



HPTN
HIV Prevention
Trials Network

Describing Sexual Risk Behaviour Amongst Injection Drug Users, Including By Drug Treatment Arm: Secondary Data Analysis of the HPTN 058 Study

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- Globally, 12.7 million people inject drugs about 1.7 million of whom are living with HIV
- Injection drug use (IDU) increases risk of HIV transmission
- In China, IDU accounted for 38.5% of new HIV infections between 2005-2009
- Sexual contact has accounted for an increasing proportion of HIV transmission over time in China

- **Study Design**

- Multicenter, phase 3, open label two-arm randomized controlled trial.
- Randomized to long-term medically assisted treatment (LT-MAT) buprenorphine/naloxone (BUP/NX) for 52 weeks vs. short-term medically assisted treatment (ST-MAT) detoxification with BUP/NX for 18 days

- **Inclusion criteria**

- HIV uninfected, Age >18 years
- DSM IV criteria for opiate dependence
- Positive urine test for opiates
- injected opiates at least twelve times in the last 28 days
- Not of reproductive potential, or effective contraception use

- **Primary endpoints:** HIV seroconversion and mortality

1. Describe sexual risk behaviours over time in the two treatment arms. a) (LT- MAT) BUP/NX and b) (ST-MAT)- BUP/NX
2. Determine if (LT- MAT) BUP/NX is associated with sexual risk behaviours when compared to (ST- MAT) BUP/NX
3. Explore other risk factors for sexual risk behaviours in this population

Outcomes

- Any condomless sex with a primary partner
- Any condomless sex with a non-primary partner
- Multiple partners
- Greater than 3 sex acts
- Any transactional sex

GEE model with logit links and binomial distributions were used for all analyses

To describe sex behaviors over time

- ❖ Plotted proportions and estimated OR at each time point and tested differences in ORs at baseline, wk 52 & 104 using Wald's test

To determine if treatment arm was associated with sex behaviors

- ❖ ITT analysis
 - ❖ Two models were built, both adjusted for site
 - ❖ Model 1 tested interaction between treatment arm and visit and Model 2 estimated overall ORs
- ❖ As treated analyses
 - ❖ Estimated the effect of current adherence (%) on current sex behavior
 - ❖ Estimated the effect of completing LT-BUP/NX treatment as directed (vs not) on future sex behaviors

To explore other risk factors for sex behaviors

- ❖ Two models fit for each outcome: a partially adjusted model adjusted for site, treatment arm and baseline v follow-up. All covariates with $p < 0.1$ were added to the fully adjusted model

Table 1: Sex behaviours at baseline

	% (N)		
	ST-MAT	LT-MAT	TOTAL
SEX BEHAVIORS^c			
Any sex	49% (306)	46% (289)	48% (595)
Primary sex partner	44% (273)	41% (256)	42% (529)
Any sex with primary	43% (271)	40% (252)	42% (523)
Any condomless sex	40% (249)	36% (222)	38% (471)
No condom use	37% (235)	34% (213)	36% (448)
Non-primary sex partner			
Any sex with non-primary	8% (53)	8% (48)	8% (101)
Any condomless sex	6% (38)	6% (36)	6% (74)
No condom use	5% (30)	4% (26)	4% (56)
Number of sex partners			
0	51% (321)	54% (335)	52% (656)
1	42% (265)	41% (253)	41% (518)
2+	7% (41)	6% (35)	6% (76)
Number of sexual acts			
0	51% (322)	54% (336)	53% (658)
1-2	17% (105)	17% (107)	17% (212)
3+	32% (200)	29% (180)	30% (380)
Transactional sex ^b	3% (17)	4% (22)	3% (40)
TOTAL	627	623	1,250

