



**What the National Institute on Drug Abuse's Clinical  
Trials Network Can Do for You?  
Major Findings from Medication Trials and  
Implications for Community-Based Settings**

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# Medication Studies in the NIDA Clinical Trials Network

## Opioid Dependence

- Buprenorphine vs. Clonidine
- Buprenorphine: Longer vs. shorter taper
- Buprenorphine for Adolescents/Young Adults
- Prescription Opioid Addiction Treatment Study

## Smoking Cessation

- Methylphenidate for Smokers with ADHD

## Adolescents

- Buprenorphine for Adolescents/Young Adults
- Methylphenidate for ADHD/SUD

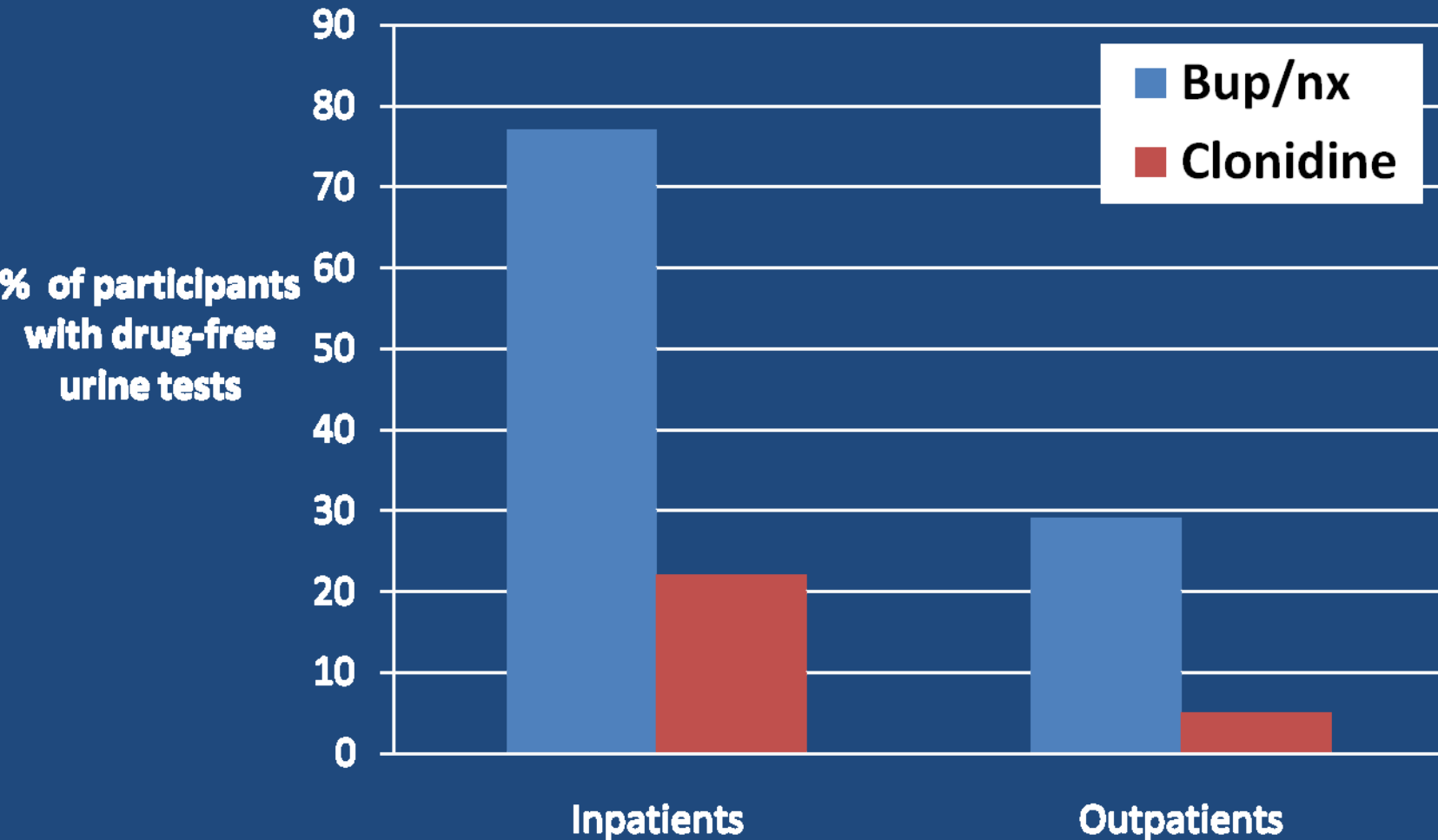
# **Buprenorphine/Naloxone vs. Clonidine for Inpatient & Outpatient Opioid Detoxification**

