

# Physician Office-Based Methadone Treatment: US Literature

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# Disclosures

## Past

- Principal Investigator of NIDA-funded study (1 U01 DA 047982) that receives medication from Indivior and Alkermes
- Consultant for Verily Life Sciences

## Current NIDA grant support

- U01DA046910 (Implementing Interim Methadone Treatment)
- 3U01DA046910-S2 (Addiction Medicine Practice-based Research Network)
- 3U01DA046910-S3 (Opioid Treatment Program-Pharmacy Methadone Collaboration)

# Office-Based Methadone Treatment

- Provides methadone treatment in physician offices rather than OTPs
- Not allowed in US without SAMHSA-approved exemption
  - Methadone must be sent from OTPs to offices or pharmacies
- Australia, Canada, Great Britain and other European countries have provided office-based methadone treatment and pharmacy collaboration for decades<sup>1</sup>
- Patients
  - new or unstable
  - stable patients

# Office-based Methadone Treatment: New or Unstable Patients

- No US-based research papers
- Routine practice internationally
  - See recent review that included US and international studies<sup>2</sup>

# Office-Based Methadone Treatment: Stable Patients

## “Methadone Medical Maintenance”

- Concept described by Dole in 1972<sup>3</sup> for patients:
  - working
  - abstinent
  - not in need of support services
- First initiated with FDA IND permit in 1983<sup>4</sup>
  - monthly physician office visits
    - 1 dose administered, 30 take-homes, counseling, and drug testing
  - Advantages
    - no weekly OTP visits
    - less stigma
    - no interaction with drug-using patients at OTP

# Medical Maintenance: Case Series

Location Article Date	N=348	Abstinence Criteria (years)	Administer Dispense	Retained (%)	+ Drug Tests (% Pts)	+ Drug Tests (% Tests)
NYC <sup>4,5,6,7</sup> 1988-2000	158	3	Office	89 3 years	Not reported	
Baltimore <sup>8</sup> 1999	21	5	Office	71 12 years	14	0,5
Seattle <sup>9</sup> 2005	30	1	Pharmacy	93 1 year	7	0,9
Bronx <sup>10</sup> 2006	127	3	Pharmacy	98 5 years	6	1,2
Lancaster, PA <sup>11</sup> 2007	12	0,5	Pharmacy	85 1 year	17	0,9

No failed call back: Baltimore, Bronx, Seattle; others not reported.

# Medical Maintenance vs. Usual OTP Care

## Randomized Trials

Location Year of Publication	Patients (N=203)	Abstinence Criteria (years)	MD Visit	Dispensary	Counseling
Chicago <sup>12</sup> 1993	130	0,5	Office	Office	MD & Counselor in OTP
New Haven <sup>13</sup> 2001	46	1	Office	Office	MD
Baltimore <sup>14</sup> 2006	92	1	<ul style="list-style-type: none"> <li>• Office</li> <li>• OTP Office</li> </ul>	<ul style="list-style-type: none"> <li>• Office</li> <li>• OTP Office</li> </ul>	MD MD
ABQ & Santa Fe <sup>15</sup> 2006	26	(2 or more earned take homes)	Office	Pharmacy	MD MSW

# Medical Maintenance vs. Usual OTP Care

## Randomized Trial Outcomes

Site Date	Follow-up (Year)	Retention	% Positive Drug Tests
Chicago <sup>12</sup> 1993	1	NS	NS
New Haven <sup>13</sup> 2001	0,5	NS	NS
Baltimore <sup>14</sup> 2006	1	NS	NS
ABQ & Santa Fe <sup>15</sup> 2006	1	Not tested	NS

- **NS = No Significant differences between Medical Maintenance and Usual OTP care**



# New Haven Randomized Trial<sup>13</sup>

## Design

- Office-based Methadone Treatment vs. OTP

## Inclusion Criteria

- $\geq 1$  year in OTP with opioid and cocaine abstinence
- No current cocaine, alcohol or other drug dependence
- Working

