CSAM-SMCA Journal Club

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ORIGINAL ARTICLE FREE PREVIEW

Bupropion and Naltrexone in Methamphetamine Use Disorder

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Background

- **NO MEDICATIONS APPROVED BY THE FDA TO TREAT METHAMPHETAMINE USE DISORDER.**

- **SOME EVIDENCE OF EFFICACY WITH BUPROPRION AND NALTREXONE INDEPENDENTLY.**

Methods

- 12 WEEK TRIAL
- INTERVENTION: NALTREXONE-BUPROPRION VS PLACEBO
- 2 STEP RANDOMIZATION:
- 1ST 0.26:0.74 INTERVENTION: PLACEBO FOR 6 WEEKS.
- 2ND 1:1 INTERVENTION:PLACEBO FOR 6 WEEKS.

HIGH PLACEBO RESPONSE CAN CAUSE A FAILURE TO SHOW A DIFFERENCE BETWEEN DRUG AND PLACEBO, RESULTING IN A NEGATIVE TRIAL. SPCD REDUCES THE DETRIMENTAL IMPACT OF PLACEBO RESPONSE BY INCLUDING TWO STAGES OF TREATMENT AND UTILIZING EACH SUBJECT AT LEAST ONCE (SOMETIMES TWICE) FOR EFFICACY ANALYSIS.

Methods Continued

- **TWO TIMES A WEEK DRUG SCREENING OR URINE** samples.

- Extended-release naltrexone was supplied in standard single-use intramuscular injection kits, each containing one 380-mg vial of naltrexone microspheres

- Extended-release bupropion (in 150-mg tablets) or placebo was provided weekly in matching blister cards.

Inclusion Criteria

- **ADULTS 18 TO 65 YEARS OF AGE WHO WANTED to quit or reduce methamphetamine use**

- **Diagnostic and Statistical Manual**

of Mental Disorders, fifth edition (DSM-5), for moderate or severe stimulant use disorder (methamphetamine type).

- **methamphetamine use on at least 18 of the 30 days before consent;**

- **two or more methamphetamine-positive urine samples (obtained ≥2 days apart) within 10 days before randomization;**

- **opioid-free at the time of randomization.**

Exclusion Criteria

- **Undergoing concurrent treatment for substance use disorder**

- **opioid-containing**

- **participation would be unsafe (e.g., participants would not be eligible if they had conditions that increased the risk of seizure or were taking medications that were contraindicated)**

*****Participants**
who had received a diagnosis of a specific medical or psychiatric disorder were not routinely excluded and were evaluated on a case-by-case basis to determinewhether it was safe for them to participate.

Methods Continued: Outcomes

Primary Outcome

• Three methamphetamine-negative urine tests out of a possible four obtained at the end of stage 1 and subsequently stage 2.

•Participants who had two or more missing results of urine drug screenings or who discontinued the trial were recorded as not having had a response

Methods Continued:

SECONDARY OUTCOMES

- **Percentage of methamphetamine-negative urine samples / 12**
- **Severity of methamphetamine craving during the previous week on an analogue scale / 100**
- **PHQ-9**
- **Treatment Effectiveness Assessment at week 6 and week 12,**

Methods Continued:

- **RANDOMIZATION**
- **Power size calculated for both steps based on pilot data response rates.**
- **Sequential Parallel Comparison Design used randomization fraction and weight to maximize power.**
- **Reevaluated results using various validation methods.**

Results

- A TOTAL OF 403 PARTICIPANTS UNDERWENT RANDOMIZATION IN STAGE 1:

- 109 PARTICIPANTS (27.0%) WERE ASSIGNED TO RECEIVE NALTREXONE–BUPROPION, AND 294 (73.0%) TO RECEIVE PLACEBO (FIGURE1).

- OF THE 225 PARTICIPANTS IN THE PLACEBO GROUP WHO DID NOT HAVE A RESPONSE IN STAGE 1 AND UNDERWENT RANDOMIZATION AGAIN IN STAGE 2, A TOTAL OF 114 (50.7%) WERE ASSIGNED TO RECEIVE NALTREXONE–BUPROPION AND 111 (49.3%) TO RECEIVE PLACEBO.

