Monitoring the Wild West of Psychedelic Proliferation

Dale Terasaki, MD, MPH

Andrew A. Monte, MD, PhD

ASAM, April 25, 2025

Disclosure Information

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Dale Terasaki, MD MPH

- Stakeholder on Denver “Natural Medicine Workgroup” (NMWG)

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Andrew A. Monte, MD, PhD

- The National Survey Investigating Hallucinogenic Trends (NSIHT) is funded by SAMHSA, grant #75S20123P00004.
- I sit on the Scientific Advisory Board of Anebulo Pharmaceuticals that is developing a cannabis intoxication antidote.

Outline

- **Learning objectives**
- **Landscape** – including connection to cannabis, Colorado Natural Medicine Act
- **Surveillance Tools** - including SPC, NSIHT
- **Connection to Addiction Medicine**
- Q+A

Learning Objectives (Suggested)

By end of session, attendees will be able to:

1. Distinguish between the approach of Colorado's Natural Medicine Act and common approaches to cannabis legalization.
2. List 2 different methods of obtaining surveillance data of psychedelics
3. Describe 2 national trends in use of psychedelic substances

Landscape


SQUAWKON
THESTREET


l!fe
THE PHILIPPINE STAR
Alaska
OFF-DUTY PILOT WHO TRIED TO SHUT DOWN ENGINES WAS ON MUSHROOMS— DOCUMENTS


CNBC

Psychedelic Clinical Trials

Backed by $15m in NIDA Funding, NYU and B.More Team Up to Trial Psilocybin for Opioid Use Disorder

October 31, 2024 - Analysis / News / Pα+

Words by Josh Hardman, edited by Michael Haichin.

Psychedelic researcher Michael Bogenschutz has scored a $15 million grant from the National Institute on Drug Abuse (NIDA) to support a phase 2 clinical trial of psilocybin in the treatment of opioid use disorder (OUD). The agency will provide $3 million per year for a total of five years, with latter disbursements dependent on the outcome of a progress review during the first two years.

Bogenschutz is collaborating with Carey Turnbull's non-profit psilocybin drug development outfit, *B.More*, which hopes to parlay the resulting data into a full-blown drug development push, with FDA approval the ultimate goal.

We spoke with Bogenschutz and Turnbull to learn more about the ambitious study...

***

The double-blind, multi-site randomised controlled trial will evaluate psilocybin's potential in reducing opioid cravings and improving emotional well-being in individuals struggling with OUD but who continue to use non-prescribed opioids despite adherence to methadone treatment.

Participants will be randomised to receive a single administration of 30, 20, or 1 mg of psilocybin, with weekly urine drug

NCT06442423 Recruiting

Open-Label Psilocybin Study in Transdiagnostic Population

Conditions

Substance Use | Substance Use Disorder (SUD) | Anxiety | Depression - Major Depressive Disorder | Show 4 more conditions

Locations

New Haven, Connecticut, United States

NCT04161066 Recruiting

Adjunctive Effects of Psilocybin and a Formulation of Buprenorphine

Conditions

Opioid Use Disorder

Locations

Madison, Wisconsin, United States

NCT04982796 Recruiting

Psilocybin-Enhanced Psychotherapy for Methamphetamine **Use Disorder**

Conditions

Amphetamine-Related Disorders

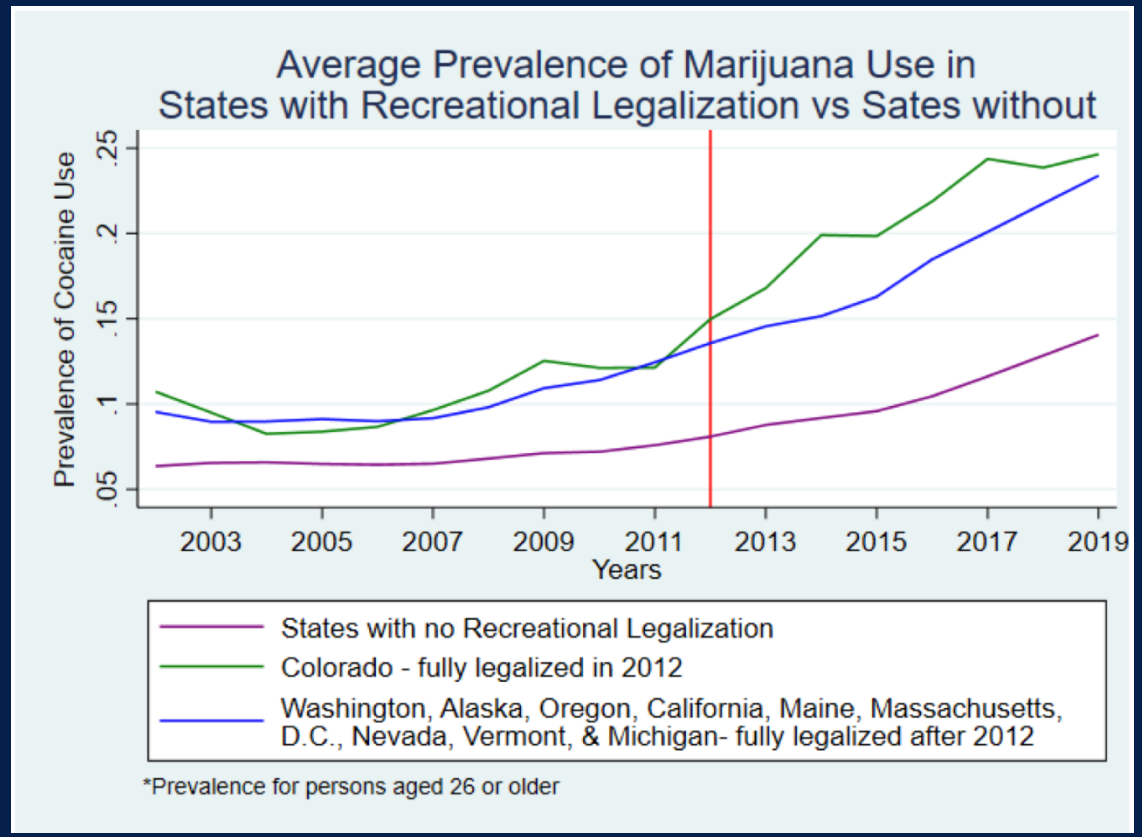
Locations

Vancouver, Washington, United States

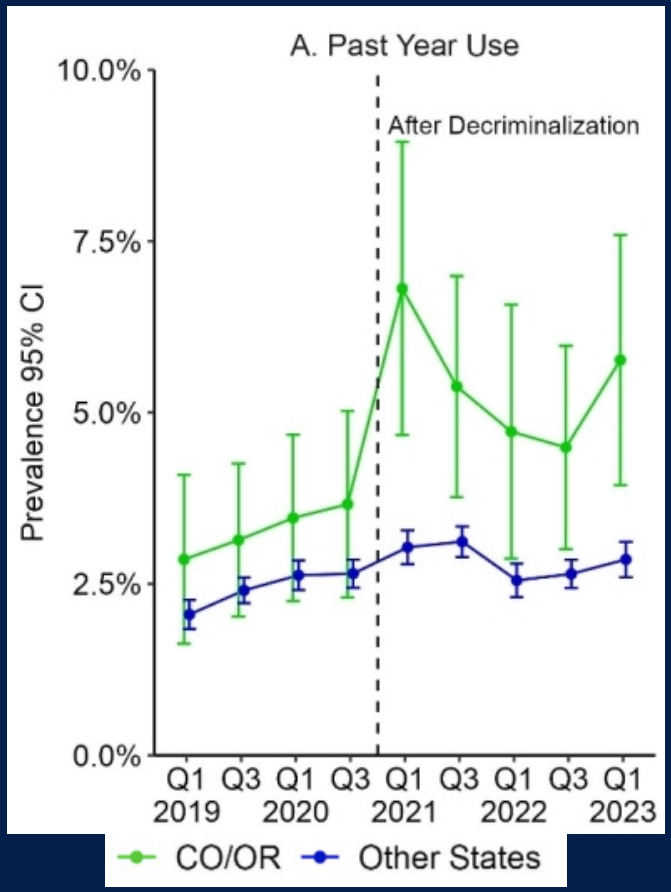
Psychedelic alpha, 2024 and Clinicaltrials.gov

