

Acceptability of Extended-Release Naltrexone as a Conduit to Care for HIV+ Criminal Justice Populations: *Preliminary results of 2 double blind placebo controlled randomized trials*

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Background

- HIV prevalence is 3x greater in CJS persons vs non-CJS ^{11,12}
- After release HIV+ prisoners do not adhere to ART and have ↑VL ↓CD4 within 3 months post-release^{1,2}
- 50-60% of U.S. CJS have alcohol and drug use disorders (compared to 6 and 3% in the community); ^{3,4} and the majority relapse after release⁵ which is associated with increased morbidity and mortality ^{5,6}
- Effective MAT for opioid & alcohol improves relapse prevention in the community, but is not routinely offered in CJS settings or at time of release ^{7,8,9}
- XR-NTX, a once monthly injectable opioid antagonist that is FDA-approved for alcohol and opioid dependence might assist in maintaining HIV VL suppression through prevention of relapse after release.⁹
- *The question is will XR-NTX be accepted by HIV+ CJ – involved persons?*

1. Springer CID 2004

2. Baillargeon, JAMA 2010

3. Karberg, 2005

4. Peters, 1998

5. Springer CID 2011

6. Binswanger NEJM 2007

7. Oser DAD 2009

8. Chandler JAMA 2009

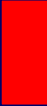
9. Springer PLoS ONE 2012

11. Maruschak LM. *Bur Justice Stat Bull.* 2009.

12. Spaulding. *PLoS One.* 2009;4:e7558

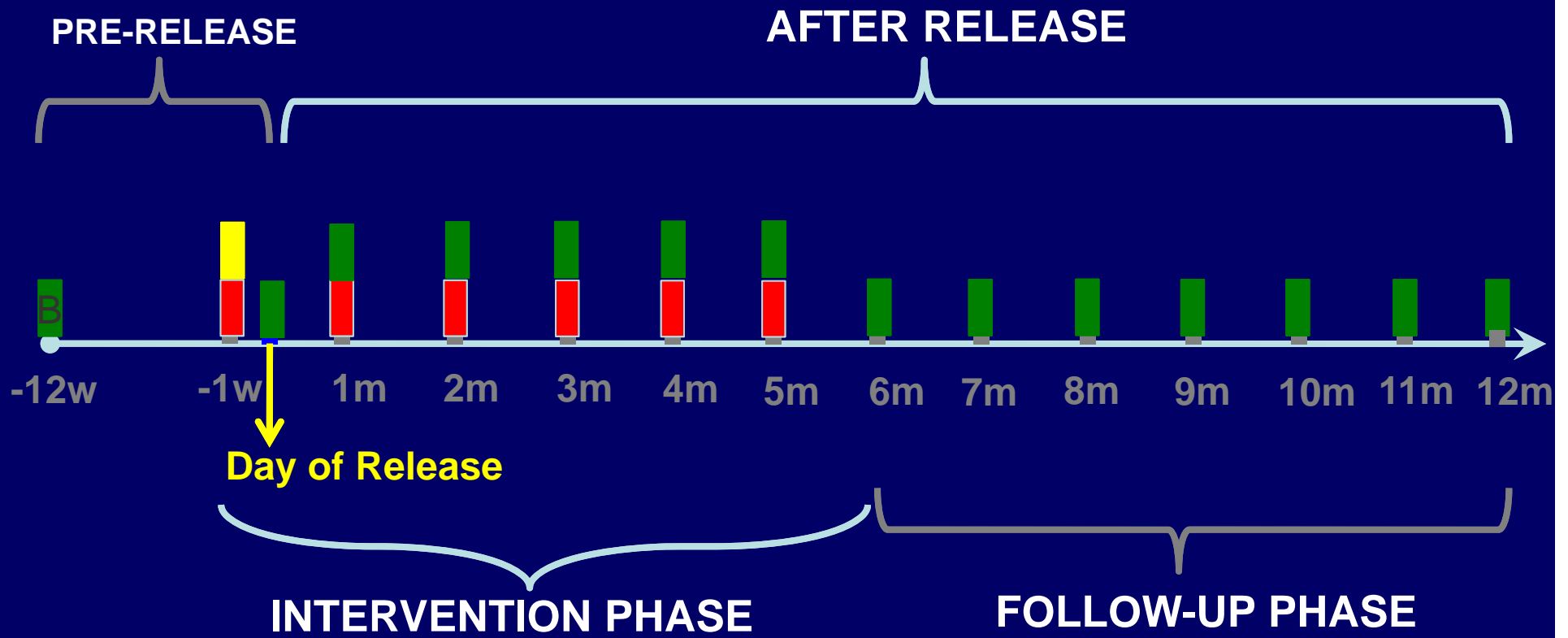
2 Double Blind Placebo Controlled Randomized Trials of XR-NTX among HIV+ CJ-involved Persons

