HOPE

THE HUB AT OXFORD FOR PSYCHEDELIC ETHICS

Response to the US Congress Request for Information (RFI) on psychedelic research for mental health, as submitted by the Hub at Oxford for Psychedelic Ethics

February 28, 2025

Introduction

About the Submitting Organization

The Hub At Oxford for Psychedelic Ethics

The Hub at Oxford for Psychedelic Ethics (HOPE) is an interdisciplinary center that aims to develop sustainable frameworks for psychedelic ethics, law, and social policy. It serves as an international academic and policy hub to bring together researchers and other stakeholders to advance psychedelic ethics, law and policy.

The organizers of the HOPE meetings have drafted these responses to the Request for Information (RFI) provided by the PATH Caucus. We have selected topics to respond to that were addressed at the meetings held in Oxford and Washington D.C, as well as issues that we have written about.

The responses below are informed by these meetings, but do not necessarily represent consensus amongst the attendees. For a consensus statement issued by the attendees of the 2023 Hopkins-Oxford Psychedelic Ethics meeting, please see the HOPE Working Group Consensus Statement.

About the Authors of this Response

Authors: Katherine Cheung[1,5], Caleigh Propes[1], Edward Jacobs[2], Brian D. Earp[3,4], David B. Yaden[4,5]

[1]*Bloomberg School of Public Health & Berman Institute of Bioethics, Johns Hopkins University*
[2]*Department of Psychiatry, University of Oxford, Oxford, UK*
[3]*Center for Biomedical Ethics, Yong Loo Lin School of Medicine, National University of Singapore, Singapore*
[4]*Uehiro Oxford Institute, University of Oxford, UK.*
[5]*Center for Psychedelic and Consciousness Research, Department of Psychiatry and Behavioral Sciences, Johns Hopkins University School of Medicine*

The Center for Psychedelic and Consciousness Research (CPCR) at Johns Hopkins University School of Medicine is the largest, most productive, and most comprehensive psychedelic research center in the world. It is the research center that is most responsible for sparking the now-global research renaissance on the therapeutic potential of psychedelics. With a mission to advance the scientific understanding of psychedelics, including risks and benefits, the center conducts rigorous scientific trials. Researchers aim to elucidate the mechanisms driving psychedelic effects and their therapeutic efficacy, while also providing evidence-based education to clinicians and the broader community. Website: hopkinspsychedelic.org

The senior and corresponding author, David B. Yaden, Ph.D., is an Associate Professor and the inaugural Roland R. Griffiths Professor of Psychedelic Research at Johns Hopkins University School of Medicine, within the Department of Psychiatry and Behavioral Sciences, at the Center for Psychedelic and Consciousness Research (CPCR). He is the co-founder and Associate Director of The Hub at Oxford for Psychedelic Ethics (HOPE). His research focuses on the psychology and neuroscience of altered states of consciousness, particularly those induced by psychedelic substances, including their risks, benefits, as well as relevant ethical and application issues.

The HOPE Consensus Statement

The **HOPE Consensus Statement** stems from the first Hopkins-Oxford Psychedelic Ethics (HOPE) workshop that was convened in Oxford in 2023 to discuss ethical matters relating to psychedelics. Workshop participants included lawyers and ethicists, Indigenous scholars, psychiatrists, psychedelic scientists, anthropologists, philosophers, entrepreneurs and harm reduction actors.

The Consensus Statement is intended to convey some central issues in psychedelic ethics, as well as a few recommendations to the field. Broadly, these are:

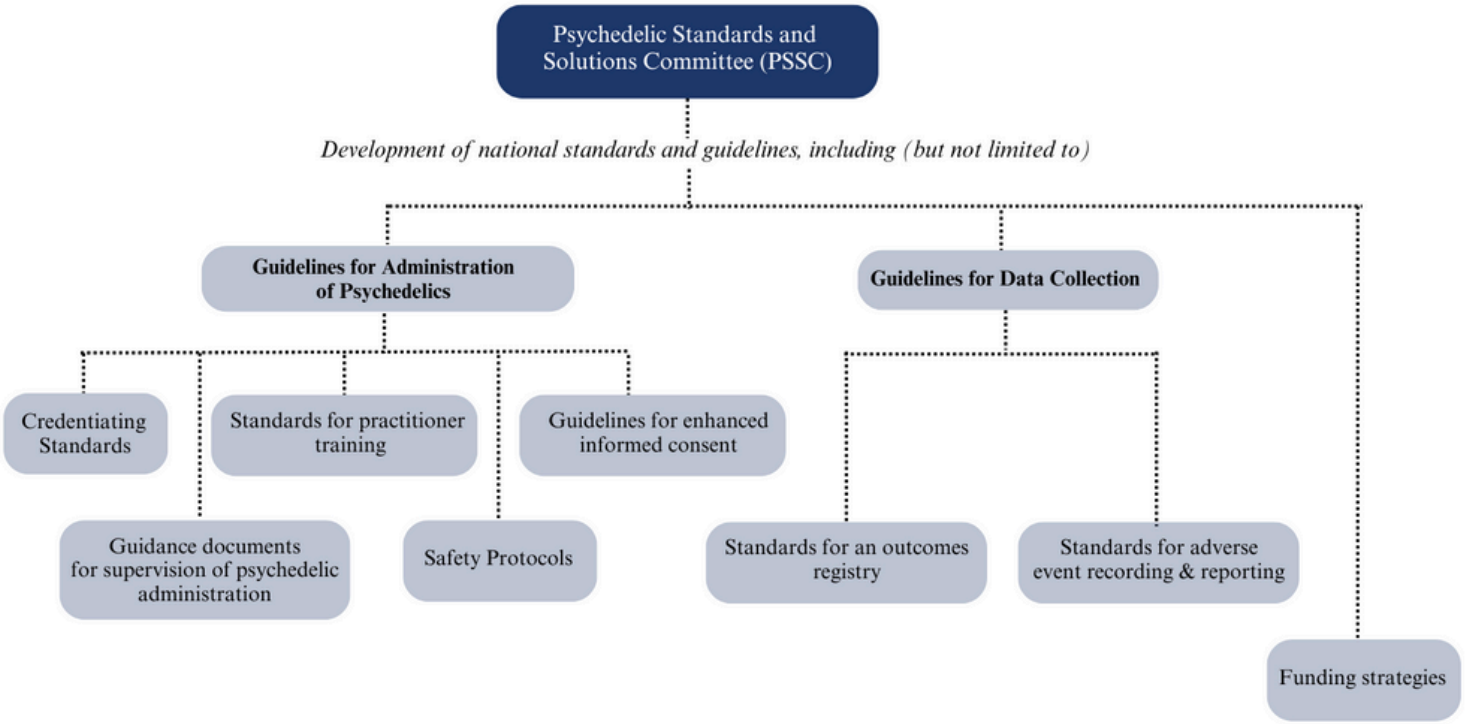
1. A recognition of the special position of communities with historical use of psychedelics.
2. The need for a precautionary approach to advancing scientific understanding.
3. A recognition of legitimacy of diverse motivations to engage with psychedelics.
4. The need for education for a wide range of groups (e.g. the public, medical associations, law enforcement, institutional review boards, insurers and the media).
5. The challenges that psychedelics pose to consent.
6. The need for equity-oriented approaches to psychedelic services.
7. The need for minimum requirements for ethical, professional conduct.
8. The special vulnerabilities that exist around psychedelic use and risks of abuse.
9. The importance of breadth of research to advancing understanding.
10. The need for responsibility and ethics in communication.