Legalization is Associated With Increased Use in All States

Cannabis

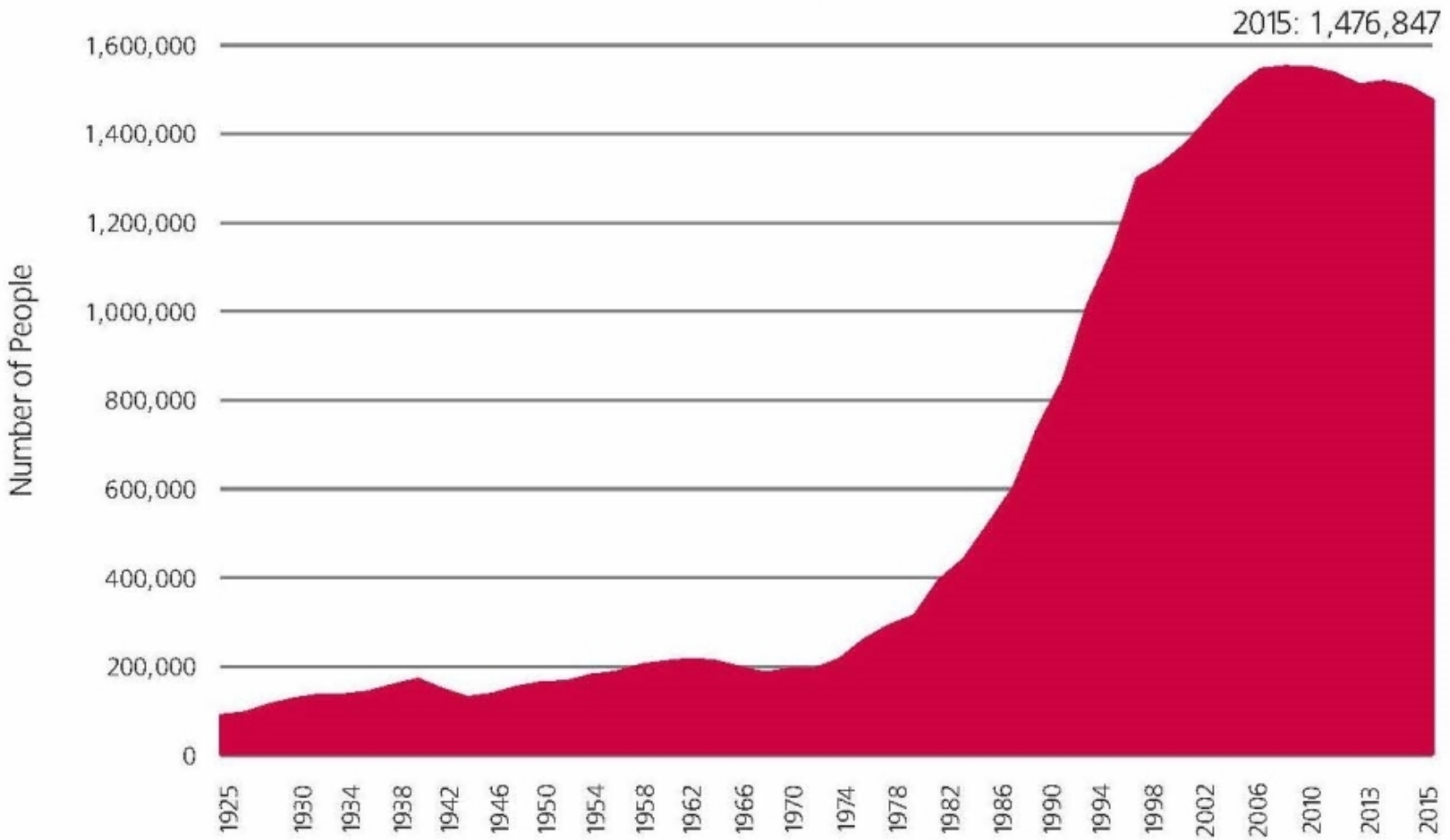


Psychedelics



NSDUH, 2020 and Monte AA, 2024 (data from NMURx)

Trends in U.S. Corrections



Source: Bureau of Justice Statistics *Prisoners Series.*

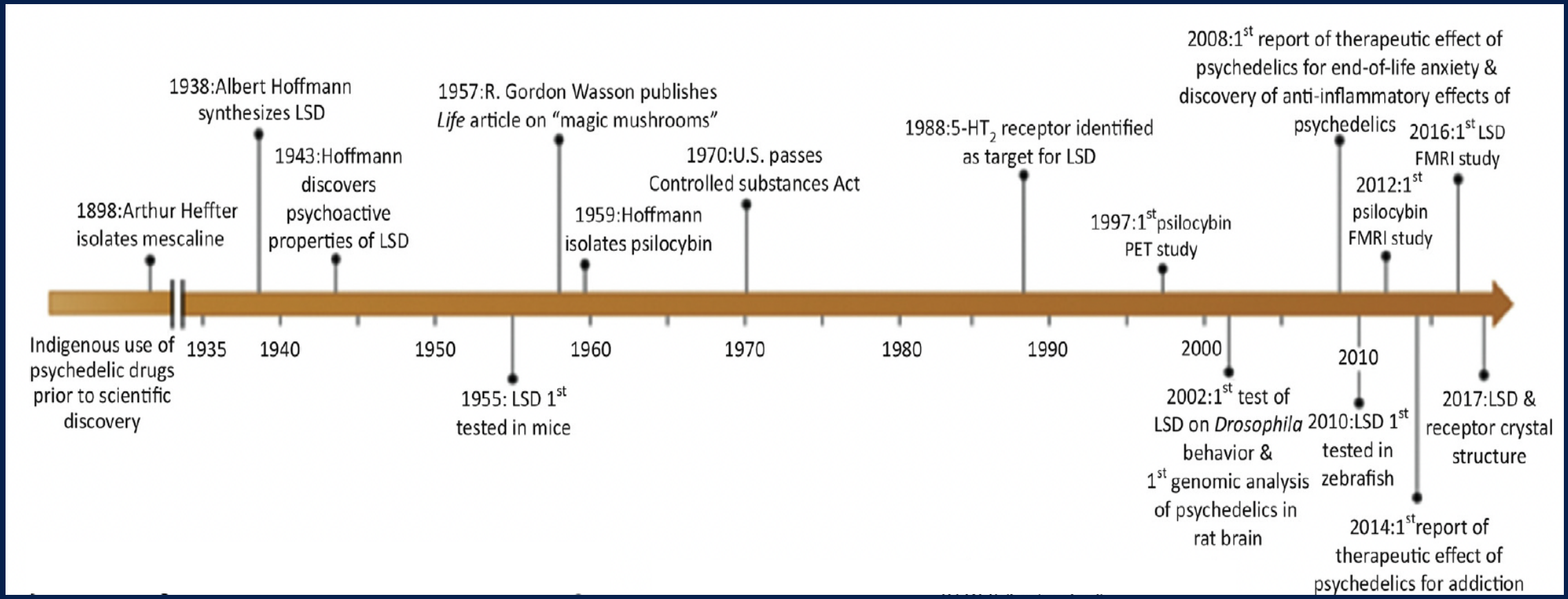
Colorad
Allo

juana stores open

2000

2014

We've Been Here Before. . .



Kyzar, Trends Pharmacol Sci, 2017

Demonstrated Medical Benefits

Cannabis

- Chemotherapy induced nausea
- Appetite stimulation in AIDS patients
- Chronic pain

