

Practical and Ethical Considerations for Psychedelic Therapy and Integration Practices

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Abstract:

While psychedelic-assisted therapies are currently being studied for several indications in clinical trials, there is legal and ethical ambiguity for mental health professionals concerning these compounds. Seventy-six mental health professionals completed an online survey asking them to rank their interest in topics related to psychedelic therapy, research, legal obstacles, barriers to incorporating psychedelics in practice, and terminology related to the field. Results showed that providers want more clearly defined terminology and operating procedures concerning business matters such as malpractice and clinic guidelines, legal and ethical clarity on administering psychedelics in private practice and integration work, and further opportunities for psychedelic therapy training. The survey responses were reflected upon through the legal and ethical lens of the current psychedelic landscape.

Key Words: psychedelic integration, psychedelic practice, ethics, harm reduction, therapy

INTRODUCTION

From harm reduction to medical marijuana, innovative mental health treatment approaches and modalities have sometimes operated in legal and ethical "gray areas." With accumulating reports of positive outcomes from psychedelic-assisted therapy clinical trials for a range of different mental health conditions, increasing numbers of people are looking for accurate information about the safety of psychedelics and how to use these substances for therapeutic benefit. Unsurprisingly, numerous practical questions about the law, policy, and ethics of working with clients who utilize psychedelics remain today.

Alongside this growing body of science, psychedelics continue to gain attention in the media, appearing on major news outlets from CNN to FOX and The New York Times. Best-selling author Michael Pollan's book *How To Change Your Mind* ^[1] presented, to a largely psychedelic-naïve audience, the case for current psychedelic-assisted healing through his experiential and research-based

reporting. The changing landscape in research and public knowledge is additionally duty-bound to consider the safety of personal psychedelic use and clinical use alike.

The most recent Global Drug Survey ^[2] showed significant use of the most commonly studied psychedelics, such as MDMA (33%), LSD (17.5%), Psilocybin (14.8%), and Ketamine (12.8%), across its 120,000+ respondents. Interestingly, 24.6% were very likely to consider using psychedelic-assisted therapy if diagnosed with a psychiatric condition, representing a greater number than those who endorsed psychiatric medications (19.3%). This increased awareness of the potential therapeutic benefit of psychedelics may lead to greater use in naturalistic settings for intended therapeutic benefit. While psychedelic-adjacent services and training are becoming more accessible to providers, there remain ambiguities that call for essential, standardized, and community-driven frameworks in this emerging field.

The current study is the product of a collaboration between individuals from the

Multidisciplinary Association for Psychedelic Studies (MAPS), MAPS Public Benefit Corporation (MAPS PBC), Psychedelic Support, and the California Institute for Integral Studies' (CIIS) Certificate in Psychedelic Assisted Therapies and Research (CTPR) Alumni Association to examine some of the undefined and unanswered concerns and terminology within the burgeoning field of psychedelic-assisted therapy and psychedelic-adjacent services. A survey was sent to licensed practitioners to understand what topics related to psychedelics were of most interest, what terminology was unclear or not well defined, what obstacles practitioners face in setting up clinics for psychedelic clinical trials, and what challenges they face in preparation for post-approval of psychedelic medicines.

Our intention was to compile and synthesize this information to be utilized as a starting point for the creation of resources and a dialogue between mental health providers and legal professionals to explore ethical considerations and bring consistency and clarity to this important and innovative work. We have identified some fundamental questions implicated by providing psychedelic care, like therapy and integration work within the present legal and economic status quo. These questions give rise to a few potential ethically problematic scenarios. Developing a shared lexicon related to psychedelic therapy and integration will facilitate communications amongst mental health professionals, licensing boards, policymakers, and the public. We hope that this work expands to include networks of people from a number of sectors who are positioned to support the field of psychedelic therapy, and develop the legal and ethical discourse within the field itself.

METHODS

An email with an invitation to fill out an online survey was sent to providers in the

Psychedelic Support Network, MAPS MDMA phase 3 trial therapists, and alumni from the California Institute for Integral Studies (CIIS) Certificate in Psychedelic-Assisted Therapies and Research (CTPR) program. Of the 290 people who were invited to complete the survey, 76 voluntarily completed it. Respondents were informed that their anonymized responses could be published. The Alder University Institutional Review Board approved using the de-identified archival dataset for research purposes in March 2019. The survey consisted of 20 questions and took approximately 15 minutes to complete. Participants selected responses from a list for most questions, while others allowed open text answers with no text limit.

The survey gathered information about the demographics of respondents, topics of interest related to psychedelic therapy and research, obstacles and barriers to incorporating legal psychedelics in their practices, and terminology used in the field that is not well defined or unclear. All available data for a given question is included in descriptive statistics.

RESULTS

Demographics & Sample Characteristics

Survey respondents (n=76) consisted of 40 males, 34 females, and 2 nonbinary/genderfluid persons. Nationalities of participants were largely from the USA (n=60) with a smaller representation from Canada (n=6), Czech/USA (n=1), and Scotland (n=1), while 8 did not respond. Respondents were White/NonLatino (n=60), Latino (n=3), Asian (n=3), mixed-race (n=3), and African American (n=1); 6 did not answer this question. While English was the primary language spoken (n=75), 27 participants were bilingual, with Spanish (n=15) and French (n=4) being the next commonly spoken languages, along with nine others. Professionally, 27.63% of respondents explicitly stated they

carried a master's degree (n=21), 14.47% stated they carried a doctoral degree (n=11), and 13.16% stated they were licensed but did not specify a degree type (n=10). 50% expressed an interest in pursuing a therapy license (n=38); 21.05% expressed no interest (n=16), 9.21% responded maybe (n=7), and 15 did not respond.