Table 1. Baseline Characteristics of the Participants in the Intention-to-Treat Population.*

Characteristic	All Participants	Stage 1		Stage 2	
	Total† (N=403)	Naltrexone–Bupropion (N=109)	Placebo (N=294)	Naltrexone–Bupropion (N=114)	Placebo (N=111)
Demographic characteristics					
Male — no. (%)	277 (68.7)	78 (71.6)	199 (67.7)	78 (68.4)	79 (71.2)
Age — yr	41.0±10.1	41.0±10.6	41.0±10.0	41.0±10.5	42.0±9.6
Hispanic or Latino ethnic group — no. (%)‡	55 (13.6)	13 (11.9)	42 (14.3)	20 (17.5)	18 (16.2)
Race or ethnic group — no. (%)‡					
White	287 (71.2)	82 (75.2)	205 (69.7)	84 (73.7)	69 (62.2)
Black	48 (11.9)	10 (9.2)	38 (12.9)	8 (7.0)	22 (19.8)
Other	68 (16.9)	17 (15.6)	51 (17.3)	22 (19.3)	20 (18.0)
High school diploma, GED, or lower education level — no. (%)	142 (35.2)	39 (35.8)	103 (35.0)	36 (31.6)	33 (29.7)
Marital status — no. (%)					
Married or living with partner	93 (23.1)	26 (23.9)	67 (22.8)	25 (21.9)	25 (22.5)
Never married	204 (50.6)	49 (45.0)	155 (52.7)	60 (52.6)	59 (53.2)
Divorced, separated, widowed, or unknown — no. (%)	106 (26.3)	34 (31.2)	72 (24.5)	29 (25.4)	27 (24.3)
Employed — no. (%)§	156 (38.7)	43 (39.4)	113 (38.4)	46 (40.4)	44 (39.6)
Methamphetamine use					
No. of days that methamphetamine was used in the 30 days before consent¶	26.7±4.1	27.0±3.9	26.5±4.2	26.7±4.1	26.1±4.3
Most frequent route of methamphetamine use — no. (%)					
Smoking	293 (72.7)	80 (73.4)	213 (72.4)	83 (72.8)	79 (71.2)
Intravenous	77 (19.1)	23 (21.1)	54 (18.4)	21 (18.4)	22 (19.8)
Nasal or oral	33 (8.2)	6 (5.5)	27 (9.2)	10 (8.8)	10 (9.0)
Participants reporting intravenous methamphetamine use ≥1 days in the 30 days before consent — no. (%)	135 (33.5)	39 (35.8)	96 (32.7)	38 (33.3)	36 (32.4)
Intensity of methamphetamine craving‖	66.1±22.3	65.7±22.2	65.8±21.6	66.7±21.3	63.7±21.9
Age of first methamphetamine use — yr	24.8±9.9	24.7±10.7	24.8±9.6	25.5±10.9	24.8±9.1
Other characteristics					
Coexisting cocaine use disorder according to DSM-5 criteria — no./total no. (%)	31/365 (8.5)	9/97 (9.3)	22/268 (8.2)	9/104 (8.7)	9/100 (9.0)
Coexisting opioid use disorder according to DSM-5 criteria — no./total no. (%)	27/370 (7.3)	7/93 (7.5)	20/277 (7.2)	7/109 (6.4)	7/104 (6.7)
Coexisting alcohol use disorder according to DSM-5 criteria — no./total no. (%)	94/293 (32.1)	25/77 (32.5)	69/216 (31.9)	23/85 (27.1)	27/75 (36.0)
Coexisting cannabis use disorder according to DSM-5 criteria — no./total no. (%)	116/318 (36.5)	29/89 (32.6)	87/229 (38.0)	33/86 (38.4)	33/85 (38.8)
Daily nicotine cigarette use — no./total no. (%)	238/337 (70.6)	66/99 (66.7)	172/238 (72.3)	73/89 (82.0)	56/89 (62.9)
Score on PHQ-9 depression scale**	19.9±6.5	19.4±6.5	20.0±6.5	20.1±6.9	19.5±5.9
Score on Treatment Effectiveness Assessment††	18.3±7.2	16.7±7.0	18.6±7.3	18.4±7.5	19.2±7.1
HIV-positive status — no./total no. (%)	90/356 (25.3)	24/92 (26.1)	66/264 (25.0)	24/96 (25.0)	33/105 (31.4)