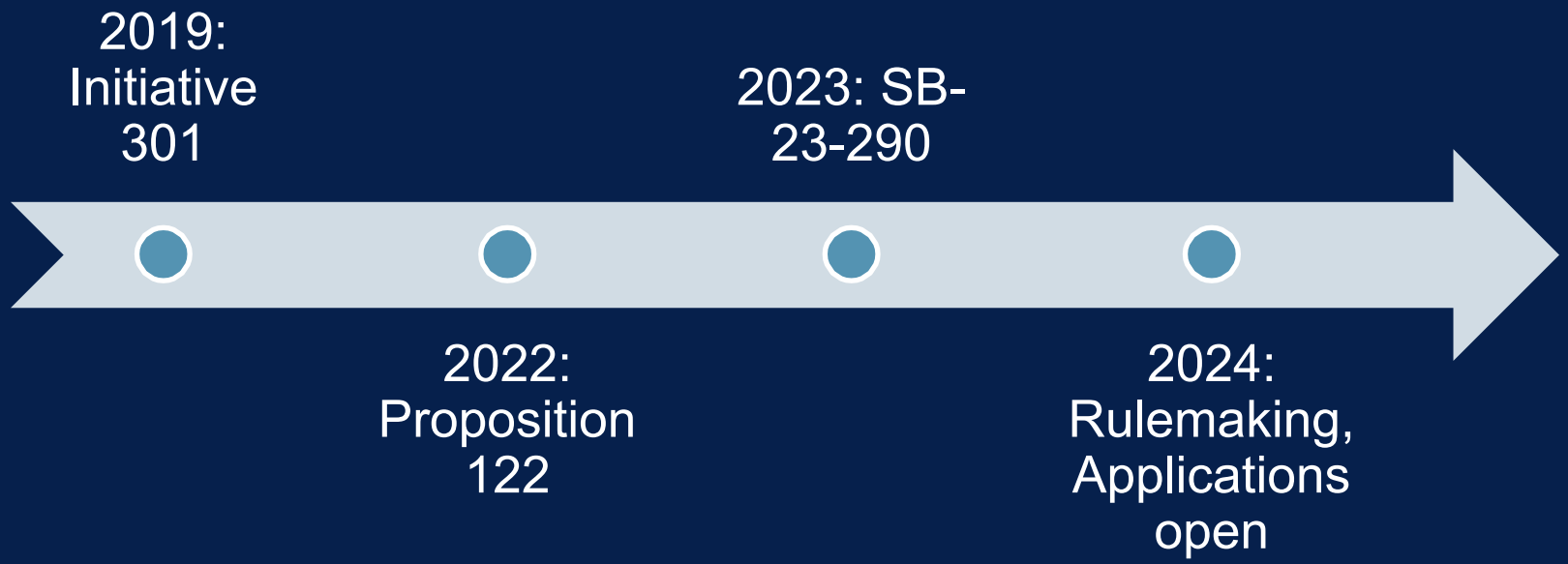
Psychedelics

- Phase 2 trials suggest benefit for LSD on bipolar, DMT on treatment resistant depression, ketamine depression, suicidality, potentially SUD
- Phase 3 trial demonstrated MDMA efficacy for PTSD.
- Trial concerns led to FDA rejection of MDMA new drug application.

Pain Symptom Manage. 1995; 10:89-97.
J Clin Oncol. 2006 Jul 20;24(21):3394-400
Pain Medicine 2009; 10(8):1353-68, Andreae. J Pain. 2015

Colorado SB-23-290

- Structure:
  - Personal use decriminalized
  - Substances: Psilocybin, psilocin, ?mescaline, ?DMT, ?ibogaine
  - State licensed “healing centers” with “facilitators”
  - State licenses for “cultivation,” “manufacture,” and “testing.”
  - Indications: if clinical, need “clinical facilitator”
  - No retail
- Timeline:



Differences with cannabis legalization

- No retail sales of product, but gray market?
- No “medical” user license
- Origins less related to law enforcement
- Different indications
- Potential difference in profitability
  - Single or intermittent use, time-intensive
  - Fewer locations and providers

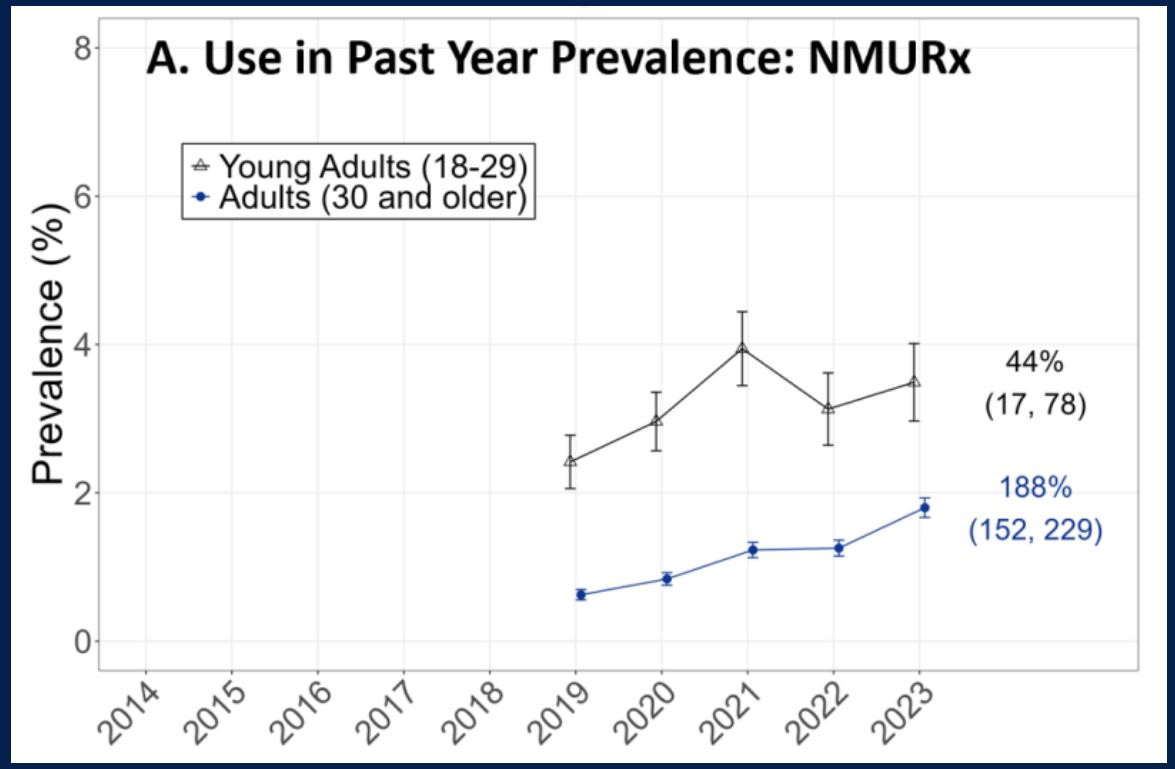
Some concerns

- Cultural appropriation
- Advertisement
- Zoning, hours of operation
- Too “little” access

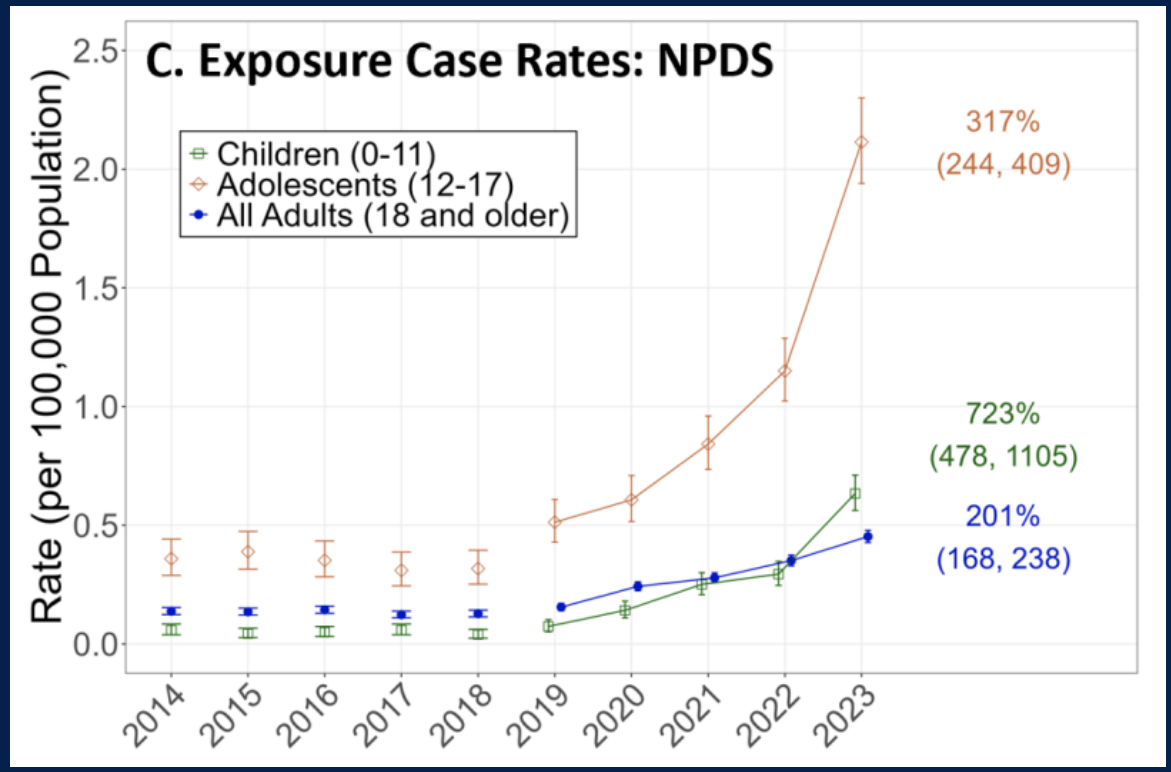
Do We Know the Risks?

