RMPDS 19TH ANNUAL SCIENTIFIC MEETING

A Mature Mosaic for Psychedelic Monitoring

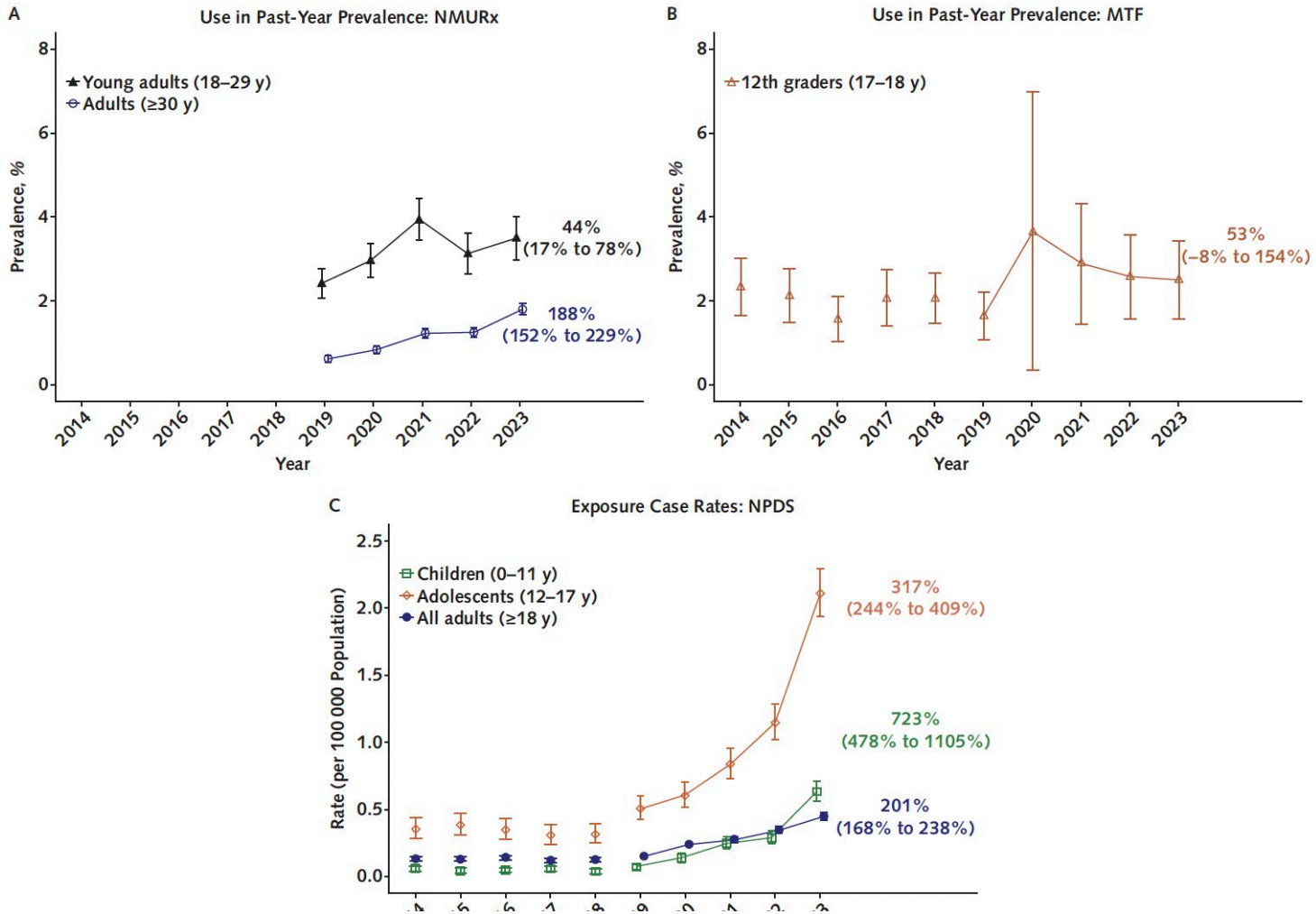
Andrew A. Monte, MD, PhD
Scientific Director
Rocky Mountain Poison & Drug Safety
Denver Health & Hospital Authority
&
Professor
Emergency Medicine & Medical Toxicology
University of Colorado School of Medicine

ROCKY MOUNTAIN POISON & DRUG SAFETY
Saving lives with answers.™

DENVER HEALTH
est. 1860
FOR LIFE'S JOURNEY

School of Medicine
UNIVERSITY OF COLORADO
ANSCHUTZ MEDICAL CAMPUS

Psilocybin Use is Rising in the United States



Confirmation of findings with a mosaic of high-quality data sources increases reliability

RMPDS 19TH ANNUAL SCIENTIFIC MEETING

Rockhill, Ann Int Med. 2025

All Studies Have Limitations



Clinical Trials Don't Necessarily Apply to the General Population

nature medicine

ARTICLES

https://doi.org/10.1038/s41591-021-01336-3

Check for updates

OPEN

MDMA-assisted therapy for severe PTSD: a randomized, double-blind, placebo-controlled phase 3 study