## Aim

Compare buprenorphine/naloxone to  
clonidine

13-day detoxification from opioids

# Buprenorphine/Naloxone vs. Clonidine for Opioid Detoxification



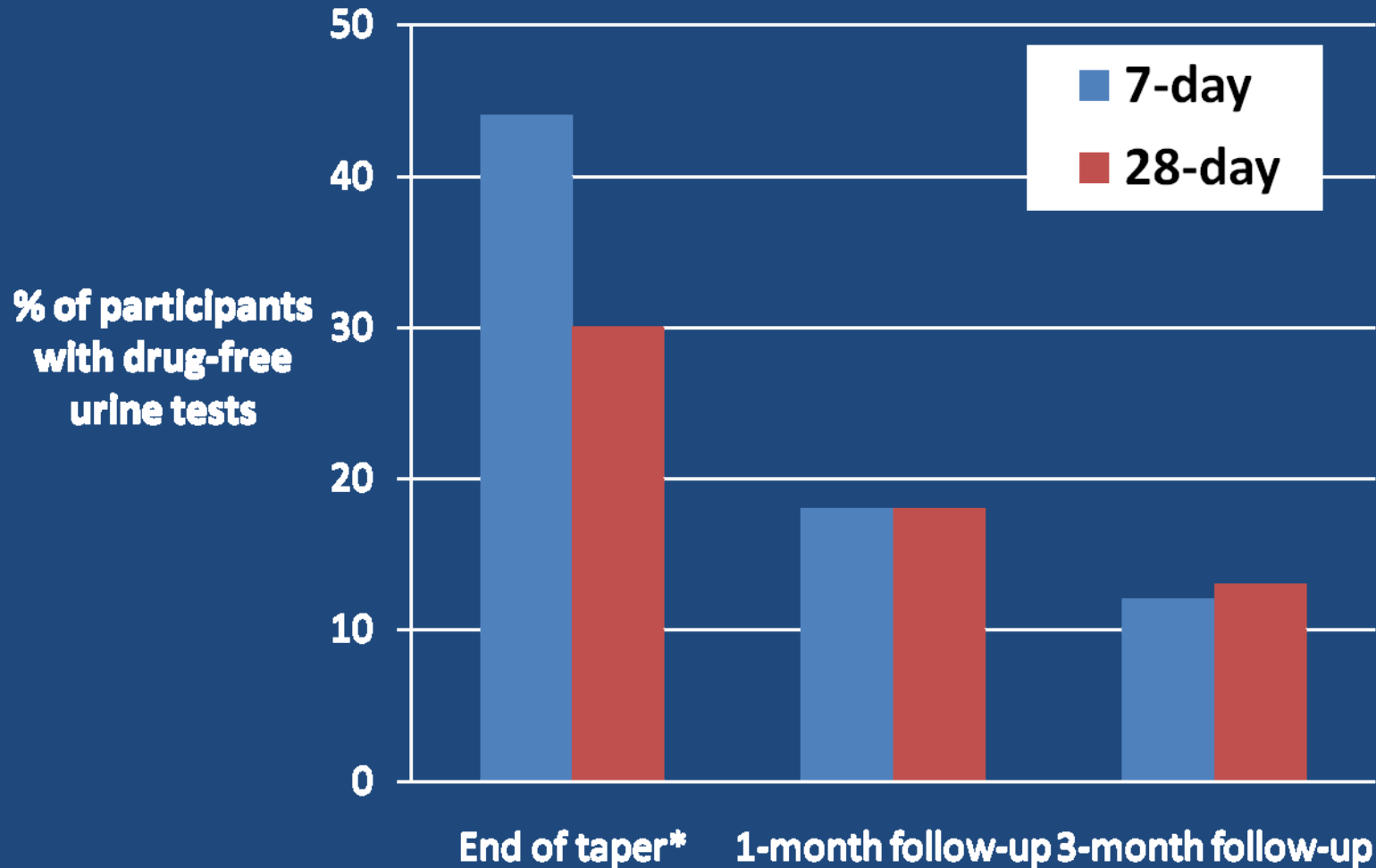
# Bup/Nx vs. Clonidine for Opioid Detox: Conclusions