Surveillance Tools

Psilocybin Use and Adverse Events are Increasing



*NMURx: Survey of Non-medical use of Prescription Drugs



*NPDS: National Poison Data System

Rockhill, KM. Annals of Inter Med. 2025

Reports of Psilocybin Exposure to US Poison Centers Are Increasing

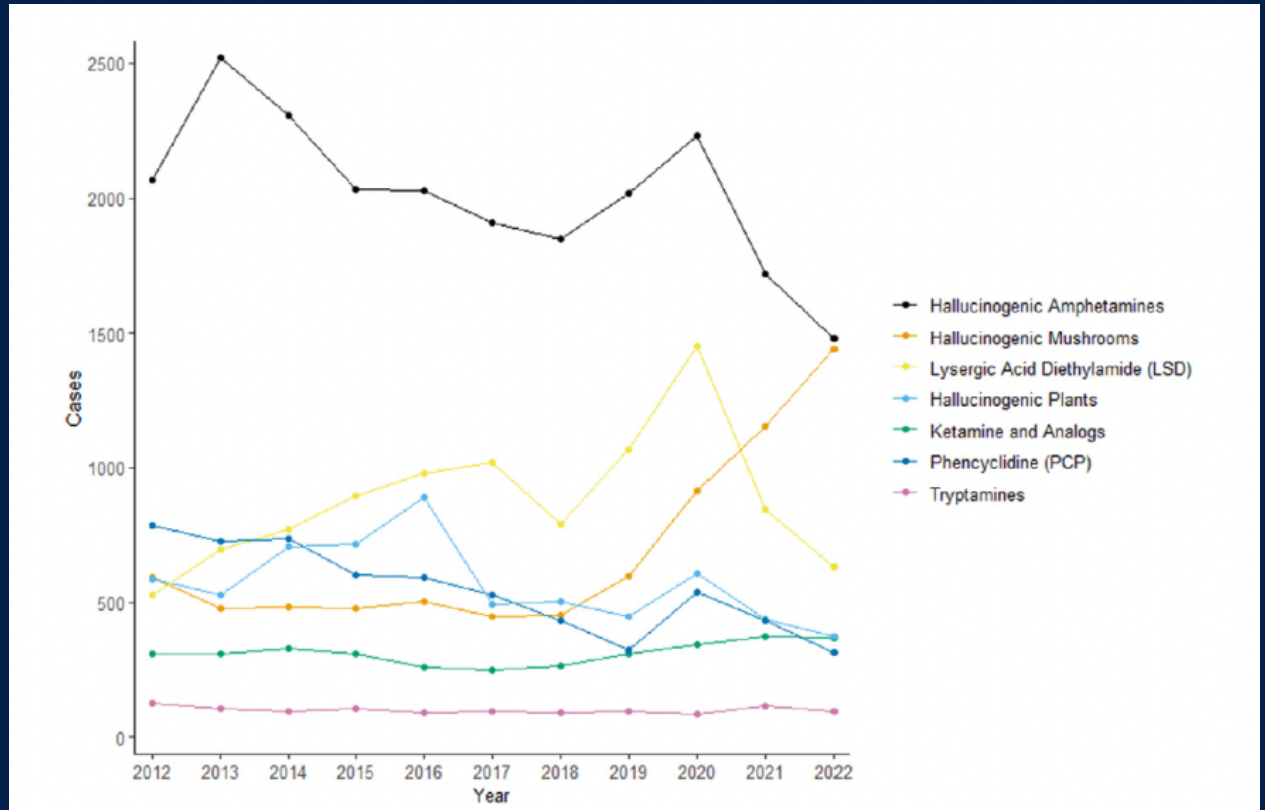


Figure 1. Annual exposures to psychedelic substances reported to US poison centers.

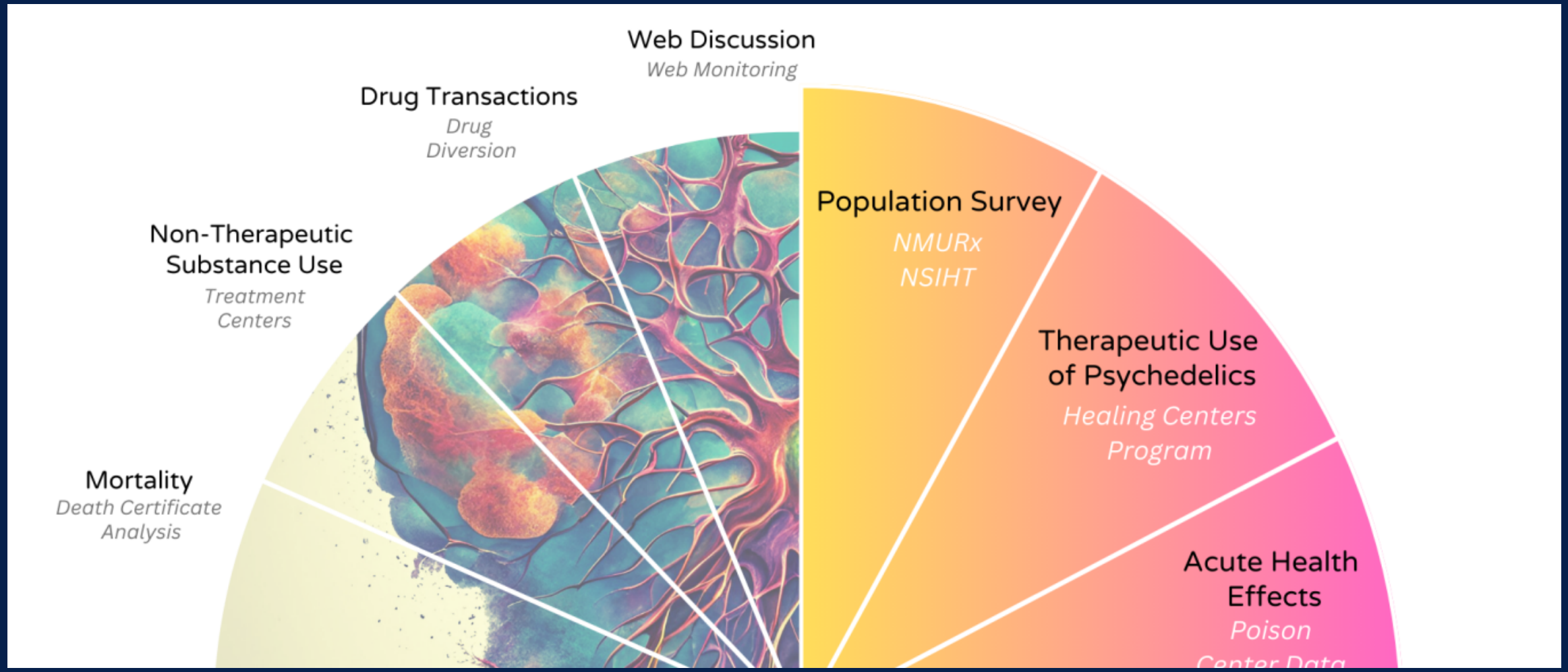
Simon. Annals of EM. 2024

Current Tools Don’t Provide the Detail Needed to Maximize Public Health

- Poison centers documented 2,022 psilocybin cases, of which 1,550 interacted with health care facilities between 2019-2023.
- National Hospital Ambulatory Medicare Survey (NHAMCS) documented only 3 psilocybin cases between 2019-2023.
- Hospital data don’t currently capture adverse events, though coding will inevitably increase.
- NSDUH captures prevalence, but no details on which drugs, reasons for use, frequency, or other use patterns.
- FDA tools (FAERS, MedWatch) don’t capture natural products.

No tool captures effectiveness in the real world.

RMPDS Surveillance Tools



Healing Center Program

- Longitudinal data collection in patients undergoing ketamine/esketamine treatments
- Aligned with OHSU group, OPEN data collection
- Planned data collection in psilocybin patients (AZ and CO)

Sentinel Poison Center Program (SPC)

- Poison center NPDS data provide real world adverse events
- Group of Poison Centers that capture additional data on patients with psychedelic exposures.
- Drug specific
- Attribution of clinical effects
- Source and environment of use.
- Co-ingestants
- Rare severe events (serotonin toxicity, agitated delirium, etc)

SPC Provides Assessment of Emerging Behaviors/Risks

- Poison Centers identify rare severe cases.
- Additional data collection fields are needed to determine source, supervision, and intent of use.
- These fields are critical to determine risk across different use behaviors.