* Plus–minus values are means ±SD. The intention-to-treat population included all participants who underwent randomization in stage 1 and the participants who underwent randomization again in stage 2. DSM-5 denotes *Diagnostic and Statistical Manual of Mental Disorders*, fifth edition, and GED General Educational Development diploma. Percentages may not total 100 because of rounding.

† The total number reflects all participants who underwent randomization in stage 1.

‡ Race and ethnic group were reported by the participants. The "other" category included American Indian or Alaska Native (6 participants), Asian (11 participants), Native Hawaiian or Pacific Islander (2 participants), other (20 participants), multiracial (16 participants), don't know (10 participants), and declined to answer (3 participants).

§ The remaining participants were unemployed, disabled, or retired; were keeping house; were students; or had other status.

¶ The number of days of methamphetamine use at baseline was assessed for the 30 days before informed consent. One participant had only 24 days of assessment. Eligibility required a minimum of 18 days of methamphetamine use at baseline.

‖ Methamphetamine craving (the intensity of the worst craving over the previous week) was assessed at each screening or baseline visit on a visual analogue scale; ratings on the scale, which range from 0 to 100, were averaged to determine a baseline craving, with 0 indicating no craving at all and 100 indicating the most intense craving possible.

** Depressive symptoms were assessed weekly with the use of the Patient Health Questionnaire 9 (PHQ-9); scores range from 0 to 27, with higher scores indicating greater depressive symptoms.

†† Life satisfaction was reported by the participants and was assessed with the use of the Treatment Effectiveness Assessment, which consists of four items; the scores for each item are summed, and total scores range from 4 to 40, with higher scores indicating greater satisfaction.

MH Trivedi et al. N Engl J Med 2021;384:140-153.

Table 2. Primary and Secondary Outcomes in the Intention-to-Treat Population.*

Outcome	Stage 1		Stage 2		Treatment Effect	
	Naltrexone–Bupropion (N=109)	Placebo (N=294)	Naltrexone–Bupropion (N=114)	Placebo (N=111)	Weighted Difference	95% CI
Primary outcome — no. of participants (%)†	18 (16.5)	10 (3.4)	13 (11.4)	2 (1.8)	11.1±2.5	—
Secondary outcomes						
Methamphetamine-negative urine samples — %‡	20.4±2.2	12.3±1.6	19.2±2.6	13.4±1.5	6.8±1.7	3.5 to 10.1
Change in methamphetamine craving according to visual analogue scale§	−30.0±3.2	−22.3±1.8	−31.8±3.2	−20.5±1.7	−9.7±2.1	−13.8 to −5.6
Change in score on PHQ-9 depression scale§	−4.8±0.7	−3.3±0.3	−4.4±0.6	−3.7±0.4	−1.1±0.4	−1.9 to −0.2
Change in score on Treatment Effectiveness Assessment§¶	6.5±1.5	2.2±1.0	6.2±1.5	2.5±1.1	4.0±0.9	2.3 to 5.7