## Physician Support

- 8 hours training
- Researchers provided monthly reviews & consultation

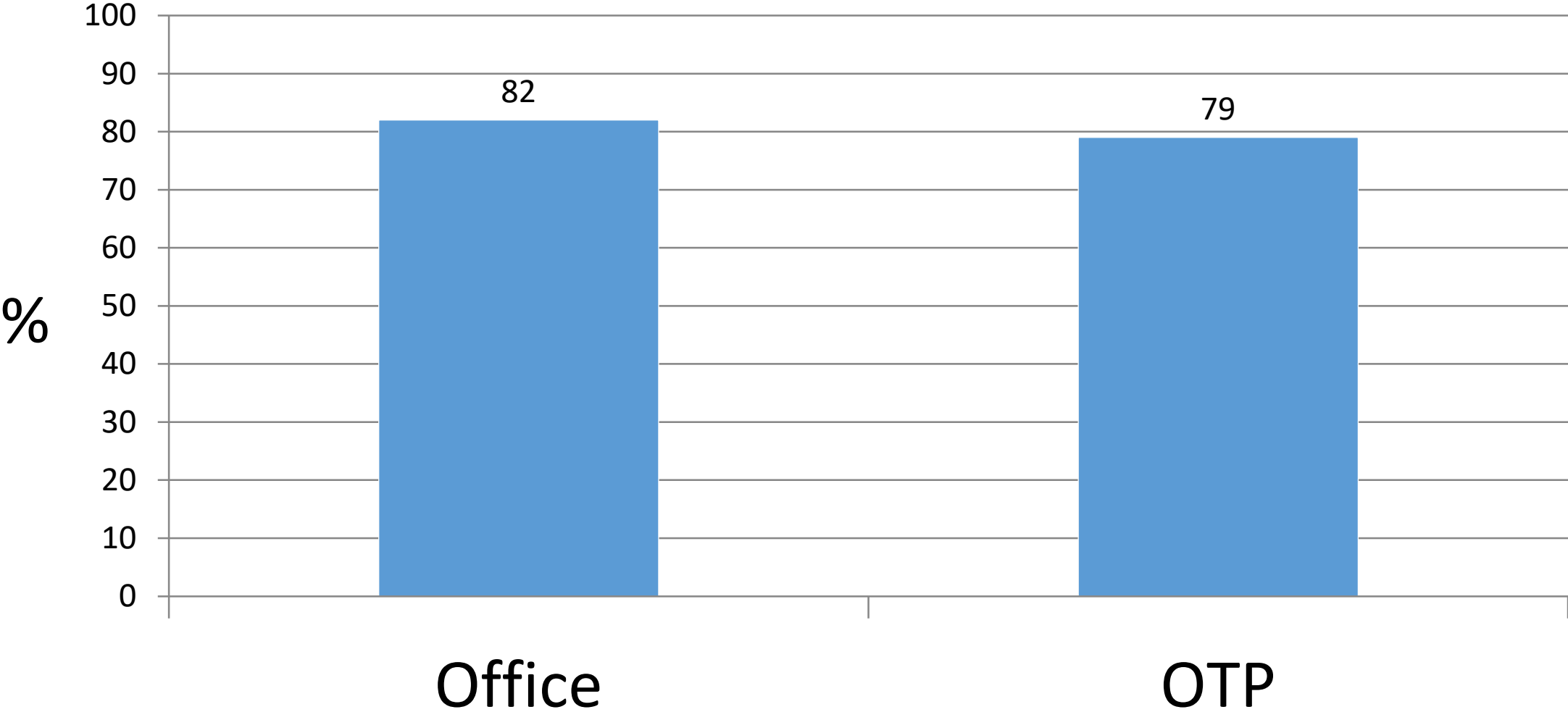
# Design Features

	Primary Care	OTP
Sites	5 Clinics	1 OTP
Take Homes (# per week)	6 doses	6 doses or 2 doses given 3 times/week
Counseling Sessions (# per month)	1 with MD	1 with counselor 4 group sessions
Drug Testing	random and non-random	random and non-random

“Clinical Instability” = 2 consecutive weekly positive drug tests or negative for methadone.