b - Missing data, c - Past 1 month

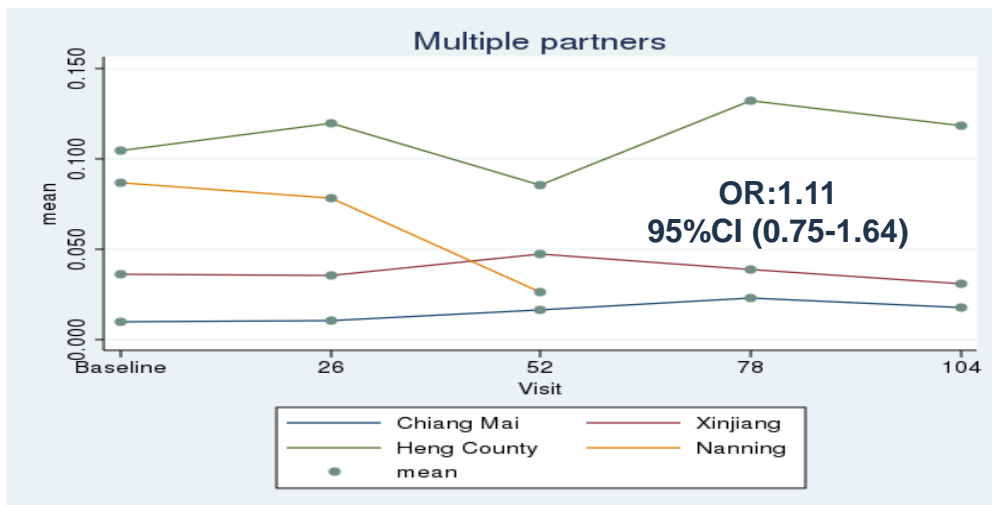
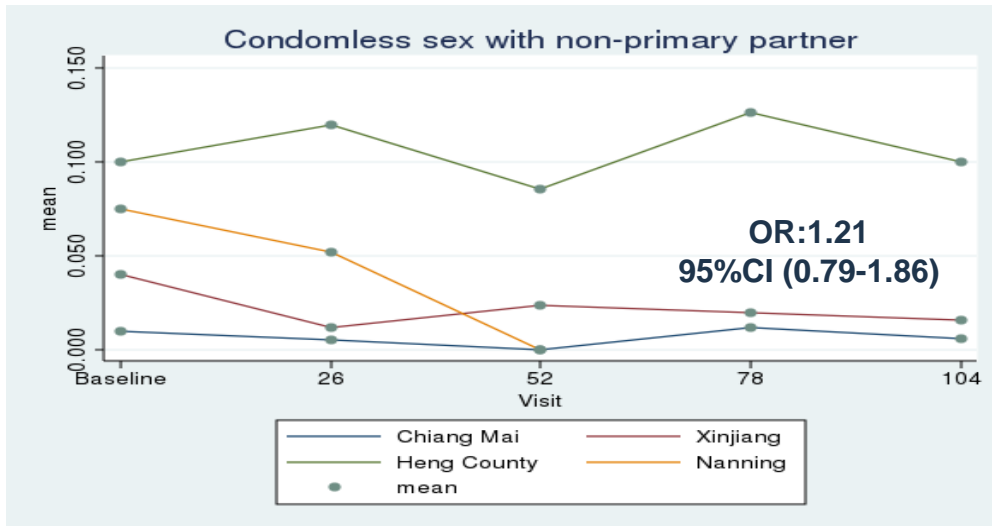
Sex behaviors over time by treatment

- OR associated with treatment were non-significant at every visit (including baseline) for all outcomes.
- ORs at wk 52 and 104 were not significantly different than the OR at baseline for all outcomes.

Association between treatment and sex behaviors

- Overall OR from the ITT analysis were non-significant for all outcomes.
- OR from both as-treated analyses were non-significant for all outcomes.

Figure 1: Outcomes over time by site



- Odds ratios of sex behaviors associated with treatment were not statistically significant at every visit (including baseline) for all outcomes.
- Odds ratios at Week 52 and Week 104 were not statistically significantly different than the odds ratio at baseline for all outcomes.
- Treatment was not significantly associated with sexual behaviour

Table 2: risk factors for sexual risk behaviour

	Any c-less primary	Any c-less non-prim	Outcomes Multiple partners	Greater than 3 sex acts	Any transa sex
DEMOGRAPHICS					
Age (years)		↓	↓	↓	
Sex (male)					
Ethnicity (minority status) ^a	↑				
Married/Living with partner	↑	↓	↓	↑	↓
Education (years)			↑		
Employed	↑			↑	
Income > \$1000		↑	↑		
History of incarceration ^{b,d}	↓	↑		↓	
Alcohol use ^{b,d}	↑			↑	
Non-injection drug use ^{b,d}		↑	↑		
INJECTION DRUG USE					
Days injected ^d				↓	
Times/day injected ^c					
Mixed different drugs ^{b,d}	↓				
Any front or back loaded syringes ^d					
Passed needles after use ^d					
Number of times passed					
Number of people passed to				↓	↑
Shared needles after use ^d				↓	
Number of times shared					
Number of people shared with			↑		↑

Significant risk factors in the fully adjusted model varied by outcome as shown in this trend summary

↓ Significant Relative Risk <1
↑ Significant Relative Risk >1

a - Minority status refers to participants who did not identify as Han in China or Thai in Thailand
b - Missing data, c - Past 1 month, d - Past 6 months

- Sexual risk behaviors amongst IDU were not significantly related to opiate dependency treatment
- Age was significantly associated with reduced sexual risk behaviours amongst IDU
- Alcohol, non-injection drug use, level of education, being employed and higher income were significantly associated with increased sexual risk behavior
- More research required using longitudinal data to determine sexual risk behaviours amongst IDUs.

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