Jennifer M. Mitchell[1,2]✉, Michael Bogenschutz[3], Alia Lilienstein[4], Charlotte Harrison[5], Sarah Kleiman[6], Kelly Parker-Guilbert[7], Marcela Ot'alora G.[8,9], Wael Garas[8], Casey Paleos[10], Ingmar Gorman[11], Christopher Nicholas[12], Michael Mithoefer[5,9,13], Shannon Carlin[5,9], Bruce Poulter[8,9], Ann Mithoefer[9], Sylvestre Quevedo[2,14], Gregory Wells[14], Sukhpreet S. Klaire[15], Bessel van der Kolk[16], Keren Tzarfaty[9], Revital Amiaz[17], Ray Worthy[18], Scott Shannon[19], Joshua D. Woolley[2], Cole Marta[20], Yevgeniy Gelfand[21], Emma Hapke[22], Simon Amar[23], Yair Wallach[24], Randall Brown[11], Scott Hamilton[25], Julie B. Wang[5], Allison Coker[1,5], Rebecca Matthews[5], Alberdina de Boer[5], Berra Yazar-Klosinski[4], Amy Emerson[5] and Rick Doblin[4]

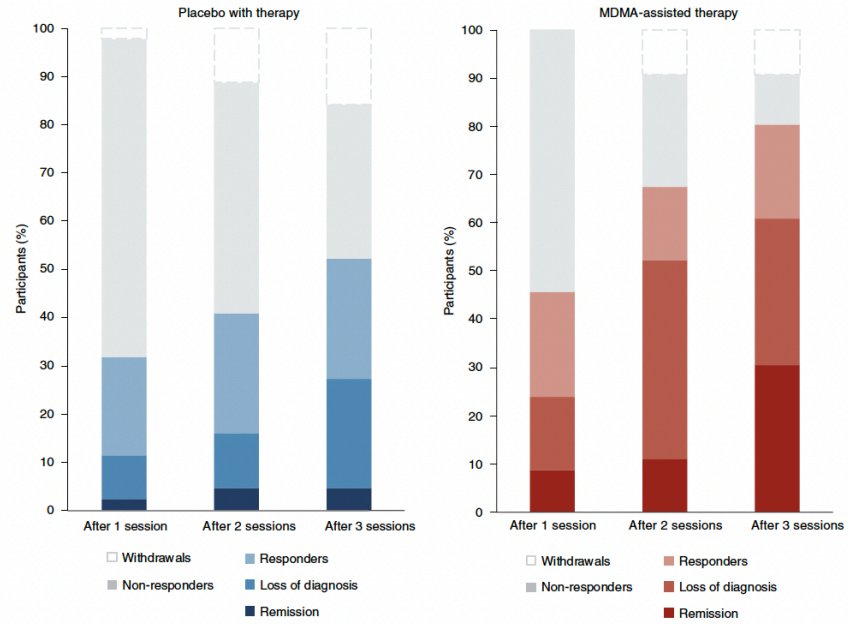
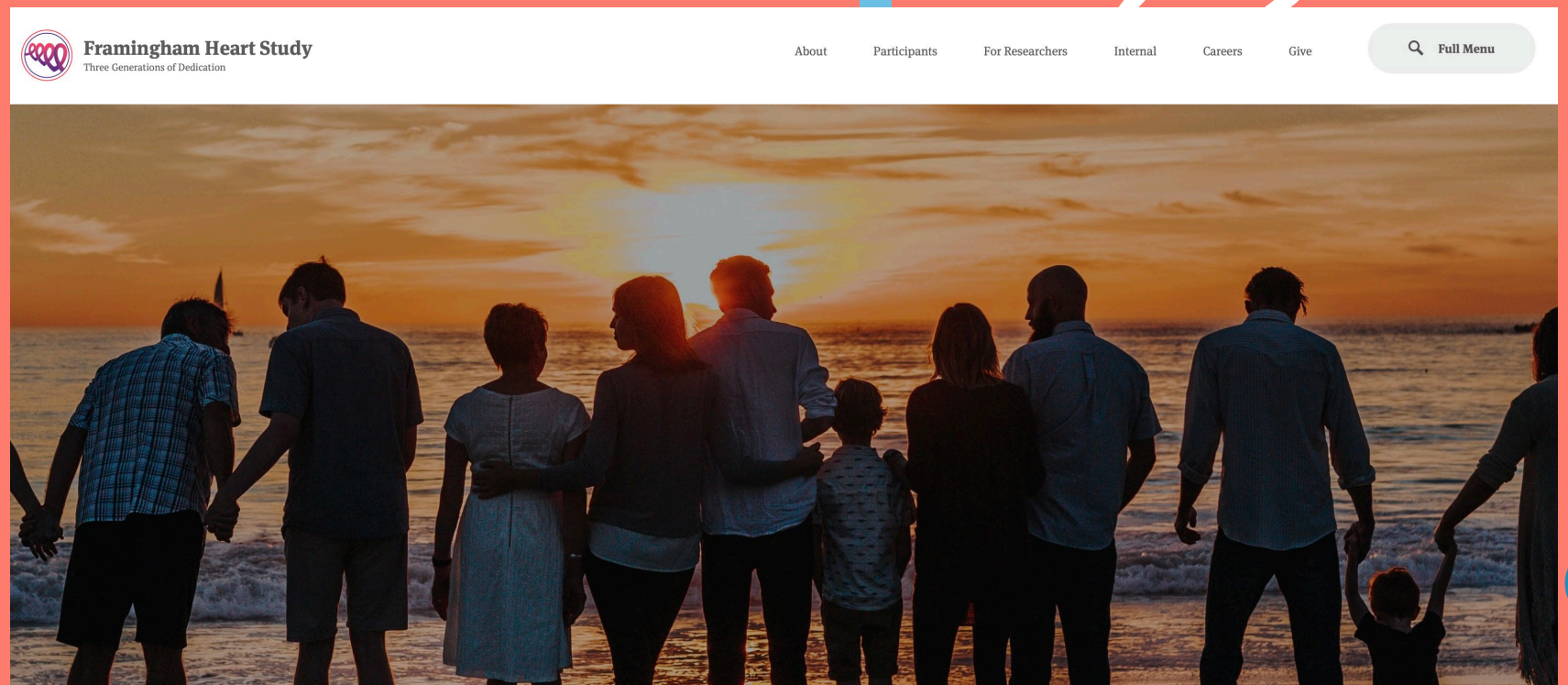