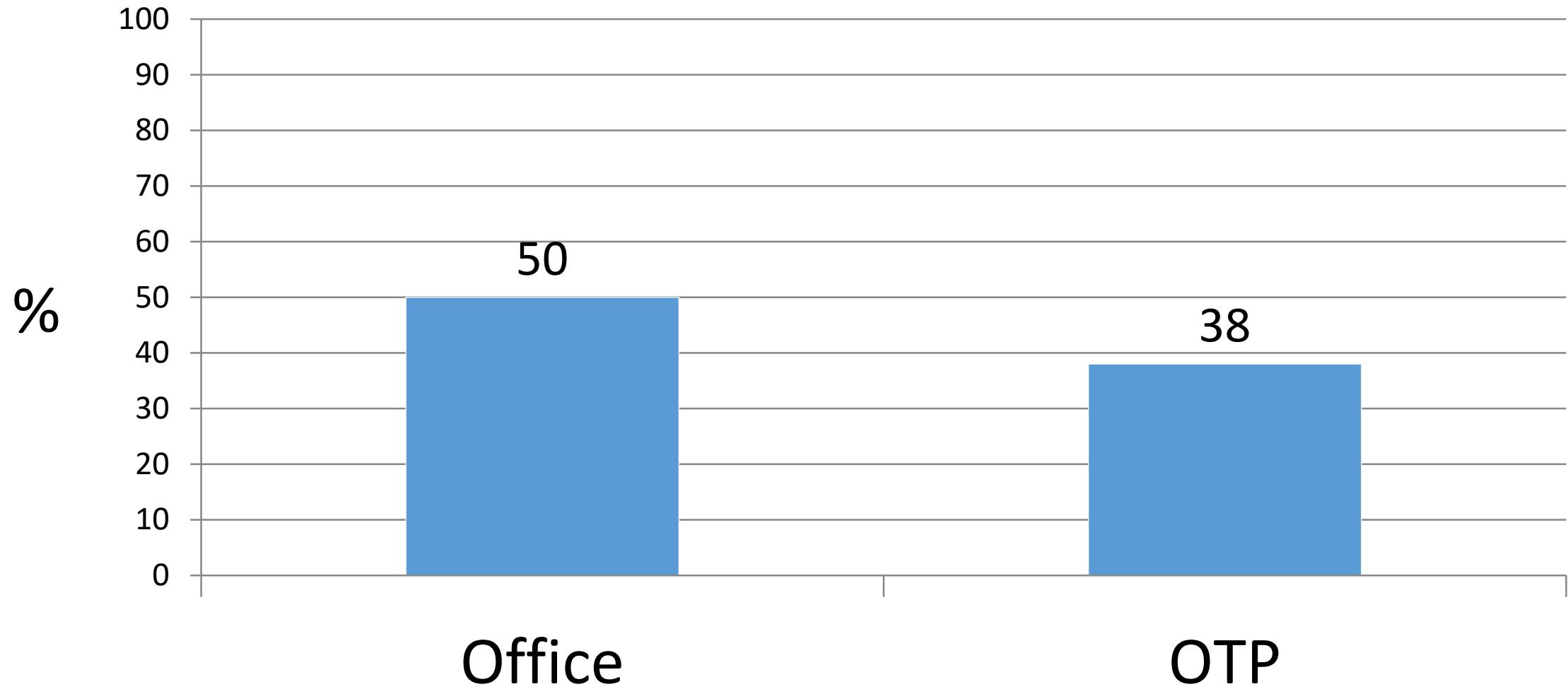
- Office-based: back to OTP for more counseling, only 1 take home dose, more drug testing
- OTP: same as above

# Six Month Retention in Treatment Condition



No significant differences.