R01-AA 018944 NIAAA (*Inspire*) & R01-DA 030762 NIDA (*New Hope*)

 = IM injection
+ MM counseling

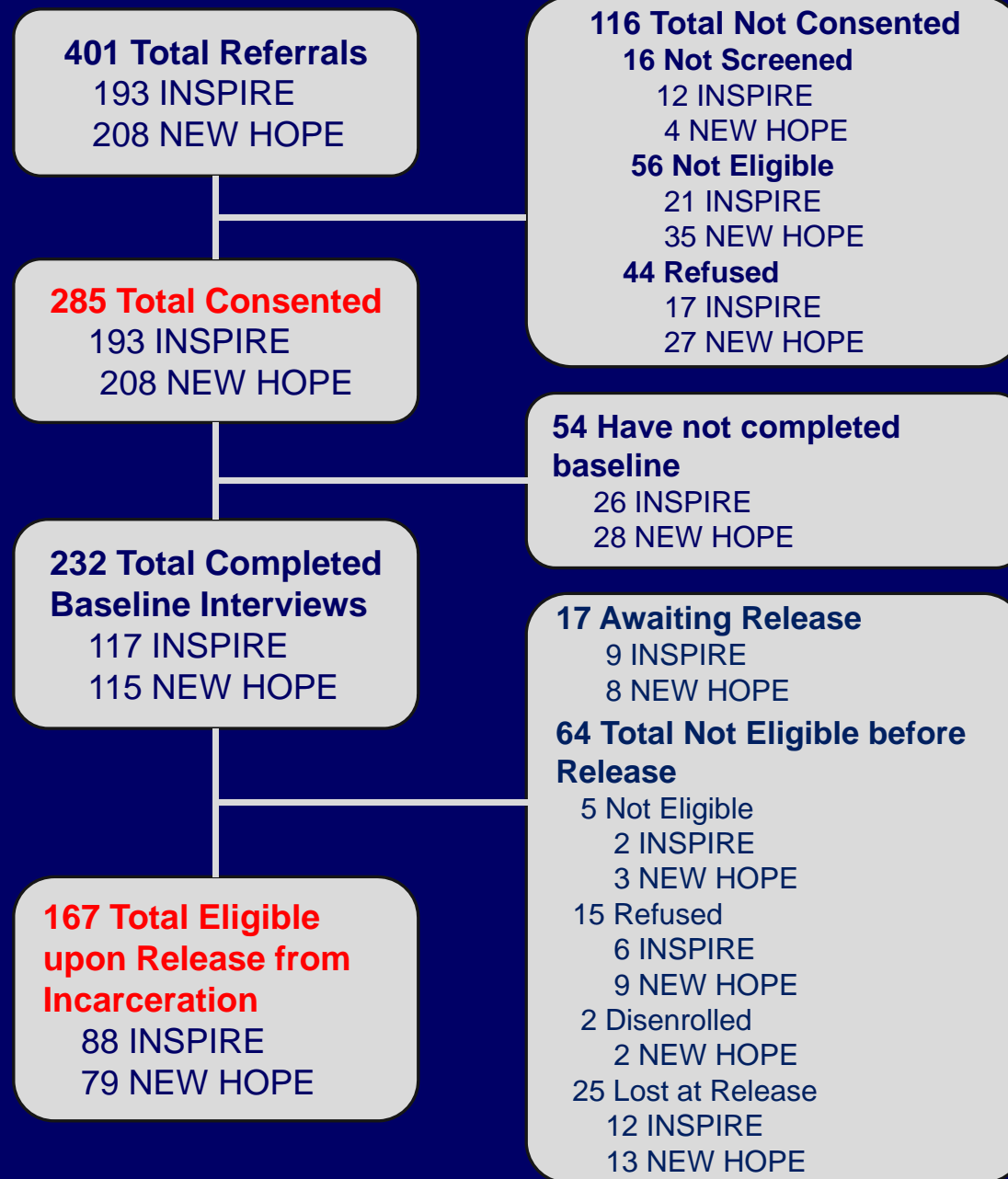
 = Interview

 = Chart Review



1. Springer et al. *Contemporary Clinical Trials* 2014; 2. Di Paola et al... *Springer. CCT* 2014.

Enrollment Consort



Injection Acceptability

	COMBINED	INSPIRE	NEW HOPE
Received <u>Initial</u> Injection	145 of 167 (86.8%)	83 of 88 (94.3%)	62 of 79 (78.5%)
Reasons did not receive injection			
Opioid dependent	3	0	3
Positive for opioids	1	0	1
Clinical need for opioids	4	2	2
Inpatient Drug Treatment	4	2	2
Moved out of area	1	0	1
Quit study	1	0	1
Refused injection	1	1	0
Temporarily Lost	5	0	5
Lost to follow-up	2	0	2
Received <u>Second</u> Injection	86 of 145 (59.3%)	48 of 83 (57.8%*)	38 of 62 (61.3%)
Reasons did not receive injection			
Opioid dependent	3	0	3
Clinical need for opioids	1	1	0
Inpatient Hospital	1	0	1
Inpatient Drug Treatment	5	2	3
No recent labs on file	1	1	0
<i>Incarcerated</i>	12	10	2
Moved out of area	1	1	0
Quit study	1	0	1
Disenrolled, dementia	1	1	0
Refused injection	3	3	0
<i>Temporarily Lost</i>	22	14	8
Lost to follow-up	7	1	6

* plus 1 that did not receive the initial injection due to inpatient drug treatment

Demographic Information

Baseline Characteristic	Total Group N=141	Returned for 2nd Injection N=83	Did NOT Return for 2nd Injection N = 58
Study			
Inspire	57%	57%	43%
New Hope	43%	62%	38%
Gender			
Male	77%	60%	40%
Mean age	44.7 (± 8.17)	45.1 (± 7.47)	44.3 (± 9.12)
Race			
White non Hispanic	11%	56%	44%
Black non Hispanic	48%	60%	40%
Hispanic	41%	59%	41%
Mean Months Incarcerated (N=138)	11.8 (± 22.80)	14.5 (± 28.38)	7.9 (± 9.10)
Housing pre incarceration			
Homeless	35%	56%	44%
AUDIT Hazardous Drinking (N=138)	70%	54%	46%
without hzd drinking	30%	73%	27%
Prescribed ART at baseline	78%	64%	36%
Experienced Serious Depression 30 days prior inc	56%	65%	35%
