Innovations in Methadone Treatment

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Declaration of Interest: Consulting for Verily Life Sciences

Methadone Maintenance Treatment

- Effective in reducing heroin use (Mattick et al., 2009)
  - Treatment retention is associated with improved outcomes (Simpson et al., 1997)
  - Higher doses are associated with lower rates of heroin use (Strain et al., 1999)
- Some quasi experimental studies found reduced:
  - HIV-risk behavior (Gowing et al., 2011)
  - HIV seroconversion (Metzger et al., 1993)
  - Criminal behavior (Ball & Ross, 1991)
  - Arrests (Newman et al., 1973)

Challenges

- Most people with OUD are not in treatment
- Methadone treatment retention is not optimal
  - ~ half of admissions are no longer in treatment 1 year later

Today's Webinar

- Our research on approaches to increase:
  - Methadone treatment entry
  - Methadone treatment retention

What are some barriers to Opioid Treatment Program (OTP) entry?

Qualitative Interviews

Out-of-Treatment participants (*n* = 27) interviewed as part of a study of treatment entry and retention

- Recruited from the street
- Neither in treatment, nor seeking treatment in the past year
- Focused on why they aren't seeking treatment

Peterson et al., 2010

Barriers to Treatment Entry: Patient Perspectives

- Waiting lists for subsidized public treatment
- Unable to navigate OTP admissions bureaucracy
  - Photo ID requirement
- Fear of incarceration while on methadone
- Real and rumored side effects
- Disinterest in adhering to OTP requirements
- “Taking care of business”

Peterson et al., 2010

What are some possible approaches to reduce barriers to treatment entry?

Interim Methadone to Address Waiting Lists

- Waiting lists
  - Shortage of subsidized methadone treatment
    - May be due to lack of counselors
- Interim Methadone (IM)
  - Methadone treatment without counseling for people on waiting lists

(Yancovitz et al, 1989)

- Federal OTP regulations passed in 1993 to permit IM
  - > 2 week delay in admissions
  - 120 day limit with no take home doses
  - Requires state and federal approval
  - For profit organizations barred

Interim Methadone Study Design

Random assignment (3:2) to IM or wait list

Interim Methadone (for up to 4 months)

- adequate methadone dose
- emergency counseling only
- transfer to OTP with counseling after 4 months

Wait list participants

- encouraged to call other OTPs
- may enter study's OTP through usual wait list

Schwartz et al., 2006; 2007

Assessments

Measures at baseline, 4-, and 10-month follow-up

- ASI
- Wait list Questionnaire
- Drug test

GLMM analysis on intent-to-treat basis

Eligibility Criteria

- Adult (18 years or older)
- Meets criteria for methadone maintenance
- Unable to gain admission to MTP within 14 days
- Not pregnant
- Medically and psychiatrically stable

Assessed for eligibility (*N*=334)

Randomized (*N*=319)

Interim Maintenance (n=199)
* Received intervention (n=194)

Wait List (n=120)
* Received intervention (n=120)

Interviewed (94.5%)
(1 in prison; 1 deceased; 9 not located)

Interviewed (89.2%)
(4 in prison; 1 deceased; 8 not located)

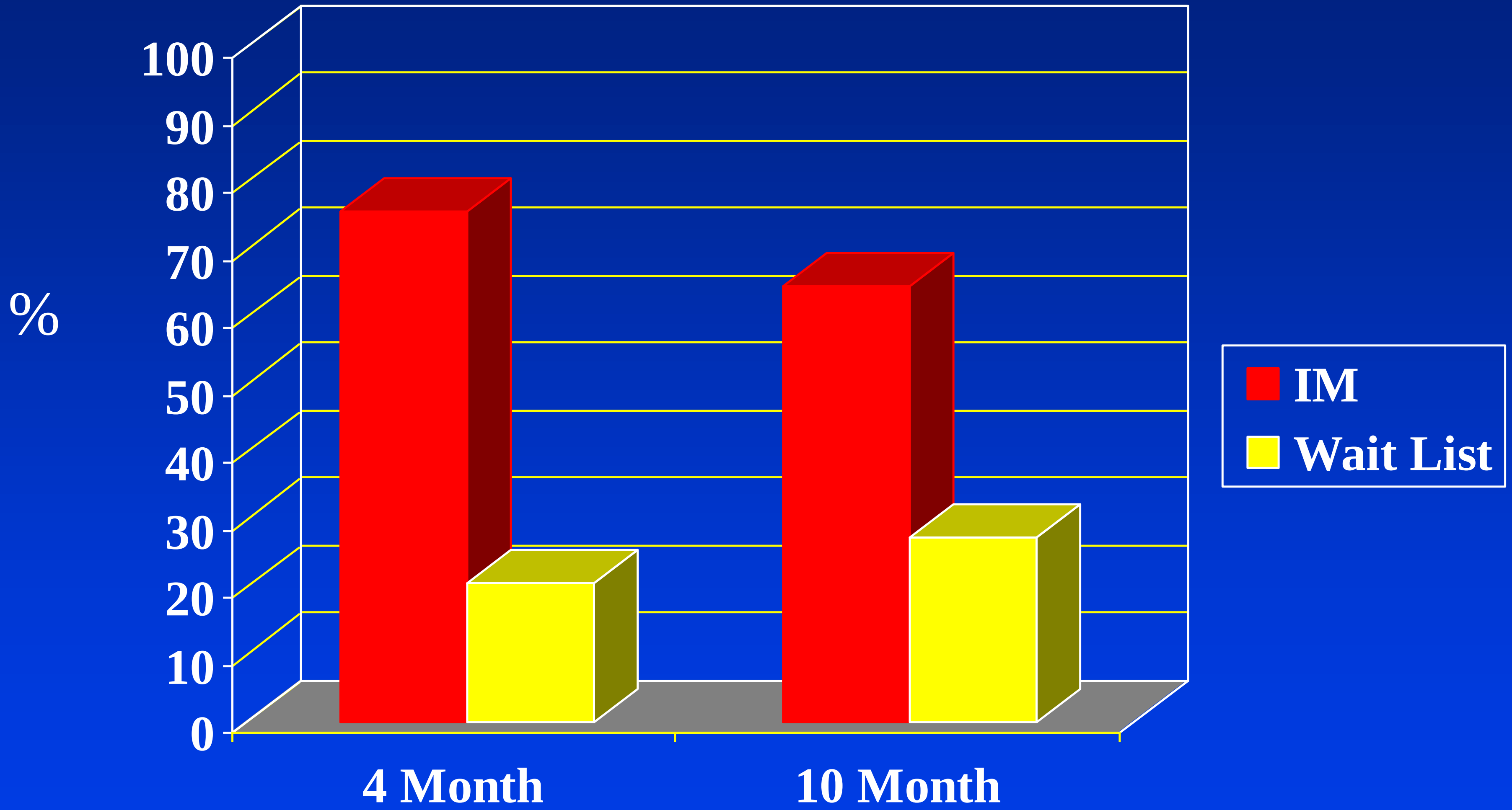
Analyzed (n=199)

Analyzed (n=120)

Baseline Characteristics

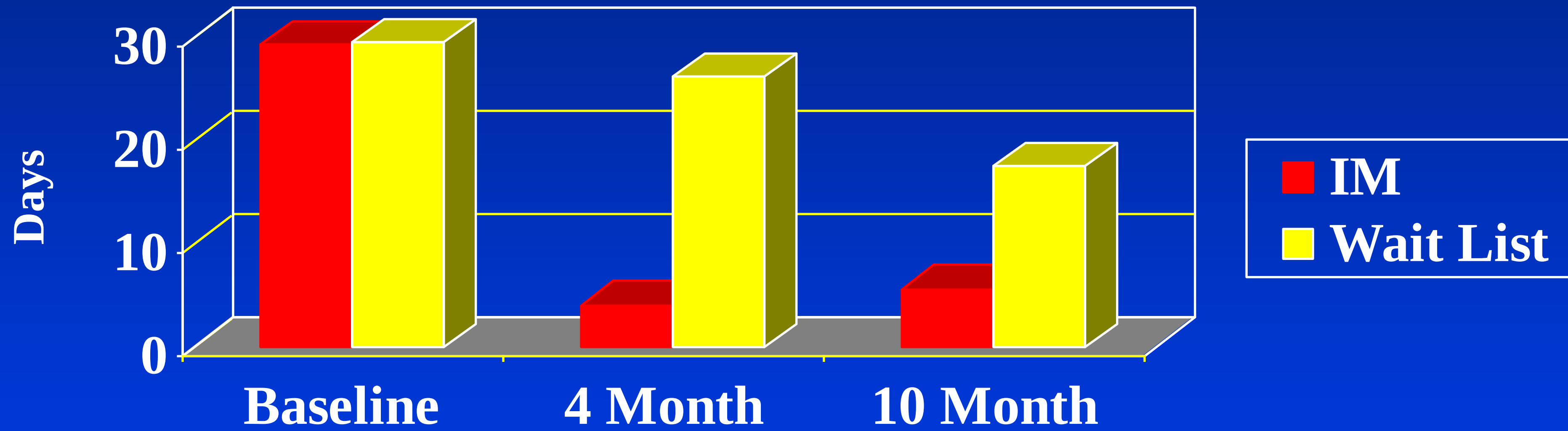
Variable	**Total (*N* = 319)**
Age, mean (*SD*)	41.4 (5.9)
Male, no. (%)	189 (59)
Race, no. (%)	
Black	297 (93.1)
White	21 (6.6)
Married, no. (%)	63 (20)
Employed/last 30 days, (% yes)	121 (38)
Age of onset heroin use	22.9 (7.0)
Days of heroin use/last 30 days	29.6 (1.8)
Days of cocaine use/last 30 days	7.0 (10.3)
Lifetime months of incarceration	21 (34)

