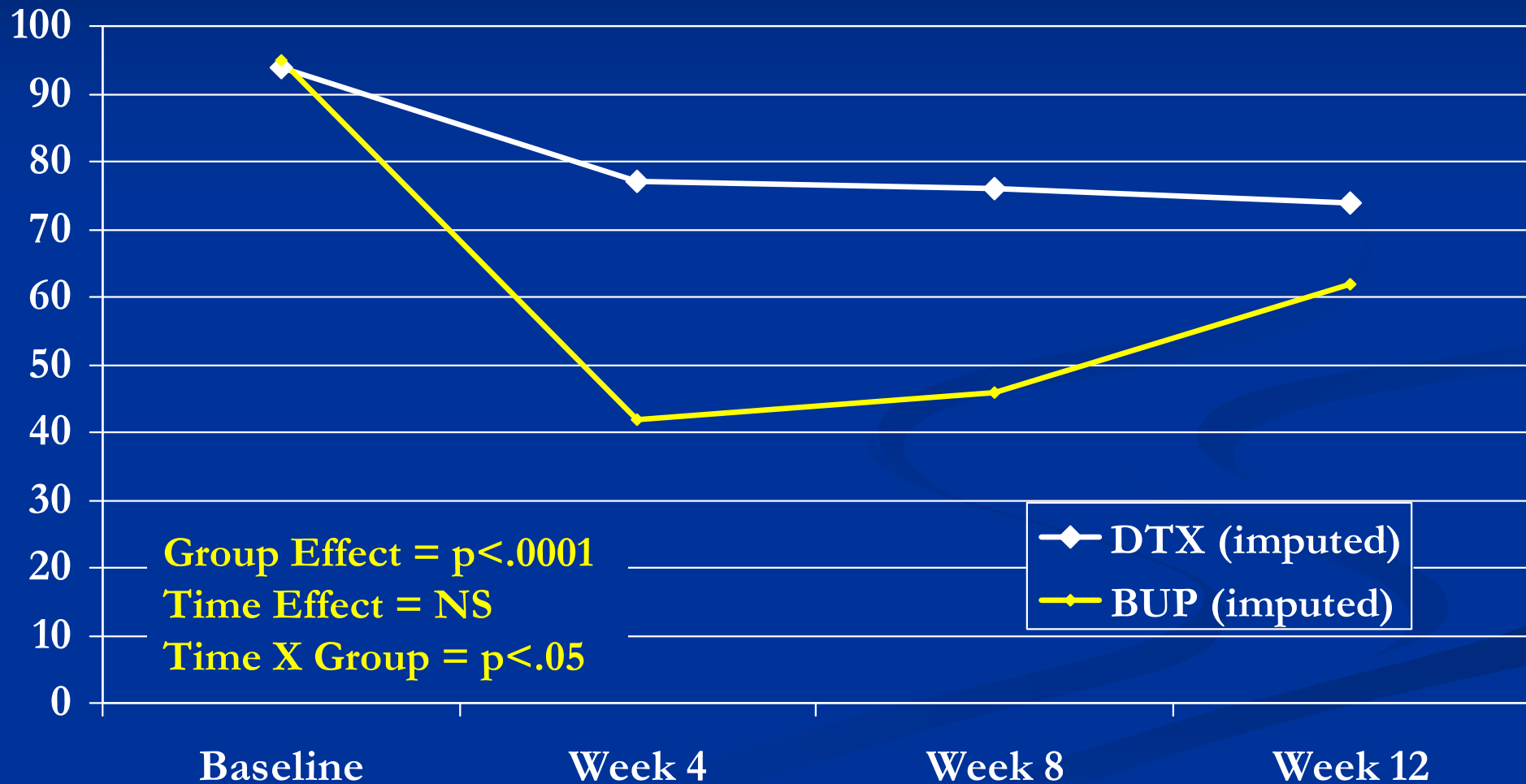
Opioid Positive Urines:

Missing = Missing



Opioid Positive Urines:

Missing = Positive



Remaining In Assigned Treatment Condition at Week 12

- **Definition:** not having period of 14 days or more when failed to see individual or group counsel, or enrolled in non-study treatment
- **About 4 times more retained in BUP (50% vs. 12%)**