- Buprenorphine/naloxone is far superior to clonidine for opioid detoxification
- Increased adoption of bup/nx at Community Treatment Programs

# Which buprenorphine/naloxone taper schedule is better? 7-day vs. 28-day taper

- Aim  
Compare 2 bup/nx tapering schedules (7 vs. 28 days) following 4 weeks of bup/nx stabilization
- N = 516
- Randomized to 7-day vs. 28-day taper schedule

# Buprenorphine/Naloxone Taper: A Comparison of 2 Schedules



# Bup/Nx Taper: A Comparison of 2 Schedules

## Conclusions

- Rapid discontinuation schedule is not disadvantageous
- Potential cost savings of a short taper without sacrificing clinical effectiveness

# Buprenorphine/naloxone-facilitated rehabilitation for opioid-dependent adolescents & young adults

- Compared 12-week bup/nx treatment (8 weeks plus 4-week taper) vs. 2-week detox in 152 patients, age 15-21
- All patients received counseling

# JAMA<sup>®</sup>

November 5, 2008

The Journal of the American Medical Association

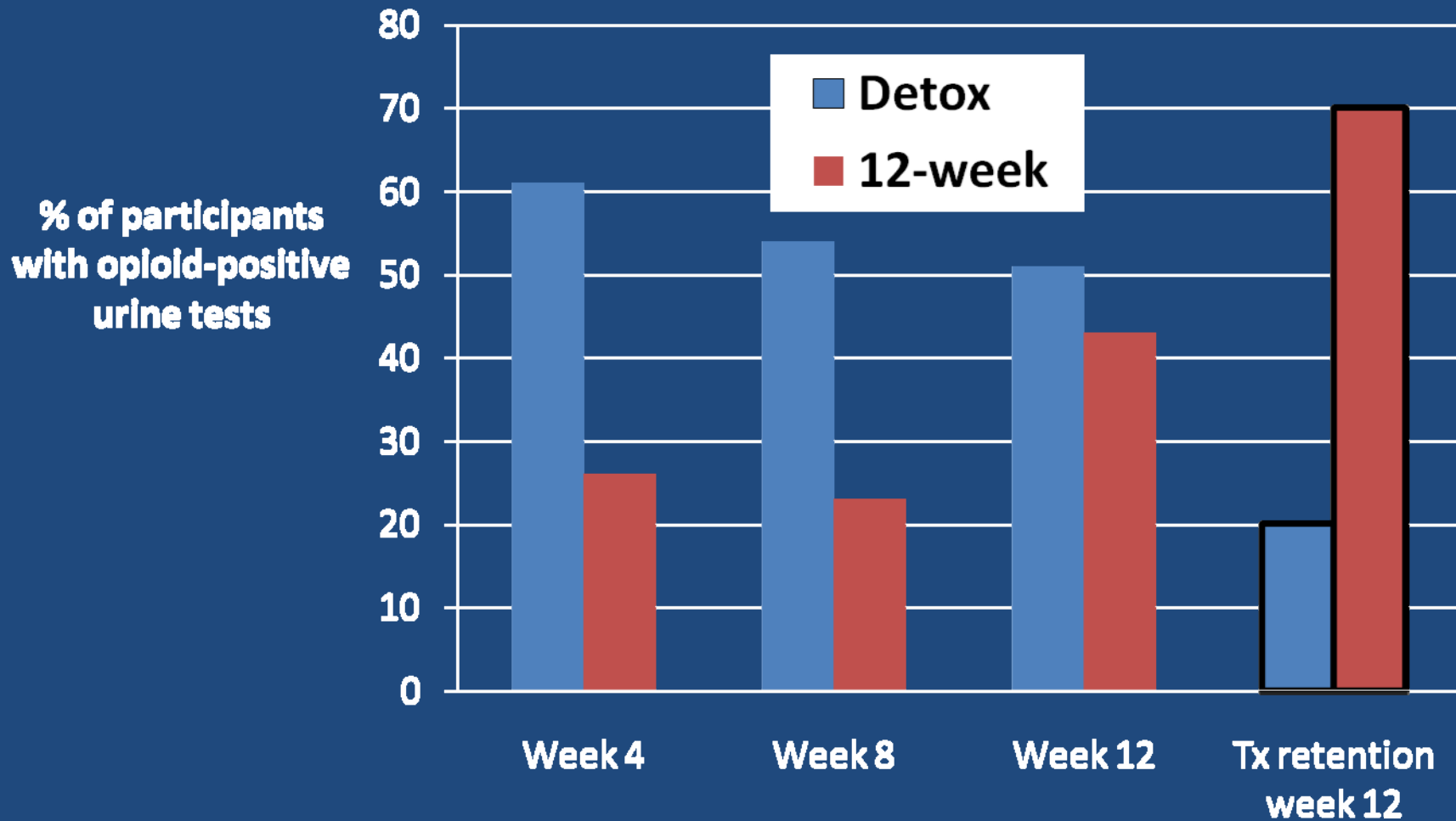


Quasiquicentennial

125 Years of  
CONTINUOUS  
PUBLICATION

*Woody GE et. al., JAMA 2008*

# Buprenorphine/naloxone-facilitated rehabilitation for opioid-dependent adolescents & young adults



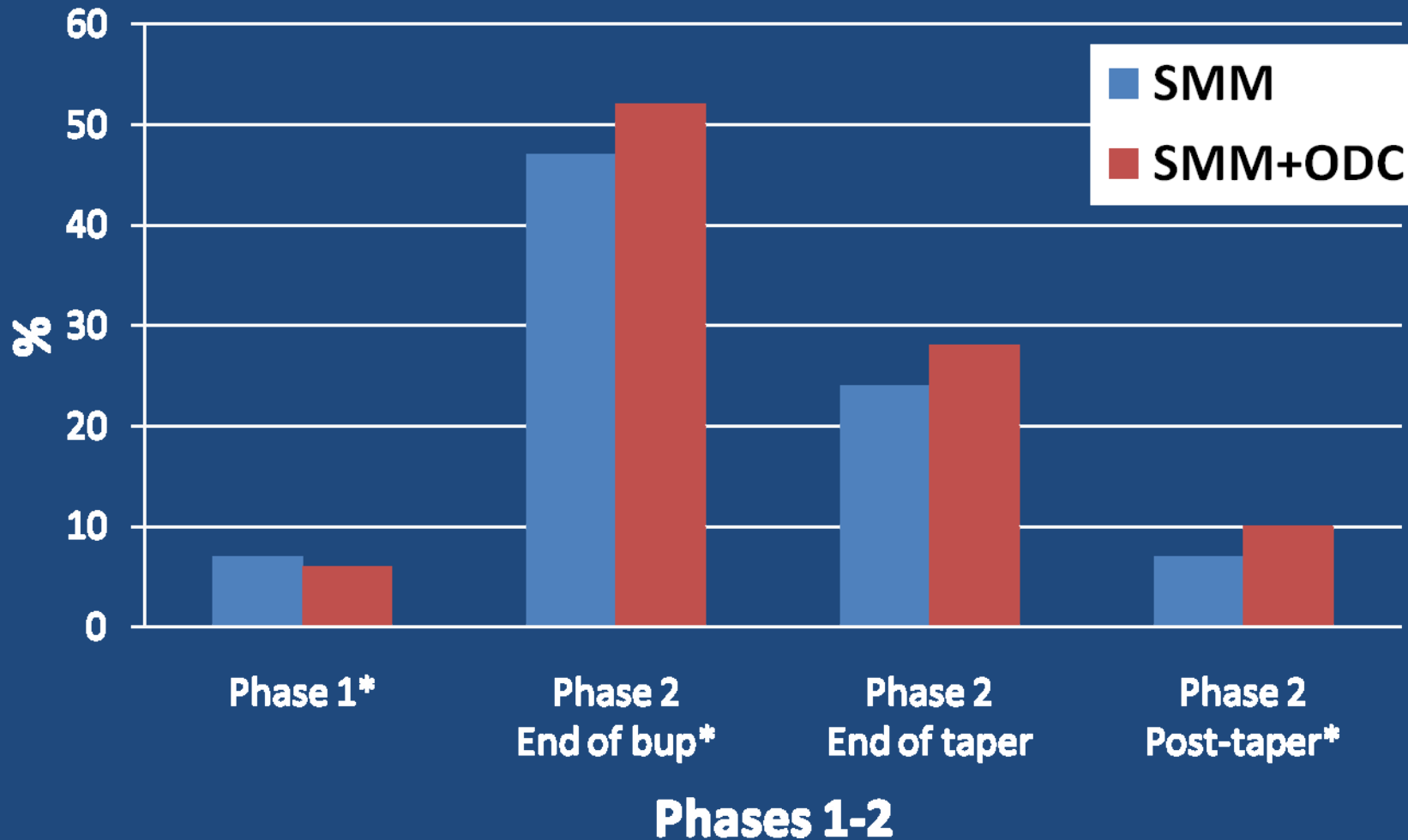
# Buprenorphine/naloxone-facilitated rehabilitation for opioid-dependent adolescents and young adults: Conclusions