Executive Summary & Recommendations

Psychedelic therapies have recently been the focus of extensive scientific research, policy initiatives, and public attention due to their potential applications in treating various psychiatric disorders. Numerous clinical trials examining psilocybin-assisted therapy have been conducted to date, including for Major Depressive Disorder, anxiety, and substance use disorders (Goodwin et al., 2022; Bogenschutz, et al., 2022; Ross et al., 2016). Similarly, a number of trials have examined MDMA-assisted therapy for PTSD (e.g. Mitchell et al., 2023). These developments have emerged in the context of a psychopharmacological research "crisis", as no new medications for mental health treatment have been developed in the past decade (or more) (Langlitz, 2022). At a time where approximately 23.1% of all U.S adults are estimated to have a mental health condition, advancing research in this area is crucial (SAMHSA, 2022).

Based on the two HOPE meetings in Oxford and Washington, DC, and our review of the literature, the overriding consensus is that there is a lack of field-wide standards and guidelines. Their development would thus be a much-needed next step to improve the entire field, but no organization at present holds this mandate. Therefore, to ensure the safe, ethical, and equitable integration of psychedelic therapies into the healthcare system, **we suggest that Congress establish a Psychedelic Standards and Solutions Committee (PSSC). This committee would develop comprehensive national standards and guidelines, encompassing practitioner training, credentialing, safety protocols, informed consent processes, measurement issues, funding strategies, and an outcomes registry.** By establishing a Psychedelic Standards and Solutions Committee (PSSC), Congress would take a proactive and constructive step toward unifying the field under a common framework that prioritizes issues such as ethical integrity, medical safeguards, clinical efficacy, and equitable access. If this is done in a brief and clear manner, it will raise standards where needed and introduce efficiencies into the regulatory process and scientific literature by including uniform reporting standards. **Moreover, enhanced federal support in the form of NIH and other governmental funding will drive sustainable progress for the field and help to ensure that rigorous, unbiased research is conducted.**

By focusing on creating robust frameworks and guidelines rather than merely addressing complaints, the PSSC would streamline oversight, enhance public trust, facilitate widespread, responsible access to psychedelic-assisted treatments and consider other forms of access. **This constructive approach not only safeguards public health and ensures consistent quality of care, science, and policy but positions the United States as the leader in the emerging field of psychedelic medicine.**



Response to RFI: Training Considerations

What is the spectrum of interdisciplinary practitioners who will be held accountable as session facilitators/monitors for the potential use of these substances in medically supervised and interpersonally supportive settings?

If psychedelic treatments are found to be effective and approved for medical use, the spectrum of practitioners who could be held accountable would vary across contexts.

This variation depends partly on whether psychedelics are prescribed alongside psychological support, psychotherapy, or a third option falling somewhere between these approaches. Roughly, the psychedelic-assisted psychotherapy model conceives of psychedelics as something that is administered as part of broader psychotherapeutic process, while the psychological support model conceives of psychedelics as a drug to be prescribed and administered, potentially with the support of healthcare professionals to ensure safety (Cohen, 2024). Currently, clinical trials administer psychedelics along with a variety of psychotherapeutic components, from psychological support to manualized therapy (Seybert et al., 2025).

If required to be administered in a psychedelic-assisted therapy model, professions like psychiatry and clinical psychology could play a crucial role in preparation, dosing and integration sessions. In the province of Alberta (Canada), which passed regulation on the therapeutic use of psychedelics in 2022, psychedelics must be administered in conjunction with psychotherapy, and only be prescribed by a psychiatrist (Sarawathula & Candon, 2023). Moreover, the Mental Health Services Protection Regulation passed by Alberta restricts the provision of psychotherapy in the context of psychedelic-assisted psychotherapy to occupational therapists, physicians and surgeons, psychologists, nurses, and social workers (Province of Alberta, 2021). Or, akin to Spravato (esketamine, administered as a nasal spray), psychedelic treatments could also be potentially administered in a model where only supervision by a healthcare provider is required (Cohen, 2024). This could take the form of supervision by physicians, nurses, social workers, or other healthcare professionals. In a psychological support model, the type of supervision needed may depend upon safety needs. In a more minimal model, this could entail supervision by staff with non-medical backgrounds, with a physician on-call and on-site. Studies with ayahuasca and 5-MeO-DMT have been conducted with no scheduled preparation or integration sessions, but medical and psychological support were available during the dosing session, and administered as needed (Palhano-Fontes et al., 2019; Reckweg et al., 2023).

In Oregon's supported adult-use model, individuals are supervised by facilitators, with facilitator licensure requiring a high-school degree and 120 hours of instruction (on safety, ethics, the underlying science, the state of research, and a practicum) (Smith, Sisti & Appelbaum, 2024). In Colorado, facilitator licenses can be obtained through a number of pathways, such as through the completion of an accredited training program (State of Colorado, 2024).

Summary

The spectrum of practitioners that could be held accountable will depend, amongst other factors, on the model that psychedelic treatments are administered in- psychedelic-assisted therapy or drug therapy with psychological support. National guidelines and standards should be created for training across a variety of contexts. The Psychedelic Standards and Solutions Committee (PSSC) would be ideally placed to create such standards and guidelines.

Key readings:

- Cohen, I. G. (2024). Psychedelics, Psychosocial Support, and Psychotherapy: Why It Matters for the Law, Ethics, and Business of Medical Psychedelic Use. Fordham L. Rev., 93, 393.
  - Link: https://ir.lawnet.fordham.edu/flr/vol93/iss2/1/
- Goodwin, G. M., Malievskaia, E., Fonzo, G. A., & Nemeroff, C. B. (2024). Must psilocybin always "assist psychotherapy"?. American Journal of Psychiatry, 181(1), 20-25.
  - Link: https://doi.org/10.1176/appi.ajp.20221043
  - Non-paywalled link: https://www.researchgate.net/publication/372309676_Must_Psilocybin_Always_Assist_Psychotherapy

Which disciplines may represent 'service providers' (e.g., clinical practitioners, counselors, peer support)?

Here, we focus on analyzing peer support as a potential supplementary "service provider", although recognizing that many other disciplines may be needed in the provision of psychedelic treatments.

Psychedelic peer support consists of educational or care services provided by an individual with firsthand experience with psychedelics, and is distinct from clinical psychedelic treatments, such as psychedelic-assisted psychotherapy (Skiles et al., 2023). Individuals may seek out peer support in the form of integration groups before or after a psychedelic experience. Although they can be led by a facilitator or healthcare professional, they constitute a form of psychedelic peer support when peer-led. These groups are often a space for individuals to share integration strategies and their psychedelic experiences with others, although they can vary in purpose, structure and format (Cheung et al., 2024). Individuals often seek out these groups, amongst other reasons, to help deal with extended difficulties, for community, and to deepen their learning and promote insight (Modlin et al., 2024). Although these groups offer many benefits, they also carry risks, such as exposure to harmful or unsustainable beliefs, breaches of confidentiality, or the possibility of inadequately prepared peer supporters (Cheung et al., 2024). There are currently no psychedelic-specific consensus guidelines or regulations applicable to these groups. Best practices for peer support groups more generally (e.g., for various mental health conditions, cancer, grief) may be a useful starting point when considering the development of guidelines for psychedelic integration groups (NAPS, 2021).