Communities and Client Demographics

Participants (n=76) served various communities in their work, with 32.90% stating they work “mostly with adults 18+”, 31.58% explicitly stated working with “racially or ethnically diverse” communities, 21.10% work with “mostly Caucasian” communities, and 5.26% work with “communities of color,” and 17.11% work with “LGBTQ+” communities. Participants also described the populations they served economically and geographically as “middle or upper class” (n=12), “low SES” (n=7), “rural” (n=3), and “urban/suburban” (n=6). 25% of respondents described the communities they serve as “diverse” or “all” (n=19).

Over half of respondents planned on serving their current client population with psychedelic-assisted therapies (n=43), while 26 responded ‘maybe.’ There were 7.90% not planning on using psychedelic-assisted therapies in their current communities (n=6). One participant’s reasoning was “while my population does very often involve those with trauma, PTSD, addiction, and anxiety (which have seen benefit from MDMA-assisted psychotherapy), my clients with severe and persistent mental illness, such as psychotic disorders, would likely not be recommended to psychedelic therapy.” Other reasons for not serving, or maybe serving, their current communities with these therapies ranged from “illegality” to “inappropriate client base” (e.g., minors). Table 3 displays the type of substances clinicians would be interested in incorporating into their practices if legal.

Participant responses highlighted research and clinical terms related to psychedelics as being unclear and needing further definition from practitioners and the psychedelic community (Appendix 1). 53.95% asked for clarity concerning the term ‘psychedelic-assisted therapy,’ and 51.33% desired a better understanding of the term ‘psychedelic integration.’ While the terms ‘guide’ (n=1), ‘participant’ (n=1), and ‘ceremony’ (n=1) were seen as needing less clarity, many respondents wanted clarity for the terms ‘psychedelic practitioner’ (n=36), ‘psychedelic medicine’ (n=26), and ‘medicine session’ (n=19). ‘Psychedelic harm reduction’ (n=31) and ‘psychedelic intention setting/preparatory support’ (n=29) were additionally seen as being unclear, while ‘psychoactive-assisted therapy’ (n=1) and ‘ethical off-label use’ (n=1) were not. Respondents were also given the opportunity to define these terms in an open response format (Appendix 1).

Additionally, participants showed interest in learning more about business, legal/ethical, and professional development items as they relate to psychedelic-assisted therapy (Table 1). Respondents also foresaw obstacles in running a psychedelic practice, setting up a psychedelic clinic, and setting the cost for services (Table 2).

Table 1. Topics of Most Interest for Having More Information

Topics	Respondents (N=76)
Business	
Malpractice insurance coverage for providers of psychedelic therapies	54 (71.05%)
Setting up a clinic	46 (60.53%)
Getting involved in clinical trials	31 (53.95%)
Insurance coverage for clients	34 (44.74%)
Obtaining Schedule 1 DEA License	30 (39.47%)
Legal	
Legal/ethical questions related to using cannabis or psychedelics in a private practice	55 (72.37%)
Legal/ethical questions related to offering preparation/integrations services	50 (65.79%)
Professional Development	
Psychedelic therapy training opportunities	56 (73.86%)
Professional Networking	51 (67.11%)
Supervision and mentorship	47 (61.84%)

Table 2. Topics Perceived as Obstacles

Obstacles	Respondents (N=76)
Client, and practice, insurance coverage	50 (65.79%)
Administrative and business tasks †	44 (57.89%)
Setting fees for services	34 (44.74%)
Obtaining a Schedule 1 license	32 (42.11%)
Payment processing	21 (27.63%)
Finding a co-therapist	13 (17.11%)
Facilities; facility regulations	5 (6.58%)
Cost of services for low income access	2 (2.63%)

† Scheduling, record keeping, office management

Table 3. Substances (if legally approved) of Interest for Use in Professional Practices

Substance	Respondents (N=76)
MDMA	63 (82.89%)
Psilocybin	62 (81.58%)
Ketamine	43 (56.58%)
Cannabis	36 (47.37%)
LSD	8 (10.53%)
Ayahuasca/DMT	7 (9.21%)
San Pedro/Mescaline	3 (3.95%)
5-MEO-DMT	2 (2.63%)
Ibogaine	1 (1.32%)

LIMITATIONS

The survey was only sent to mental health providers who were already affiliated with a psychedelic organization. Thus the sample does not represent the general population of mental health care professionals. Still, there was significant uncertainty even among this group of practitioners who are reasonably knowledgeable about psychedelics. It can be expected that as new practitioners become interested in these novel modalities, there will be additional questions. There are many unknown factors related to the regulation of psychedelic therapies, and new information is constantly emerging. For this reason, speculations around legal and ethical oversight discussed here will likely change as the field moves forward.

The information in this article is not intended to be taken as legal advice. Practitioners seeking answers about these issues as it relates to their practice should consult legal counsel within their jurisdiction.

DISCUSSION

The responses from this survey offered a comprehensive view of questions and challenges currently facing practitioners who work with clients that use psychedelics or plan to include psychedelics in their practices

after projected regulatory approval. The use of Spravato (esketamine) and off-label racemic ketamine in treating depression and other psychiatric conditions is quickly growing and requires practitioners to follow specific guidelines to safely and legally administer it. By offering interpretations of commonly used terminology in this field, we have begun to establish a means to communicate more effectively between mental health care providers, clients, and policymakers. Many practitioners expressed the need for more information around several topics of interest and perceived obstacles, and more opportunities for professional networking and sharing of informational resources. Questions around legality and standards of care will need to be addressed for both public safety and provider liabilities.