National Survey Investigating Hallucinogenic Trends (NSIHT)

- Population survey focused on psychedelic safety and perceived effectiveness outcomes stratified by use patterns
- Drug specific
- Reasons for use
- Source and environment
- Regional differences (3 digit zip code)
- Validated symptomatology scales

Clinical Condition	Validated Scale
General Health	SF-12
Wellbeing	WEMWBS-7
Depression	PHQ-9
Anxiety	GAD-7
Substance Use Disorder	DAST-10

NSIHT findings related to SUD

Past-year substance use	n (%)
Alcohol	
Past year alcohol (at least 12 drinks total)	1489 (64.6)
Weekly frequency	
0	117 (7.9)
1-7	825 (55.4)
8-14	392 (26.3)
15-21	102 (6.9)
22+	53 (3.6)
Cigarettes	
Every day	406 (17.6)
Some days	663 (28.8)
Not at all	1173 (50.9)
Don't know	64 (2.8)

Total N=2306

Those reporting being diagnosed with a **substance use disorder**: 792 (34.3%)

Past-year substance use	n (%)
Any (excluding alcohol, tobacco, and cannabis)	1200 (52.0)
Amphetamines	414 (18.0)
Methamphetamine	511 (22.2)
Amph or meth	701 (30.4)
Cathinones	338 (14.7)
Synthetic cannabinoids	449 (19.5)
Cocaine	656 (28.4)
Amph or meth or coc	953 (41.3)
Fentanyl	416 (18.0)
Heroin	333 (14.4)
Fent or heroin	572 (24.8)
Kratom	394 (17.1)
GHB	394 (17.1)
PCP	344 (14.9)
Cannabis	1104 (47.9)

[Unweighted pilot data, not nationally representative, exercise caution with interpretation]

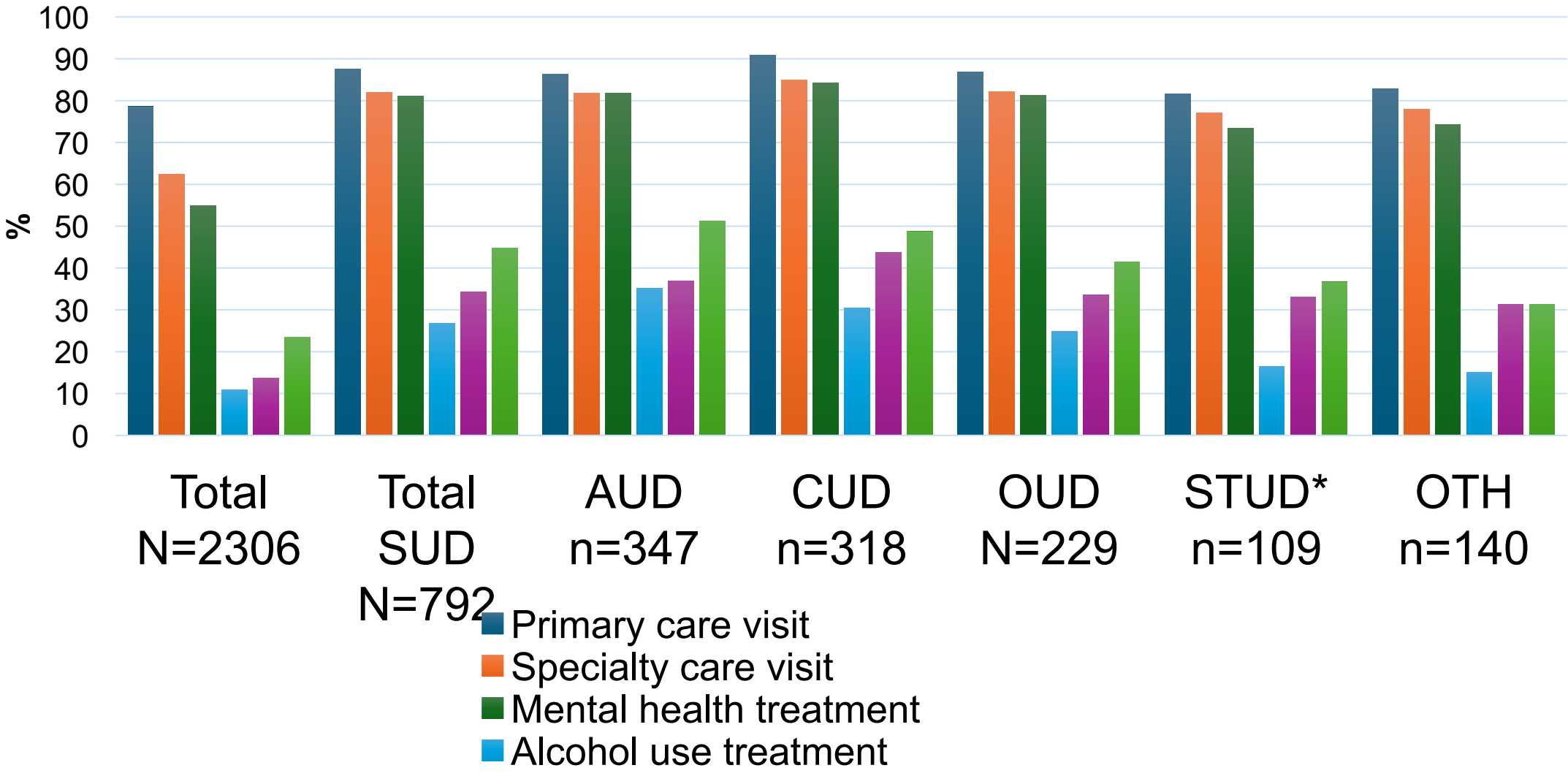
NSIHT findings related to SUD

Among SUD:

- Average DAST-10: 4.5 (“moderate level”)
- # Past-month days *physical* health NOT good: 14.7
- # Past-month days *mental* health NOT good: 15.0

[Unweighted pilot data, not nationally representative, exercise caution with interpretation]

Health Care Utilization



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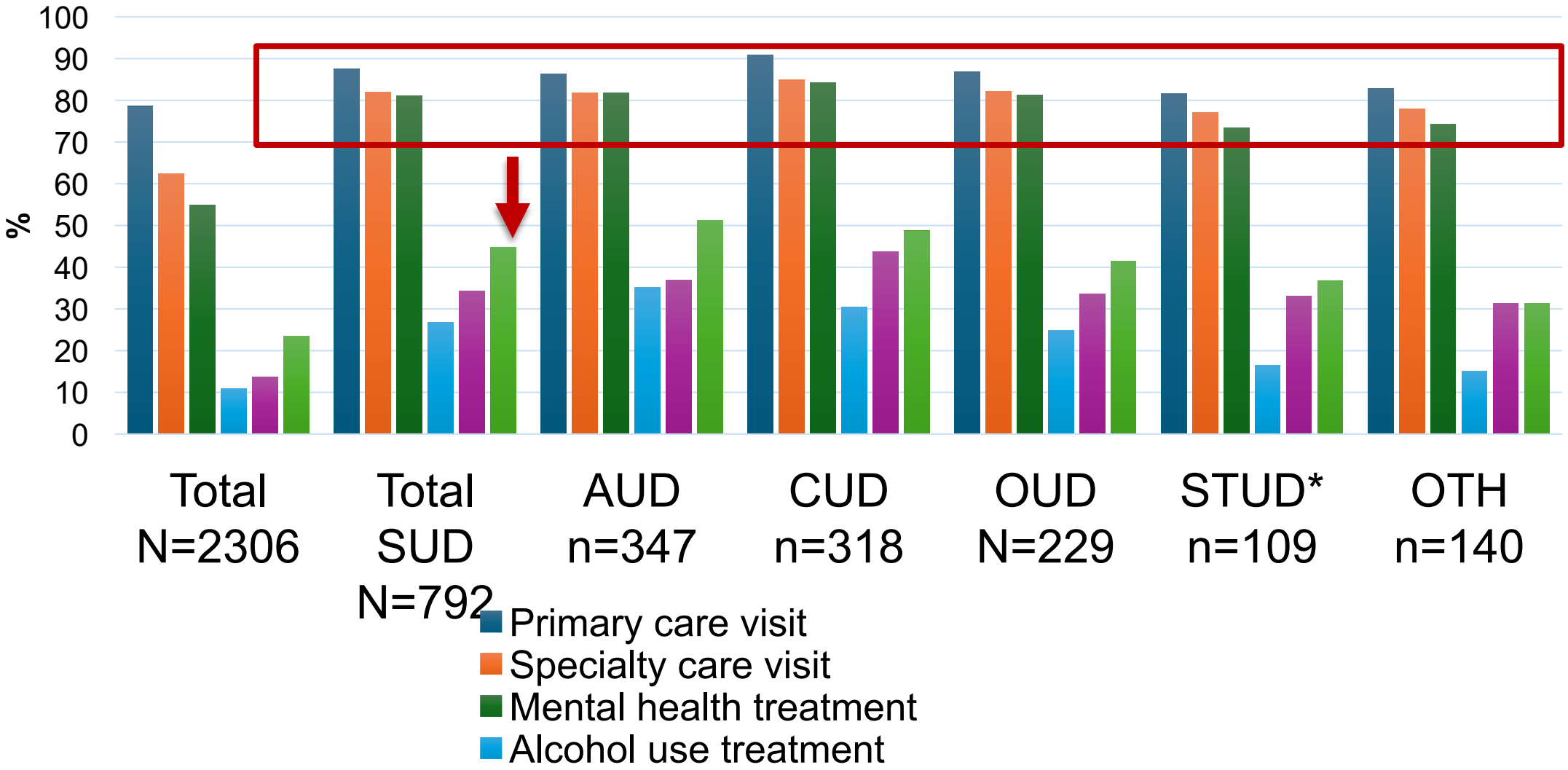


