

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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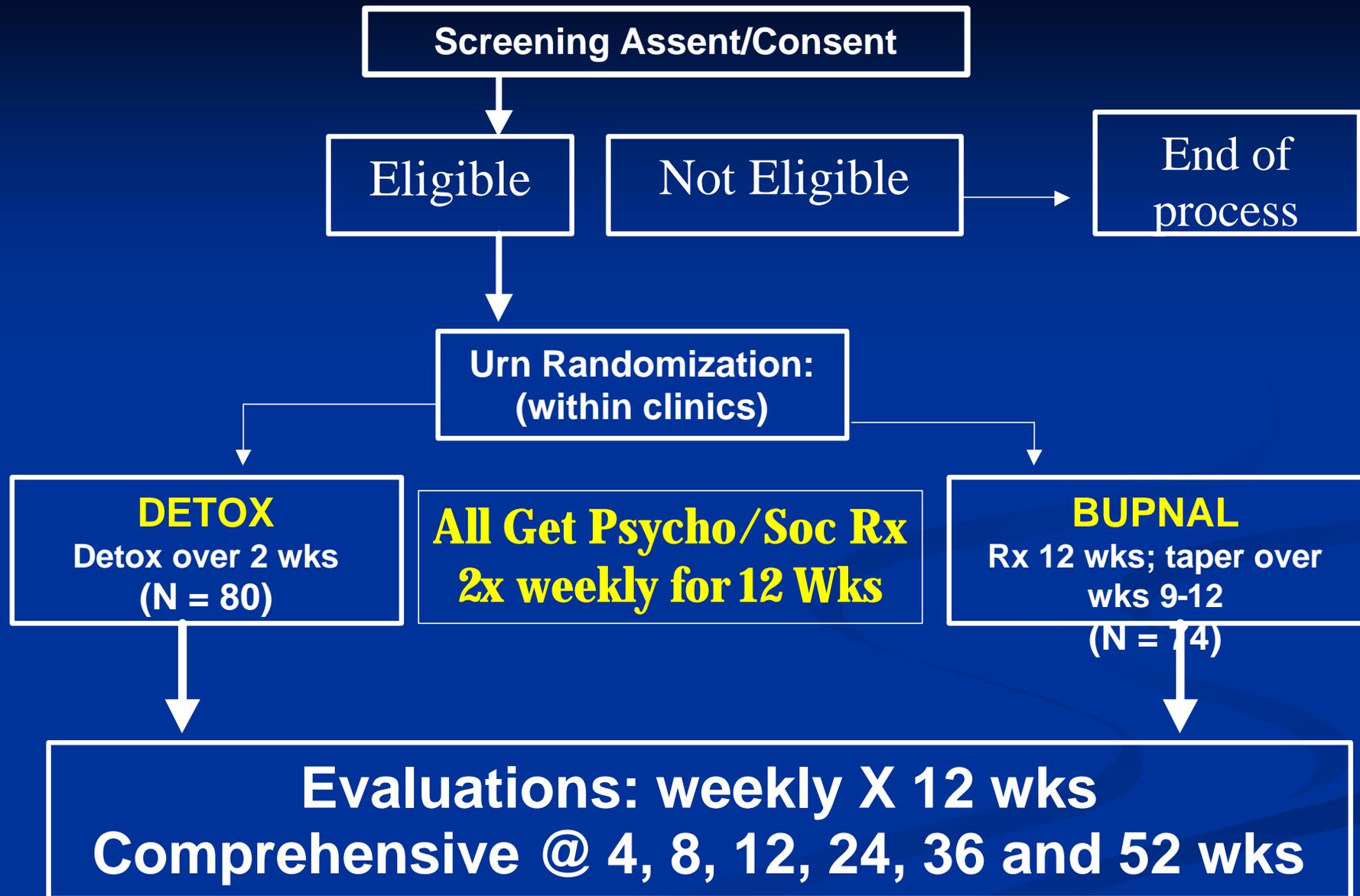
Pennsylvania