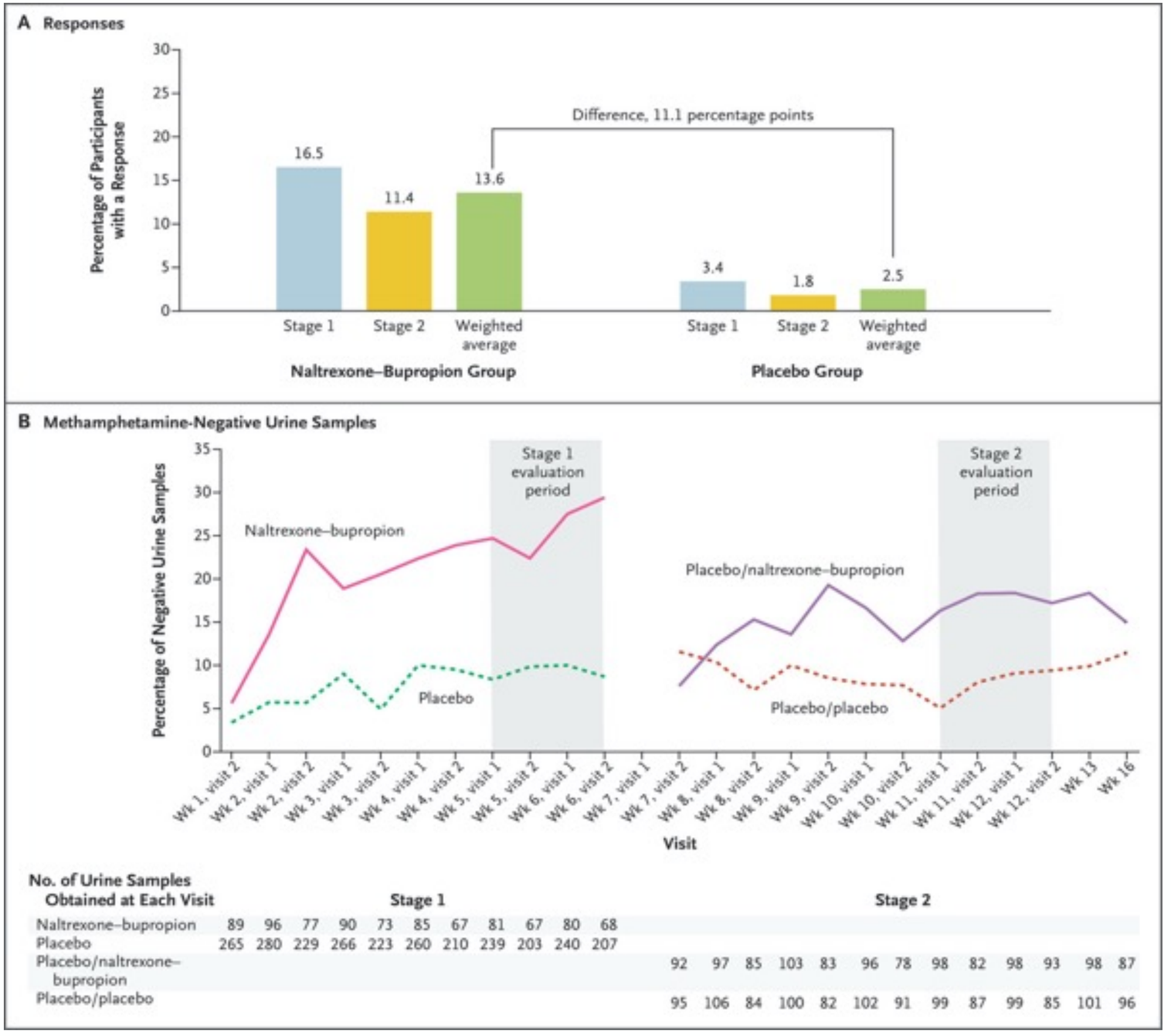
* Plus–minus values are means ±SE unless otherwise noted. The total number in stage 1 reflects the number of participants who underwent randomization. The total number in stage 2 reflects the number of participants in the placebo group who did not have a response in stage 1 and therefore underwent randomization again in stage 2. No clinical conclusions can be drawn from secondary outcomes because confidence intervals were not adjusted for multiple comparisons.