Other forms of psychedelic peer support that currently exist include the Fireside Project, a free peer support telephone hotline staffed by volunteers (who have undergone training). In their analysis of survey data, Pleet and colleagues suggest that the Fireside Project plays an important role in de-escalating callers from distress, offsetting some burden from emergency rooms, and in reducing risks during psychedelic integration (Pleet et al., 2023).

Summary

Peer support in the form of integration groups are a supplementary service provider to consider, with the development of best practices and facilitation guidelines being a useful next step for the field. The Psychedelic Standards and Solutions Committee (PSSC) would be ideally placed to create such standards and guidelines.

Key readings:

- Cheung, K., Propes, C., Jacobs, E., Earp, B. D., & Yaden, D. B. (2024). Psychedelic group-based integration: ethical assessment and initial recommendations. International Review of Psychiatry, 1-11.
  - Link: https://doi.org/10.1080/09540261.2024.2357678
  - Non-paywalled link: https://www.researchgate.net/publication/380728906_Psychedelic_Group_Based_Integration_Ethical_Assessment_and_Initial_Recommendations
- Modlin, N. L., McPhee, T., Zazon, N., Sarang, M., Hignett, R., Pick, S., ... & Rucker, J. (2024). Participants' Experience of Psychedelic Integration Groups and Processes: A Qualitative Thematic Analysis. Psychedelic Medicine.
  - Link: https://doi.org/10.1089/psymed.2024.0027
  - Non-paywalled link: https://www.researchgate.net/publication/386158229_Participants'_Experience_of_Psychedelic_Integration_Groups_and_Processes_A_Qualitative_Thematic_Analysis

What types of guidance documents may be necessary for those who provide close supervision/monitoring of participants using psychedelics or entactogens?

A number of guidance documents will be helpful for those supervising participants using psychedelics. These should be tailored according to the specific contexts in which psychedelics may be administered therapeutically. These may include: research contexts, medical settings, and service centers.

Scientific Research Contexts

1. Emergency procedures / referral protocols in case of situations such as medical emergencies, adverse reactions or psychological distress
2. Guidelines on addressing challenging psychedelic experiences
3. Guidelines on adverse events recording and reporting in scientific studies and publications.
4. Guidelines and policies on professional boundaries such as therapeutic touch
5. Guidelines on enhanced informed consent
6. Guidelines on standardizing measurement strategies
7. Public education on the physical and psychological effects of psychedelics. This could include information on the typical effects of different psychedelic drugs at different dosages

Medical & Clinical Settings

1. Emergency procedures / referral protocols in case of situations such as medical emergencies, adverse reactions or psychological distress
2. Guidelines on addressing challenging psychedelic experiences encountered by first responders and members of the public
3. Guidelines on adverse events recording and reporting for collection in centralized databases
4. Guidelines and policies on professional boundaries such as therapeutic touch for clinicians
5. Public education on the physical and psychological effects of psychedelics. This could include information on the typical effects of different psychedelic drugs at different dosages
6. Clinical Assessment: Guidelines on assessing patient eligibility based on a set criteria
7. Pharmacovigilance and Drug Interactions: Guidelines on how psychedelics interact with other medications and how to manage risks.

Service centers:

1. Emergency procedures / referral protocols in case of situations such as medical emergencies, adverse reactions or psychological distress
2. Guidelines on addressing challenging psychedelic experiences encountered in service centers
3. Guidelines on adverse events recording and reporting for collection in centralized databases
4. Guidelines and policies on professional boundaries such as therapeutic touch for clinicians
5. Public education on the physical and psychological effects of psychedelics. This could include information on the typical effects of different psychedelic drugs at different dosages
6. Assessment guidelines: guidelines on screening and exclusion criteria for clients
7. Guidelines on physical safety, for preventing injuries or dangerous behavior during altered states.

Summary

The Psychedelic Standards and Solutions Committee (PSSC) would be ideally placed to develop guidance documents across contexts such as scientific research, medical and clinical research contexts, and non-medical service center and retreat contexts, among others.

Overview of Psychedelic Ethics and Exceptionalism

When thinking about strategies for participant protections, we emphasize the need for consistent ethical rules and normative standards to be applied across all relevant areas of clinical medicine.

Psychedelics should not be subject to a higher, or lower, normative standard than other areas facing similar issues. Importantly, this does not preclude the possibility that changes to existing standards are needed: however, such changes should not be justified by the alleged uniqueness of psychedelics, but instead by appealing to a range of relevant cases besides, or in addition to, psychedelic treatments (Cheung et al., 2025).

Summary

Normative standards for psychedelics should be taken from existing resources whenever possible rather than generating new rules for psychedelics. That is, *psychedelic ethical exceptionalism* should be avoided.

Key readings:

- Cheung, K., Earp, B. D., Patch, K., & Yaden, D. B. (2025). Distinctive but not exceptional: The risks of psychedelic ethical exceptionalism. The American Journal of Bioethics, 25(1), 16-28.
  - Link: https://doi.org/10.1080/15265161.2024.2433421
  - Non-paywalled link: https://www.researchgate.net/publication/384326499_Distinctive_but_not_Unique_The_Risks_of_Psychedelic_Ethical_Exceptionalism
- Cohen, I. G., & Marks, M. (2025). Psychedelic medicine exceptionalism. The American Journal of Bioethics, 25(1), 6-15.
  - Link: https://doi.org/10.1080/15265161.2025.2434398
  - Non-paywalled link: https://www.researchgate.net/publication/387976511_Psychedelic_Medicine_Exceptionalism

Response to RFI: Promoting Participant Protections

What strategies will be needed to ensure participant education, screening for medical or mental health conditions that may disqualify from participation, and informed consent prior to an individual participating in a therapy that may use a psychedelic or entactogenic drug substance?

There are several considerations that should be taken into account when developing informed consent forms for psychedelic treatments.

Scholars have argued for an "enhanced consent process" for psychedelic treatments (Smith & Sisti, 2020), that could cover areas such as: the possibility of long-term changes (e.g. personality and value changes), discussions of therapeutic touch, information on the experience itself, the potential for patient vulnerability, information on trial withdrawal, a discussion of options for patients if they wish to leave during a dosing session, and the risks and benefits of the data collection to be performed (Smith & Sisti, 2020; Harrison, 2023; Appelbaum, 2024; Marks et al., 2024). Psychedelic informed consent forms should also include information on the legal status of psychedelics, as well as strategies that will be used to alleviate adverse events (Cheung et al., under review). Overall, care should be taken to ensure that the participant is not "overloaded" with information, and that informed consent forms are at an appropriate reading level. Text formatting strategies, such as bolding text or using tables, can help with accessibility, while participant comprehension should be assessed with a short quiz or through oral questions at the end (Lentz et al., 2016). Clear and accessible language will be essential, in addition allowing ample time for participant questions during the informed consent process. Obtaining consent for psychedelic treatments should also be multi-modal (e.g. an informed consent conversation), and should ideally not just consist of the reading and signing of an informed consent form.