Fig. 3 | Treatment response and remission for MDMA and placebo groups as a percentage of total participants randomized to each arm (MDMA, *n* = 46; placebo, *n* = 44). Responders (clinically significant improvement, defined as a ≥10-point decrease on CAPS-5), loss of diagnosis (specific diagnostic measure on CAPS-5), and remission (loss of diagnosis and a total CAPS-5 score of ≤11) were tracked in both groups. Non-response is defined as a <10-point decrease on CAPS-5. Withdrawal is defined as a post-randomization early termination.

Cohort Studies are Limited by Who is in the Cohort

- Lack of diversity. Mostly White of European descent.
- Framingham limited by overestimation of disease in under-represented racial and ethnic groups.



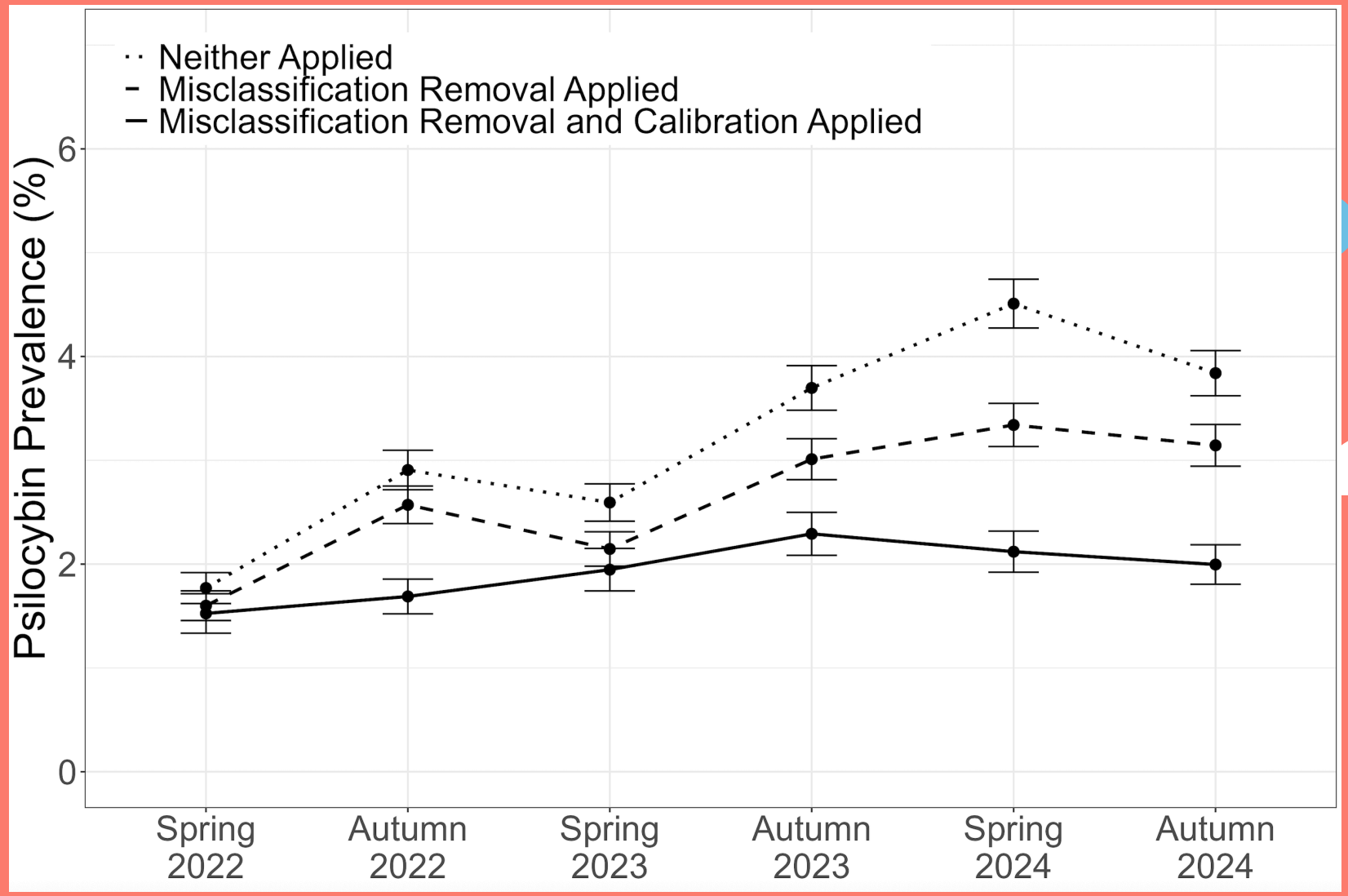
Hospital Records Only Capture What is Documented