Psychedelic-assisted therapy practices will bring logistical challenges not currently faced by many providers we surveyed in traditional therapy or healthcare practices. Private practices will require several adaptations to meet the unique needs of delivering psychedelics in medicalized settings. To establish long-lasting, successful treatment practices, psychedelic providers will need to receive appropriate training and find competent professional partnerships while juggling higher regulatory requirements for Psychedelic integration & practice survey: Report & analysis of results 8 dispensing scheduled substances, business management, administrative duties and oversight, and client care.

Professional networking opportunities specifically on therapeutic applications of psychedelics are very limited at this time, but large psychiatric and psychological conferences are beginning to feature symposiums and discussions of psychedelic research. Information in this field is mostly amassed by groups conducting research trials or small grassroots efforts to share educational content online and at community gatherings. Recently, a few professional associations

specific to psychedelic medicine have begun to appear. More general harm reduction conferences and organizations tend to be open to discussions and topics of all drugs, including psychedelics. More in-person events, online discussion forums, and video conference meetings would facilitate networking between professionals and cross-pollination of information across disciplines.

Most survey respondents (73.86%) wanted more details around training opportunities and supervision/mentorship (61.84%). A greater number of training programs for psychedelic-assisted therapy are becoming available from clinical trials sponsors, such as MAPS PBC, and other academic or private institutions. However, the training requirements for delivering approved psychedelic treatments remain unknown until final negotiations with FDA and other regulatory agencies. Ketamine use, on the other hand, is rapidly expanding for mental health indications, but since it is prescribed off-label, there are no formal training requirements for providers. There are a growing number of training and continuing education courses on ketamine therapy being offered by clinicians, but again there are no agreed-upon competencies and certifications available.

The criteria for drug delivery and overnight stays will likely be stipulated in the drug safety program of the FDA for MDMA and psilocybin, known as the Risk Evaluation and Mitigation Strategy (REMS), which will be specific to each approved drug. Survey participants anticipated incorporating several psychedelics in their practices if approved, which could present currently unknown challenges.

For many reasons, MDMA and psilocybin trials have two therapists or guides for each study participant. The individual undergoing treatment is not left alone and having a team of two is practical for lunch and bathroom breaks during all-day sessions. Therapeutically, working with two providers

enhances feelings of safety and support, provides opportunities to more effectively manage transference, countertransference, and attachment issues in treatment, and can balance the dynamics between the patient and therapy team [3]. In addition, therapists working together can help each other manage the more intense countertransference that can come up in psychedelic sessions. Only a small number of respondents (17.11%) thought that finding a co-therapist would be an obstacle. Nonetheless, having to work on a team presents challenges of finding a compatible person to work with, both in terms of personality fit, scheduling, billing, and often business partnerships. Practices may benefit from having providers with complementary yet different therapeutic modality proficiencies and professional experiences.

Insurance Coverage

Currently, health insurers do not reimburse for co-therapists working concurrently with a single client, which will provide a challenge in implementing a co-therapist model in practice. The qualifications of providers may also affect fees for services. The amount of time a patient spends in a clinic for psychedelic-assisted therapy is substantially more than the typical 60-90 minute office visit. Ketamine infusions without therapy are often scheduled for 60-90 minutes, but when integrated with therapy, a minimum of two hours appears needed. In clinical trials, sessions of MDMA and psilocybin last for 6-8 hours, and some studies require participants to stay overnight with a night attendant. Many survey respondents (60.53%) endorsed the need for more information in regards to clinic setup. However, finding a suitable space to accommodate a comfortable overnight visit where zoning regulations allow for such can be difficult in many locations. Although overnight stays may not be required post-FDA approval, the option to stay overnight has advantages for safety and a more immersive therapeutic

process. Arranging for meals, cleaning of bedding and facilities, and night attendants are necessary details that are not needed in traditional therapy practices. While some insurers allow practitioners to bill for extended psychotherapy sessions using specific billing codes as add-ons (CPT codes 99354 and 99355), it is unknown how insurers would respond to billing for 6-8 hours long sessions or overnight stays at this time. Perhaps “partial hospitalization” or “day program” billing codes could be utilized, but this remains uncertain.

The specific needs of offering psychoactive pharmacotherapies that carry requirements for greater patient supervision, time in a clinic, regulatory compliance, training requirements, and administrative tasks will inevitably result in higher costs. Barriers to access are created for low income clients because fees for services escalate to cover the additional criteria. Survey respondents highly endorsed and expressed interest in related topics like setting fees for services and offering insurance coverage for psychedelic therapies.

Based on the data submitted for FDA review and drug approval, insurance companies may end up covering an entire therapy-drug treatment package, only the drug, only the therapy, or in the worst-case scenario, nothing at all. It is currently unknown how providers will bill insurance companies for psychedelic-assisted therapies. Given the anticipated high price of psychedelic-assisted therapy [4], insurance companies may require robust health outcomes from widespread population data outside of clinical trials to justify reimbursement of the high price of treatment packages. Compared to the standard of care treatments, preliminary cost-effectiveness of MDMA phase 2 trials of MDMA-assisted psychotherapy for chronic PTSD suggests the treatment would generate a net savings of \$103.2 million for 1,000 patients over 30 years [5].