# % Participants with Self-reported Drug Use or Positive Drug Test

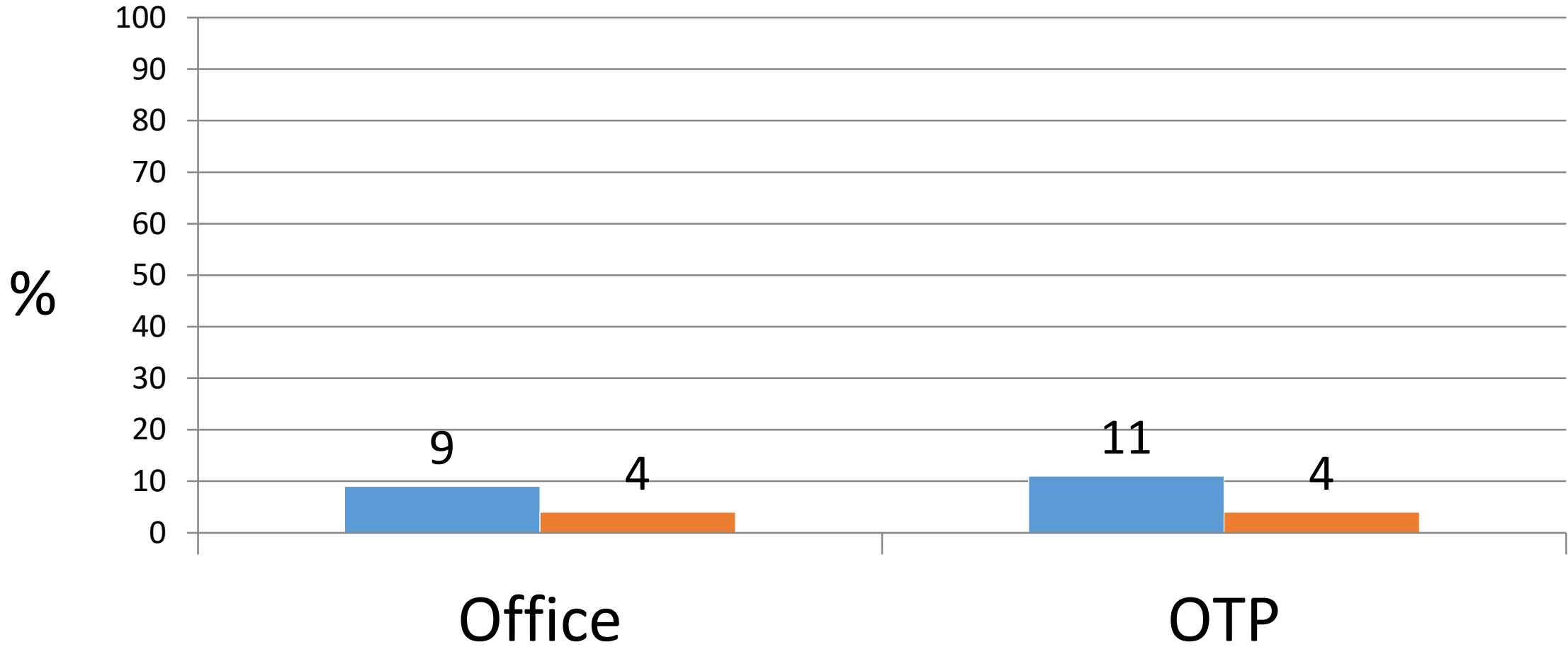


**No significant differences.**

# % Positive Drug Tests

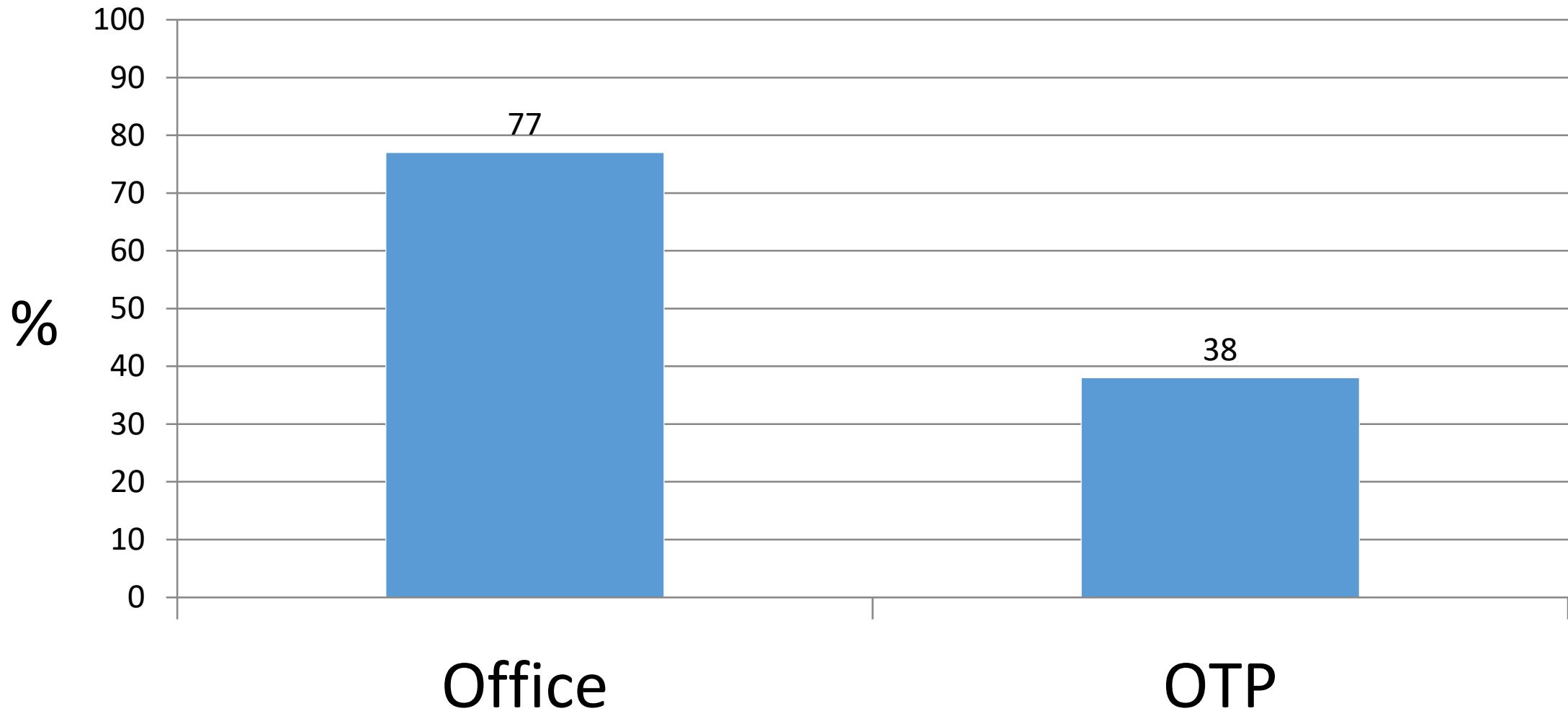
■ Opioid

■ Cocaine



No significant differences.

# Patient Satisfaction: Very Satisfied



$p = .01$

# Other Findings

- No significant differences of clinical instability
  - 18% in OBOT vs 21% in OTP
- MDs reported handling methadone dispensing records was burdensome and better handled by a pharmacist

# Baltimore Randomized Trial<sup>14</sup>

- Design

- 3 group randomized trial
  - Office-based
  - Office-based in OTP
  - OTP

- Inclusion Criteria

- $\geq 1$  year in OTP with negative drug tests
- Working
- No failed methadone recalls