- National Hospital Ambulatory Medical Care Survey (NHAMCS)
- NHAMCS collected data about medical services provided in hospital emergency and outpatient departments. (ended in 2022)
- 500 representative hospitals provided ED visit data over 4 week period each year.
- Only 3 cases of psilocybin poisoning were captured from 2015-2021.



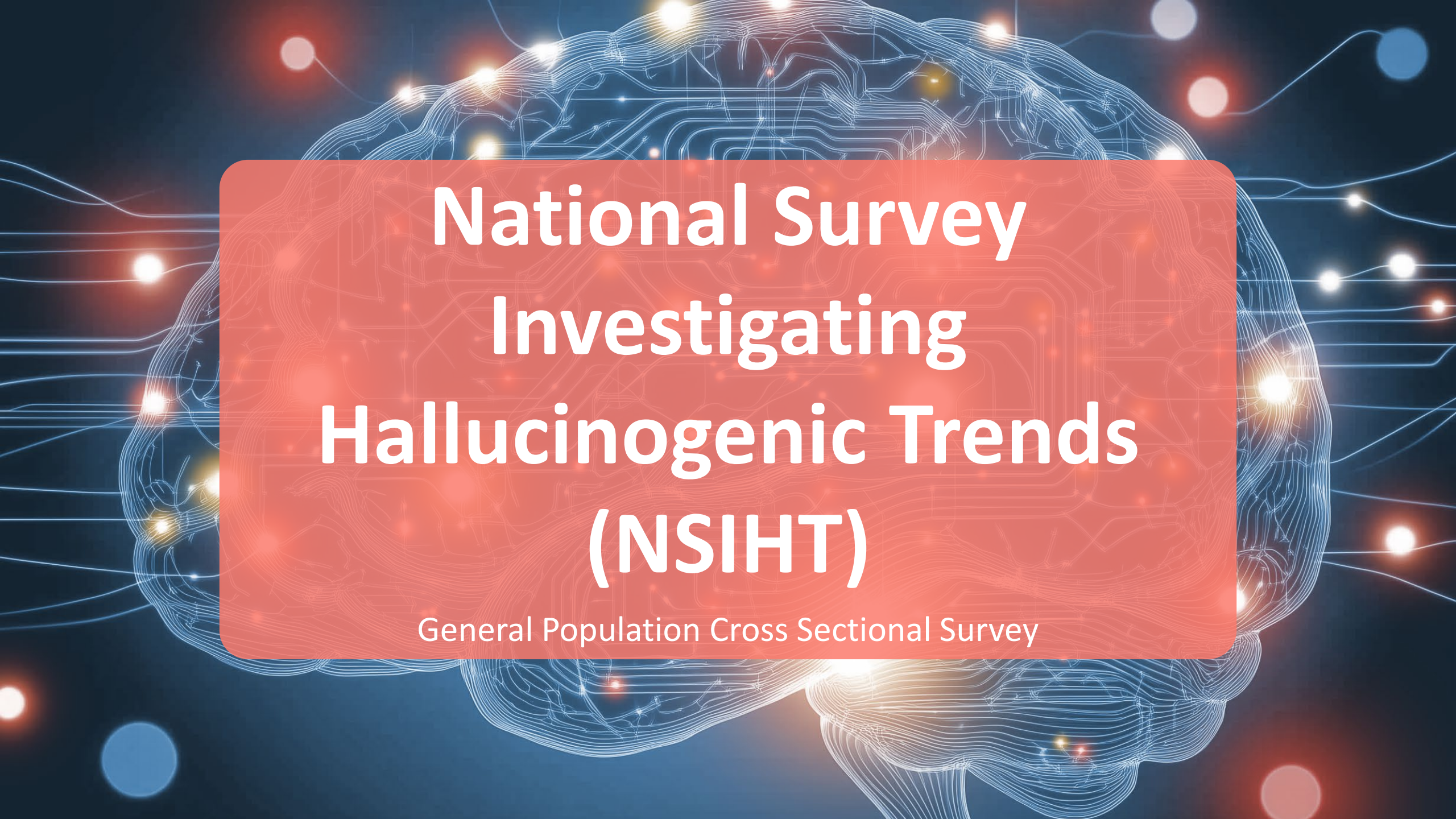
Rockhill, Ann Int Med. 2025

Surveys Limited by Sampled Population and Ability to Control Bias



NMURx, unpublished data

Combining Data Sources Mitigates the Limitations of Each and Increases Reliability of Findings