Although generic ketamine has been prescribed off-label for mental health disorders for years, the lack of FDA clinical trials has limited insurance companies from covering off-label ketamine even with demonstrated efficacy outside of FDA-approved trials. The nasal spray Spravato (esketamine) received marketing approval by FDA for treatment-resistant depression in 2019 after the drug manufacturer, Janssen, demonstrated safety and efficacy in phase 3 trials when esketamine was administered with an antidepressant [6]. However, there are key differences between Spravato and generic ketamine and between ketamine treatment providers. Spravato must be used in a clinic, can be covered by insurance, and aims for a sub-dissociative/ sub-psychedelic experience. In contrast, generic ketamine may be prescribed for home use at lower doses and may or may not incorporate psychotherapy at higher doses, where the dissociative and psychedelic effects of ketamine are viewed as central to the healing process. Ketamine also has relatively few drug interactions as compared to other psychedelics, which should help it remain an important treatment option even as other serotonin-targeting psychedelics become available.

Ethical and Legal Implications of Harm Reduction, Psychedelic-assisted Therapy, and Integration

As described in the appendix, psychedelic harm reduction “refers to the peer to peer or practitioner to participant practices and protocols that are intended to reduce the risk of mental, physical, spiritual or social/legal harm associated with the use of psychedelics.” These practices are drawn from the broader theory of harm reduction, which may refer simultaneously to a set of public health practices, an approach to psychotherapy, or a social justice movement focused on the rights and wellbeing of people who use drugs [7]. Licensed practitioners may engage at one or all of these levels.

To engage in harm reduction work, practitioners need to gain comprehensive and accurate knowledge about a range of different substances and how they are used. This includes understanding risks and safety measures. Harm reduction generally also requires a philosophical stance of radical acceptance, respect for client autonomy, willingness to meet the client “where they are at” and work at their pace, an empowerment/strengths focus, acceptance of non-abstinence goals, and a willingness to explore one’s own biases and conditioning about “drugs [7].”

The lack of even-handed mass education, paired with biased messaging, perpetuates the stigmatization of drugs and people who use drugs. In addition to stigma and lack of information, prohibition on substances can exacerbate potential harm by forcing markets and use underground. Use of any substances may indeed come with risks of harm, which can be influenced by the set (attributes and current state of the person), setting (factors outside the person including physical, social, or cultural environment), substance, or dose. However, the lack of accurate, evidence-based information about drugs and prohibition amplifies these risks. Without accurate information about the benefits and risks of a given substance from a trusted source, a potential user cannot make an evidence-based decision about whether and how to use that substance. In the context of psychedelics, as with other substances, there is a recognition that the risks and harms of any drug are not just a natural consequence of the drug itself. Factors like prohibition, social stigma, and drug purity/consistency can create more harm than the drugs themselves. Drug prohibition and abstinence-focused policy choices have given rise to a dearth of evidence-based education; programs like D.A.R.E. focused on and exaggerated the risks of using controlled substances and failed to acknowledge benefits or provide information about how to use

them in ways that reduce risks. Education and knowledge about drugs are also distorted by media and commercial motives. Marketing of legal substances like alcohol and tobacco minimizes perceived risks associated with those substances, while depictions of illicit drug use overemphasize or misrepresents associated risks. When a practitioner or other professional discusses the harm associated with any currently illegal drug, they should acknowledge that they are generally talking about the harm of that drug when handled, produced, and sold without liability, quality control, or safety checks. By definition, a substance can only be regulated (for quality control, recommended use and dosage, monitoring for side effects, etc.) when it is legal.

Legality can take different forms - from federal medical approval to unscheduled but commercially distributable supplements - and varies from country to country and state to state. A substance intended for human ingestion may be unscheduled under the US Controlled Substances Act (CSA) and commercially produced and obtained on a small scale, giving rise to virtually no regulation beyond standard product liability. For widely marketed products like supplements and food, a substance may be subject to FDA regulation and any relevant state and local regulations covering labeling and restricting false or misleading claims about health benefits. Over-the-counter and unscheduled prescription drugs must nonetheless be shown to be safe and effective (through the FDA) and have stricter marketing rules. Prescription status of some substances marks a drug as “safer” in the minds of many consumers, and doctors may be incentivized to offer branded drug products--thereby needing to minimize risks while selling patients on benefits. Finally, drugs in Schedules II-V of the CSA and analogous state laws must meet the FDA requirements, be prescribed, and control their production and distribution. Schedule I substances are entirely prohibited except for in

scientific research settings with high barriers to entry.

For example, in 2019, the U.S. experienced a record 49,860 overdose deaths involving opiates^[8], yet numerous drug administrations at over 100 sites worldwide have occurred in Safe Consumption Spaces (SCS) around the world with apparently zero fatal overdoses^[9]. When discussing harm reduction in relation to psychedelics, we can assume there are contexts in which psychedelic use is more dangerous (e.g., consuming illicitly-produced MDMA, potentially adulterated with unknown other drugs, with inaccurate drug knowledge, alone or in an unfamiliar setting) and situations in which it is safer (e.g., pharmaceutical quality MDMA, taken by someone with accurate drug knowledge, in the presence of trusted others who have accurate drug and harm reduction knowledge). Licensed practitioners can help people who are using drugs do so more safely by utilizing harm reduction practices.