Entry & Retention in OTP*



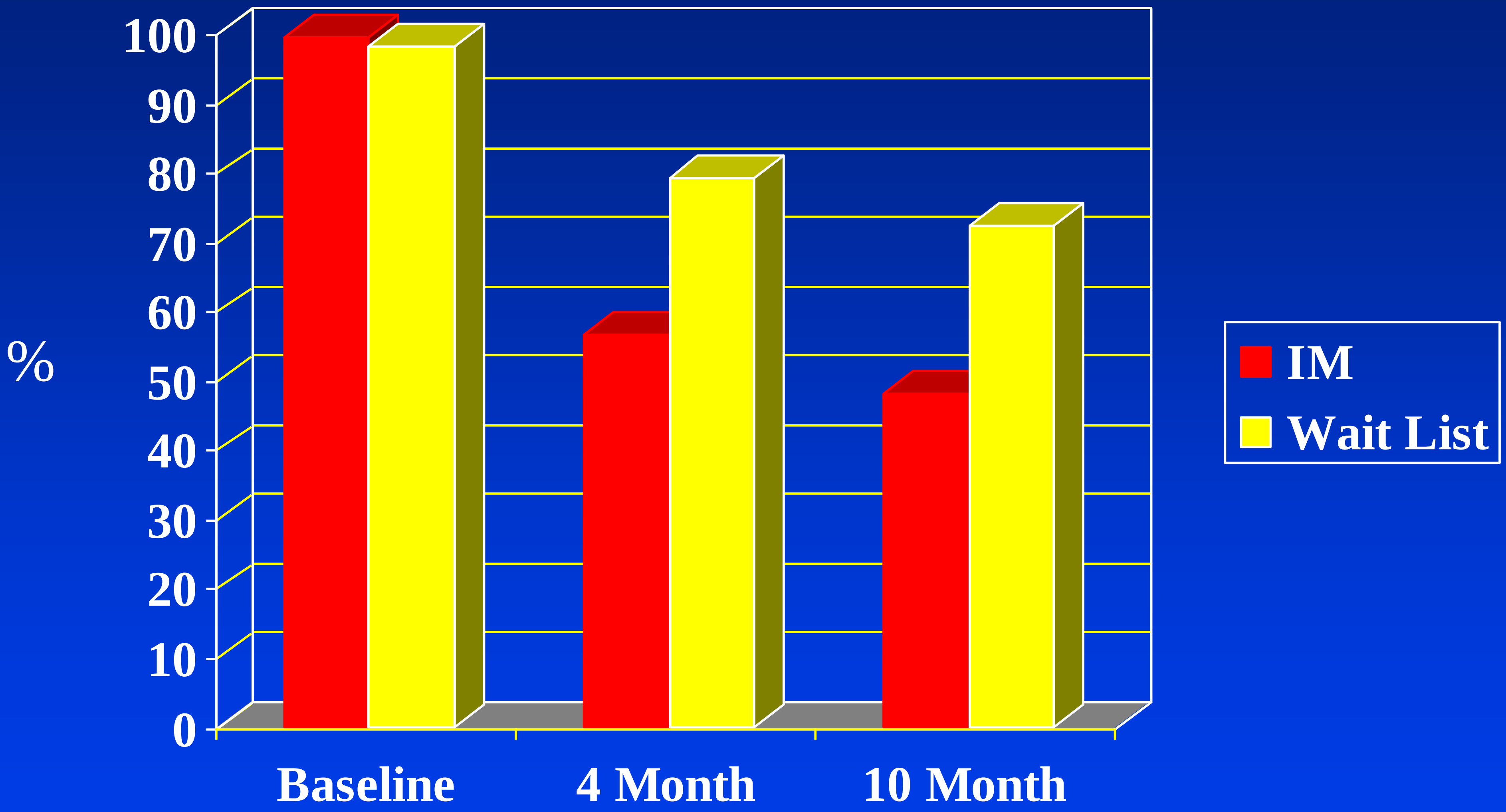
*Chi-square goodness of fit tests at 4 and 10 months, both *ps* < .001