National Survey Investigating Hallucinogenic Trends (NSIHT)

General Population Cross Sectional Survey

NSIHT



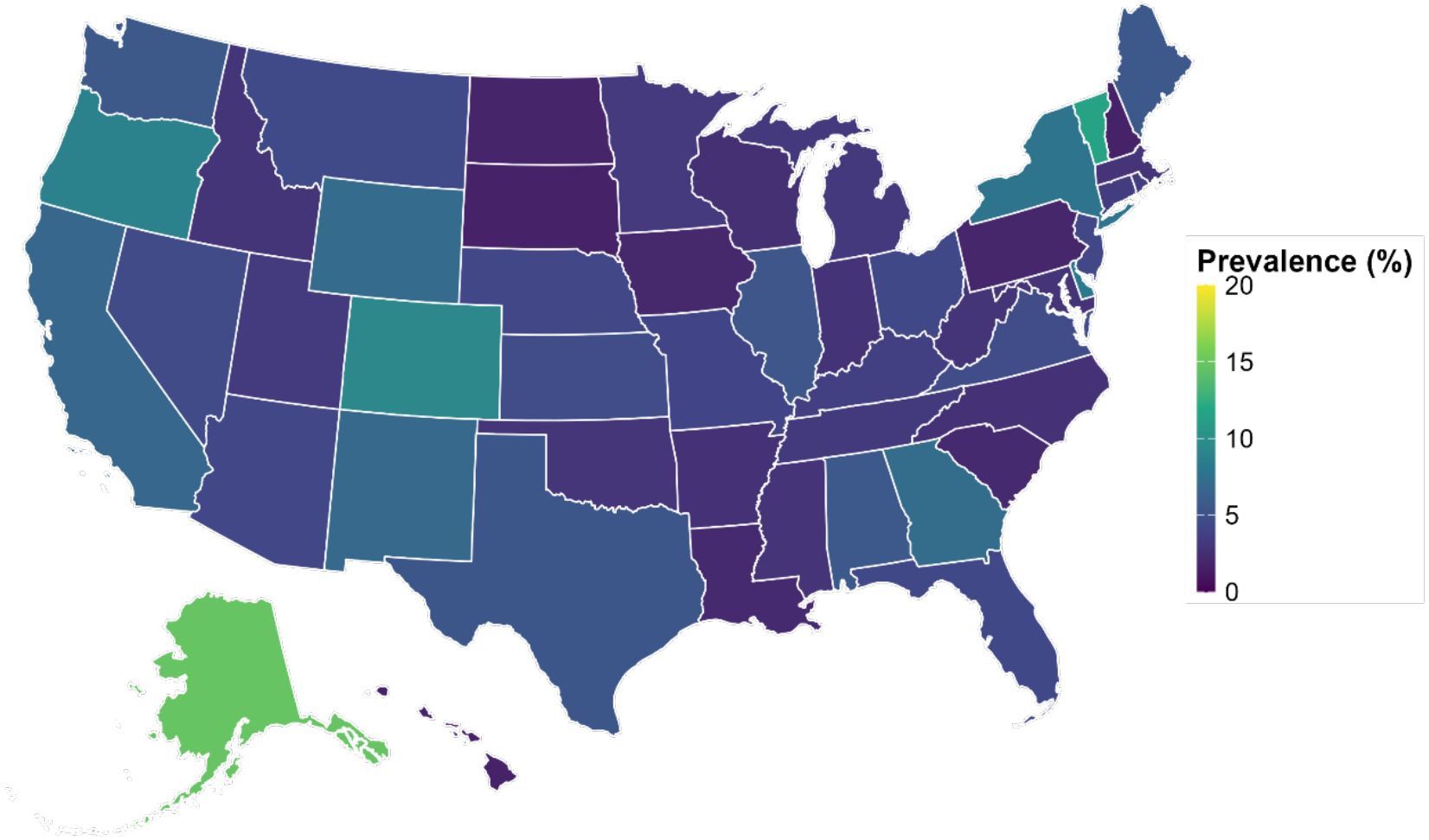
- Largest ongoing survey of adult psychedelic use in the US, >8000 respondents by end 2025
- Online panel
- Detailed use patterns
- Validated scales to measure clinical outcomes
- Validated survey methodology[1-2]
- Relied upon by SAMHSA, individual states (AZ, CO)
- Funded by SAMHSA grant# 75S20124P00003

Key Measures:

- Prevalence of use across 16 substances
- Detailed reason for use
- Demographics
- Recency/frequency of use
- Perceived benefits