Unweighted pilot data, not nationally representative, exercise caution with interpretation

NSIHT findings related to SUD

	Ketamine N=261	Psilocybin N=262
To treat a medical symptom	62 (23.8)	66 (25.2)
>SUD	17 (6.5)	24 (9.2)
>chronic pain	22 (8.4)	27 (10.3)
>depression	40 (15.3)	45 (17.2)
>anxiety	37 (14.2)	39 (14.9)
To improve or change myself	73 (28.0)	61 (23.3)
For spiritual reasons	43 (16.5)	47 (17.9)
To participate in a ceremonial event	44 (16.9)	32 (12.2)
To have fun, for enjoyment, or to celebrate	73 (28.0)	87 (33.2)
Curiosity	46 (17.6)	56 (21.4)
To enhance sex	52 (19.9)	60 (22.9)
To deepen connection with others or nature	44 (16.9)	59 (22.5)
For another reason	8 (3.1)	8 (3.1)

sentative,

NSIHT findings related to SUD

	Ketamine N=261	Psilocybin N=262
PREPARATION		
Found someone trusted to accompany	108 (41.4)	107 (40.8)
Spoke with a licensed provider	126 (48.3)	90 (34.4)
Spoke with a non-licensed but trained person	68 (26.1)	70 (26.7)
Other activities to prepare	32 (12.3)	35 (13.4)
No preparation	25 (9.6)	45 (17.2)
INTEGRATION		
Reflected on own	63 (24.1)	74 (28.2)
Reflected with licensed provider	120 (46.0)	100 (38.2)
Reflected with non-licensed but trained person	101 (38.7)	82 (31.3)
Other activities	30 (11.5)	29 (11.1)

USE (IN LAST YEAR)		
Supervised by licensed provider	132 (50.6)	106 (40.5)
Supervised by non-licensed but trained person	108 (41.4)	91 (34.7)
Supervised by another trusted person	32 (12.3)	53 (20.2)
Not supervised	28 (10.7)	42 (16.0)
Used alcohol during	91 (34.9)	73 (27.9)
Used cannabis during	86 (33.0)	112 (42.7)
Used stimulant during	107 (41.0)	83 (31.7)
Used opioid during	70 (26.8)	64 (24.4)
Used other psychedelic during	35 (13.4)	22 (8.4)
Used any subst (besides alcohol) during	201 (77.0)	201 (76.7)

[Unweighted pilot data, not nationally representative, exercise caution with interpretation]

NSIHT findings related to SUD

	Ketamine n=261	Psilocybin n=262
"Positive" effects (Likert 1-5, rated 4-5)		
Personal growth	188 (72.0)	175 (66.8)
Physical health improved	156 (59.8)	146 (55.7)
Mental health improved	170 (65.1)	154 (58.8)
Made a major life change	189 (72.4)	175 (66.8)
"Challenging" effects (Likert 1 to 5, rated 1-2)		
A "bad trip"	34 (13.0)	32 (12.2)
Altered sense of reality	28 (10.7)	29 (11.1)
Intense anxiety, paranoia	24 (9.2)	29 (11.1)

[Unweighted pilot data, not nationally representative, exercise caution with interpretation]

NSIHT findings related to SUD

- Overall:
  - High (other) substance use among total sample
  - Among SUD subset using ketamine or psilocybin:
    - Surprisingly many (80-90%) had “preparation,” “integration,” and “supervision.”
    - Frequently used other substances simultaneously
    - Likely to report benefit
    - “Bad trip” somewhat rare
    - High primary care, specialty care, mental health care utilization
- Therefore, may be a population to target screening and counseling about risks/benefits. Would emphasize avoiding simultaneous cannabis and stimulants.

Connection to Addiction Medicine

SUD treatment data

JAMA Psychiatry

RCT: Psilocybin-Assisted Treatment of Alcohol Use Disorder

POPULATION

53 Men, 42 Women

Adults with alcohol dependence

Mean age, 45.8 y

SETTINGS / LOCATIONS

2 Academic centers in New York and New Mexico

INTERVENTION

95 Individuals randomized

49 Psilocybin
Administered orally in 2 all-day sessions (dose range, 25-40 mg/70 kg)

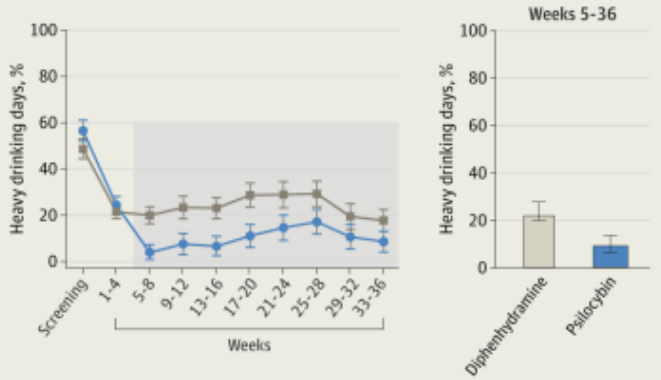
46 Diphenhydramine control
Administered orally in 2 all-day sessions (dose range, 50-100 mg)

PRIMARY OUTCOME

Percent heavy drinking days (scale, 0-100), assessed using the timeline followback interview, contrasted between groups over the 32-wk period following the first administration of study medication.

FINDINGS

Percent heavy drinking days during the 32-wk double-blind period was lower in the psilocybin group compared with the diphenhydramine group



Percent heavy drinking days
Psilocybin=9.7%
Diphenhyramine=23.6%

Mean difference, 13.9 (95% CI, 3.0-24.7; *P* = .01)

Bogenschutz MP, Ross S, Bhatt S, et al. Percentage of heavy drinking days following psilocybin-assisted psychotherapy vs placebo in the treatment of adult patients with alcohol use disorder: a randomized clinical trial. *JAMA Psychiatry*. Published online August 24, 2022. doi:10.1001/jamapsychiatry.2022.2096

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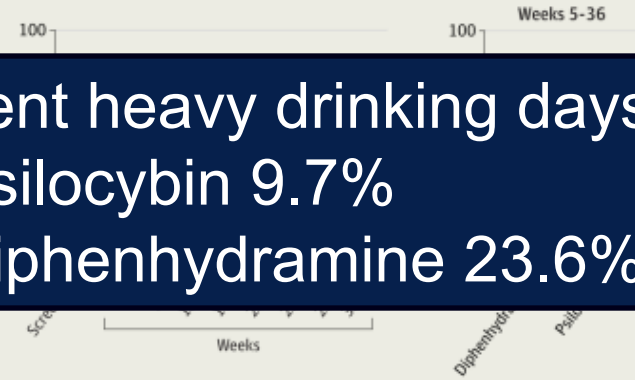

- Percent heavy drinking days
  - Psilocybin 9.7%
  - Diphenhydramine 23.6%

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SUD treatment data

THE AMERICAN JOURNAL OF DRUG AND ALCOHOL ABUSE
2017, VOL. 43, NO. 1, 55–60
http://dx.doi.org/10.3109/00952990.2016.1170135

Taylor & Francis
Taylor & Francis Group

ORIGINAL ARTICLE

Long-term follow-up of psilocybin-facilitated smoking cessation

Matthew W. Johnson, PhD[a], Albert Garcia-Romeu, PhD[a], and Roland R. Griffiths, PhD[a,b]

[a]Department of Psychiatry and Behavioral Sciences, Johns Hopkins University School of Medicine, Baltimore, MD, USA; [b]Department of Neuroscience, Johns Hopkins University School of Medicine, Baltimore, MD, USA