Number of Days Used Heroin (past 30 days)*



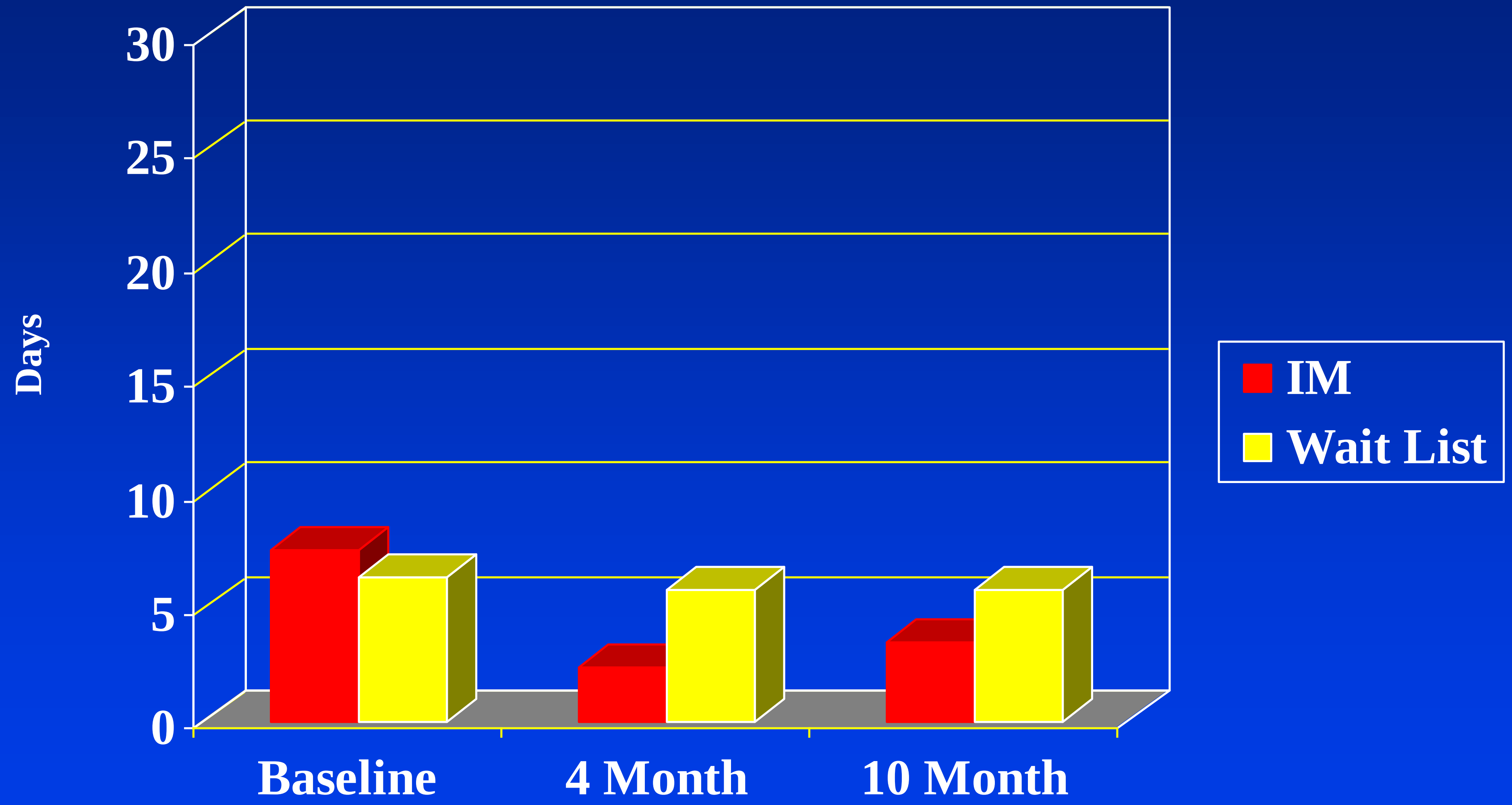
* $p < .001$

Heroin Positive Drug Tests*



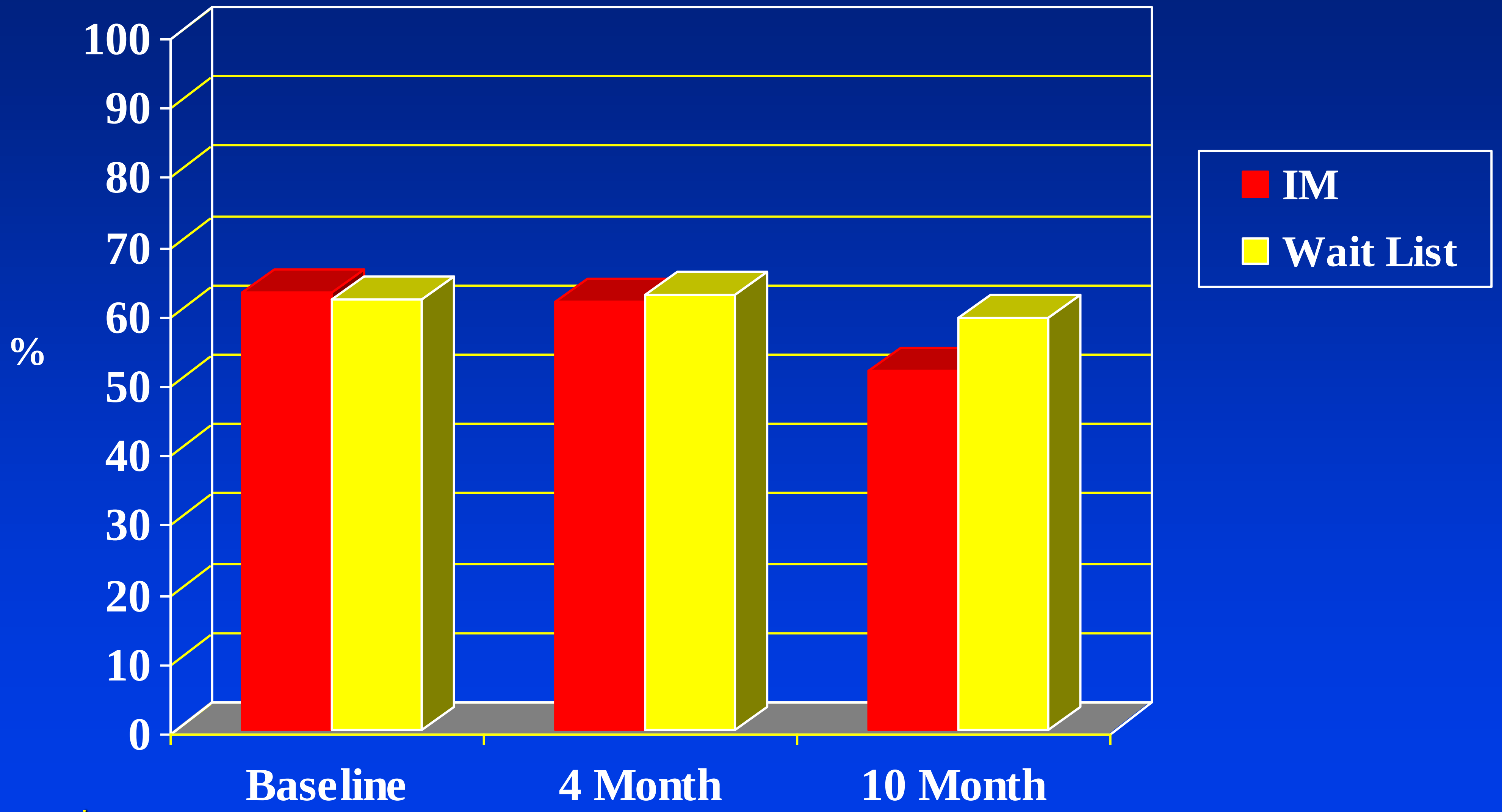
* $p < .001$ and $p = .001$ at 4- and 10-months, respectively.