In the clinical trial context, continued and increased participant education on the purpose of clinical trials, their risks and benefits, and participant rights will be valuable. Providing more information what research participation does, or does not, entail may help to ensure that participants do not have inflated expectations of their trial participation, and potentially help some individuals make a more informed decision about whether or not to participate in research (Cameron et al., 2013; Yaden, Potash and Griffiths, 2022). General education to participants on psychedelics, their risks and benefits, history and applications may also be useful.

Summary

When considering informed consent forms for psychedelic treatments, the following should be included, amongst other elements: information about the experience, long-term effects, discussion of therapeutic touch, and risk mitigation strategies. Standardized language for informed consent documents in psychedelic science should be generated and distributed.

Key readings:

- Marks, M., Brendel, R. W., Shachar, C., & Cohen, I. G. (2024). Essentials of informed consent to psychedelic medicine. JAMA psychiatry, 81(6), 611-617.
  - Link: 10.1001/jamapsychiatry.2024.0184
  - Non-paywalled link: https://www.researchgate.net/publication/379729693_Essentials_of_Informed_Consent_to_Psychedelic_Medicine
- Smith, W. R., & Sisti, D. (2021). Ethics and ego dissolution: the case of psilocybin. Journal of medical ethics, 47(12), 807-814.
  - Link: https://jme.bmj.com/content/47/12/807.abstract

Response to RFI: Promoting Participant Protections

What information is available or needed on how medically supervised and interpersonally supportive settings might incorporate substance misuse screening and prevention, risk mitigation, safety and ethical monitoring strategies that protect participants from potential ethical boundary violations from providers?

A number of strategies have been applied in clinical trial settings to protect participants from potential ethical boundary violations from providers/facilitators.

Regarding facilitators, one measure that can be applied is specific training for facilitators on topics such as the effects of psychedelics, relational ethical challenges that may arise (e.g. a participant expressing a desire for a handhold during a dosing session, but had previously not consented to touch during the informed consent process), the use of therapeutic touch, and past harm and misconduct that has occurred in research settings (Villiger, 2024; Harrison et al., 2025), as well designing and implementing protocols that provide guidance to facilitators. Having clear guidelines on forms of acceptable touch will also be essential, as their absence can lead to boundary violations when facilitators are left to individually interpret what ethically acceptable forms of touch look like (McNamee et al., 2023). Another safety measure is conducting dosing sessions with two facilitators, which can provide a check on facilitator misconduct (although not a foolproof safeguard). Having a female and male co-therapist team may also help to mitigate any gender-related biases, and provide a more inclusive environment for the participant (Harrison et al., 2025). Alternatively, others have suggested having one facilitator in the dosing room, while the second monitors via video (potentially supervising multiple sessions at the same time) — such an approach may reduce costs and facilitate access.

Establishing boundaries and participant comfort with therapeutic touch during preparation and informed consent is essential (Marks et al., 2024). Video recordings of participant interactions and dosing sessions can help ensure accountability in cases of unethical conduct and abuse (as well as protecting facilitators from false allegations) (for an overview of its benefits and risks, see Rajwani, 2023). These recordings could be reviewed by an independent researcher or organization to mitigate the influence of investigator biases and misconduct in their review. Bringing a close friend or support person to attend the dosing session as an advocate is another option that has been proposed to ensure the safety of the participant, by providing another layer of oversight (Villiger, 2024; Harrison et al., 2025).

Summary

To protect participants from potential ethical boundary violations, methods that can be applied include: facilitator training, having clear guidelines on acceptable touch, having two facilitators per dosing session, audio/video recordings of dosing sessions, and bringing a support person to attend the session. This set of standards should be codified into a document listing these standards for all psychedelic science settings.

Key readings:

- Harrison, T. R., Faber, S. C., Zare, M., Fontaine, M., & Williams, M. T. (2025). Wolves among sheep: Sexual violations in psychedelic-assisted therapy. The American Journal of Bioethics, 25(1), 40-55.
  - Link: https://doi.org/10.1080/15265161.2024.2433423
  - Non-paywalled link: https://www.researchgate.net/publication/387977186_Wolves_Among_Sheep_Sexual_Violations_in_Psychedelic-Assisted_Therapy
- McNamee, S., Devenot, N., & Buisson, M. (2023). Studying harms is key to improving psychedelic-assisted therapy—participants call for changes to research landscape. JAMA psychiatry, 80(5), 411-412.
  - Link: 10.1001/jamapsychiatry.2023.0099
  - Non-paywalled link: https://www.researchgate.net/publication/369624658_Studying_Harms_Is_Key_to_Improving_Psychedelic-Assisted_Therapy-Participants_Call_for_Changes_to_Research_Landscape
- Villiger, D. (2025). How to make psychedelic-assisted therapy safer. Cambridge Quarterly of Healthcare Ethics, 1-15.
  - Link: https://doi.org/10.1017/S0963180124000604

Response to RFI: Engagement of Communities

Are there examples of best practices that facilitate provider (e.g., clinical practitioners, counselors, and peer support) engagement with vulnerable populations?

Multiple stakeholder groups will need to be involved in the regulation of psychedelics, including vulnerable populations and those that have been inequitably burdened by past controlled substance laws. To do so, one model, proposed by Belouin et al. (2022), is a public-private partnership that brings together government agencies and a consortium representing the interests of various stakeholders involved. Such a partnership could leverage subject-matter expertise to address the numerous ethical, legal and societal issues around psychedelics.

Other practices that may be helpful to draw upon include community-based participatory research (CBPR) methods. Green and colleagues offer a definition of CBPR for the Royal Society of Canada, defining it as the "systematic investigation with the participation of those affected by an issue for purposes of education and action or affecting social change" (Green et al., 1995). Core principles of CBPR include the involvement of the affected community in theory making and research design, a commitment to cultural humility, and an emphasis on local community capacity development. CBPR can help ensure that the research questions being investigated reflect the concerns of the community, and increase community trust and ownership of the research (Minkler, 2005).

Summary

Potential models to look to include public-private partnerships to bring together stakeholders, and community-based participatory research methods.

Key readings:

- Belouin, S. J., Averill, L. A., Henningfield, J. E., Xenakis, S. N., Donato, I., Grob, C. S., ... & Anderson, B. T. (2022). Policy considerations that support equitable access to responsible, accountable, safe, and ethical uses of psychedelic medicines. Neuropharmacology, 219, 109214.
  - Link: https://doi.org/10.1016/j.neuropharm.2022.109214

How do we effectively navigate societal stigma associated with psychedelic or entactogenic use?

Stigma against psychedelics can be held by a number of stakeholders, including clinicians, patients, insurance companies, and employers, due to their classification as a Schedule I substance and other cultural and historical factors (Marks, 2018).