General Scope of Legal Needs

The survey also sought input from current or potential practitioners about their legal concerns and ethical considerations. Practitioners’ legal concerns span interactions with presently illegal therapeutic contexts, the legal landscape related to preparation and integration services, and the logistics of clinical management and regulatory compliance. Ethical questions focused primarily on referrals, underground culture, training and oversight, and management of adverse or unexpected outcomes. In general, survey respondents reported challenges to retaining sufficient and competent legal counsel to address their questions. It would be advantageous to the field if practitioners in different states who seek answers from subject matter experts on this myriad of legal questions share them in the spirit of “open access.” Doing so would help protect both clients and providers, and over time would provide a consistent body of

knowledge regarding the legal landscape of psychedelic care practice.

Practitioner licensing boards have never overseen psychedelics in mental health, and they have not defined what falls within and outside of accepted and ethical practices for many years. Thus, they are of limited utility in answering inquiries about the best practices for offering harm reduction or integration services, despite being responsible for governing these practices. Nevertheless, psychedelic use in the public has been steadily trending upwards for over a decade, and new medications are gaining FDA approval. Legal and ethics professionals may provide nimble legal guidance for practitioners working in this space and to future entities charged with regulating it.

In general, licensed practitioners avoid most legal risks by completely avoiding engagement with clearly illegal behavior, including underground psychedelic therapy. However, many questions about emergent frameworks for legal psychedelic-assisted psychotherapy also still fall into legal gray areas.

Many licensed practitioners, including prescribers, have questions about the extent to which they can discuss psychedelic modalities with their clients. In *Conant v Walters* ^[10], the Ninth Circuit Court of Appeals held that the federal government could not punish a doctor merely for telling a patient that their use of marijuana for medical use is proper, which lends support to licensed practitioners interested in similarly “recommending” psychedelic-assisted therapy. Referrals to legal clinical trials or licensed practitioners utilizing psychedelic-assisted therapy as the off-label use of an approved drug (i.e., ketamine) should not pose legal or licensure threats so long as the referring practitioner believes in their professional opinion that the treatment offered meets the standard of care required for the referred client. Furthermore, licensed practitioners can safely discuss their

knowledge of or professional opinions about psychedelic care or underground practices as part of their free speech rights outside of a patient-provider setting. However, can licensed providers discuss or recommend illegal psychedelic therapy?

Based on the logic in *Conant* and other First Amendment law, licensed practitioners may also be able to safely discuss currently illegal psychedelic-assisted therapy with clients in the way marijuana was discussed as a modality in *Conant*--including the pros and cons, details of modalities, and theoretical applicability of the therapy to the client and their circumstances or condition. However, recommendations for medical treatment with controlled substances as protected free speech by practitioners is not completely settled. Even in *Conant*, the court stated that if a recommendation was being used to obtain federally illegal substances with enough requisite knowledge and intent on behalf of the recommending physician, the physician could be subject to charges of aiding and abetting in federal drug crimes ^[1].

A district court case in Washington D.C. challenging the same policy challenged in *Conant* found that medical marijuana recommendations were effectively prescriptions because they operated as the means to receive cannabis under state laws. See *Pearson v. McCaffrey* ^[11] (analogizing recommendations to prescriptions under the California Compassionate Use Act). Prescriptions of controlled substances were not found to be protected speech. See *id.* at 121 (stating that speech that is part of the practice of medicine is subject to reasonable licensing and regulation and that speech in the commission of a crime is not subject to First Amendment protection). However, speech about “potential medical benefits of marijuana use” short of these prescriptions or recommendations was not interfered with under the government’s policy. *Id.* No appeal was taken in this case, but analogous litigation (about First

Amendment rights to recommend or refer patients to treatment with Schedule I substances) that comes to similar conclusions could give rise to a circuit split in the future. Of course, all of these rulings are limited to their jurisdictions.

In addition to asking about the legal limits of what practitioners can say and do with respect to recommendations, a number of survey respondents also asked about whether or not practitioners can directly refer a patient or client to underground therapists. A referral to an underground practitioner may expose a licensed practitioner to higher legal risk based on the aforementioned law. Doing so could be seen as an action meant to aid and abet or conspire in criminal activity, rather than merely discuss or recommend a potential modality. However, one of the most complex and potentially nuanced issues that emerged in survey responses was the ethical obligations of practitioners as they relate to referrals because the desire to avoid legal risk comes into tension with the desire to provide the best care for their participant or client (which some practitioners believe may be through psychedelic-assisted therapy).

One survey respondent noted that “One of the fundamentals in good therapy is not requiring clients to bear secrets - that can be deeply damaging to clients. So, when we are discussing these options, what does that look like ethically if a client is asking for underground referrals?” Going one step further, another practitioner questioned whether or not it is “ethical to withhold referrals when it's clear someone could greatly benefit from working with psychedelics/entheogens and don't have the time/means to travel to a country where it's legal?” These are the types of conundrums that practitioners face, but referring clients to anything other than legally available options such as ketamine, research trials, and international ayahuasca and psilocybin retreats would likely be interpreted as a violation of their license.

Practitioners also had questions about prescribing psychedelic substances off-label to patients with and without a diagnosed mental health condition. According to the FDA itself, “once the FDA approves a drug, healthcare providers generally may prescribe the drug for an unapproved use when they judge that it is medically appropriate for their patient ^[12].” Specifically, within the context of mental health treatment, ketamine has set this precedent—the development of ketamine as a modality for treating chronic depression was established by years of off-label use by providers using generic, racemic ketamine, prior to FDA’s recent approval of Spravato. Although Spravato is now approved for the treatment of treatment-resistant depression (TRD), racemic/generic ketamine remains available and legal to use in off-label contexts for the same treatment. There have been a small number of licensing board investigations into ketamine practitioners, but the authors are not aware of any that have resulted in direct disciplinary action. So, while MDMA and psilocybin are on track to be approved by FDA based on their ability to treat specific indications, it is plausible that a body of research develops to support the off-label use of MDMA or psilocybin as a treatment for other indications as well.