Number of Days Used Cocaine (past 30 days) *



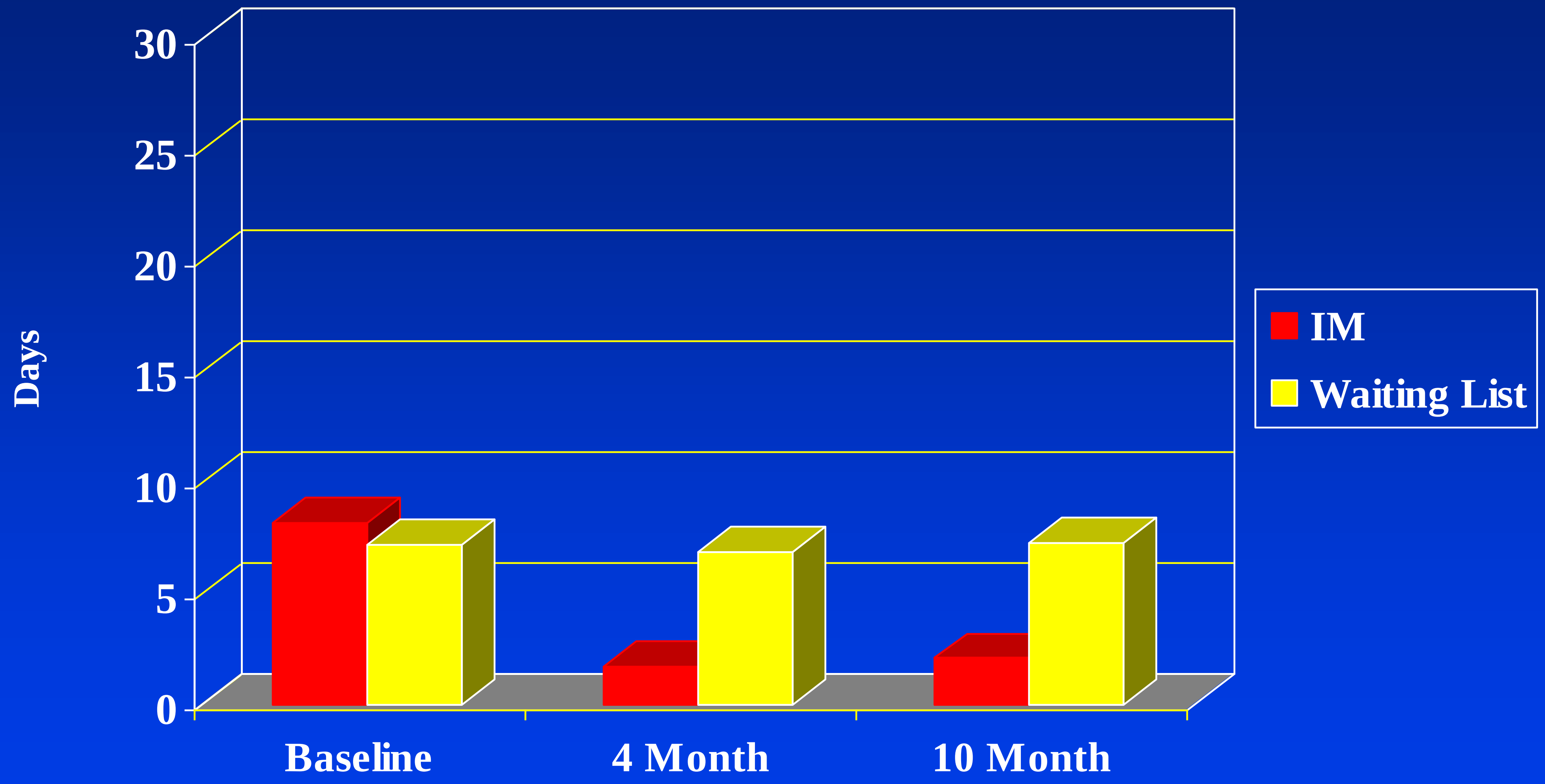
* $p < .001$

Cocaine Positive Drug Tests*



* ns

Days of Illegal Activity (past 30 days)*



* $p < .001$

Summary: IM v. Waiting List

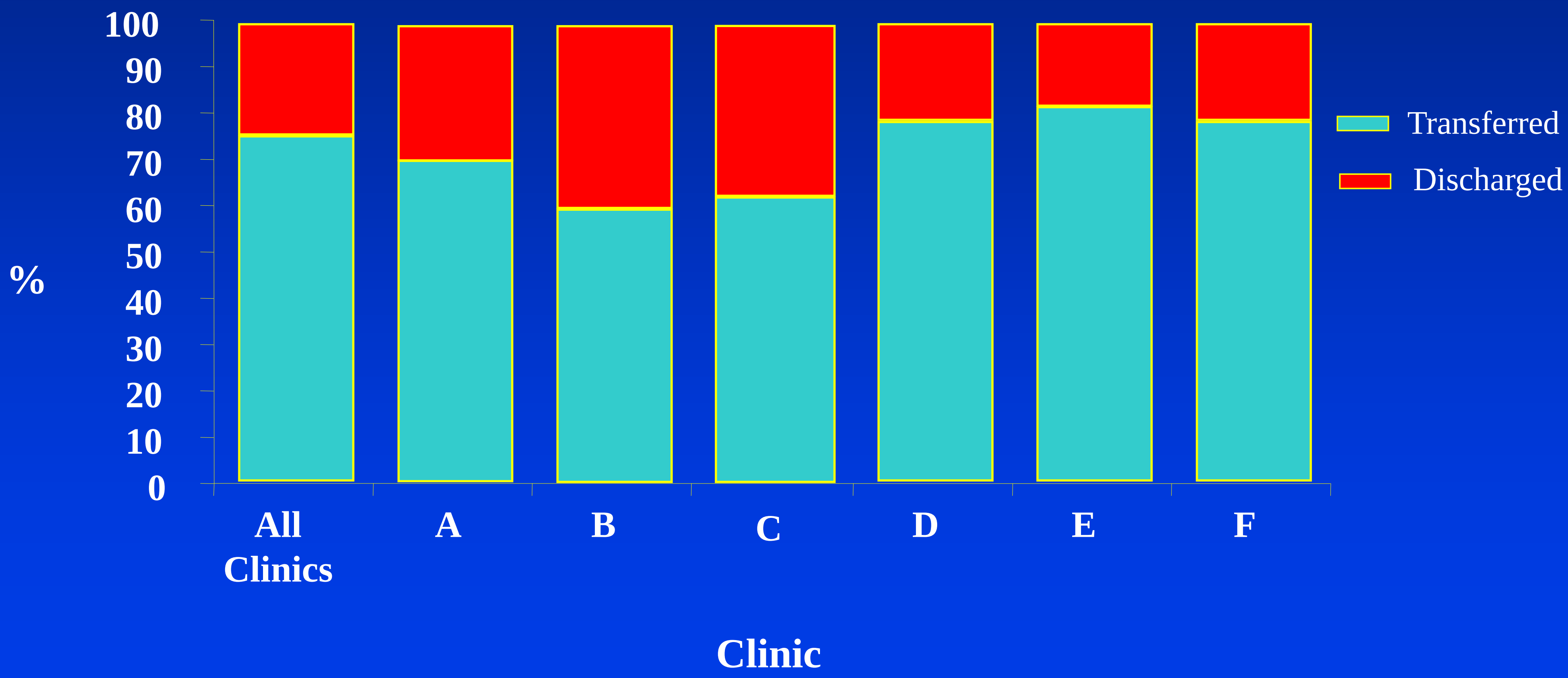
- Facilitated OTP entry
- Reduced heroin use significantly
- Mixed findings for cocaine use
- Reduced self-reported criminal behavior
- Significantly fewer arrests at 6 but not 12 month follow-up (Schwartz et al., 2009)

Scaling Up Interim Methadone

- 1,045 adults admitted to IM at 6 OTPs in Baltimore over 18 months
- Half with free treatment and half with $10/week fee
- Outcome variables
  - % transferred to standard MTP after 4 months of IM
  - Heroin and cocaine test results at entry and transfer to standard OTP

** Schwartz, Jaffe, O'Grady et al., 2009*

Successful Transfer to Standard OTP from IM



Urine Drug Testing Results

Testing results	Baseline	Transfer
Opioid Positive Tests (%)	89.6%	38.4%
Cocaine Positive Tests (%)	49.9%	44.9%

No significant association between payment Condition and % transferred

Why has Interim Methadone rarely been used outside of research, despite the presence of waiting lists for OTPs since 1993 in various parts of the country?

Implementation Facilitation of Interim Methadone

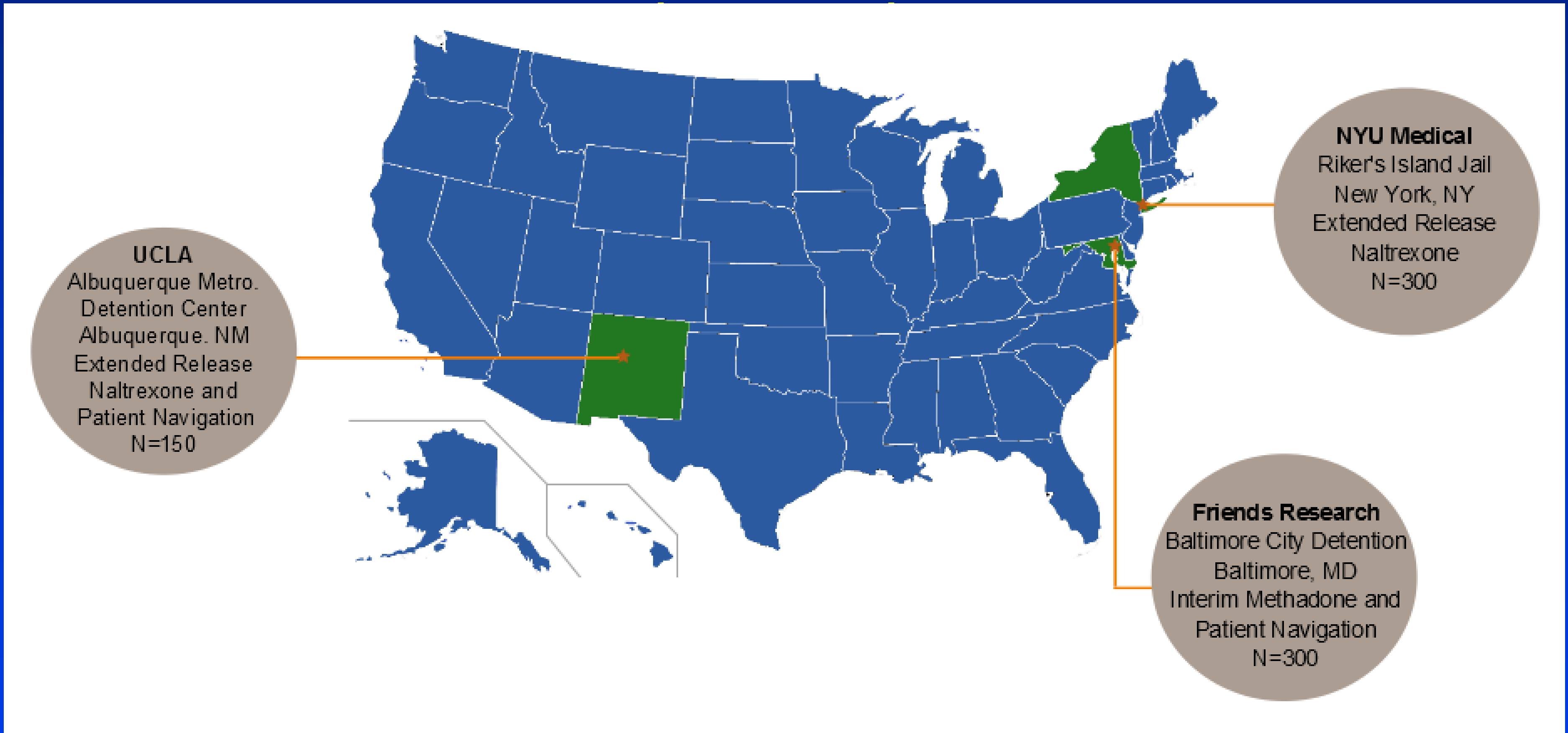
- Delayed OTP entry persists in some parts of the US
- Stepped wedge implementation study
- Testing an implementation facilitation intervention
  - Technical assistance and learning communities to implement IM
  - PI & National Association of State Alcohol and Drug Abuse Directors (NASADAD) will work with 9 to OTPs with waiting lists to implement IM

Outcomes

- Qualitative assessment of process
- Accessibility to methadone treatment
- Uptake of IM
- Efficiency (time to admission)
- Fidelity to IM
- Sustainability

What are the barriers to starting methadone in jail?

SOMATICS Collaborative



Jail-based Methadone Treatment

Recommended by the W.H.O. (WHO, 2004)

Common outside of US (Larney & Dolan, 2009)

Rare in the US (Nunn et al., 2009)

- Numerous barriers to implementation including lack of funding for counselors

Methadone Treatment at Rikers Island, NY

Available since the 1980s (Tomasino, 2001)

Low rates of methadone treatment entry post-release (Magura et al, 2009)

Patient Navigation

Individualized help to overcome barriers to entry & adherence to medical care

Uses strengths-based case management & active outreach

Effective in linking to:

- HIV care (Gardner et al,. 2005)
- Drug treatment (Mejta et al., 1997; Sorensen et al., 2005)

Treatment Arms

Medically Supervised Withdrawal
(N=225)

Interim Methadone (IM)
(n=74)

(IM + Patient Navigation)
(n=75)

Enhanced Treatment as Usual
(n=76)

33

Outcomes: 1, 3, 6 and 12 month post-release

Primary Outcome	Measure
Treatment participation at 1 month	Self report
Opioid Use	Urine Drug Screen

Secondary Outcomes	Measure
Days of Opioid Use in Past 30 days	ASI
DSM-5 Diagnosis for Opioid Use Disorder	CIDI
HIV Risk Behavior	Risk Assessment Battery
Number of Days Incarcerated	EF-90
Number of Arrests	EF-90
Quality of Life	WHOQOL-BREF

Summary

- 12 month follow-up nearly complete
- 24 month follow-up ongoing

- This study will provide data on benefits of different approaches to engaging out-of-treatment jail inmates in OUD treatment

Why is retention in methadone treatment less than optimal?

Staff Impressions of Interim Methadone

- Intake process was the same as usual care
- Little need for emergency counseling
- IM was an efficient way to keep OTP census full
- Some IM patients asked nurses when they were going to start counseling
  - In contrast to usual care patients who often do not attend counseling

Would Starting Treatment without Counseling Improve Outcomes Compared to Standard OTP?