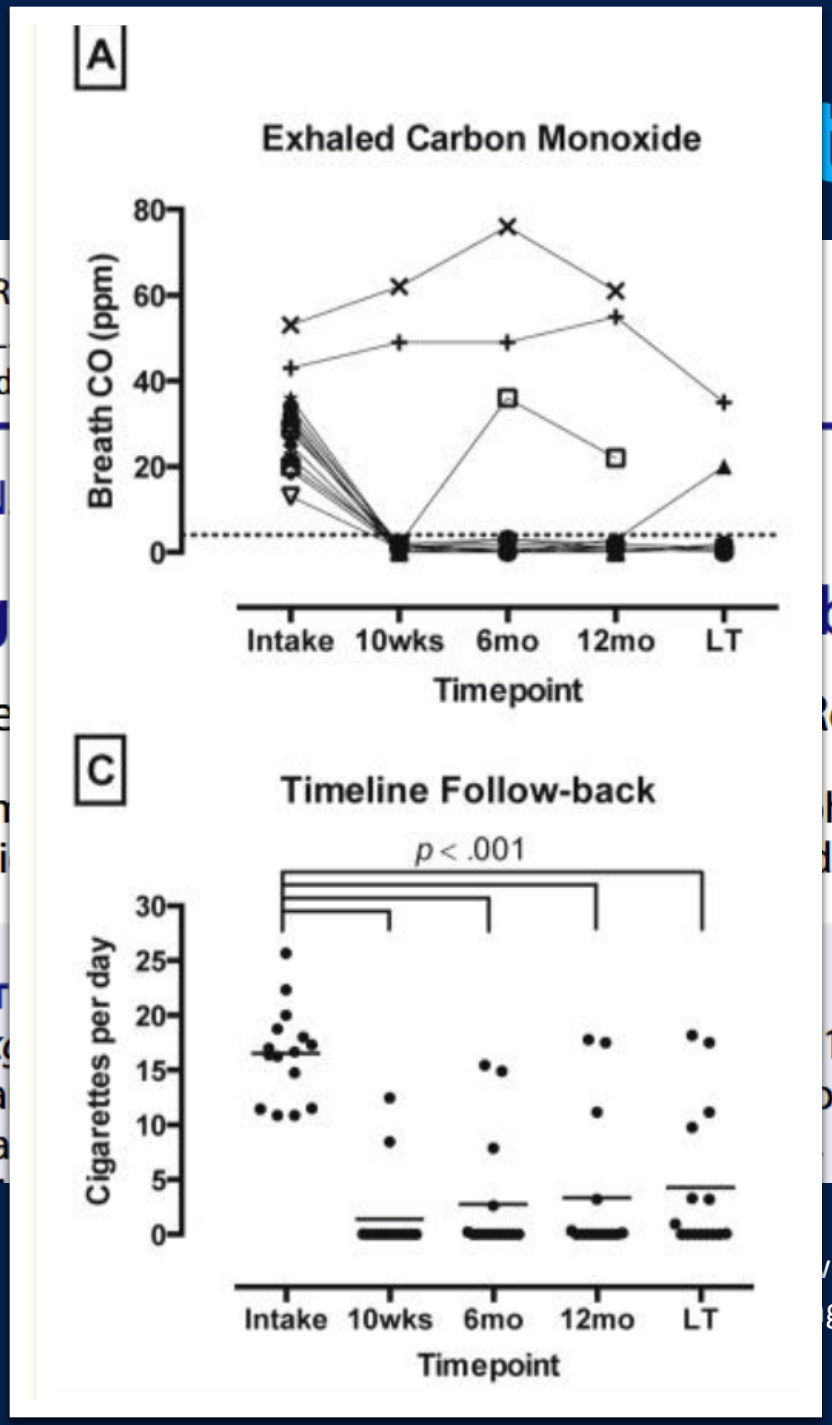
ABSTRACT

Background: A recent open-label pilot study ($N = 15$) found that two to three moderate to high doses (20 and 30 mg/70 kg) of the serotonin 2A receptor agonist, psilocybin, in combination with cognitive behavioral therapy (CBT) for smoking cessation, resulted in substantially higher 6-month smoking

ARTICLE HISTORY
Received 21 January 2016
Revised 2 March 2016
Accepted 21 March 2016

Johnson, Matthew W., Albert Garcia-Romeu, and Roland R. Griffiths. “Long-Term Follow-up of Psilocybin-Facilitated Smoking Cessation.” *The American Journal of Drug and Alcohol Abuse* 43, no. 1 (January 2, 2017): 55–60.

treatment data



- "At 12-month follow-up, 10 participants (67%) were confirmed as smoking abstinent"
- "At 12-month follow-up 13 participants (86.7%) rated their psilocybin experiences among the five most personally meaningful and spiritually significant experiences of their lives."

Taylor & Francis
Taylor & Francis Group

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W., Albert Garcia-Romeu, and Roland R. Griffiths. "Long-Term Follow-up of Psilocybin-
g Cessation." *The American Journal of Drug and Alcohol Abuse* 43, no. 1 (January 2, 2017):

SUD treatment data

A Single Ketamine Infusion Combined With Mindfulness-Based Behavioral Modification to Treat Cocaine Dependence: A Randomized Clinical Trial

Elias Dakwar, M.D., Edward V. Nunes, M.D., Carl L. Hart, Ph.D., Richard W. Foltin, Ph.D., Sanjay J. Mathew, M.D., Kenneth M. Carpenter, Ph.D., C.J. "Jean" Choi, M.S., Cale N. Basaraba, M.P.H., Martina Pavlicova, Ph.D., Frances R. Levin, M.D.

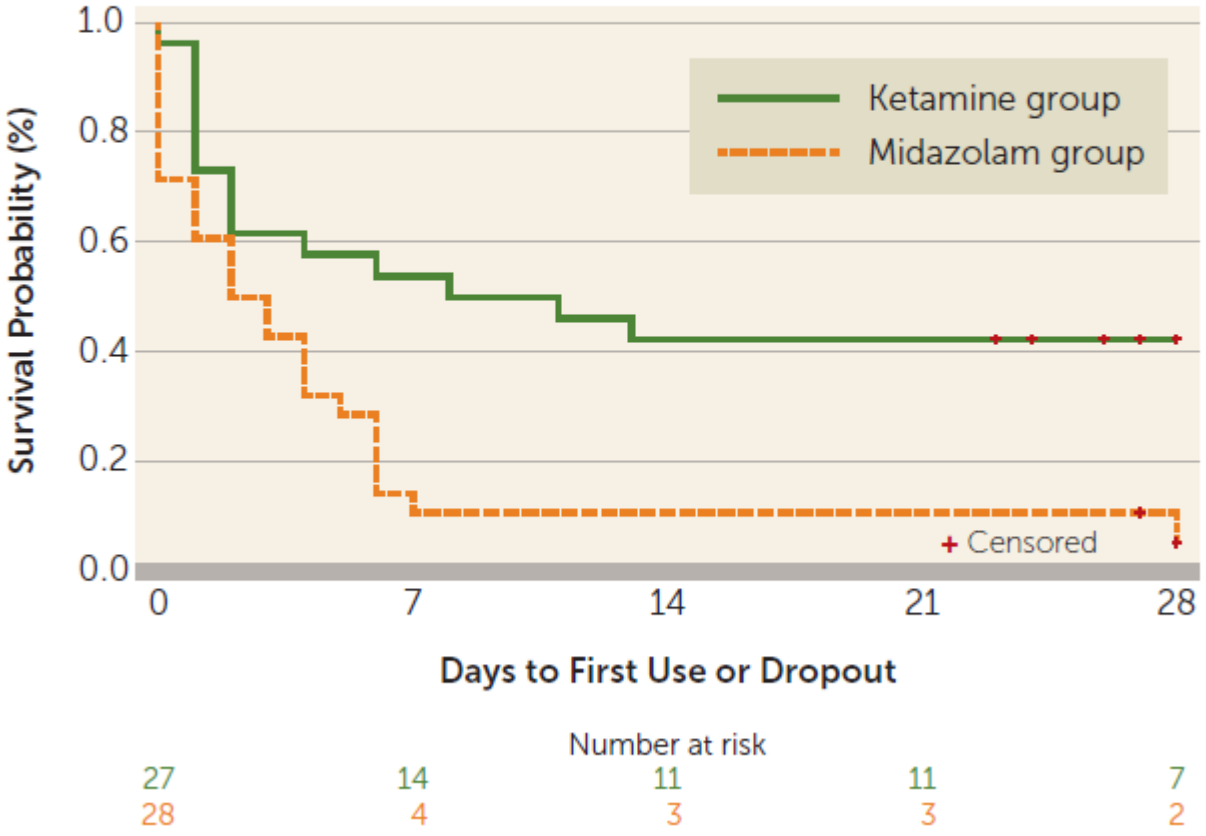
Objective: Research has suggested that subanesthetic doses of ketamine may work to improve cocaine-related vulnerabilities and facilitate efforts at behavioral modification. The purpose of this trial was to test whether a single ketamine infusion improved treatment outcomes in cocaine-dependent

compared with 10.7% in the midazolam group (intent-to-treat analysis). The ketamine group was 53% less likely (hazard ratio=0.47; 95% CI=0.24, 0.92) to relapse (dropout or use cocaine) compared with the midazolam group, and craving scores were 58.1% lower in the ketamine group throughout

Dakwar, Elias, Edward V. Nunes, Carl L. Hart, Richard W. Foltin, Sanjay J. Mathew, Kenneth M. Carpenter, C. J. Jean Choi, Cale N. Basaraba, Martina Pavlicova, and Frances R. Levin. "A Single Ketamine Infusion Combined With Mindfulness-Based Behavioral Modification to Treat Cocaine Dependence: A Randomized Clinical Trial." *The American Journal of Psychiatry* 176, no. 11 (November 1, 2019): 923–30.