Another question that emerged was the legal status of incorporating experiential training as part of the education of psychedelic therapists, where the trainee undergoes a psychedelic session as part of their instruction. Experiential training has a long history in the training of psychotherapists, where it was once required and remains encouraged that students receive their own therapy, to experience the client role and resolve their own issues. MAPS PBC has permission from FDA to offer an optional experiential MDMA session through a study protocol as part of its training for therapists learning the MDMA-assisted psychotherapy modality. Although the use of scheduled substances for

experiential training outside of FDA-approved contexts is not clearly established, these factors together suggest that permitting practitioners to be taught through experiential methods may result in improved outcomes. While schedule II through IV medications can be used off-label as described above, a clinical rationale is generally required to prescribe them.

Another category of questions concerned screening, liability, and release forms. Specifically, practitioners seek appropriate templates for forms regarding informed consent, including potential side effects of psychedelic substances. The field would benefit from creating norms and boilerplate language to ensure that people unfamiliar with psychedelic therapy are fully briefed on how it is similar or different from other forms of therapy. In this vein, and related in part to the issues of off-label use referenced above, there are also questions about what screening methods are most appropriate for different patients. This is a question that we anticipate the field collectively answering over time, as more modalities emerge and different types of patients begin to engage with psychedelic therapy.

Practitioners are unclear about the extent to which informed consent/release forms provide protection from civil or criminal liability. There is currently a misperception that signing release forms in underground contexts provide protection from civil or criminal penalties; however, in the United States, contracts formed on the basis of currently illegal behavior are not enforceable, so release forms used in underground therapy contexts may not carry legal weight. However, they may still provide useful information to clients and have value as one way to put potential underground clients on notice and receive informed consent about the risks, legal and otherwise, in engaging with underground work.

Given this context, questions remain about which liabilities are incurred regarding the risk of mental injuries or negative experiences, including therapy abuse in which a therapist takes inappropriate advantage of or otherwise harms a client.

- Novel Issues in Compliance & Logistics
 - Over the last years, a number of practitioners have expanded their practice to include teleconferencing. During the coronavirus pandemic, this became more common as more physicians began prescribing take-home doses of ketamine. However, this is a novel phenomenon, and many practitioners are undereducated about the nuances of the legality regarding teleconferencing, particularly in how it can be utilized in psychedelic contexts. One survey respondent even asked whether or not there is “a case to be made for accompanying a client virtually (via video) who is under the influence of a psychedelic?”
 - In addition to novel approaches including telemedicine, a number of questions about the logistics of clinical practice and regulatory compliance remain, including questions about the storage, tracking, and dosing of medicines; and questions about screening, disclosure, and liability. Other practitioners are concerned about the technical aspects of how medicines will be stored, tracked, dispensed, disposed of, and dosed. Practitioners will need to work with the DEA office in their jurisdiction to maintain compliance. It should be noted that these requirements are stringent for all scheduled drugs, but particularly for schedule I drugs. These questions and more will be answered as

more information about psychedelic medicine REMS is published.

- Elective Use and Social Care
 - For clients without any diagnosed mental health condition, the path toward legal access is less clear. Elective cosmetic medicine (cosmetic surgery, injectables, prescription eyelash growth serums, dermatological laser treatments, etc.) has become normalized in medical culture^[13]. There are examples of providing prescription medications to individuals who are healthy but want to chemically alter some system of their body (e.g., FDA approved giving human growth hormone to children who are healthy but may end up in the lowest percentiles of height (shorter than 97% of their peers)). Outside of talk therapy modalities, however, the mental healthcare profession and our other mainstream institutions have not conceived of a care paradigm that includes chemical intervention for the mentally “well” in addition to the full spectrum of individuals, including those with diagnoses of varying degrees and severities.
 - Concepts of psychedelic therapy or healthcare for the general population align well with modern concepts of well-being and individual determination but can clash with drug stigma and may not as easily fit into the standardized lifestyle of our society (i.e., the productivity-focused, 40-hour workweek). Because governing institutions like FDA have legislative mandates based on treating diagnoses, practitioners looking to extend psychedelic-assisted therapies to “well” patients

may need to be activists in support of this far-from-inevitable expansion in their field. As in the case of cannabis, legal changes at the state and local level could provide some opportunities for practitioners; however, practitioners will still need to be mindful of licensing and ethics-monitoring bodies, as well as federal enforcement bodies like the DEA. Finding and developing a body of evidence that supports the gradual expansion into this “betterment” model of care could allow practitioners to maintain their ethical and professional standing and obligations, while cleverly innovating at the edges of their fields.

- Other Ethical Issues
 - Survey respondents also identified a number of critically important ethical questions that are beyond the scope of this article. Numerous practitioners have questions about how transference and countertransference are impacted by other power dynamics, including racial, socio-economic, and cultural ones. This is further complicated by how boundaries - i.e., with touch - are different in psychedelic-assisted therapy. MAPS PBC has recently published a second edition of the MDMA-Assisted Psychotherapy Code of Ethics^[14] which touches on some of these topics, and the Journal of Psychedelic Psychiatry published Ethical Guidelines for Ketamine Practitioners in December 2020^[15].
 - However, at least one survey respondent recognized the ethical expectations of clients themselves, something rarely discussed in traditional therapy contexts. A number of questions also remain about the

legality of psychedelic preparation and integration support services. Specifically, practitioners are interested in providing “auxiliary” services (that is, services that “don’t touch the drug”) but obviously wish to do so without jeopardizing their license or risking getting sued or arrested.