Correspondingly, navigating the stigma associated with psychedelic use will need to occur at several levels. Regarding clinicians or other individuals in the medical profession, evidence-based education on psychedelics' therapeutic applications, risks, benefits and limitations will be important in addressing stigma, as knowledge about psychedelics obtained from media or news articles can often skew overly positive or negative (Shane, Cho & Akhar, 2024; Wells et al., 2024). Similarly, public education on the risks and benefits of psychedelics and psychedelic treatments will be important in countering excessive hype (positive and negative), as increasing advocacy and positive media coverage of psychedelics may lead to public beliefs of psychedelics' treatment efficacy being beyond what has been currently found (Smith & Appelbaum, 2022; Andrews et al., 2024). Education should be responsive to concerns and questions from the public (Belouin et al., 2022). Overall, rescheduling psilocybin and other classic psychedelics from Schedule I under the Controlled Substances Act may also help to significantly address stigma. The categorization of psychedelics as Schedule I, or as drugs with "no currently accepted medical use and a high potential for abuse", currently hinders research efforts that aim to test psychedelics for various medical conditions (Belouin & Henningfield, 2018). Rigorous evidence should drive discussion of rescheduling, while recognizing that preliminary evidence has pointed to the therapeutic potential of some psychedelics (Herkenham, 2023).

Finally, there is some evidence that stigma against psychedelics may be decreasing. Attitudes towards psychedelic-assisted therapy have been found to be generally favorable amongst physicians and other healthcare professionals (Davis et al., 2021), while a nationally representative survey of individuals in the United States found strong bipartisan support for the use of psychedelics in non-medical contexts (Sandbrink et al., 2024).

Summary

Navigating societal stigma will need to occur at several levels (although there is evidence that it is decreasing). Public education initiatives on the risks, benefits and applications of psychedelic treatments will be important.

Key readings:

- Marks, M. (2018). Psychedelic medicine for mental illness and substance use disorders: overcoming social and legal obstacles. NYUJ Legis. & Pub. Pol'y, 21, 69.
  - Link: https://heinonline.org/HOL/P?h=hein.journals/nyulpp21&i=75
- Sandbrink, J. D., Johnson, K., Gill, M., Yaden, D. B., Savulescu, J., Hannikainen, I. R., & Earp, B. D. (2024). Strong bipartisan support for controlled psilocybin use as treatment or enhancement in a representative sample of US Americans: need for caution in public policy persists. AJOB neuroscience, 15(2), 82-89.
  - Link: https://doi.org/10.1080/21507740.2024.2303154

Response to RFI: Safeguarding Equitable Access

What should be considered critical elements to the development of capabilities across the following domains or activities?

We focus here upon one aspect listed by the PATH Caucus in the RFI as part of safeguarding equitable access: namely, insurance reimbursement.

Reimbursement will play an important role in ensuring equitable access to psychedelic treatments, as if approved, they will be likely to be inaccessible to the most in-need populations without coverage (Candon, 2024). Without insurance coverage, these treatments could cost patients over $10,000 out-of-pocket (Marseille et al., 2022). In its current form, psychedelic therapies are relatively costly, given the lengthy dosing session, number of preparation and integration sessions, and therapist hours required (McCrone et al. 2023). If approved, government licensure and certification will be important to ensure safety-however, greater regulatory requirements will translate to increased costs for practitioners and patients (Belouin et al., 2022; McGuire et al., 2024). In the United States, some initial positive signals of possible insurance coverage are present. The American Medical Association announced in 2023 the creation of new Current Procedural Terminology (CPT) codes for "Psychedelic Drug Monitoring Services" (McGuire et al., 2024). The creation of this billing code contributes towards equitable access, as many therapists would likely be unwilling to administer the treatment if it reduced their income (PSFC, 2021), and reimbursement is important to ensure clinical uptake of psychedelic therapies (Barnett & Ostrovsky, 2023).

The roll-out of Spravato may also help to inform insurance reimbursement for psychedelic treatments, as the centers for Medicare and Medicaid Services have established coding rules for its administration (Aday et al., 2023). Drawing upon Spravato's experience, many insurers will be unlikely to cover use of psychedelic therapies outside of their approved indications (Joralemon, 2024). Clinics offering off-label access to ketamine for a variety of indications have proliferated, and often vary widely in dosing, safety and pricing (O'Brien et al., 2022). In these settings, ketamine is often administered intravenously and for a variety of indications, many of which have insufficient evidence to show that ketamine would be effective (e.g. migraines, postpartum depression, Lyme disease). As clinics are outpatient and promote off-label use, they fall beyond the purview of the FDA and thus often have insufficient regulatory and legislative oversight, with many having raised concerns about patient safety (Pai & Gries, 2022). Moreover, this may be ethically concerning for vulnerable patient populations that may be paying significant costs out-of-pocket for these treatments (Wexler & Sisti, 2022).

Finally, considering different models of insurance may be helpful. Outcome-based payment models tie payments to predefined outcome-indicators, and are designed to positively affect the quality of care received (Vlaanderen et al., 2018). Another option that may help to defray upfront costs and increase patient access are annuity payment models, which spread the cost of the treatment over several years (Jorgensen & Kefalas, 2017).

Summary

Insurance reimbursement will be a crucial aspect of equitable access, as psychedelic treatments will likely be inaccessible to many if not covered. The experiences of ketamine and Spravato may offer some parallels when thinking about reimbursement and rollout.

Key readings:

- McGuire, A. L., Cohen, I. G., Sisti, D., Baggott, M., Celidwen, Y., Devenot, N., ... & Yaden, D. B. (2024). Developing an Ethics and Policy Framework for Psychedelic Clinical Care: A Consensus Statement. JAMA Network Open, 7(6), e2414650-e2414650.
  - Link: https://jamanetwork.com/journals/jamanetworkopen/fullarticle/2819456
- Wexler, A., & Sisti, D. (2022). Brain wellness "spas"—Anticipating the off-label promotion of psychedelics. JAMA Psychiatry, 79(8), 748-749.
  - Link: 10.1001/jamapsychiatry.2022.1619
  - Non-paywalled link: https://www.researchgate.net/publication/361649707_Brain_Wellness_Spas-Anticipating_the_Off-label_Promotion_of_Psychedelics

What types of data standards and repositories (e.g., Coordinated Registry Networks) may be created to collect data that continually informs best practices and vice versa?

Adverse events (AE) (defined as any untoward effect occurring during the study, whether or not it is related to the intervention) collection and reporting is a crucial component of data collection to help inform best practices, as a clear and comprehensive understanding of the risks associated with psychedelics will help to shape clinical-decision making.

Hinkle and colleagues, in a recent systematic review, found that in 114 studies (3504 participants), serious adverse events were reported by no healthy volunteers and by 4% of participants with preexisting neuropsychiatric disorders. However, they noted that there was significant heterogeneity in AE collection and reporting across studies, with only 23.5% of studies since 2005 describing a systematic approach to AE assessment. 53.5% of studies in their sample reported some AE data (although higher than the median of 46% for clinical trials for health interventions) (Hinkle et al., 2024)- much room for improvement therefore remains across all fields.