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

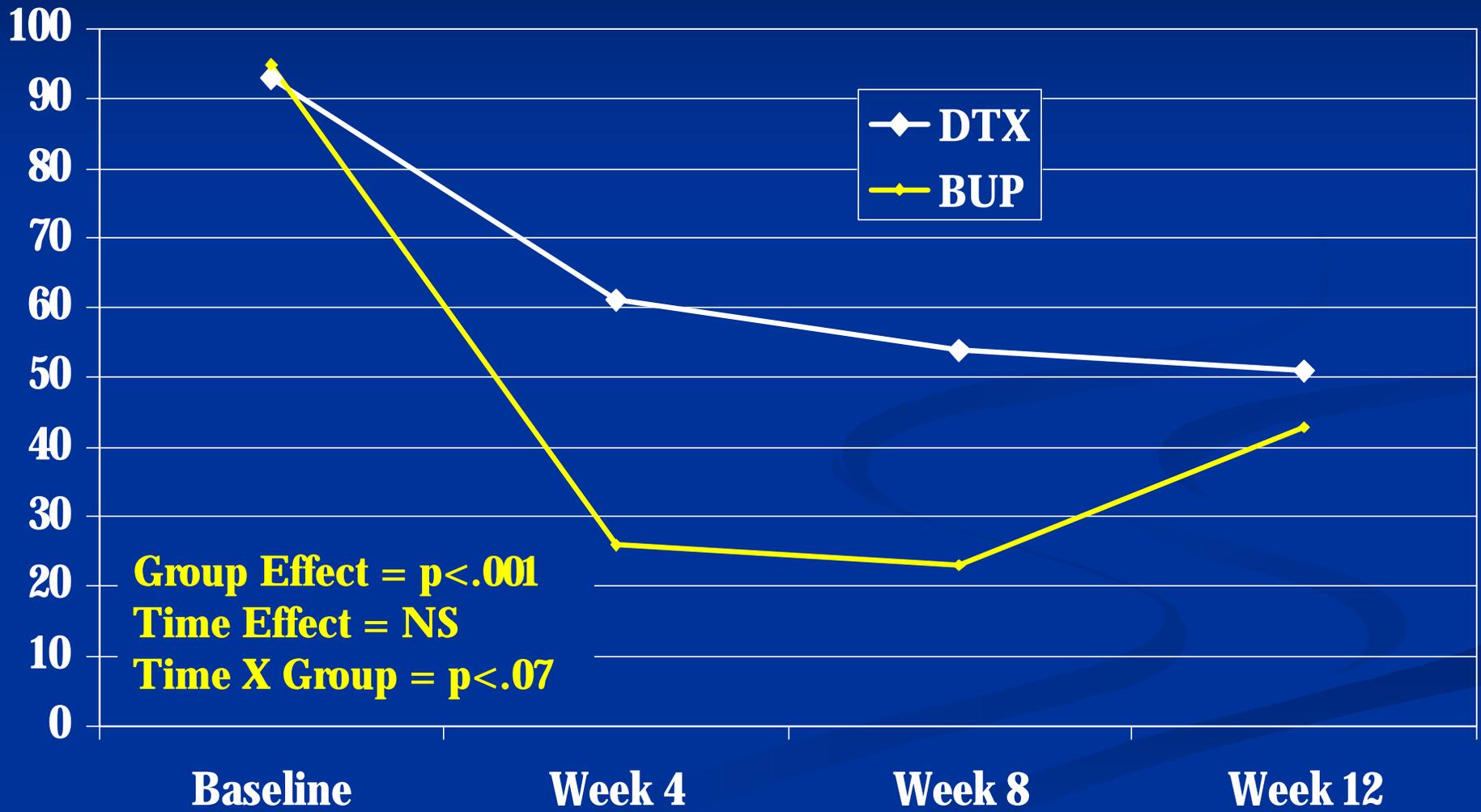
- Heroin 84 (55%)
- Opiates/analgesics 53 (35%)
- Polydrug 16 (10%)