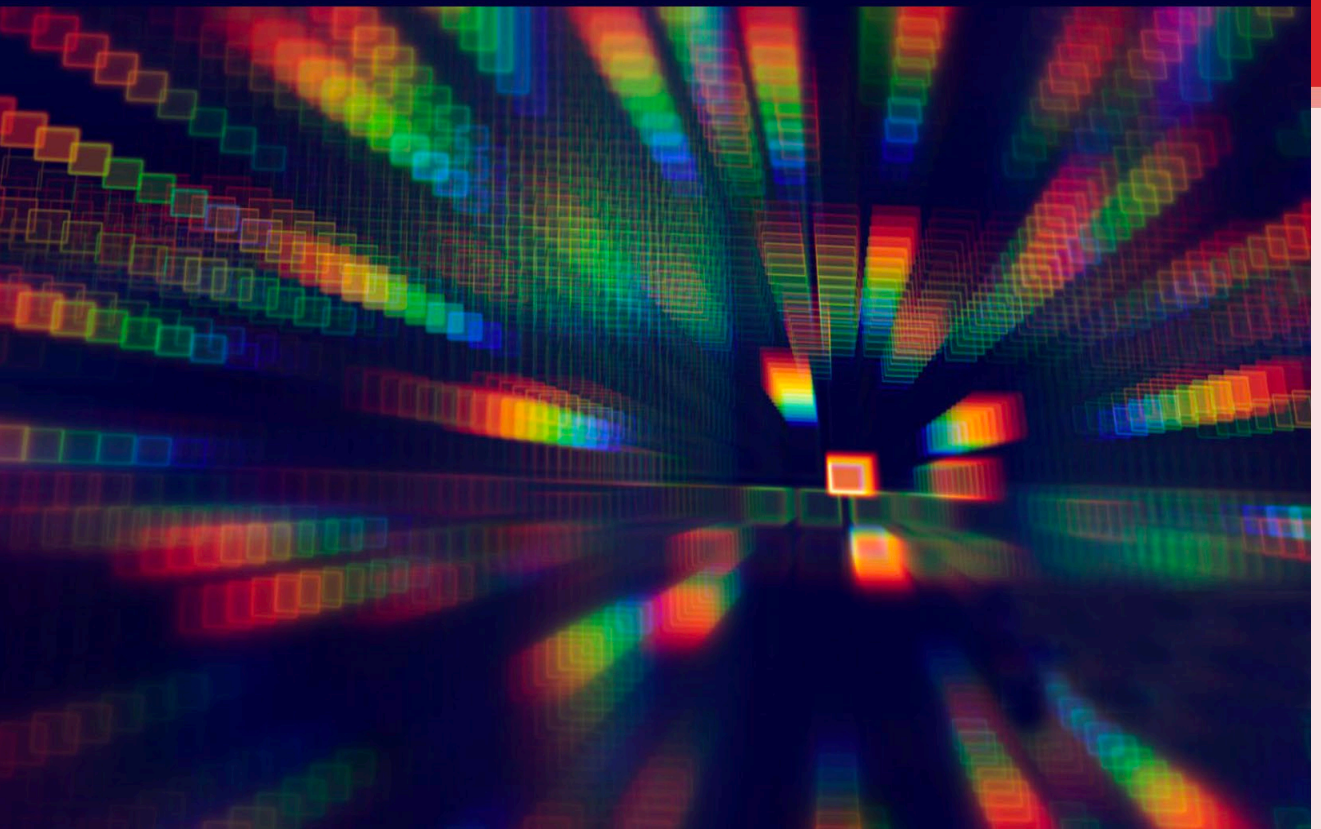
Prevalence of Any Psychedelic Use in the US in 2024

National Survey Investigating Hallucinogenic Trends (NSIHT)



USE OF PSYCHEDELIC SUBSTANCES IN THE UNITED STATES, 2024:

Results from the National Survey Investigating Hallucinogenic Trends (NSIHT)



Annual Data Report

https://www.rmpds.org/nsiht

National Prevalence of Psychedelic Use

NSIHT asked U.S. adults if they used any psychedelics in the last year, including the substances highlighted in this report (psilocybin, MDMA, LSD, and prescription ketamine/esketamine) and seven other psychedelic substances.

Psychedelic Use in the Last Year

	Overall	Aged 18-25	Aged 26-49	Aged 50+	Female	Male
Any Psychedelic	4.5%	7.9%	7.0%	1.4%	3.2%	5.9%
	12.0 million	2.8 million	7.4 million	1.7 million	4.3 million	7.6 million
Psilocybin	2.1%	3.1%	3.0%	1.0%	1.5%	2.6%
	5.5 million	1.1 million	3.2 million	1.2 million	2.1 million	3.4 million
MDMA	1.5%	3.5%	2.1%	0.2%	1.0%	2.0%
	3.9 million	1.3 million	2.3 million	306,000	1.3 million	2.6 million
LSD	0.9%	1.8%	1.4%	0.3%	0.6%	1.3%
	2.5 million	626,000	1.5 million	326,000	836,000	1.6 million
Prescription Ketamine or Esketamine	1.2%	2.2%	2.0%	0.3%	0.8%	1.7%
	3.2 million	787,000	2.1 million	313,000	1.1 million	2.1 million