HIV Risk : Injecting drug use

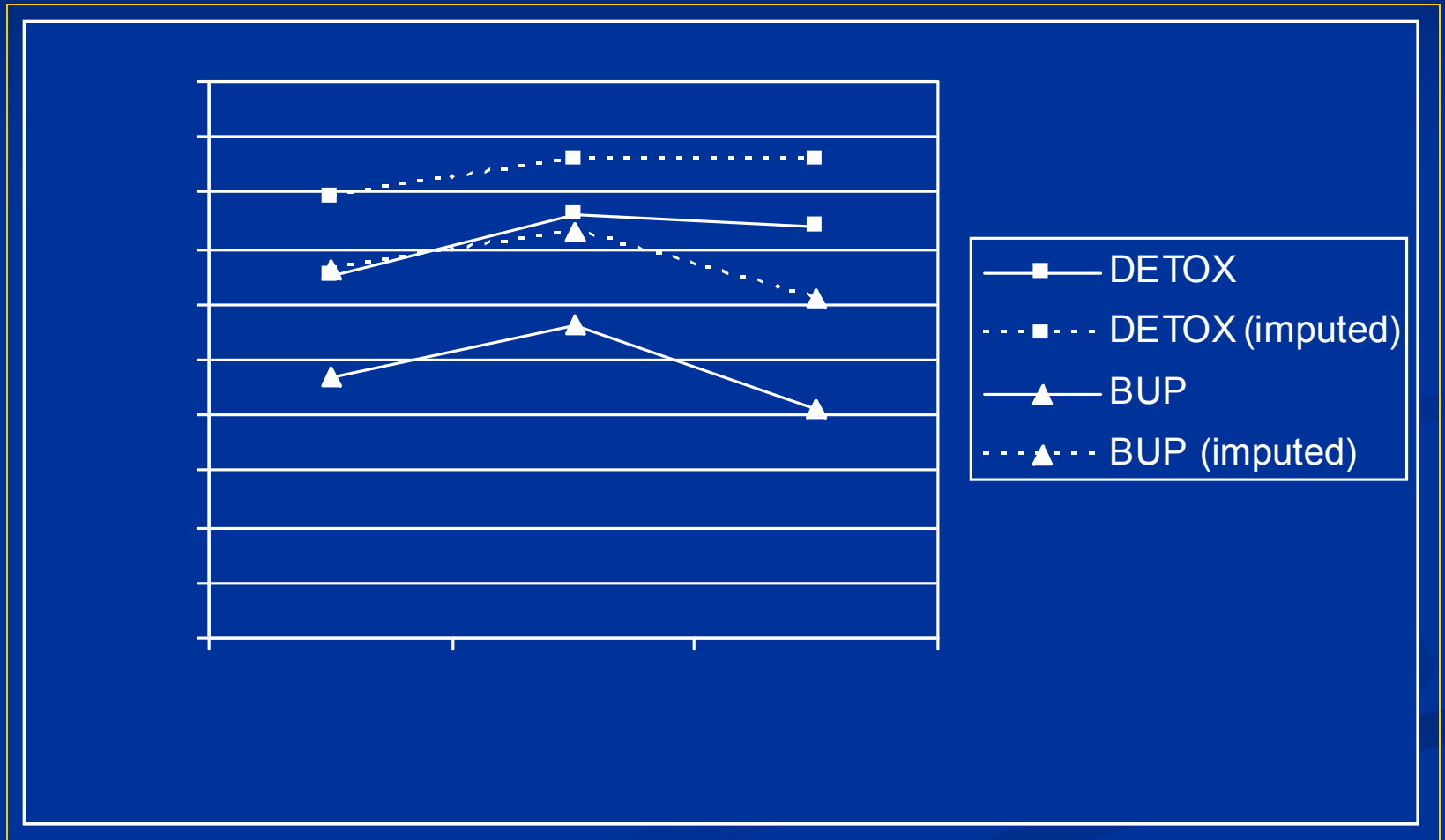
	Wk 4	Wk 8	Wk 12
DTX	37%	26%	33%
BUP	21%	13%	16%

Patients Treated Outside Study In Weeks 1-12

DTX = 27

BUP = 3

Opioid Positive Urine at Months 6, 9, 12



% Reporting possible drug-related side effects

- Headaches most common (20-23%)
- All other AE's less than 10%
- 4/83 who were hepatitis C - at baseline, became + at wk 12
 - 4.8% conversion in 12 wks
- No ECG or liver changes clearly attributable to bup

Cost Effectiveness (Addiction, in press)

- 12-week study outpatient rx \$1514 ($p < 0.001$) higher for BUP
- 1-yr total medical costs \$83 higher for BUP ($p = 0.97$)
- 1-year cost per QALY was \$1,376 for BUP
- Cost per opioid-free year \$308 for BUP

Cost Effectiveness (cont.)

- From outpt rx perspective, cost-effectiveness ratios \$25,049 (95% CI: 11,616 to dominated) per QALY & \$5,610 per opioid-free yr
- Net costs from the societal perspective were \$31,264 ($p=0.20$) lower for BUP.
- Extended buprenorphine-naloxone treatment versus brief detoxification is cost effective.

Summary

- Longer-term bup use was safe & effective
- Difficult to recruit, but conditions more stringent than usual practice
 - **Dosing 5-7 days/wk = transportation problems**
 - **Parental consent if <18 caused some to decline**
 - **Multiple assessments**
 - **Probably easier to enroll and retain under non-research/usual practice conditions**

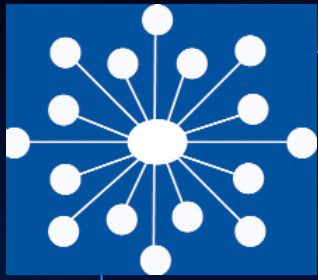
Summary (cont)

- **DETOX:**

- **Higher dropout;**
- **More opioid+ urines**
- **Bup ends = opioid use increases**
- **Though mean age 19.1, addicted 2 years, course **appeared** similar to adults**

Treatment Implications (cont.)

- Potentially life-saving as data from France, Finland, Czech Republic show marked reduction in overdose deaths associated with use of bup
- Patients can enter abstinence-oriented rx any time if indicated and possible
- Resistance expected from specialty programs (like doing cognitive therapy in a psychoanalytic institute)



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**BUPRENORPHINE/NALOXONE-
FACILITATED REHABILITATION
FOR OPIOID DEPENDENT
ADOLESCENTS/YOUNG ADULTS**

**Thanks to NIDA and
Participating Program Staff for
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