■ Average Years Addicted 2

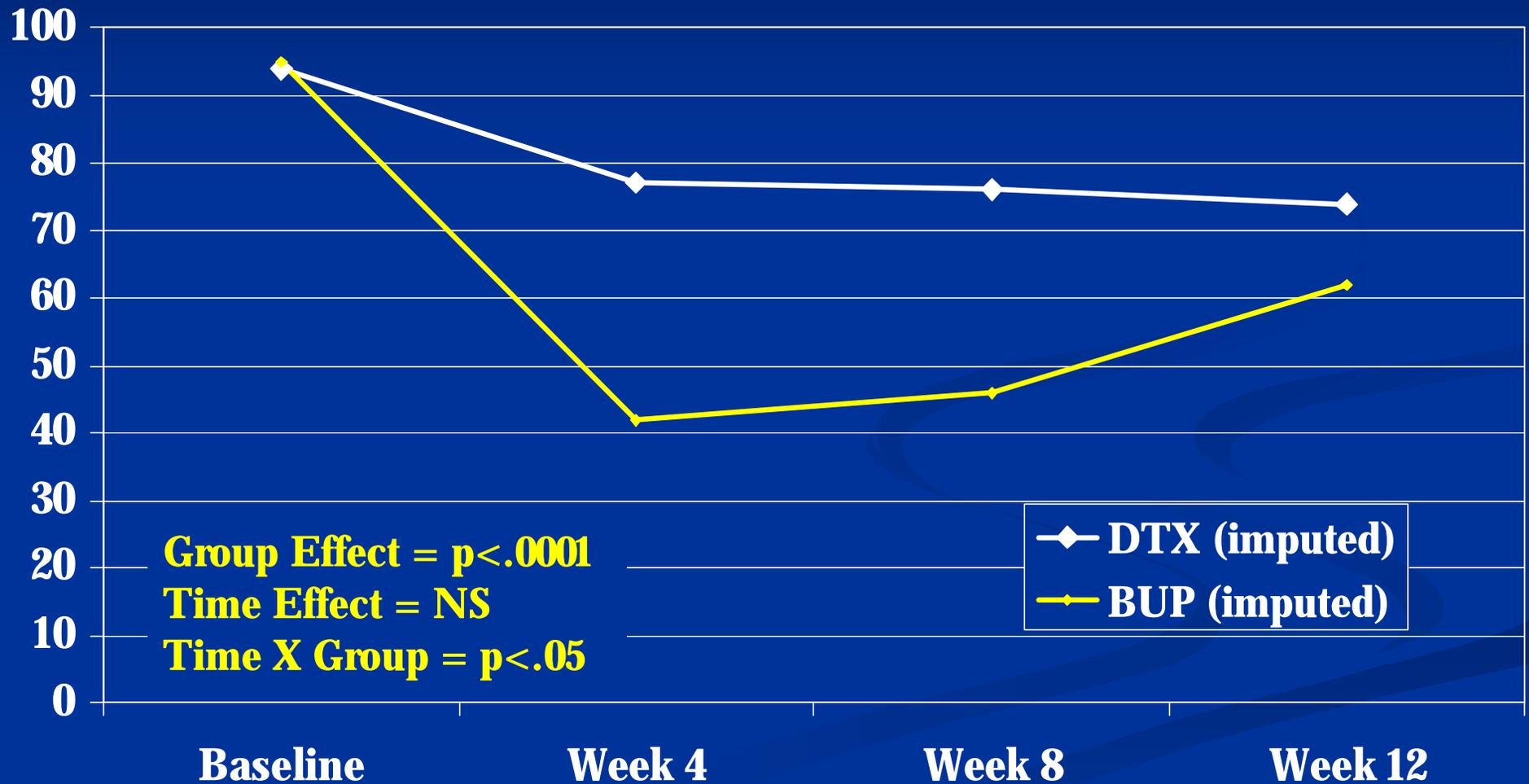
■ Mean age 19.1 (SD: 1.49)