† The primary outcome was a response, defined as at least three methamphetamine-negative samples out of four obtained at the end of stage 1 or stage 2. The overall treatment effect was defined as the weighted average of the responses in the naltrexone–bupropion group minus the responses in the placebo group, reported in percentage points ±SE, determined with the use of a weight of 0.43 in stage 1 and a weight of 0.57 in stage 2. The formula for this calculation is provided in the statistical analysis plan, available with the protocol at NEJM.org. The Wald z-test statistic for the primary outcome was 4.530 (P<0.001).

‡ The percentage of methamphetamine-negative urine samples per participant was calculated by dividing the number of methamphetamine-negative urine samples obtained per stage by 12 (the number of expected samples per stage). The treatment effect is the between-group difference in the weighted average of negative urine samples, reported as percentage points ±SE.

§ The changes in stage 1 reflect the change from baseline, and the changes in stage 2 reflect the change from the end of stage 1. The treatment effect is the between-group difference in the weighted average change in scores, reported as the difference in points ±SE.

¶ Data were available for 306 participants in stage 1 (74 in the naltrexone–bupropion group and 232 in the placebo group) and for 196 in stage 2 (98 in the naltrexone–bupropion group and 98 in the placebo group).



No. of Urine Samples Obtained at Each Visit	Stage 1											Stage 2											
Naltrexone–bupropion	89	96	77	90	73	85	67	81	67	80	68												
Placebo	265	280	229	266	223	260	210	239	203	240	207												
Placebo/naltrexone–bupropion												92	97	85	103	83	96	78	98	82	98	93	98	87
Placebo/placebo												95	106	84	100	82	102	91	99	87	99	85	101	96

MH Trivedi et al. N Engl J Med 2021;384:140-153.

Discussion

- **THE OVERALL WEIGHTED RESPONSE WAS 13.6% in the naltrexone–bupropion group and 2.5% in the placebo group.**
- **This is defined as ¾ negative urines in last two weeks of the intervention.**
- **Secondary outcomes were similar.**
- **The number needed to treat in order for one patient to have a response under the assumptions in this trial is 9.**

Strengths & Limitations

STRENGTHS:

- **Low attrition, high adherence to the trial regimen, a prospective evaluation to establish illness severity, and an objective primary outcome assessed on the basis of valid urine sample**

Limitations:

- **low attrition and high adherence may limit generalizability**
- **low representation of women**
- **Adherence was determined on the basis of participant report and cannot be confirmed because ingestion was not observed by trial clinicians.**
- **Replication of our trial results in a more naturalistic effectiveness design could be a next step**

Our Discussion

ORIGINAL RESEARCH

Predictors of Opioid and Alcohol Pharmacotherapy Initiation at Hospital Discharge Among Patients Seen by an Inpatient Addiction Consult Service

Englander, Honora MD; King, Caroline MPH; Nicolaidis, Christina MD, MPH; Collins, Devin MA; Patten, Alisa MA; Gregg, Jessica MD, PhD; Korthuis, P. Todd MD, MPH **Author Information**

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doi: 10.1097/ADM.0000000000000611

Background

- Little is known about who might benefit from hospital –based addictions care
- Understanding which patients are most likely to initiate MOUD and MAUD can inform interventions and deepen understanding of hospitals' role addressing substance use disorders (SUD)
- hospitalization is a high-risk touchpoint after which people with opioid use disorder are at increased risk for overdose and death
- Medication, combined with psychosocial interventions, comprise first line treatment for moderate to severe alcohol use disorder

Methods

Setting & Study Design

• Survey data collected as part of a study of the improving addiction care team (impact) at an urban, academic medical center in Portland, Oregon

•Performs an initial comprehensive assessment;

•elicits patient-centered goals;

•initiates SUD treatment, including pharmacotherapy& behavioral treatments;

•offers harm reduction services.

•robust referral pathways to post-hospital SUD care.