- Newly-admitted OTP patients may benefit from methadone without counseling as an introduction to treatment
  - To increase their readiness for counseling
  - To reduce drop-out
  - To improve outcomes

Schwartz et al., 2011a, b

Aims

To determine if IM v. Standard Methadone Treatment would:

1) increase treatment retention

2) reduce heroin and cocaine use

3) reduce criminal behavior

Methods

Eligibility Criteria:

- 18 years or older
- Unable to enter OTP for > 2 weeks

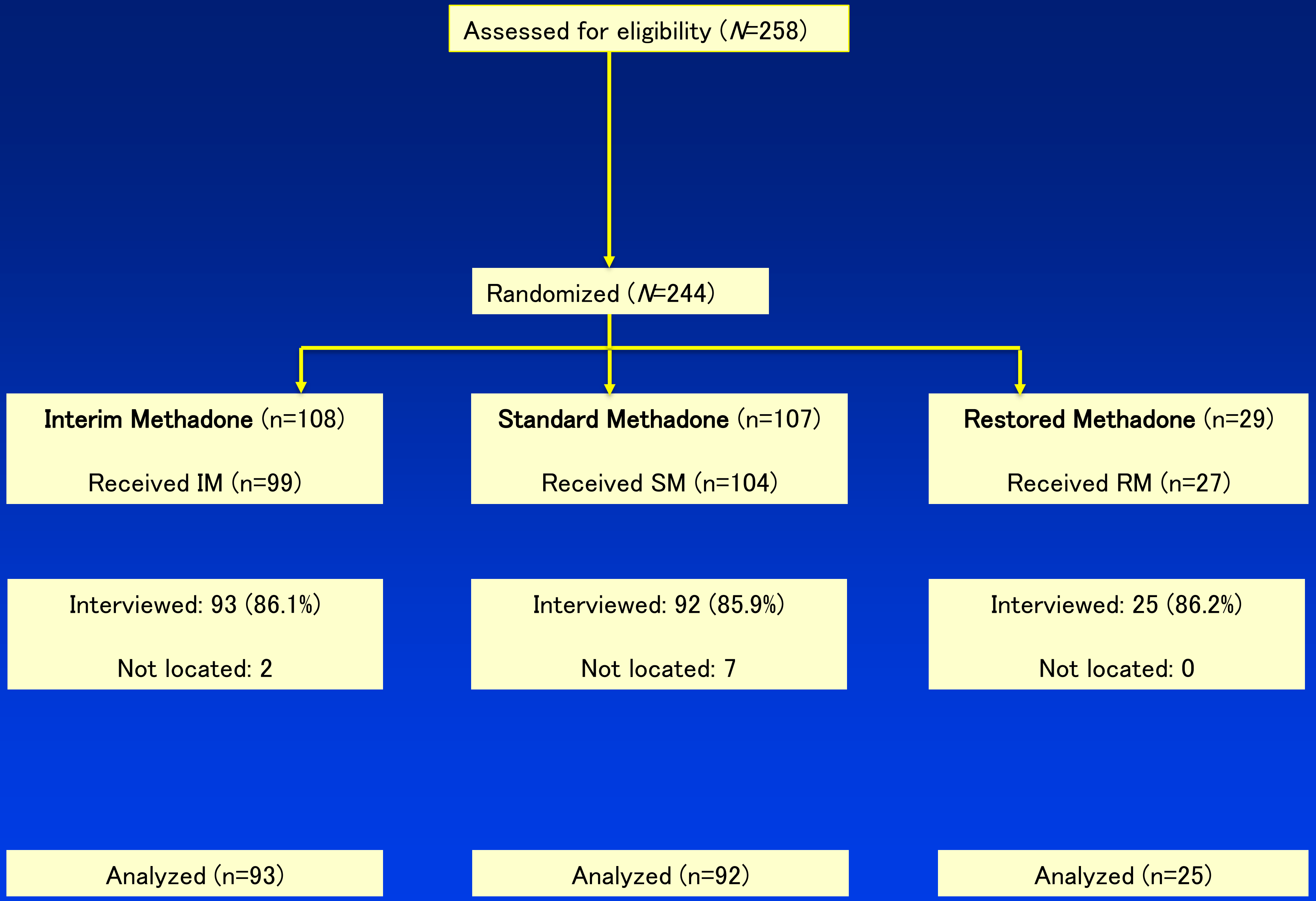
Assessments

- ASI and drug tests at baseline, 4-, and 12-month follow-up

Random Assignment:

- IM *v.* Standard Methadone *v.* Restored Methadone (counselor with ½ caseload at one of two study sites)

GLMM Analysis on intent-to-treat basis

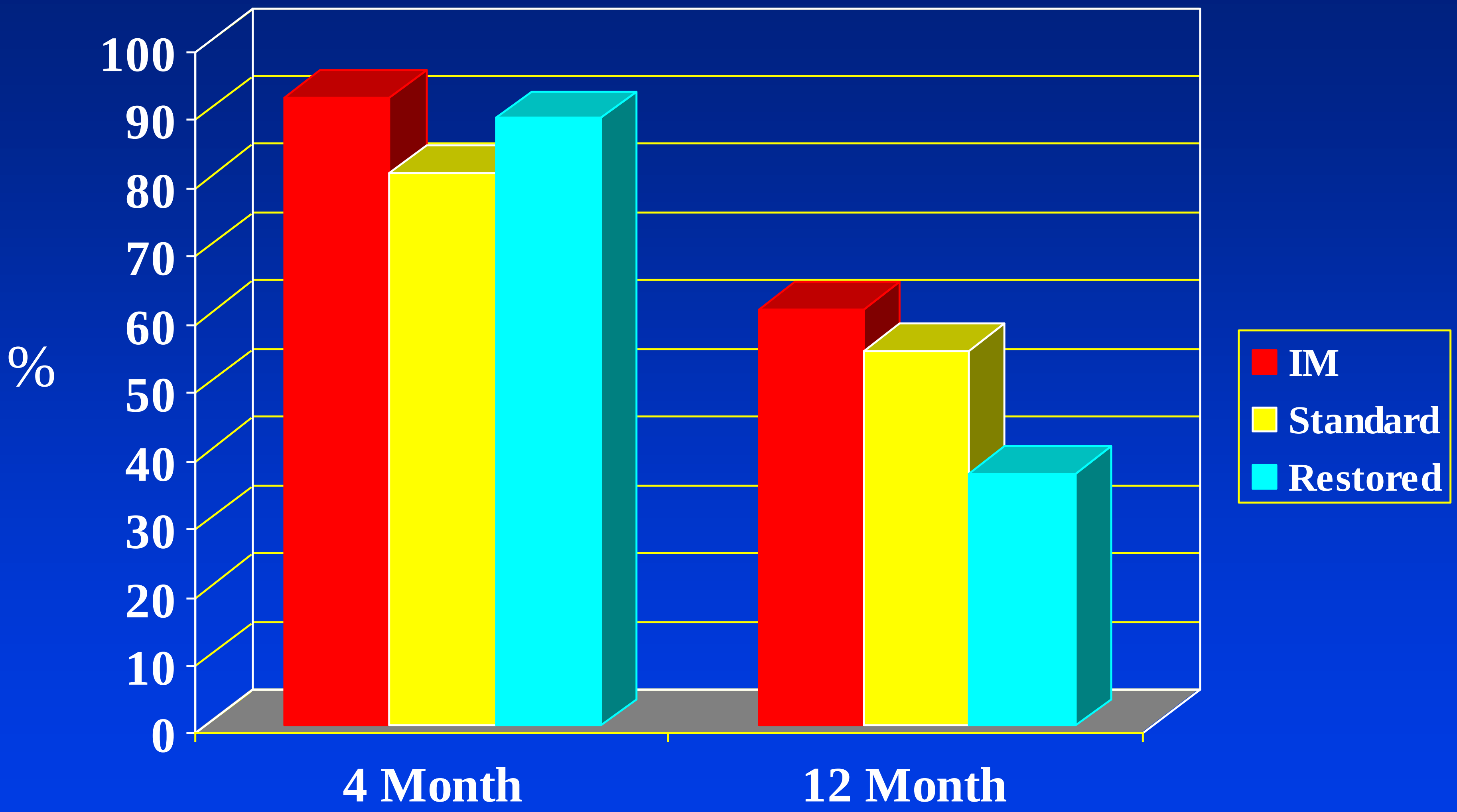

Assessed for eligibility (N=258)
Randomized (N=244)
Interim Methadone (n=108)
Received IM (n=99)
Standard Methadone (n=107)
Received SM (n=104)
Restored Methadone (n=29)
Received RM (n=27)
Interviewed: 93 (86.1%)
Not located: 2
Interviewed: 92 (85.9%)
Not located: 7
Interviewed: 25 (86.2%)
Not located: 0
Analyzed (n=93)
Analyzed (n=92)
Analyzed (n=25)

Participants *

Demographics	***N* = 230**
Mean age (years)	43
Male	70 %
Black	77 %
White	23%
Married	14 %
Prior MTP treatment (%Yes)	46.5%
Lifetime months incarcerated	50.6 (67)
Education	11.3 (1.9)
Employed past 30 days (% Yes)	30.5%