The FDA's draft guidance for psychedelic research recommends using "validated subjective scales and through monitoring abuse-related AEs, such as euphoria, hallucinations, stimulation, and emotional lability" (p.7) and that "narratives describing these events should also be provided" (p.10) (FDA, 2023). Psychedelics can result in AEs that are not well captured by existing instruments, given their unique perceptual, physiological and psychological effects. Subsequently, several psychedelic-specific AE assessment frameworks have been put forward, such as Calder & Hasler's (2024) and Palitsky et al.'s (2024). As the field works towards substance-specific, systematic assessment frameworks, we emphasize the need to retain open-ended assessment as part of the AE assessment process, which could then be accompanied by other methods, as no list could possibly contain all possible AEs. Moreover, maintaining a balance between brevity and comprehensiveness will be crucial for effective assessment, as one of the most common critiques of AE assessment tools concern their length (Cheung et al., 2024). Methods can also be applied in AE assessment to help reduce the influence of investigator biases, such as introducing an independent arbiter to help determine whether an AE is related to the study drug (van Elk & Fried, 2023).

Overall, AE reporting for psychedelics should be held to the same standard and rigor as other fields (this importantly does not preclude these standards being raised for all fields). As the field grows, diverse perspectives and input, such as anecdotes from people who have suffered harms, clinical trial data, and legal and scholarly perspectives, will all be needed for a holistic and comprehensive view of psychedelic risks and harms (Ehrenkranz et al., 2024).

Summary

Systematic and comprehensive adverse event reporting will be important as the field progresses. The Psychedelic Standards and Solutions Committee (PSSC) would be ideally placed to develop guidance documents on adverse event recording and reporting.

Key readings:

- Hinkle, J. T., Graziosi, M., Nayak, S. M., & Yaden, D. B. (2024). Adverse events in studies of classic psychedelics: A systematic review and meta-analysis. JAMA psychiatry.
  - Link: https://jamanetwork.com/journals/jamapsychiatry/fullarticle/2822968
- Ehrenkranz, R., Agrawal, M., Nayak, S. M., & Yaden, D. B. (2024). Adverse events should not be surprising in psychedelic research. Psychedelic Medicine.
  - Link: https://doi.org/10.1089/psymed.2024.0006

How might current surveillance systems of regulated and unregulated settings be improved?

The growing use of psychedelics in the United States, in both regulated and unregulated settings, necessitates rigorous safety monitoring systems.

Oregon and Colorado have both legalized supervised psilocybin services, with no clinical indication needed, and present an opportunity to assess the safety, quality and outcomes of the psychedelic services offered. One Delphi panel of experts generated consensus recommendations for core measures to track, including process measures (e.g. whether the facilitator asked for client preferences around touch, whether the facilitator asked for the client's prior history with psychedelics) and outcome measures (e.g. how did the psychedelic enhance the overall wellbeing of the client?, how was the overall safety of the experience?) (Korthius et al., 2024).

Having a centralized monitoring system, instead of leaving monitoring up to the individual service center, will also be helpful to aggregate safety and demographic information (Smith, Sisti & Appelbaum, 2024).

The increasing use of psychedelics in unregulated settings also calls for ethical reporting systems, given the vulnerability of individuals during psychedelic dosing sessions. Systems and organizations for individuals to report ethical abuses and professional and interpersonal boundary violations will be crucial (Belouin et al., 2022). Having an independent third party where complaints and reports of abuse from underground practitioners and integration groups can be registered and investigated is another potential safety measure for the field (Cheung et al., 2024).

Finally, if psychedelic treatments are approved, several gaps will need to be filled for effective post-market surveillance. These include methods for collecting data from providers and patients on adverse events, more detailed national drug surveys to assess the use of psychedelics in depth, and increased qualitative evaluation of patients' experiences with psychedelics (Black et al., 2024).

Summary

The rollout of psychedelic services in Oregon and Colorado offer opportunities to track safety, quality and outcomes. Comprehensive postmarket surveillance will be important if psychedelic treatments are approved. We advocate for a centralized monitoring system.

Key readings:

- Black, J. C., Monte, A. A., Dasgupta, N., Jewell, J. S., Rockhill, K. M., Olson, R. A., & Dart, R. C. (2024). Optimizing real-world benefit and risk of new psychedelic medications: the need for innovative postmarket surveillance. Nature Mental Health, 1-9.
  - Link: https://doi.org/10.1038/s44220-024-00233-1
  - Non-paywalled link: https://www.researchgate.net/publication/380341599_Optimizing_real-world_benefit_and_risk_of_new_psychedelic_medications_the_need_for_innovative_postmarket_surveillance
- Korthuis, P. T., Hoffman, K., Wilson-Poe, A. R., Luoma, J. B., Bazinet, A., Pertl, K., ... & Stauffer, C. S. (2024). Developing the Open Psychedelic Evaluation Nexus consensus measures for assessment of supervised psilocybin services: An e-Delphi study. Journal of Psychopharmacology, 02698811241257839.
  - Link: https://doi.org/10.1177/02698811241257839

Conclusion

The rapid growth of psychedelic research, applications, and policy proposals presents both opportunities and challenges.

While clinical trials continue to demonstrate promising therapeutic potential, the absence of standardized guidelines, training protocols, and ethical oversight mechanisms poses risks to patient safety, research integrity, equitable access, and research efficiency. **The establishment of a Psychedelic Standards and Solutions Committee (PSSC), possibly through a public-private partnership, would provide a framework to address these issues, ensuring that psychedelic-assisted treatments are implemented responsibly and with rigorous scientific and ethical safeguards, while making the regulatory process simpler and clearer.** By setting national standards for practitioner training, informed consent, safety protocols, and data reporting, the PSSC would help unify the field, reduce regulatory inconsistencies, and facilitate the safe integration of psychedelics into mainstream healthcare.

Additionally, robust public education and interdisciplinary collaboration will be necessary to prevent misinformation, mitigate risks, and establish trust with patients, clinicians, and policymakers. Surveillance and reporting mechanisms—particularly in unregulated or semi-regulated settings—must be improved to protect participants from ethical and professional misconduct.

By proactively developing ethical, medical, and legal standards, the United States has the opportunity to lead the global conversation on psychedelic therapies. A balanced, evidence-based approach—grounded in scientific rigor and ethical responsibility—will ensure that psychedelic science and any potential applications proceed rationally. **Enhanced support through NIH and other federal funding sources will help to drive the research necessary to establish a robust evidence base for evaluating psychedelic therapies, and ensure that unbiased, rigorous research on their therapeutic use is conducted.** Through thoughtful regulation, interdisciplinary engagement, and the creation of the PSSC, Congress can take a decisive step toward realizing the benefits of psychedelic research while minimizing potential harms.

References

Aday, J. S., Barnett, B. S., Grossman, D., Murnane, K. S., Nichols, C. D., & Hendricks, P. S. (2023). Psychedelic commercialization: A wide-spanning overview of the emerging psychedelic industry. Psychedelic Medicine, 1(3), 150-165.

Appelbaum, P. S. (2024). Informed Consent to Psychedelic Treatment—A Work in Progress. JAMA Psychiatry, 81(6), 543-544.