Methods Continued

PARTICIPANTS:

- **Participants included patients seen between September 2015 and August 2018.**

- **Patients were eligible for this analysis if they (1) had moderate to severe opioid use disorder, alcohol use disorder, or both, and (2) were not already receiving MOUD or MAUD upon hospital admission.**

- **Surveys focused on demographics, substance use, and patient experience, and took approximately 15 to 20 minutes to complete.**

Covarites Measured

- Gender, race, income
- Partner with substance use
- Rural home zip code
- History of past but not current methadone maintenance engagement (yes/no) and access to a usual primary care clinic
- Opioid use disorder
- alcohol use disorder
- methamphetamine use disorder
- Peer support delivered in hospital
- Patient age (years), Insurance status
- Medications used
- Dose indicator based on total

provider interactions over time admitted.

Analysis

- **Logistic regression model to estimate the relationship of baseline participant characteristics with the binary outcome variable MOUD and/or MAUD initiation.**

- **Backwards stepwise elimination with a relaxed P value of 0.20 to finalize our model and did not force any covariates into our model.**

- **Continuous covariates for linearity in the log-odds using Lowess scatter plot**

- **Hosmer-Lemeshow test to evaluate model goodness-of-fit Sensitivity analysis was conducted.**

Results

- 760 patients were referred to IMPACT

- 401 had moderate to severe OUD and/or AUD and 349 had no pharmacotherapy for OUD/AUD before admission

Table #1

	Total Sample (n = 346)	Medication Plan at Discharge (n = 248)	No Medication Plan at Discharge (n = 98)	Univariate *P* Value
Age, years (SD)	43.5 (12.8)	44.2 (12.9)	41.8 (12.3)	0.11
Male gender (n = 343)	218 (63.0%)	153 (61.7%)	65 (66.3%)	0.40
Caucasian race	280 (80.9%)	199 (80.2%)	81 (82.7%)	0.61
Opioid Use Disorder (without alcohol use disorder)	180 (52.0%)	125 (50.4%)	55 (56.1%)	0.34
Alcohol Use Disorder (without opioid use disorder)	127 (36.7%)	90 (36.3%)	37 (37.8%)	0.80
Both Alcohol and Opioid Use Disorders	39 (11.3%)	33 (13.3%)	6 (6.1%)	0.06
History of past methadone maintenance	126 (36.4%)	100 (40.3%)	26 (26.5%)	0.02
Co-occurring methamphetamine use disorder	104 (30.0%)	61 (24.6%)	43 (43.9%)	<0.001
No income in previous year	195 (56.4%)	141 (56.9%)	54 (55.1%)	0.53
$1 to $10,000	45 (13.0%)	31 (12.5%)	14 (14.3%)	
$10,001 to $20,000	50 (14.5%)	37 (14.9%)	13 (13.3%)	
$20,001 to $30,000	20 (5.8%)	16 (6.5%)	4 (4.1%)	
$30,001 to $40,000	5 (1.4%)	3 (1.2%)	2 (2.0%)	
$40,001 to $50,000	6 (1.7%)	4 (1.6%)	2 (2.0%)	
>$50,000	25 (7.2%)	16 (6.5%)	9 (9.2%)	
Current Homelessness (n = 340)	192 (55.5%)	149 (60.1%)	43 (43.9%)	0.004
Partner with substance use (n = 348)	101 (29.2%)	82 (33.1%)	19 (19.4%)	0.01
Rural zip code	63 (18.2%)	44 (17.7%)	19 (19.4%)	0.72
Medicaid	264 (76.3%)	194 (78.2%)	70 (71.4%)	0.18
Peer support in hospital	105 (30.3%)	79 (31.9%)	26 (26.5%)	0.33
Established primary care clinic (n = 344)	212 (61.3%)	155 (62.5%)	57 (58.2%)	0.40
1 or more IMPACT clinical encounters per day	111 (32.1%)	88 (35.5%)	23 (23.5%)	0.03

*values shown are n (%) or mean (SD).
OUD, opioid use disorder; AUD, alcohol use disorder.