Cocaine Postive Urine Tox. at Day of Release	15%	39%	61%
Mini International Psychiatric Interview			
Current Major Depression (N=136)	35%	62%	38%
Alcohol Use Disorder (N=135)	61%	55%	45%
Narcotic Use Disorder (N=126)	50%	60%	40%
Marijuana Use Disorder (n=117)	20%	65%	35%
Cocaine Use Disorder (N=126)	71%	57%	43%
Any Substance Use Disorder (N=135)	80%	58%	42%
Any Alcohol AND SUD (N=134)	48%	41%	39%
without comorbid Alcohol and SUD	52%	67%	33%

Significant in Bivariate Regression $p < 0.10$

Multiple Regression Model

Baseline Characteristic	p value	Odds Ratio	95% Confidence Interval
AUDIT Hazardous Drinking*	0.159	0.448	0.146-1.371
Prescribed ART at baseline	0.975	0.981	0.293-3.278
Experienced Serious Depression 30 days prior incarceration	0.415	1.443	0.598-3.483
Cocaine Pos. Urine Toxicology on Day of Release	0.005	0.207	0.068-0.623
Any Alcohol AND SUD (N=134)	0.463	0.698	0.267-1.822

Goodness of Fit = .156

Conclusions

- XR-NTX is highly acceptable among HIV+ CJS populations with opioid and alcohol use disorders and high levels of comorbid psychiatric illness
- Cocaine use disorders are associated with possible poorer treatment retention and interventions for cocaine treatment are urgently needed
- XR-NTX may be a feasible conduit to care for HIV+ opioid and alcohol use disorders among CJ-involved persons as they transition to the community

Acknowledgements

- **NIAAA:** R01-AA018944 (Springer, PI)
- **NIDA:**
 - R01:DA 030762 (Springer, PI)
 - K02: DA032322 (Springer, PI)
- **Alkermes Inc.:** Providing in-kind XR-NTX and placebo through Investigator-initiated applications
- The Participants!
- All Yale Clinical and Community Research Staff
- Angela Di Paola, MS (Project Coordinator)
- Connecticut Department of Correction (CTDOC):
- Springfield- Hampden County Correctional System and Bay State Medical Center: Tom Lincoln, MD and Dan Skiest ,MD and Maureen Desabrais