Andrews, C. M., Hall, W., Humphreys, K., & Marsden, J. (2024). Crafting effective regulatory policies for psychedelics: What can be learned from the case of cannabis?. Addiction.

Barnett, B. S., & Ostrovsky, A. (2023). Psychedelic medicine's future depends on proactive development of a robust medical billing and coding strategy. Psychedelic Medicine, 1(1), 14-17.

Belouin, S. J., Averill, L. A., Henningfield, J. E., Xenakis, S. N., Donato, I., Grob, C. S., ... & Anderson, B. T. (2022). Policy considerations that support equitable access to responsible, accountable, safe, and ethical uses of psychedelic medicines. Neuropharmacology, 219, 109214.

Belouin, S. J., & Henningfield, J. E. (2018). Psychedelics: Where we are now, why we got here, what we must do. Neuropharmacology, 142, 7-19.

Black, J. C., Monte, A. A., Dasgupta, N., Jewell, J. S., Rockhill, K. M., Olson, R. A., & Dart, R. C. (2024). Optimizing real-world benefit and risk of new psychedelic medications: the need for innovative postmarket surveillance. Nature Mental Health, 1-9.

Bogenschutz, M. P., Ross, S., Bhatt, S., Baron, T., Forcehimes, A. A., Laska, E., ... & Worth, L. (2022). 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, 79(10), 953-962.

Calder, A. E., & Hasler, G. (2024). Validation of the Swiss Psychedelic Side Effects Inventory: Standardized assessment of adverse effects in studies of psychedelics and MDMA. Journal of Affective Disorders, 365, 258-264.

Candon, M. (2024). A Roadmap to Reimbursement for Psychedelics. The Regulatory Review. https://www.theregreview.org/2024/04/16/candon-a-roadmap-to-reimbursement-for-psychedelics/

Cameron, P., Pond, G. R., Xu, R. Y., Ellis, P. M., & Goffin, J. R. (2013). A comparison of patient knowledge of clinical trials and trialist priorities. Current Oncology, 20(3), e193.

Cheung, K., Propes, C., Jacobs, E., Earp, B. D., & Yaden, D. B. (2024). Psychedelic group-based integration: ethical assessment and initial recommendations. International Review of Psychiatry, 1-11.

Cheung, K., Earp, B. D., Patch, K., & Yaden, D. B. (2025). Distinctive But Not Exceptional: The Risks of Psychedelic Ethical Exceptionalism. The American Journal of Bioethics, 25(1), 16–28.

Cohen, I. G. (2024). Psychedelics, Psychosocial Support, and Psychotherapy: Why It Matters for the Law, Ethics, and Business of Medical Psychedelic Use. Fordham L. Rev., 93, 393.

Davis, A. K., Agin-Liebes, G., España, M., Pilecki, B., & Luoma, J. (2022). Attitudes and beliefs about the therapeutic use of psychedelic drugs among psychologists in the United States. Journal of Psychoactive Drugs, 54(4), 309-318.

Ehrenkranz, R., Agrawal, M., Nayak, S. M., & Yaden, D. B. (2024). Adverse events should not be surprising in psychedelic research. Psychedelic Medicine.

van Elk, M., & Fried, E. I. (2023). History repeating: guidelines to address common problems in psychedelic science. Therapeutic Advances in Psychopharmacology, 13, 20451253231198466.

FDA. (2023). Psychedelic Drugs: Considerations for Clinical Investigations Guidance for Industry. https://www.fda.gov/media/169694/download

Green, L. W., Royal Society of Canada, & BC Consortium for Health Promotion Research. (1995). Study of participatory research in health promotion: Review and recommendations for the development of participatory research in health promotion in Canada. Royal Society of Canada.

Goodwin, G. M., Malievskaia, E., Fonzo, G. A., & Nemeroff, C. B. (2024). Must psilocybin always “assist psychotherapy”?. American Journal of Psychiatry, 181(1), 20-25.

Goodwin, G. M., Aaronson, S. T., Alvarez, O., Arden, P. C., Baker, A., Bennett, J. C., ... & Malievskaia, E. (2022). Single-dose psilocybin for a treatment-resistant episode of major depression. New England Journal of Medicine, 387(18), 1637-1648.

Harrison, T. R. (2023). Altered stakes: Identifying gaps in the informed consent process for psychedelic-assisted therapy trials. Journal of Psychedelic Studies, 7(S1), 48-60.

Herkenham, K. (2023). A regulatory framework review of Schedule I psychedelics in the United States. Journal of the American College of Clinical Pharmacy, 6(10), 1117-1124.

Hinkle, J. T., Graziosi, M., Nayak, S. M., & Yaden, D. B. (2024). Adverse events in studies of classic psychedelics: A systematic review and meta-analysis. JAMA Psychiatry.

References

Joralemon, V. (2024). Insurance Coverage for Psychedelic Therapy. Bill of Health - Blog of the Petrie Flom center. https://petrieflom.law.harvard.edu/2024/03/27/insurance-coverage-for-psychedelic-therapy/

Jørgensen, J., & Kefalas, P. (2017). Annuity payments can increase patient access to innovative cell and gene therapies under England's net budget impact test. Journal of Market Access & Health Policy, 5(1), 1355203.

Korthuis, P. T., Hoffman, K., Wilson-Poe, A. R., Luoma, J. B., Bazinet, A., Pertl, K., ... & Stauffer, C. S. (2024). Developing the Open Psychedelic Evaluation Nexus consensus measures for assessment of supervised psilocybin services: An e-Delphi study. Journal of Psychopharmacology, 02698811241257839.

Langlitz, N. (2024). Psychedelic innovations and the crisis of psychopharmacology. BioSocieties, 19(1), 37-58.

Lentz, J., Kennett, M., Perlmutter, J., & Forrest, A. (2016). Paving the way to a more effective informed consent process: Recommendations from the Clinical Trials Transformation Initiative. Contemporary Clinical Trials, 49, 65-69.

National Association of Peer Supports (NAPS). (2021). National Practice Guidelines for Peer Specialists and Supervisors. Available at: https://www.peersupportworks.org/wp-content/uploads/2021/07/National-Practice-Guidelines-for-Peer-Specialists-and-Supervisors-1.pdf

Marks, M., Brendel, R. W., Shachar, C., & Cohen, I. G. (2024). Essentials of informed consent to psychedelic medicine. JAMA Psychiatry, 81(6), 611-617.

Marks, M. (2018). Psychedelic medicine for mental illness and substance use disorders: overcoming social and legal obstacles. NYUJ Legis. & Pub. Pol'y, 21, 69.

Marseille, E., Mitchell, J. M., & Kahn, J. G. (2022). Updated cost-effectiveness of MDMA-assisted therapy for the treatment of posttraumatic stress disorder in the United States: findings from a phase 3 trial. PLoS One, 17(2), e0263252.

McCrone, P., Fisher, H., Knight, C., Harding, R., Schlag, A. K., Nutt, D. J., & Neill, J. C. (2023). Cost-effectiveness of psilocybin-assisted therapy for severe depression: exploratory findings from a decision analytic model. Psychological Medicine, 53(16), 7619-7626.