JOURNAL OF ADDICTION MEDICINE

Predictors of Opioid and Alcohol Pharmacotherapy Initiation at Hospital Discharge Among Patients Seen by an Inpatient Addiction Consult Service

Englander, Honora; King, Caroline; Nicolaidis, Christina; Collins, Devin; Patten, Alisa; Gregg, Jessica; Korthuis, P. Todd

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Participant Characteristics Among IMPACT Patients With OUD, AUD or Both, 2015 to 2018

Table #2

	Unadjusted Odds Ratios (95% CI)	Adjusted Odds Ratios (95% CI)*
Age (years)	1.01 (0.996, 1.03)	1.02 (0.997, 1.04)
Male gender	1.23 (0.75, 2.03)	1.50 (0.87, 2.58)
Concurrent methamphetamine use disorder	0.42 (0.25, 0.68)	0.32 (0.18, 0.56)
Ever received methadone	1.87 (1.12, 3.13)	2.24 (1.28, 3.94)
Current homelessness	1.99 (1.24, 3.21)	2.52 (1.47, 4.30)
Partner with substance use	2.07 (1.17, 3.64)	2.06 (1.13, 3.75)

*Only covariates listed in Table 2 were included in the final adjusted model.
IMPACT, Improving Addiction Care Team; OUD, opioid use disorder; AUD, alcohol use disorder.

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Unadjusted and Adjusted Logistic Regression Models of Medication Initiation Among IMPACT Patients With OUD, AUD or both, 2015 to 2018

Table #3

	All Participants (n = 346)	Opioid Use (With no Alcohol) (n = 180)	Alcohol Use (With no Opioid Use) (n = 127)	Opioid and Alcohol Use (n = 39)
Methadone	80 (23.1%)	71 (39.4%)	0	9 (23.1%)
Buprenorphine-naloxone	62 (17.9%)	49 (27.2%)	0	13 (33.3%)
Naltrexone oral	23 (6.6%)	1 (0.6%)	20 (15.7%)	2 (5.1%)
Naltrexone IM	23 (6.6%)	4 (2.2%)	15 (11.8%)	4 (10.3%)
Acamprosate	39 (11.3%)	0	36 (28.3%)	3 (7.7%)
Gabapentin	21 (6.1%)	0	19 (15.0%)	2 (5.1%)
Total receiving medication	248 (71.7%)	125 (69.4%)	90 (70.9%)	33 (84.6%)

IM, intramuscular injection.

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Medication Initiation by Substance Use Disorder and Medication Type

Methods Cont

- Randomization
- Power size calculated for both steps based on pilot data response rates.
- Sequential Parallel Comparison Design used randomization fraction and weight to maximize power.
- Reevaluated results using various validation methods.

Discussion

- **Current homelessness and partner is substance use predicted medication starts.**

- **ME**

- **Residing in a rural area, having a usual source of primary care, and Medicaid insurance had no association with MOUD/MAUD initiation. thamphetamines negatively impacted starts of treatment.**

Other Key Findings

- **74% of people with moderate to severe OUD and/or AUD initiated medication**
- **Hospitalization can be a reachable moment and opportunity engage non-treatment seeking adults by interrupting drug use and serving as a “wakeup call”**
- **Patients with methamphetamine use may perceive their alcohol and/or opioid use as secondary and not needing MOUD/MAUD**
- **methamphetamine withdrawal, cravings, or psychiatric symptoms may interfere with patients’ or providers’ ability to initiate MOUD/MAUD during hospitalization**

Limitations

- Single study site
- Survey participants were possibly more or less likely to engage in treatment.
- Past treatment was not necessarily evaluated on how it impacts current treatment.
- 1st encounter with hospital service was only explored.

Discussion

•Interprofessional hospital - based addictions team with resources dedicated to addressing social factors that may influence treatment retention after discharge

Further research in:

- Association of methamphetamine use and OAT, Alcohol anticraving, and hospital-based addiction medicine care
- OAT/Alcohol craving initiation during hospitalization on pertinent clinical outcomes including substance use, long-term SUD treatment engagement, healthcare utilization, quality of life, overdose risks, and other health outcomes.

Our Discussion

Thank You For Joining Us!

Next session is March 11, 2021 @ 6:00pm MST via Zoom

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