SUD treatment data

FIGURE 2. Time to first use or dropout, by treatment group, in a randomized controlled trial of ketamine and a mindfulness-based behavioral modification for cocaine dependence



- HR: 0.47 for cocaine use or dropping out

Mathew, Kenneth M. Carpenter, C. J. Jean Choi, Cale N. [illegible] Infusion Combined With Mindfulness-Based Behavioral Modification to Treat Cocaine Dependence: A Randomized Clinical Trial." *The American Journal of Psychiatry* 176, no. 11 (November 1, 2019): 923–30.

SUD treatment data

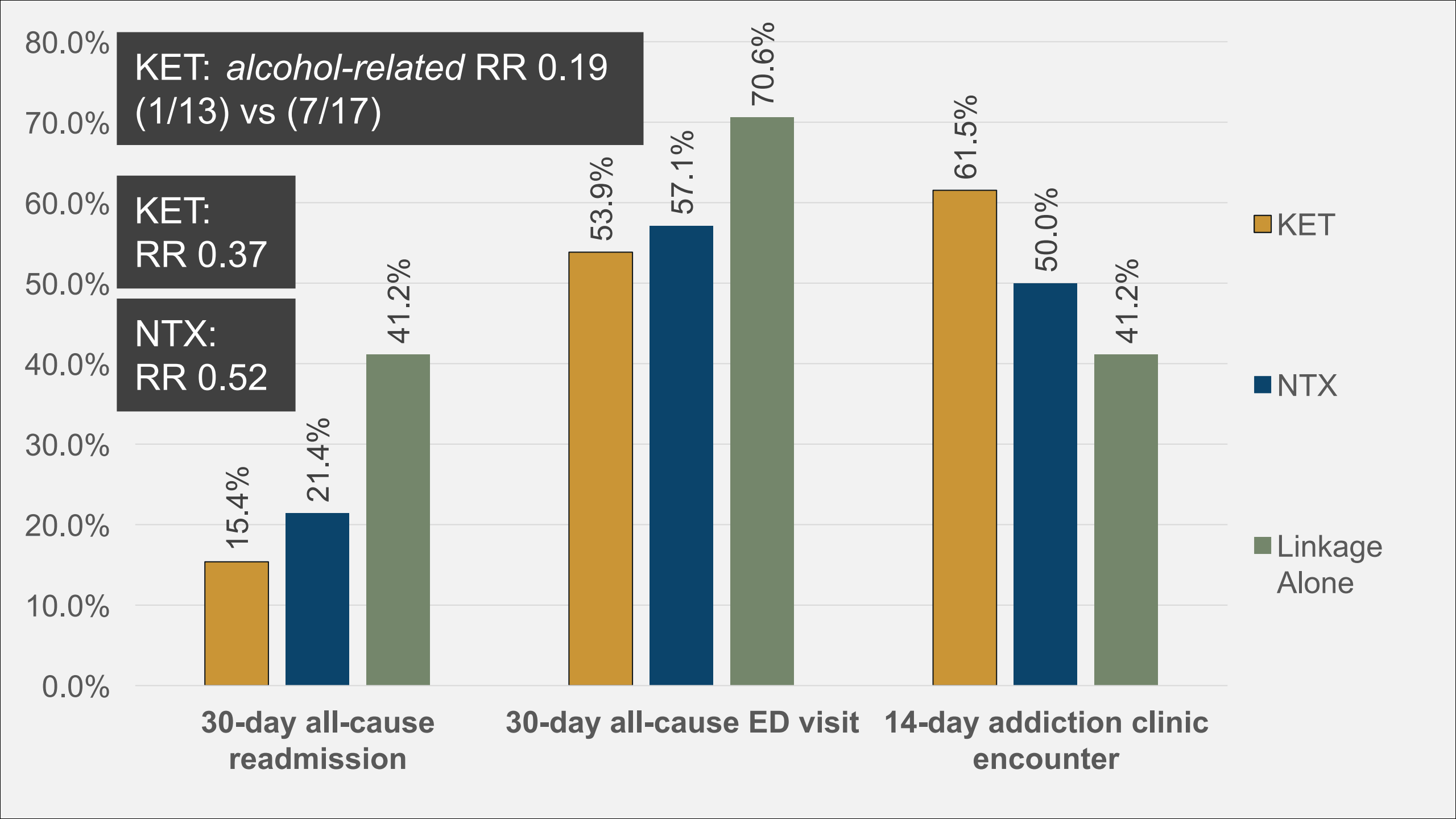
- Pilot clinical trial (n=44) of ketamine, naltrexone, neither for “refractory” AUD in hospital

“It was like a roller coaster, but it was smooth…I lost track of being…it was like I was here but not” (40M, accept 10, f/u+, readmit+)

“I started feeling not ecstatically happy, but just good…no feelings of depression or anxiety…I felt secure.” (37F, accept 10, f/u+, readmit-)

“Made me think twice… not to drink alcohol anymore. Do you want this or do you want alcohol? Which one?” (42M, accept 9, f/u-, readmit-)

Terasaki, Dale, Ryan Loh, Anastasia Cornell, Julie Taub, and Christian Thurstone. “Single-Dose Intravenous Ketamine or Intramuscular Naltrexone for High-Utilization Inpatients with Alcohol Use Disorder: Pilot Trial Feasibility and Readmission Rates.” Addiction Science & Clinical Practice 17, no. 1 (November 22, 2022): 64.


KET: *alcohol-related* RR 0.19 (1/13) vs (7/17)
KET: RR 0.37
NTX: RR 0.52
80.0%
70.0%
60.0%
50.0%
40.0%
30.0%
20.0%
10.0%
0.0%
15.4%
21.4%
41.2%
53.9%
57.1%
70.6%
61.5%
50.0%
41.2%
30-day all-cause readmission
30-day all-cause ED visit
14-day addiction clinic encounter
KET
NTX
Linkage Alone

Administration in hospital setting

- Severe, “refractory” cases of SUD often show up in medical hospitals, may not respond to conventional Rx
- Leverage inherent motivation of acute health risk
- Extensive monitoring, support from psychiatric and/or addiction consult services
- Ketamine therapy for AUD specifically appears promising: already available, overlap with MDD, alcohol cross-tolerance, brief, investigated for withdrawal

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Cases from the consult service

Mr. S: 35yo M with seizure activity in setting of recent alcohol and benzodiazepine cessation

- Hx severe anxiety, chronic benzodiazepine Rx, “fired” by prescriber. Drank large amounts when off benzo -> hospital admits.
- Referred to multiple programs (including residential), but pt often had non-epileptic seizures -> discharge.
- Used psilocybin and LSD as teen. Once, “overdosed” on LSD, taking entire sheet of blotter paper (perhaps 100x instructed) -> persistent visual “hallucinations” when looking at lights. Diagnosed as Hallucinogen Persisting Perception Disorder (HPPD).
- Unfortunately he passed away due to alcohol-related liver complications.

Cases from the consult service

Mr. H: 37yo M who presented with nausea and vomiting, admitted to medicine for alcohol withdrawal management.

- Hx severe anxiety, PTSD.
- For AUD, preferred acamprosate.
- Curiosity about ketamine being helpful (anti-NMDA mechanism, comorbid psych) if he continued to struggle.
- Attended a ketamine clinic, received treatments over 8 months (~monthly), leading to near-complete abstinence.
- About to start a different approach – ketamine "psycholytic" therapy, but he decided to stop treatments. Life stressors -> return to use -> repeat hospitalization.
- Planned to continue ketamine therapy afterwards.

Cases from the consult service

Mr. G is a 40yo M who presented with a thigh abscess related to injection drug use.

- Hx car crash in his 20s, given heroin by friend. Eventually had withdrawal sx -> cycles of cessation and return to use.
- Started cocaine, ketamine IV/IM “socially” -> cystitis.
- For opioid withdrawal, would use ketamine and ibogaine. For ibogaine, would take a “loading dose” (psychedelic experience), then would “microdose” to keep withdrawal and cravings away. QT interval ok.
- Offered buprenorphine or methadone; he was disgusted.
- Per chart review, he eventually did start buprenorphine in the outpatient setting, but working on tapering off.

Connection to Addiction Medicine Summary

- Psychedelics (including ketamine) use may begin to arise in health care settings more frequently, including the hospital.
- Addiction medicine clinicians ought to be aware of use and potential disorders (particularly non-prescribed ketamine)
- Philosophical rift regarding MOUD
- Potential benefits of psychedelics for SUD when administered safely, need more data

In Summary

- Psychedelics policy is following a similar blueprint as cannabis, though different model and mechanics.
- Benefits and risks in the real world are not fully known.
- Various tools can be deployed to monitor both.
- Some of SUD population interested in psychedelics may use many substances and be interfacing with health care, which provides opportunity to screen and counsel.
- Psychedelics may become a more established Rx for SUD

Q+A

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