Sentinel Poison Center Program

Enriched adverse event detection with case granularity

SPC



- Augmented poison center data capture – key source of safety information relied upon by FDA
- Safety outcomes including adverse events, healthcare utilization and medical outcomes
- Designed to differentiate between illicit and prescription use
- Complements national poison center database National Poison Data System (NPDS)

Captures nuanced context information:

- Set/setting
- Reason for use
- Source and dose
- Colorado, Oregon, Hawaii, Montana, Nevada

SPC Data: April 2024-June 2025

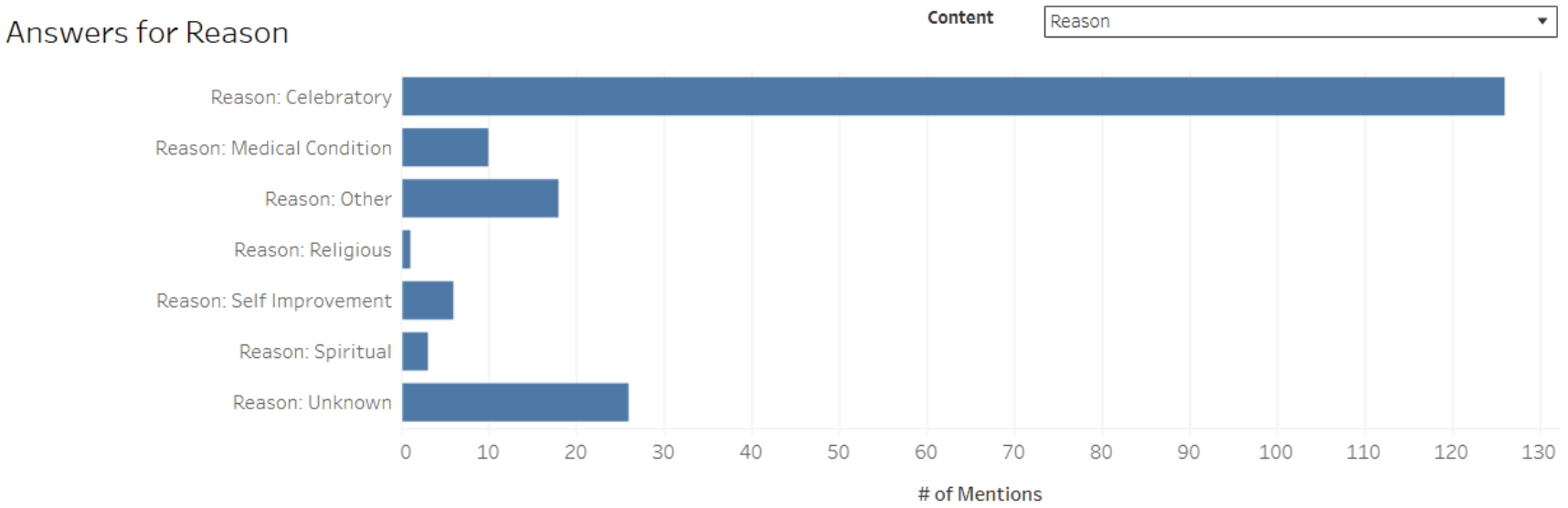
Endorsed	
Psilocybin	141
MDMA	36
Other Drug	27
LSD	26
Phencyclidine	5
Unknown Drug	5
DMT	3
2CB	1
Ayahuasca	1
Esketamine	1
Salvia	0
Mescaline	0
Ibogaine	0

N=246 cases reported over this period (57% involved psilocybin)

52% report celebratory/recreational use as reason for use.

78% of psilocybin users reported recreational reasons for use (NSIHT)