McGuire, A. L., Cohen, I. G., Sisti, D., Baggott, M., Celidwen, Y., Devenot, N., ... & Yaden, D. B. (2024). Developing an Ethics and Policy Framework for Psychedelic Clinical Care: A Consensus Statement. JAMA Network Open, 7(6), e2414650-e2414650.

McNamee, S., Devenot, N., & Buisson, M. (2023). Studying harms is key to improving psychedelic-assisted therapy—participants call for changes to research landscape. JAMA Psychiatry, 80(5), 411-412.

Metzl, J. M., & Hansen, H. (2014). Structural competency: theorizing a new medical engagement with stigma and inequality. Social Science & Medicine, 103, 126-133.

Minkler, M. (2005). Community-based research partnerships: challenges and opportunities. Journal of Urban Health, 82, ii3-ii12.

Modlin, N. L., McPhee, T., Zazon, N., Sarang, M., Hignett, R., Pick, S., ... & Rucker, J. (2024). Participants' Experience of Psychedelic Integration Groups and Processes: A Qualitative Thematic Analysis. Psychedelic Medicine.

O'Brien, B., Wilkinson, S. T., & Mathew, S. J. (2022). An update on community ketamine practices. American Journal of Psychiatry, 179(5), 393-394.

Pai, S. M., Gries, J. M., & ACCP Public Policy Committee. (2022). Off-label use of ketamine: a challenging drug treatment delivery model with an inherently unfavorable risk-benefit profile. The Journal of Clinical Pharmacology, 62(1), 10-13.

Palhano-Fontes, F., Barreto, D., Onias, H., Andrade, K. C., Novaes, M. M., Pessoa, J. A., ... & Araújo, D. B. (2019). Rapid antidepressant effects of the psychedelic ayahuasca in treatment-resistant depression: a randomized placebo-controlled trial. Psychological Medicine, 49(4), 655-663.

Palitsky, R., Kaplan, D. M., Perna, J., Bosshardt, Z., Maples-Keller, J. L., Levin-Aspenson, H. F., ... & Dunlop, B. W. (2024). A framework for assessment of adverse events occurring in psychedelic-assisted therapies. Journal of Psychopharmacology, 38(8), 690-700.

Pleet, M. M., White, J., Zamaria, J. A., & Yehuda, R. (2023). Reducing the harms of nonclinical psychedelics use through a peer-support telephone helpline. Psychedelic Medicine, 1(2), 69-73.

Province of Alberta. (2021). Mental Health Services Protection Regulation. https://kings-printer.alberta.ca/1266.cfm?page=2021_114.cfm&leg_type=Regs&isbncln=9780779848898

Rajwani, K. (2023). The "Third" Eye: Ethics of Video Recording in the Context of Psychedelic-Assisted Therapy. Canadian Journal of Bioethics, 6(3), 8-15.

Reckweg, J. T., van Leeuwen, C. J., Henquet, C., van Amelsvoort, T., Theunissen, E. L., Mason, N. L., ... & Ramaekers, J. G. (2023). A phase 1/2 trial to assess safety and efficacy of a vaporized 5-methoxy-N, N-dimethyltryptamine formulation (GH001) in patients with treatment-resistant depression. Frontiers in Psychiatry, 14, 1133414.

Ross, S., Bossis, A., Guss, J., Agin-Liebes, G., Malone, T., Cohen, B., ... & Schmidt, B. L. (2016). Rapid and sustained symptom reduction following psilocybin treatment for anxiety and depression in patients with life-threatening cancer: a randomized controlled trial. Journal of psychopharmacology, 30(12), 1165-1180.

References

Sandbrink, J. D., Johnson, K., Gill, M., Yaden, D. B., Savulescu, J., Hannikainen, I. R., & Earp, B. D. (2024). Strong bipartisan support for controlled psilocybin use as treatment or enhancement in a representative sample of US Americans: need for caution in public policy persists. AJOB Neuroscience, 15(2), 82-89.

Saraswathula, V., & Candon, M. (2023). Exploring Regulatory Frameworks For Psychedelic Services To Treat Mental Illnesses. Health Affairs Forefront.

Schenberg, E. E., King IV, F., da Fonseca, J. E., & Roseman, L. (2024). Is poorly assisted psilocybin treatment an increasing risk?. American Journal of Psychiatry, 181(1), 75-76.

Seybert, C., Schimmers, N., Silva, L., Breeksema, J. J., Veraart, J., Bessa, B. S., ... & Oliveira-Maia, A. J. (2024). Quality of reporting on psychological interventions in psychedelic treatments: a systematic review. The Lancet Psychiatry.

Shane, D., Cho, M., & Akhtar, S. (2024). Psychedelics in medicine-a call for educational action. Canadian Medical Education Journal, 15(4), 132.

Skiles, Z., Dixon, J. R., Friedrich, D., Reed, D., & Stauffer, C. S. (2023). Peer support and psychedelics. Journal of Military, Veteran and Family Health, 9(5), 80-87.

Smith, W. R., & Appelbaum, P. S. (2022). Novel ethical and policy issues in psychiatric uses of psychedelic substances. Neuropharmacology, 216, 109165.

Smith, W. R., & Sisti, D. (2021). Ethics and ego dissolution: the case of psilocybin. Journal of Medical Ethics, 47(12), 807-814.

Smith, W. R., Sisti, D. A., & Appelbaum, P. S. (2024). The safety of supported psilocybin use in Oregon. Nature Medicine, 30(1), 17-18.

State of Colorado. (2024). Natural Medicine Licensure Rules and Regulations. https://www.sos.state.co.us/CCR/GenerateRulePdf.do?ruleVersionId=11504&fileName=4%20CCR%20755-1#:~:text=A%20Clinical%20Facilitator%20licensee%20must,or%20behavioral%2Fmental%20health%20conditions.&text=A%20Clinical%20Facilitator%20licensee%20shall,generally%20accepted%20standards%20of%20practice

Substance Abuse and Mental Health Services Administration. (2023). Key substance use and mental health indicators in the United States: Results from the 2022 National Survey on Drug Use and Health (HHS Publication No. PEP23-07-01-006, NSDUH Series H-58). Center for Behavioral Health Statistics and Quality, Substance Abuse and Mental Health Services Administration. https://www.samhsa.gov/data/report/2022-nsduh-annual-national-report

Villiger, D. (2025). How to make psychedelic-assisted therapy safer. Cambridge Quarterly of Healthcare Ethics, 1-15.

Vlaanderen, F. P., Tanke, M. A., Bloem, B. R., Faber, M. J., Eijkenaar, F., Schut, F. T., & Jeurissen, P. P. (2019). Design and effects of outcome-based payment models in healthcare: a systematic review. The European Journal of Health Economics, 20, 217-232.

Wells, A., Fernandes, M., & Reynolds, L. (2024). Perceptions and attitudes towards psychedelic-assisted psychotherapy among health professionals, patients, and the public: A systematic review. Journal of Psychedelic Studies, 8(1), 43-62.

Yaden, D. B., Potash, J. B., & Griffiths, R. R. (2022). Preparing for the bursting of the psychedelic hype bubble. JAMA Psychiatry, 79(10), 943-944.