- On a more conceptual level, numerous practitioners brought up questions about the ethics of medicalization of psychedelic experiences in general. Working with psychedelic substances becomes complicated when practitioners work with medicines - traditional plant-based ones in particular - that are being used outside of or beyond their cultural context. There is an open question about how to appropriately train practitioners working with these substances, unlike MDMA, ketamine, and LSD - which clearly emerged from a primarily scientific, “Western” paradigm - mushrooms, ayahuasca, iboga, and other substances have a historical context which should be considered by practitioners seeking to work with these medicines.
- In addition, there seemed to be a general concern among respondents with a paradigm which necessitates finding and defining mental health as having local causes (uniquely within a single person), places primary control in the hands of experts instead of democratizing knowledge and emergent experience, and frames that control within the influence of profit-oriented motivations for research, use, and treatment. The authors look forward to continued engagement with this issue even as we continue to operate

within the present regulatory paradigm and the reality of its limitations.

CONCLUSION

Psychedelic clinical trials are advancing through the FDA development pipeline, and ketamine and esketamine have already seen a rapid adoption by many clinics and therapists. The emergence of psychedelics in healthcare practices brings forth the need to modify current operational procedures and structures to accommodate the specific criteria necessary for treatments and safety. With the uptake of these medicinal technologies, practitioners must be educated on well-defined terminology, safety, and effects, harm reduction practices, and receive legal and ethical guidelines for establishing clinics and administering psychedelics. The very nature of psychedelic medicine will require the intersection of many disciplines, including health care providers, legal counsel, federal and state regulatory agencies, healthcare boards, insurance companies, and other payers. If psychedelic treatments prove to be safe and effective for the growing list of indications under study, the coming decades could represent a major evolution in mental health care.

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FOOTNOTES

1. It may be important to note that the federal policy challenged in both court cases discussed is a distinction with the current situation around psychedelic-assisted psychotherapy. After a handful of states passed medical marijuana legislation, the federal government announced, via the Office of National Drug Control Policy, that the DOJ's position was that recommendation or prescription of Schedule I controlled substances was

considered inconsistent with the “public interest” as used in the Controlled Substances Act. As of this writing, the government’s intentions and position toward practices adjacent to psychedelic-assisted psychotherapy is unclear. Open are questions exist about the comparative nature of public support for psychedelics relative to public support for cannabis, about the intentions of law enforcement and other political bodies around enforcement priority for psychedelics in therapeutic contexts, and about legislative and rulemaking intentions around these topics that could move the conversation away from first amendment conversations.

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APPENDIX

Supplemental Material

Terms and Interpretations of Phrases

The survey asked respondents what terms in the psychedelic field were unclear and how they would interpret the meaning of specific

phrases. Table 1 displays the percentage of participants reporting the term could use more precise definitions and their response on how to define the term or phrase. Following the survey participants’ responses, the authors have attempted to provide concise interpretations of the terms, based on survey responses and language used in clinical research and cultural settings, as a means of facilitating further discussion around a shared terminology. However, the field of psychedelics is multidisciplinary and rapidly evolving, therefore the interpretations of these phrases are fluid and dependent on the context of use.

Table 1. Survey Response to Terms and Interpretation of Meaning

Terms	Respondent Interpretation of Meaning
Psychedelic-assisted therapy (53.95%)	<p>A. “Using psychedelics to explore the experience of non-dual awareness under the guidance of a therapist who can contribute to a safe drug, set and setting; and can assist in setting intentions and integrating the experience in terms of making sense of/ figuring out how to talk about a space that is outside of typical, normal daily reality.”</p> <p>B. “Psychedelic-assisted therapy is a treatment utilizing psychedelic medicine as a catalyst for opening up the capacity of the participant to the treatment during the medicine session. The medicine itself is not the treatment, as preparatory and integration sessions are the major components.”</p> <p>C. “Psychedelic assisted therapy is any type of therapy that is performed with the client under the influence of a short-acting psychoactive mind-altering substance to potentiate the effects of the therapy.”</p>
Psychedelic integration (51.33%)	<p>A. “The integration of externally-sourced psychotropic medications into the practice of internal, emotional and psychological self-exploration and healing.”</p> <p>B. “Integration involves ‘meaning making’ that brings the psychedelic experience into everyday consciousness...”</p>
Psychedelic practitioner (47.37%)	<p>A. “I understand there have been many underground practitioners of psychedelic ‘therapies’ that are not traditionally trained and have done great work with people. However, as this work is everything in the legitimate therapy world, I believe it is important that a psychedelic practitioner be someone with extensive training in clinical practice, as well as in psychedelic-assisted therapy. It is important that this field embodies legitimacy.”</p> <p>B. “A psychedelic practitioner is someone who uses expanded states of mind to resolve psychological issues.”</p> <p>C. “I wonder if that could mean anyone who practices aspects of that process - ie, until it is legal, I would call myself this in terms of prep and integration work and knowledge base, with clear discernment I don’t provide the medicine session.”</p>
Psychedelic harm reduction (40.79%)	<p>A. “Some objections have been raised to the term ‘psychedelic harm reduction,’ and I can understand the concern. I have heard some talk of changing language to ‘optimization’ or something else that does not suggest that psychedelics are inherently harmful or dangerous. Though I do recognize that ‘harm reduction’ is a term that has familiarity and traction.”</p> <p>B. “Psychedelic integration and Psychedelic harm reduction: Includes having a presence that is easily accessible for persons who have had psychedelic experiences that are outside of the realm of a controlled setting and need help making sense of what they have experienced.”</p>