# Design Features

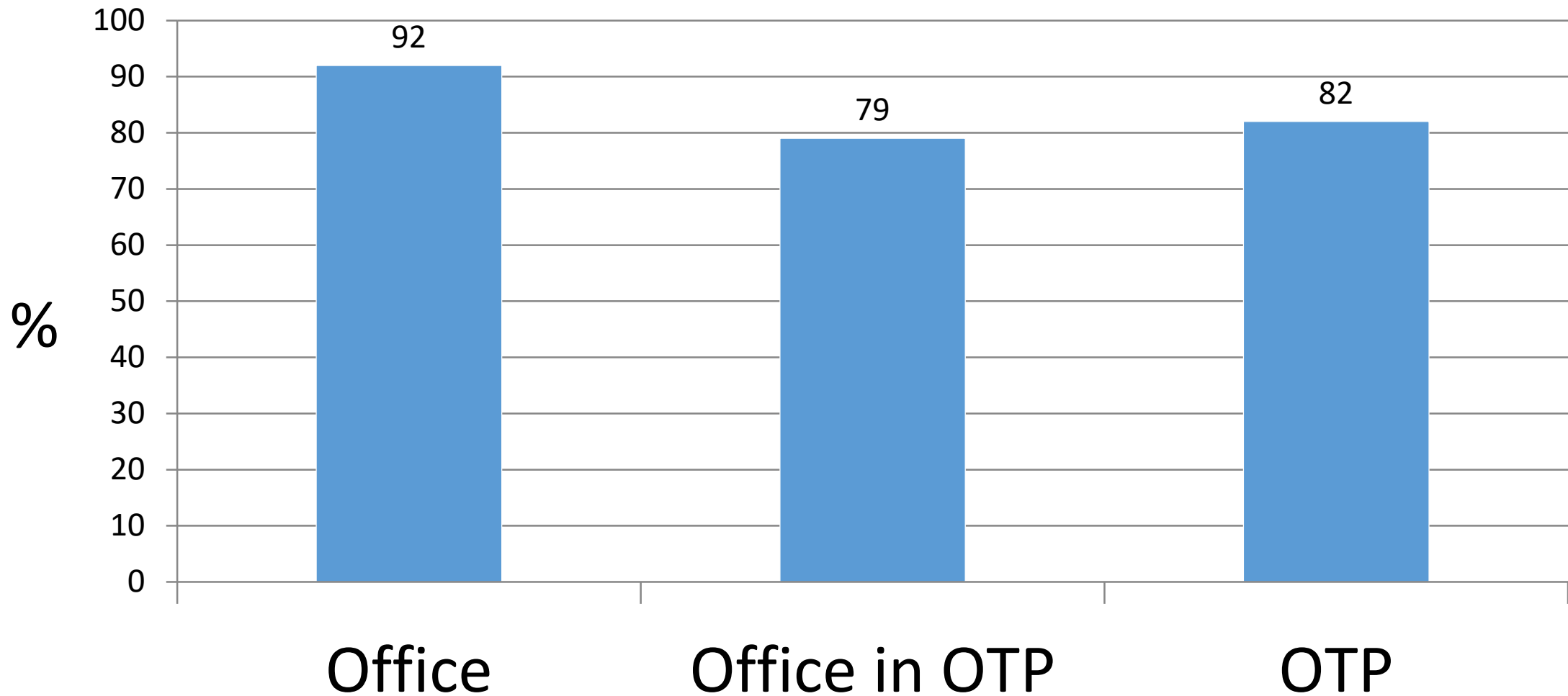
	Office-based	OTP
Sites	<ul style="list-style-type: none"><li>• 2 MD offices</li><li>• 1 MD office in OTP</li></ul>	2 OTPs
Take Home Doses (# )	27 per month	5 - 6 per week
Counseling Sessions (# per month)	1 by MD	1 by counselor
Drug Testing (# per month)	2	2
Call Back (# per month)	1	1

“Treatment Intensification Criteria” = 1 positive drug test or 1 failed call back.

Office-based: back to OTP for weekly counseling and drug testing, only 2 take homes/week.