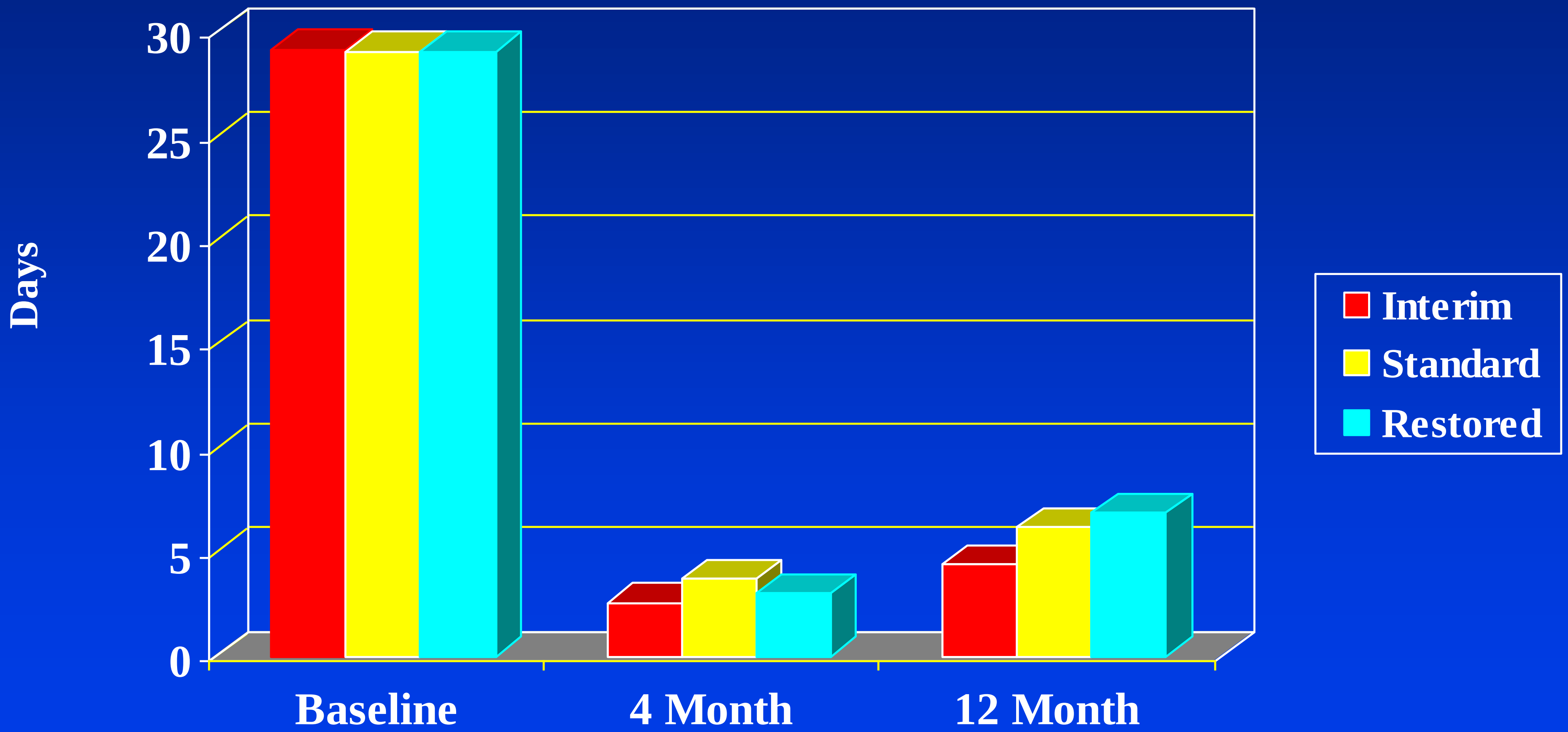
* No significant group differences

Treatment Retention*



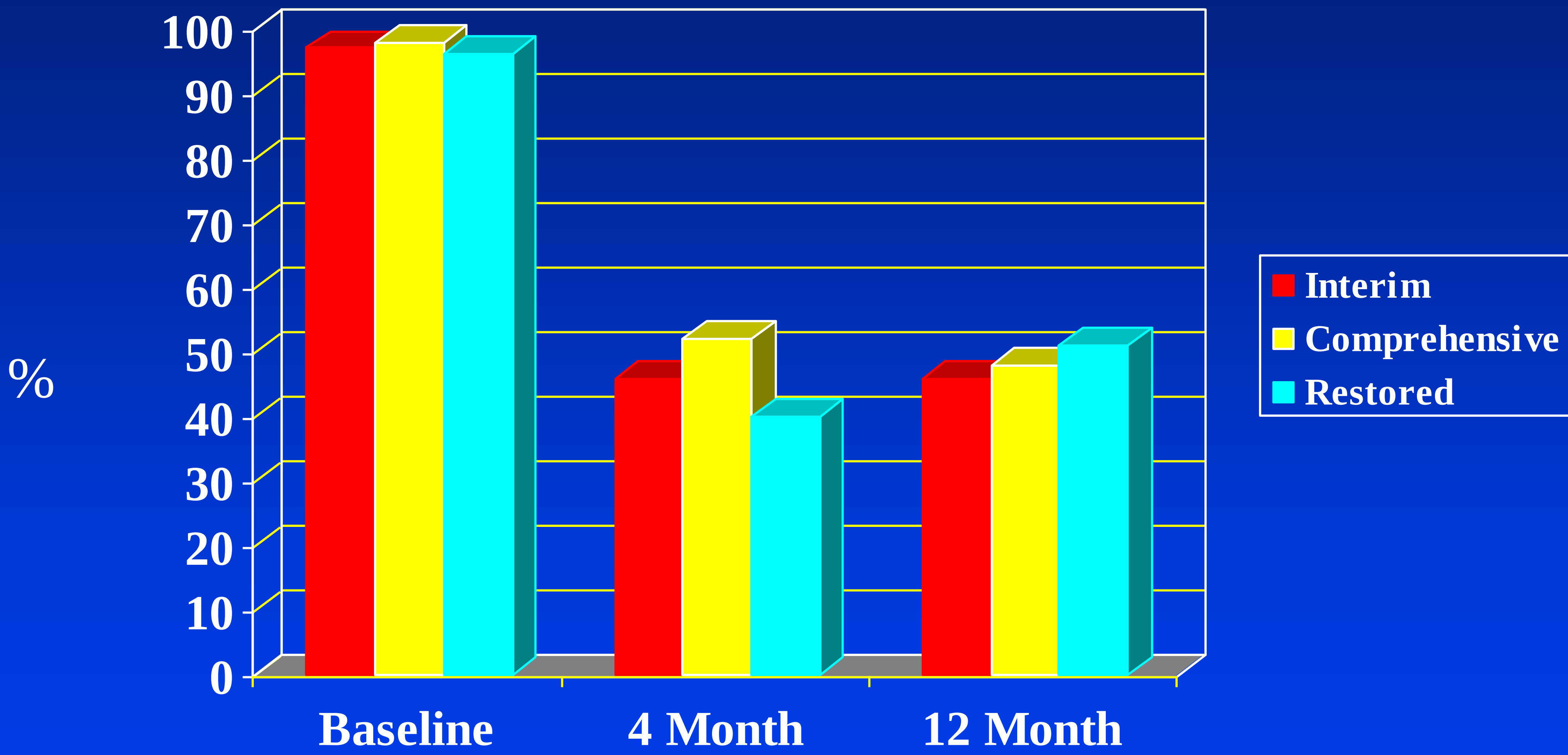
* Not significant: 4-month and 12 months