- Primary and secondary outcomes strongly favored longer-term bup/nx
- Major implications for treatment:  
Life-saving treatment in an extremely high-risk group (very high rates of hepatitis C; 5% converted during trial)

# Prescription Opioid Addiction Treatment Study (POATS)

- Aim Compare treatments for rx opioid dependence, using buprenorphine-naloxone of **varying durations** & **varying counseling intensities**
  - Does **adding drug counseling** to bup/nx + Standard Medical Management improve outcome?
  - How does **length of bup/nx treatment** affect outcomes in patients with rx opioid dependence?
- **Largest study** ever conducted for rx opioid dependence (N = 653)

# Successful outcomes over time



# Prescription Opioid Addiction Treatment Study

## Conclusions

- Prescription opioid-dependent patients most likely to reduce opioid use **during bup/nx treatment**
- Likelihood of unsuccessful outcome is extremely high when tapered off bup/nx, even among patients receiving counseling in addition to medical management

# Osmotic Release Methylphenidate (OROS-MPH) in Adolescents with SUD & ADHD

- Aim  
Evaluate the efficacy of **OROS-MPH/Concerta vs. placebo**
  - to treat ADHD &
  - to decrease substance usein adolescents with ADHD & a substance use disorder (SUD)
- 16-week, Randomized Controlled Trial
- N = 303 adolescents with ADHD & SUD
- Interventions
  - OROS-MPH 72 mg daily dose or placebo &
  - CBT: weekly, individual, manual-standardized outpatient substance abuse treatment

# Osmotic Methylphenidate (OROS-MPH) in Adolescents with SUD and ADHD

## Results

- OROS–MPH safe & well-tolerated
- **Reduction in ADHD symptoms** were greater than those reported for psychostimulant treatment of ADHD in youth without SUD
- Similar reduction of ADHD symptoms and substance use in patients receiving active medication or placebo
- Possible **contribution of CBT** to both SUD & ADHD outcomes, though no control group without CBT

# Osmotic Methylphenidate (OROS-MPH) in Smokers with ADHD

## Aim

Evaluate whether **OROS-MPH (Concerta) vs. placebo** increases the effectiveness of standard smoking treatment (i.e., nicotine patch & individual smoking cessation counseling) for 255 smokers with ADHD

# Osmotic Methylphenidate (OROS-MPH) in Smokers with ADHD

Smoking outcomes		
	OROS-MPH	Placebo
<b>Prolonged abstinence</b>	43%	42%

- OROS-MPH, relative to placebo
  - Effectively treated ADHD
  - Safe & generally well tolerated
  - However, no improvement of smoking

# Summary

## Buprenorphine

- Demonstrated efficacy & tolerability in important populations not previously studied
- Longer treatment shows better outcomes than detox
- Increased acceptability at community tx programs

## Adolescent studies

Important information about use of medication tx in an understudied population

# Areas for ongoing and future medication research in the CTN

- Buprenorphine vs. methadone liver safety
- Buprenorphine to treat cocaine dependence
- Bupropion for smokers with stimulant dependence
- Long-acting injectable naltrexone for opioid dependence
- Buspirone for cocaine dependence
- Treatments for cannabis dependence

# Conclusions

- Medication studies - - both straightforward studies and highly complex studies - - can be conducted safely and effectively in community drug abuse treatment programs
- Staff members highly enthusiastic
- Successful trials can lead to increased use of empirically validated pharmacotherapies