Policy Suggestions to Support the Safe Uses of Psychedelics

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Disclosures

Industry Relations / Conflicts of Interest (last 3 years):
Advisor – Journey Colab

No FDA-approved uses:
Ayahuasca, LSD, MDMA, mescaline, psilocybin

Open Science
“Statement on Open Science and Open Praxis with Psilocybin...”
https://files.csp.org/open

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Policy considerations that support equitable access to responsible, accountable, safe, and ethical uses of psychedelic medicines

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Disclosures
Psychedelic Medicines

**Tryptamines**
- LSD
- Psilocybin
- DMT

**Phenethylamines**
- Mescaline
- MDMA
Psychedelic Therapy

(No Rx) Preparation visits (~6-8 hr)

(Rx) Medication visit (~8 hr)

(No Rx) Integration visits (~4-8 hr)
Psychedelic Care

(No Rx) Preparation Session?

(Rx) Psychedelic Session

(No Rx) Integration Session(s)?
Traditional Knowledge

- Ceremonies, like protocols, are intentional rituals
- Healing, knowledge, and power
- Community-based, relational forms of care
- Unlicensed, faith-based practice is not necessarily unregulated practice
Effect size $d = 0.91$ (N=91)

Effect size $g = 0.52$ (N=93)
Biomedical Care

• SWITZERLAND
  • Compassionate Use

• CANADA
  • Special Access Program

• AUSTRALIA
  • Authorized Prescriber Scheme
Increasing Concern

Toward Risk-Benefit Assessments in Psychedelic- and MDMA-Assisted Therapies

Mazalak M. Bradberry, PhD
Department of Neuroscience, University of Wisconsin

As a result of demonstrating promise in a range of clinical studies, psychedelic and 3,4-methylenedioxymethamphetamine (MDMA)-based treatments have generated a tsunami of optimistic public interest and media attention.

Pressing regulatory challenges for psychedelic medicine

Policy must support generation of evidence on safety and effectiveness

By Amy L. McGuire¹, Holly Fernandez Lynch², Lewis A. Grossman³, I. Glenn Cohen⁴

Addressing Abuse and Repair: An Open Letter to the Psychedelic Community
Misconceptions in Public Discourse

“It’s legal”

“Science proved that psychedelics are safe”

“Science showed that psychedelics treat depression, anxiety and PTSD”
Public Education

- Public education needs to include professional education
- ‘Expert’ knowledge may not be ‘Professional’ knowledge
- ‘Bio-psycho-social-spiritual healing’ may happen, but not all Adult Use is necessarily Psychedelic Therapy
- Need for impartial assessment of medical evidence, emphasizing limitations
Assessing Safety and Risk

**NSDUH (SAMHSA), 2020:** 2.6% of people in the USA >12 years old (7.1 million) used “hallucinogens” in the past year

**National Poison Data System, 2000-2016, “Psilocybin mushrooms”:**

<table>
<thead>
<tr>
<th>Cases</th>
<th>Major Effects, n(%)</th>
<th>Deaths, n(%)</th>
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<tbody>
<tr>
<td>5883</td>
<td>126 (2.1%)</td>
<td>3 (0.05%)</td>
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**Global Drug Survey, 2017, (n=9233) past year psilocybin mushroom users:** 0.2% sought emergency medical treatment
Common & Concerning Psychedelic Risks

• Headache, Insomnia, Fatigue

• Drug-drug Interactions

• Nausea and Vomiting

• Hypertensive Urgency/Emergency

• QTc Prolongation

• Client Vulnerability

• Dysphoria & Stress Reactions

• Persisting Perceptual Distortion

• Psychosis, Mania, Agitation

• False Memories and Personality Change
Towards psychedelic apprenticeship: Developing a gentle touch for the mediation and validation of psychedelic-induced insights and revelations

Christopher Timmermann¹, Rosalind Watts¹ and David Dupuis²

FEATURED

A Theological Reckoning with ‘Bad Trips’

We need a more sophisticated assessment of these experiences.
Attend to Facilitator Training & Peer-review

• Widely-accepted, consensus-based, and peer-endorsed practice guidelines do not yet exist
  • e.g., the market for combination services/products

• Which discipline(s) could truly oversee all of psychedelic care?
  • Medicine, counseling, faith-based (spiritual direction), peer-support...

• Is 5 years of Apprenticeship enough?
Gather Data, Learn as You Go

• Patient Registries and Prescription Drug Monitoring Programs?

• Balancing demands for Privacy, Accountability, Equity, and Accessibility
  • Incentive: ‘Protecting People, Programs and the Plants’

• Counts of adverse events without prevalence of use (or sales) is insufficient

• Middle road: Training lay Facilitators in Quality Improvement

• Hope for the Future: Community Engaged Research
Community Uses of Psychedelics & Safety (CUPS)

Co-PI Jennifer Mitchell

FDA BAA for Advanced Research & Development of Regulatory Science

FDA (2021) Focus Areas of Regulatory Science
  • Public Health Preparedness & Response
    • Substance Use Disorders
  • Empowering Patients & Consumers
    • Patient & Consumer Preferences and Perspectives
CUPS1
Dr. Maha Mian
Safety and harms in US psychedelic churches: A community-based participatory research study
Ethnographic observations and interviews about harms and safety practices in long-standing US psychedelic churches

CUPS2
Dr. Nicky Mehtani
Examining motivations, benefits, and harms of ayahuasca-augmented 12 Step Recovery for the treatment of substance use disorders: An exploratory mixed-methods study
Surveys and interviews conducted in collaboration with a community partner with lived experience

CUPS3
Dr. Juan Carlos Montoy
Association of implementation of drug regulatory changes in Oregon with psilocybin-related adverse outcomes
Methods assessment for capturing psilocybin-related SAEs in medical settings via national databases and EHRs

CUPS4
Dr. Paulo Barbosa
Persisting, acute and subacute effects of ayahuasca: A Cross-cultural neuropsychiatric evaluation
A 3-language online cross-sectional survey of ayahuasca users’ psychological status and use patterns
Conclusions

• Psychedelics present unusual Opportunities for providing Care, which also carry unusual Risks

• Public Education (informed by the Community and Evidence) is needed

• Facilitator Quality is key to Safety

• Research with and for the Community will be essential
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Thank You

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