Number of Days Used Heroin (past 30 days)*



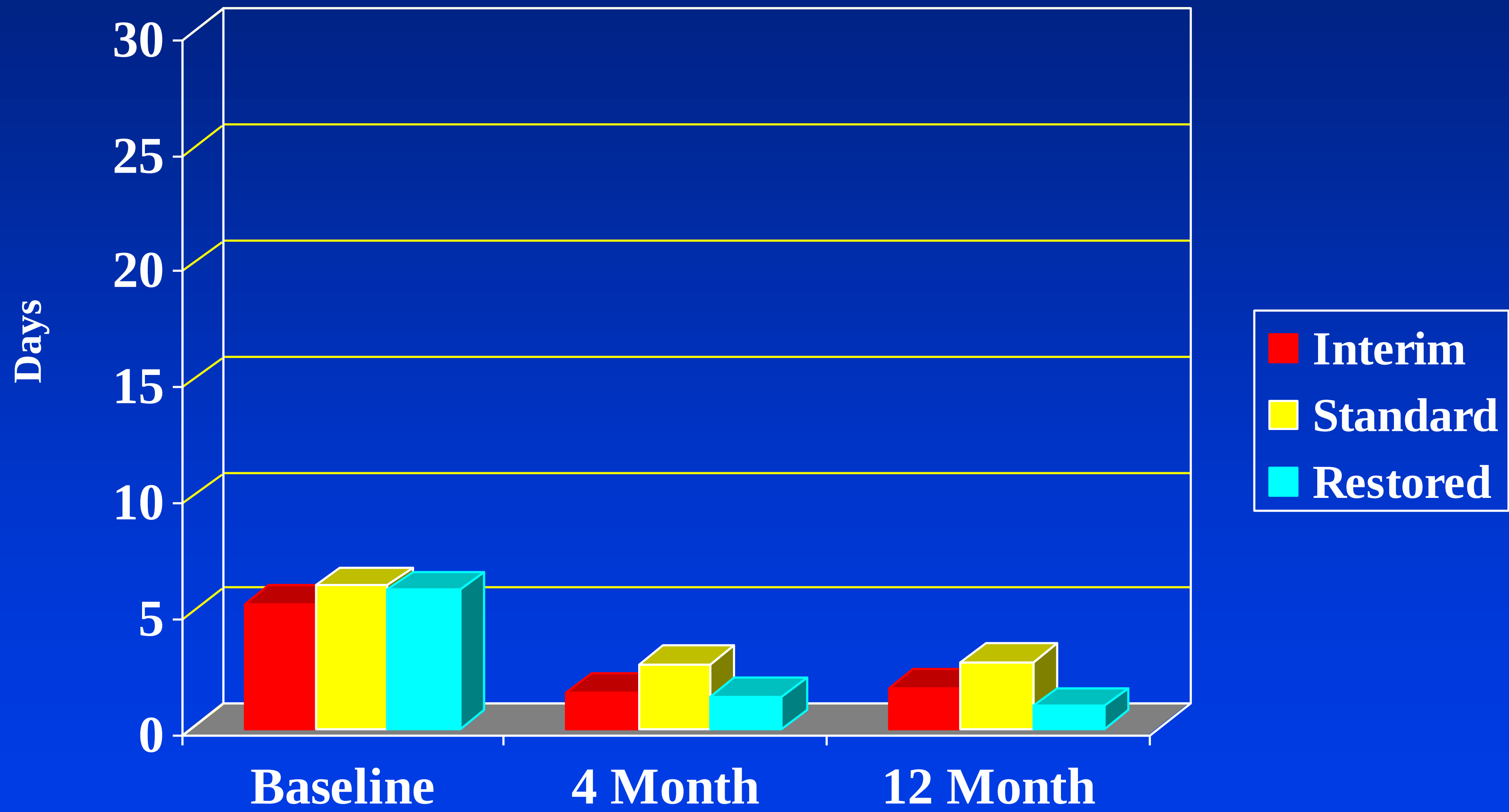
* Not significant: Group x Time interaction

Opioid Positive Drug Tests*



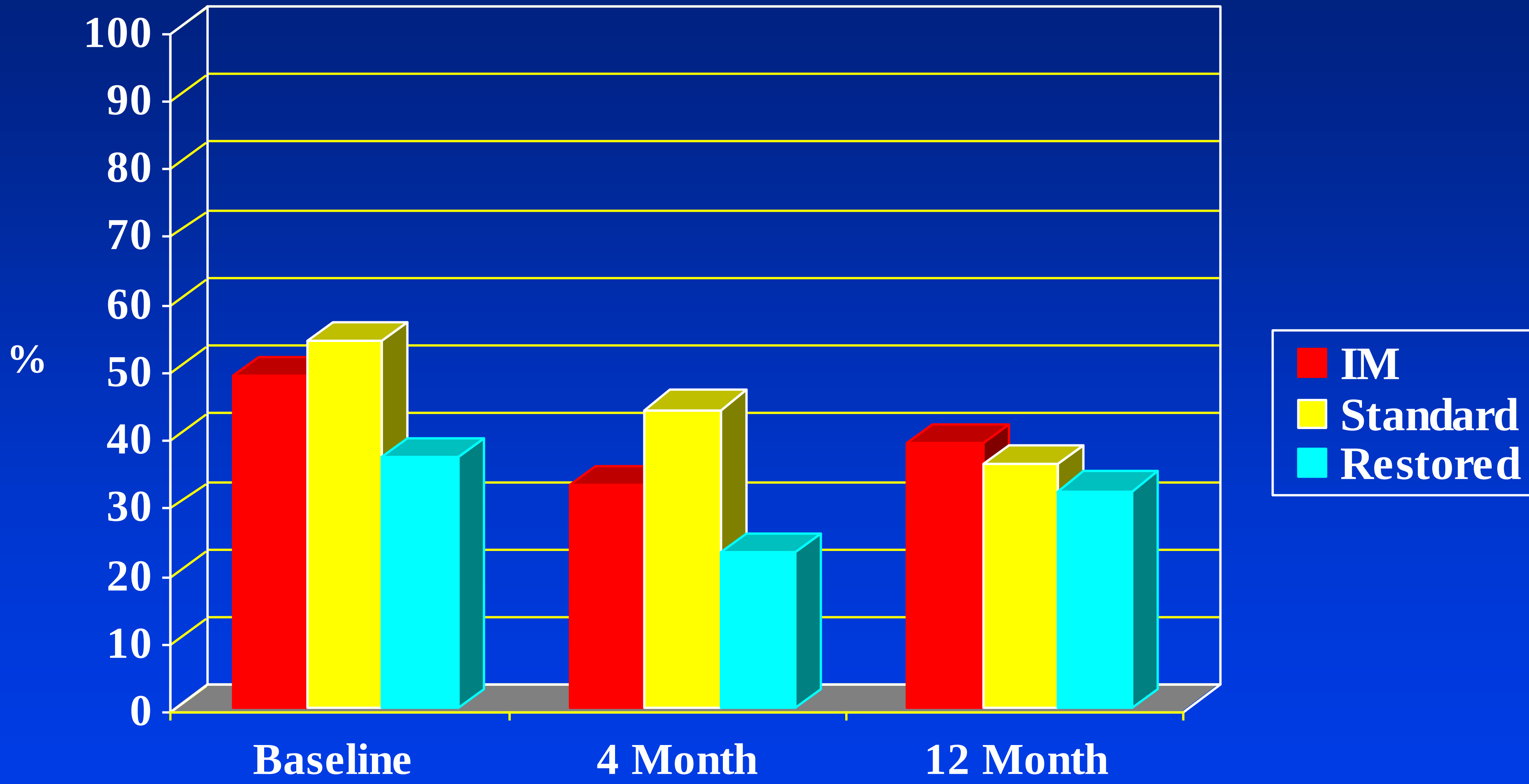
*Not significant: Group X Time interaction

Number of Days Used Cocaine (past 30 days)*



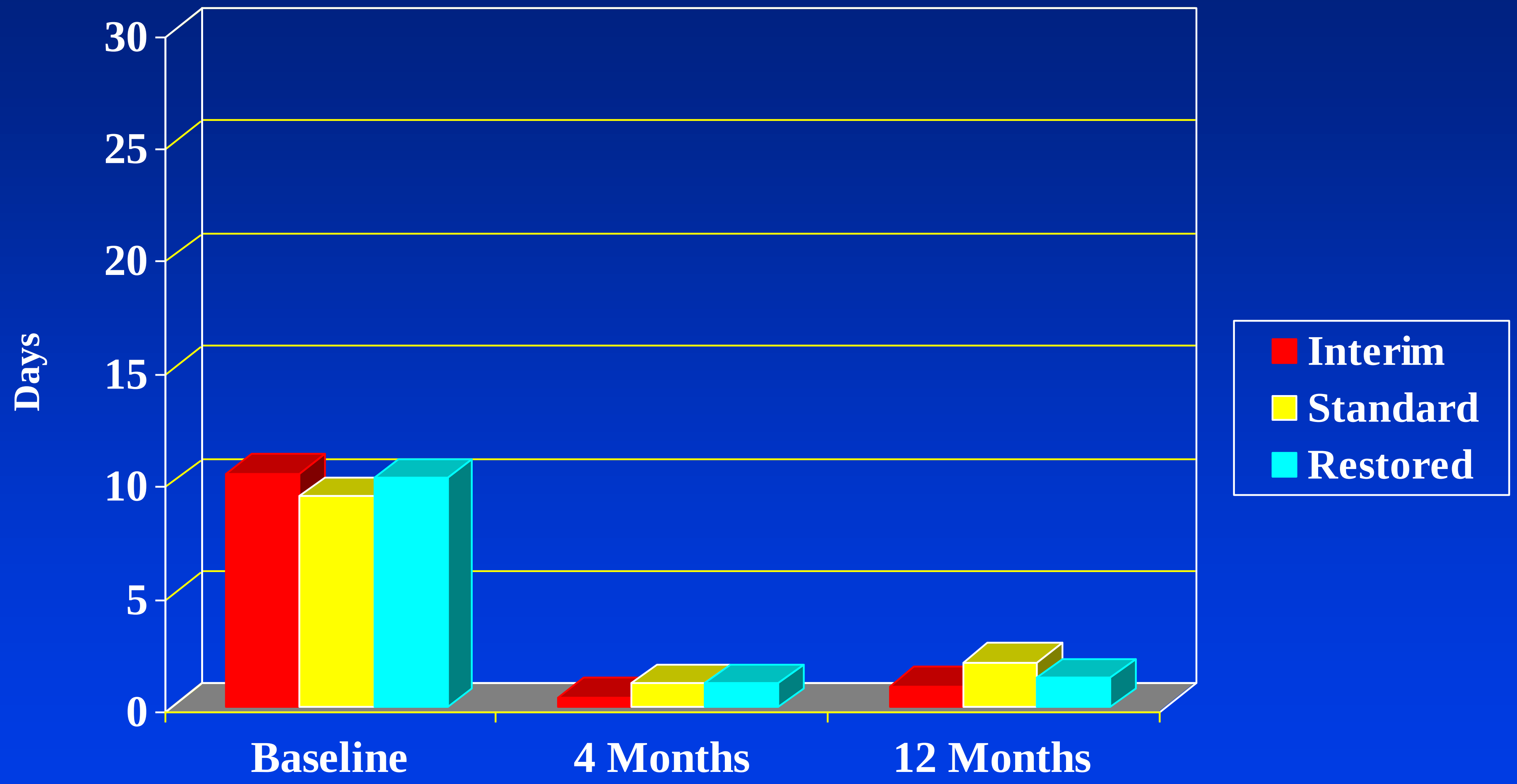
* Not significant: Group X Time interaction