Office-based in OTP and OTP : same as above at OTP

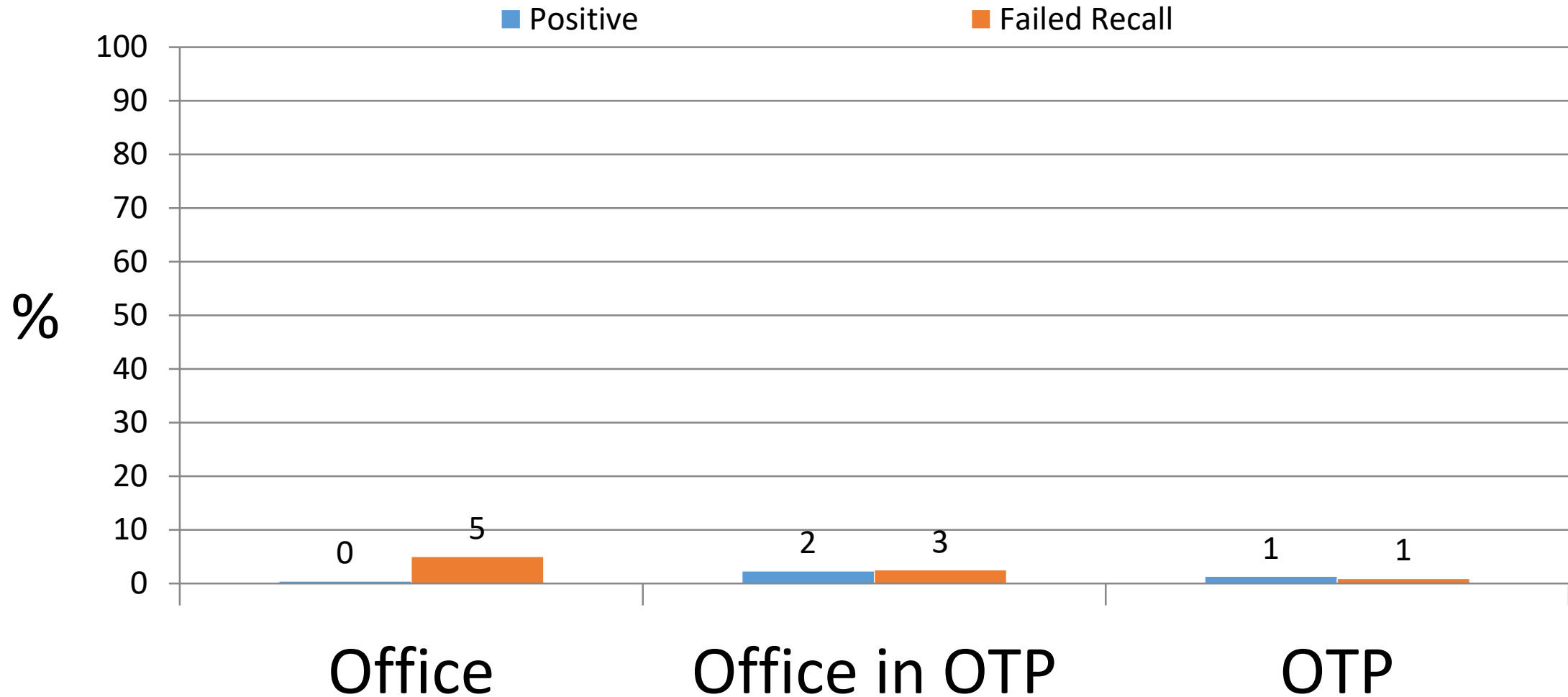
# 12 Month Study Retention



**No significant differences.**

Among non-retained participants: 6 reported being unable to handle 27 take home doses.

# Positive Drug Tests & Failed Methadone Recall



Failed recall = incorrect # of Take Homes.

No significant differences for drug tests or failed

# Other Outcomes

- No significant differences meeting criteria for intensified treatment (36% of participants)
  - most returned to their original Treatment Condition
- Both Office-based Conditions reported significantly higher rates of new employment or social/family activities than OTP Condition.

# Future Considerations: New or Unstable Methadone Patients

Goal: Increase access, patient choice, and number of people in treatment

- Select and implement best international approach using offices and pharmacies
  - evidence of safety, efficacy, and impact on overdose death rate
  - adapt existing training & procedure manuals
    - safe dose induction guidelines and methadone administration
    - take home rules consistent with OTPs
  - evaluate outcomes with comparison group
- Leverage
  - DATA 2000 waiver system
  - community health center infrastructure
- Link offices with OTPs or addiction treatment specialists
  - for consultation and to help treat poor-responders

# Future Considerations: Stable Patients Medical Maintenance

Goal: Increase patient choice, reduce stigma, integrate care, and create openings for new OTP admissions

- Expand Medical Maintenance under current regulations
  - Supported by existing evidence
  - Inform States and providers about how to obtain exemptions
    - Disseminate best practices and payment guidance
- Update regulations to permit
  - Trained pharmacists with connection to office-based sites to:
    - administer and dispense methadone
    - supply methadone directly to approved office-based sites
  - Take home rules consistent with OTPs

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