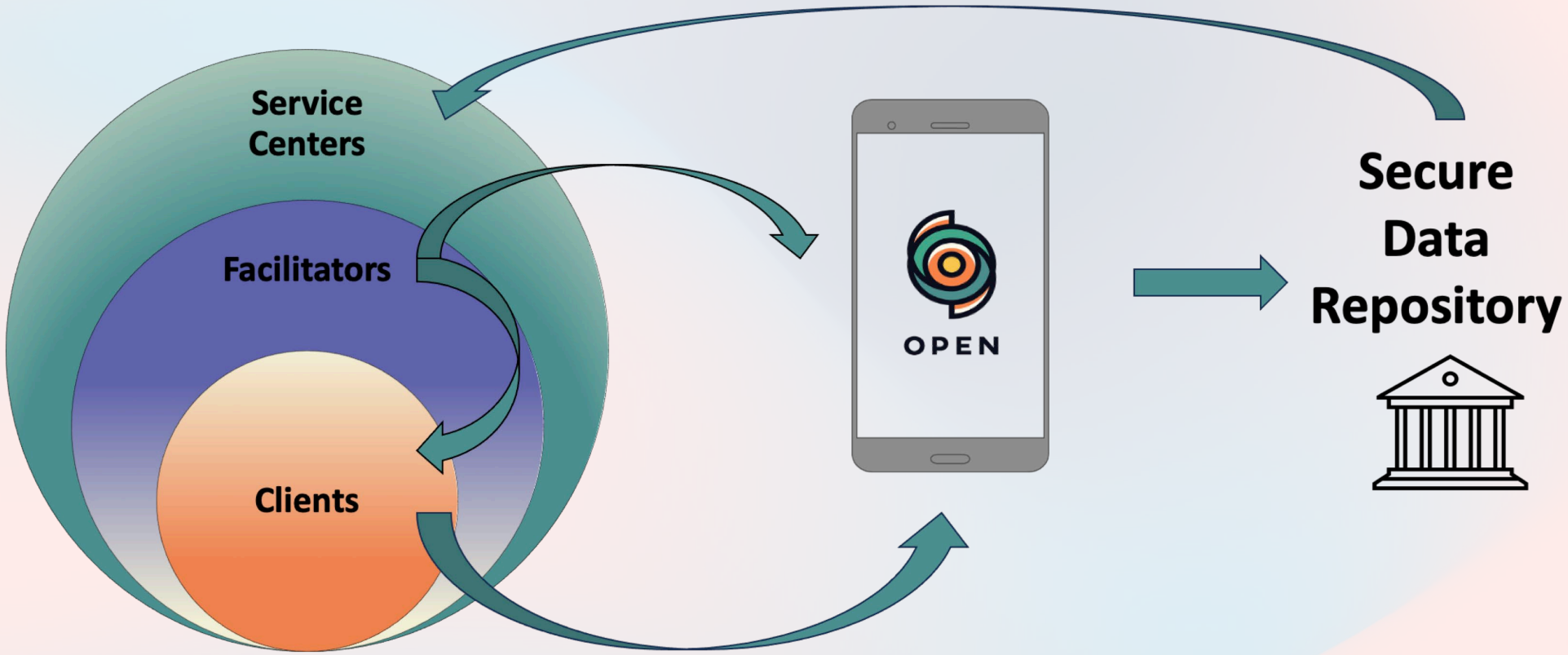
Validation of data through case note abstraction
Minimizes misclassification
Analysis of precipitants of symptoms and focus on attribution



Oregon Psychedelic Evaluation Nexus

Longitudinal Cohort Study

Oregon Psychedelic Evaluation Nexus (OPEN) Longitudinal Patient Registry



Funded by SAMHSA grant# 75S20124P00002

The Safety and Clinical Outcomes of Psychedelic Use (SCOPE Center)

A collaboration of RMPDS and OHSU with Scientific Advisement from experts at CU, Stanford, Emory, RAND, etc

A Mature Mosaic for Psychedelic Outcomes

Contact: info@rmpds.org



What's Next?

- State prevalence estimates for individual drugs
- Continuous NSIHT enrollment
- Expansion of SPC across the US
- Expansion of OPEN across the US
- Assessment of reasons for medical use and perceived effectiveness across different regulatory frameworks
- Mosaic assessment of adverse events

Thanks to Sue Sisley, MD for this picture

Focus on Methods and Rigor

- How do these tools work?
- What have we done to ensure the validity and reliability?
- How do the tools work together?



RMPDS 19TH ANNUAL SCIENTIFIC MEETING

Thank you

Andrew A. Monte, MD, PhD
Vice Chair & Professor
Rocky Mountain Poison & Drug Safety
Andrew.monte@rmpds.org

DENVER HEALTH est. 1860 FOR LIFE'S JOURNEY

ROCKY MOUNTAIN POISON & DRUG SAFETY Saving lives with answers.™

RADARS® SYSTEM

Tools of the Mosaic

	NSIHT-Population	OPEN-Cohort	SPC-Reconciled AEs
Adverse events	X	X	X
Longitudinal follow up		X	
Concomitant drug/med use	X		X
Use outside of state programs	X		X
Use in traditional medical system	X		X
Substances	16 Psychedelics	Psilocybin	8 psychedelics
Effectiveness w/ validated Scales	X	X	
Demographics	Robust	Robust	Limited
Durability of effects	X	X	
Facilitator evaluation		X	

References

- Rockhill, K. M., Black, J. C., Ladka, M. S., Sumbundu, K. B., Olsen, H. A., Jewell, J. S., Hunt, J., Wolf, R. C., Nerurkar, K., Dart, R. C., & Monte, A. A. (2025). The Rise of Psilocybin Use in the United States: A Multisource Observational Study. Ann Intern Med, 178(7), 1052-1054. https://doi.org/10.7326/ANNALS-24-03145.

- Mitchell, J. M., Bogenschutz, M., Lilienstein, A., Harrison, C., Kleiman, S., Parker-Guilbert, K., Ot'alora, G. M., Garas, W., Paleos, C., Gorman, I., Nicholas, C., Mithoefer, M., Carlin, S., Poulter, B., Mithoefer, A., Quevedo, S., Wells, G., Klaire, S. S., van der Kolk, B.,…Doblin, R. (2023). MDMA-Assisted Therapy for Severe PTSD: A Randomized, Double-Blind, Placebo-Controlled Phase 3 Study. Focus (Am Psychiatr Publ), 21(3), 315-328. https://doi.org/10.1176/appi.focus.23021011