Cocaine Positive Drug Tests*



*Not significant: Group X Time interaction

Days of Illegal Activity (past 30 days)*



* Not Significant: Group X Time interaction

Summary

No significant difference between methadone with counseling vs. without counseling for first 4 months of treatment in terms of:

- Treatment Retention
- Heroin use
- Cocaine use
- Illegal activity
- HIV risk-behavior (Kelly et al., 2012)

Reasons for MTP Discharge: Patients' Perspectives

- In-depth qualitative interviews with participants (*N = 42)* who left one of six OTPs during the first year of treatment
- Interviews focused on:
  - Their treatment experience
  - Why they left
- Data coded and analyzed using Atlas.ti

Reisinger et al., 2009

Patient Perspectives on Leaving MTP

- Incarceration [38.1%]
- Program-related Reasons for Discharge [40.5%]
  - Disagreement with program rules
  - Conflict with staff
  - Dissatisfaction with program

Reisinger et al., 2009

Reducing Barriers to Treatment Retention

- Many OTPs provide patients with limited autonomy
- Patient-centered treatment should be a key aim of high quality health care (IOM, 2006)
  - Respectful of, and responsive to, patient preferences and need
  - Permits patients to exercise control over their health care decisions
    - Even when in disagreement with providers

The OTP staff want you to discharge patients who continue to use illicit drugs and refuse to attend counseling.

As Medical Director, how would you assess the situation?

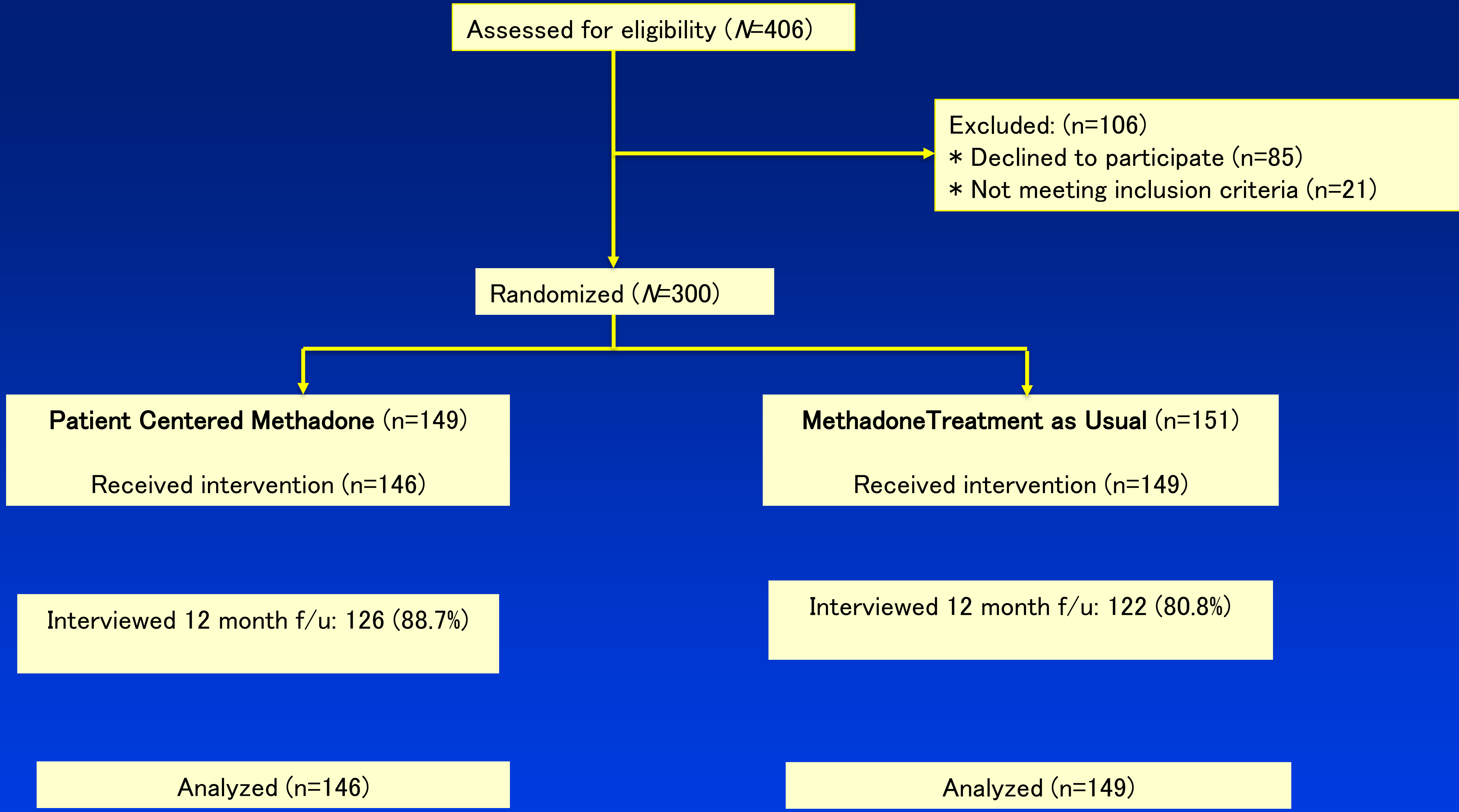
What are your options?

Patient-Centered Methadone Treatment

- Patients are mandated to receive counseling that they may neither need nor want
  - May be discharged from OTP for not complying with counseling requirements
- Idiosyncratic and arbitrary rules can lead to discharge against the patient's will
- Patient-centered treatment
  - Reduce rules to a minimum
  - Counseling attendance voluntary
  - Separated the counselor and disciplinarian role

Comparison of Treatment Conditions: TAU v. PC-MTP

Roles & Rules	**TAU**	**PC-MTP**
Missed methadone > 3 days	Discharge standard	Dose adjustment & reassessment
Counseling	Mandatory	Offered but not mandatory
Switching Counselors	Almost never permitted	Permitted at patient request
Loitering	Discharge standard	Alternative approaches to discharge
Non-payment of fees	Discharge standard	Alternatives to discharge
Threats to staff/ patients	Discharge standard	Discharge rare; case-by-case
“Bogus urine”	Discharge standard	Delay in receiving take homes
Multiple positive drug tests	May lead to discharge	Never leads to discharge
Counselor Role	Counselor & disciplinarian	Counselor role only


Assessed for eligibility (N=406)
Excluded: (n=106)
* Declined to participate (n=85)
* Not meeting inclusion criteria (n=21)
Randomized (N=300)
Patient Centered Methadone (n=149)
Received intervention (n=146)
MethadoneTreatment as Usual (n=151)
Received intervention (n=149)
Interviewed 12 month f/u: 126 (88.7%)
Interviewed 12 month f/u: 122 (80.8%)
Analyzed (n=146)
Analyzed (n=149)

No Significant Differences Between Conditions

Opioid positive tests
Cocaine positive tests
DSM-IV opioid dependence diagnosis
DSM-IV cocaine dependence diagnosis
Number of days of heroin use (past 30 days)
Number of days of cocaine use (past 30 days)
Quality of Life (WHO QoL BREF)
HIV risk behavior (RAB)
Treatment retention at 12 months

Physician Office Based Methadone Treatment

- Used widely throughout the world with pharmacy dispensing
- Studied in the US for stable patients (Senay et al., 1993; Novick et al., 1998; Schwartz et al., 1999; Fiellin et al., 2001; Merrill et al., 2005; King et al., 2002; Tuchman et al., 2006; Samet et al., 2018)
- US federal regulations permit opening medication units of OTPs that can be a pharmacy or physician office.
  - Used in KY for rural patients
- This approach could be expanded

Mobile Methadone Treatment

- Mobile van used in Amsterdam to provide low threshold treatment to marginalized populations (Buning et al., 1996)
- Studied in the US (Greenfield et al., 1996; Kuo et al., 2003; Hall et al., 2014)
- Vans are expensive and patients have to wait outside in line
- Useful to treat hard to reach populations
- New regulatory barriers created to opening new programs
  - Revised DEA regulations are under review

Challenges Remain

1. Reduce barriers to treatment entry

- Interim Methadone
- Start OTPs
- Engage individuals on parole and probation, hospitals, SEPs

2. Improve treatment retention

- Continue methadone treatment during incarceration
- Examine novel OTP structures/services to enhance retention
- Mobile units
- Physician office treatment

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