■ <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

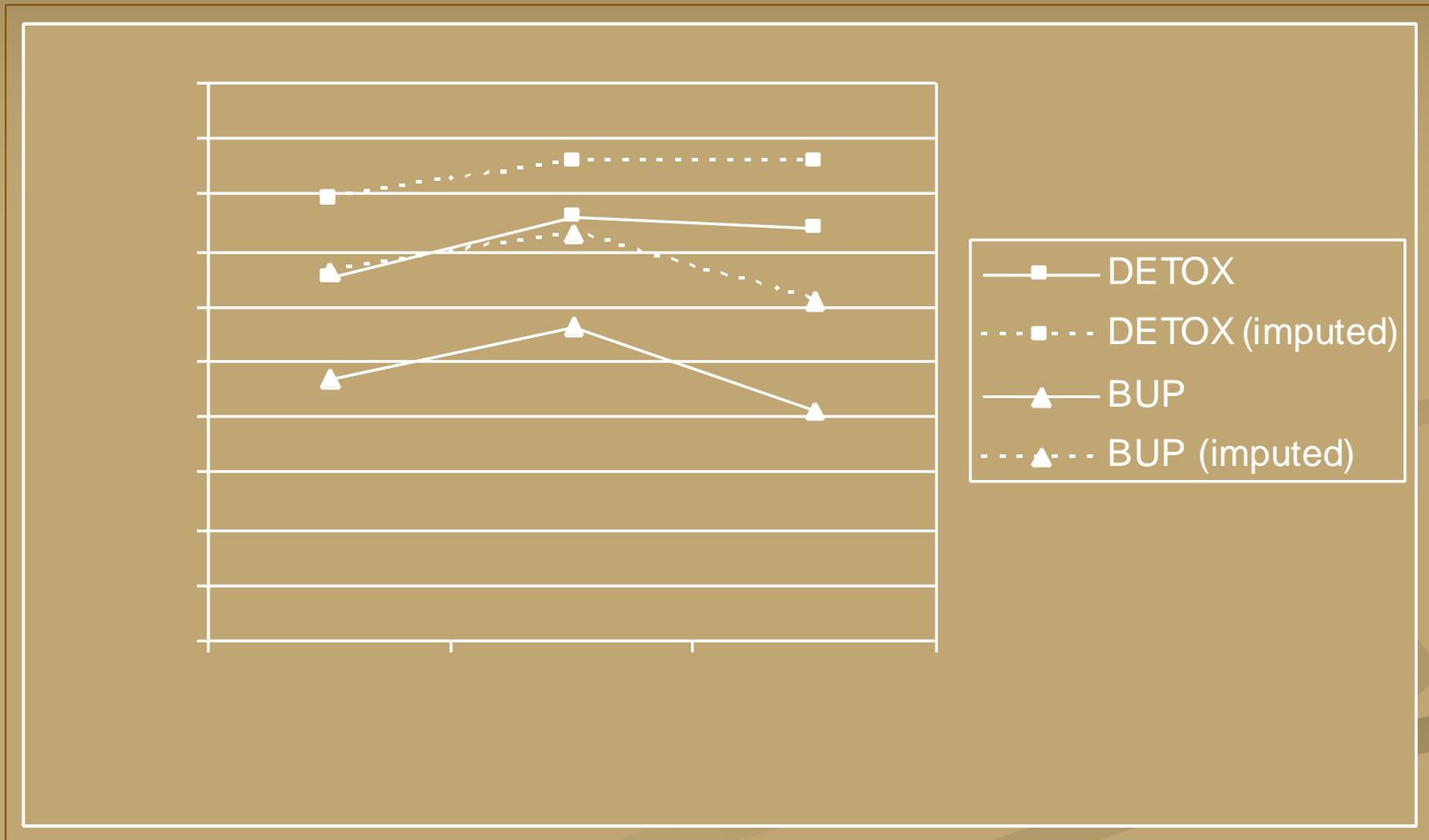
	Wk 4	Wk 8	Wk 12
DTX	37%	26%	33%
BUP	21%	13%	16%

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**

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**

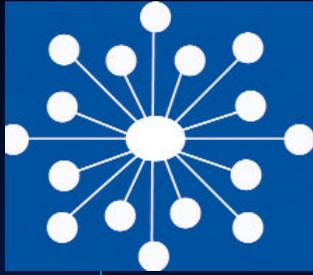
Summary (cont)

- **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
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