Psychedelic intention-setting/preparatory support (38.16%)	A. "What I envision psychedelic intention setting and prep support to be is: an opportunity to assist the client in defining why they want to have an experience and preparing them with tools to use during the session, especially if you will not be there as a practitioner. This may change as we are allowed to be with people during sessions."
Psychedelic medicine (34.21%)	A. "Psychedelic medicine is the medicine used in psychedelic-assisted therapy, and other spiritual and cultural contexts with the intention for healing." B. "Soul-manifesting substances."
Medicine session (25%)	A. "Sessions that use or refer to psychedelics"
Psychoactive-assisted therapy (1.32%)	A. "Either psychedelic or psychoactive terms are fine with me. They both represent an altered state of consciousness that is going to be supported by a clinician."
Ceremony (1.32%)	Respondents: N/A
Participant (1.32%)	Respondents: N/A
Guide (1.32%)	Respondents: N/A
Ethical Off-label use (1.32%)	Respondents: N/A

‘Psychedelic-assisted therapy’ is the process of using a psychedelic substance alongside a therapeutic approach to support a person’s mental healing or well-being; hallmarks of the process include supportive and non-directive psychotherapy during prior preparatory sessions with the participant, the sessions themselves, and post-session integration. This term can be applied broadly to a range of substances, dosage levels, and theoretical orientations. Current clinical teams, such as MAPS, have standardized their definition of psychedelic-assisted therapy in trials to also include “client safety and wellbeing,” “provider training and experience,” “nondirective therapeutic approach based on empathetic rapport,” the use of “inner healing intelligence,” by the client, the therapeutic team’s ability to “guide or redirect” the client, as well as “enable the processing of trauma” by “maximizing the inner experience” with caution placed on “client safety and the avoidance of being retraumatized”; “addressing somatic manifestations”, creating a therapeutic environment that “evokes and supports emotional experiences [3].” However, therapeutic approaches are varied across trials, substances, and indications under study.

‘Psychedelic medicine’ is defined here as a class of naturally occurring or derived compounds or substances known to produce strong phenomenological experiences, in either clinical and research settings. These substances have also often been used in indigenous cultures and naturalistically throughout time. Often categorized into entactogenic, serotonin enhancing substances (such as MDMA) and ‘classical psychedelics’, such as LSD and psilocybin, which act as agonists to the 5-HT2A receptors, the latter is often found in naturally occurring fungi or plants and has been used by traditional cultures for thousands of years [16]. Clinical trials in recent years are now showing efficacy for psychedelics used more commonly in cultural settings, like psilocybin, in modern medical practice to treat a variety of mental health disorders such as depression, end-of-life distress, and addiction [17, 18, 19, 20]. The Food and Drug Administration (FDA) describes only substances that have been approved through the federal drug development pathway as ‘medicines’.

The word ‘participant’ is used to describe one who intentionally, and knowledgeably, consents to a psychedelic experience or psychedelic-assisted therapy in either naturalistic, culturally specific, or clinical settings. In clinical research, a person can also be referred to as a ‘subject’, whereas a person who pays a practitioner for mental health services is called a ‘client’ or ‘patient’. Clinical trials, therapeutic settings, and many culturally focused psychedelic ceremonies have unique inclusionary/exclusionary criteria that require participants to be in good health, or to be specifically suffering from an ailment before psychedelic-assisted treatment is allowed.

The word ‘medicine sessions’ specifically references the active time under the influence of a psychedelic substance as a means of mental, physical, or spiritual healing. A medicine session may refer to the

administering of psychedelics in naturalistic settings by users, clinically administered to patients in research, or experiential settings with practitioners. In many studies, double-blind experimental designs may mean a medicine session is conducted with an active dose of a psychedelic or with a placebo. In ceremonial contexts, medicine sessions may be seen as the specific rituals, traditions, and language that different cultures employ when using psychedelics in a ceremonial or spiritual setting.

Prior to a medicine session, ‘psychedelic intention setting’ or ‘preparatory support’ occurs, where participants are offered supported discussion and reflection as a means of examining the user’s goals and intentions for the psychedelic-assisted sessions. Intention setting can act as a priming effect in therapy. Clinically, preparatory and intention setting is defined as meeting with clinical therapists in which the therapeutic alliance is solidified, the participant is given information of what they can expect to experience, and there is ample opportunity to discuss the participants’ intentions and concerns prior to psychedelic-assisted session^[3]. Explanations of possible sensations, challenges, fears, and procedures are also addressed. Historically, psychedelic literature has pointed to appropriate preparation activities, such as in Dr. James Fadiman’s 2011 book, *The Psychedelic Explorer’s Guide: Safe, Therapeutic, and Sacred Journeys*, which offers readers preparation insight that is based on both historical and clinical uses of psychedelics^[21]. Further, there are a myriad of intention-setting protocols that vary from culture to culture prior to the use of psychedelic substances in ritualistic or spiritual contexts. Some therapists offer preparatory services in which drugs are not administered, but a person using in naturalistic settings is offered support and a chance to ask questions or set intentions.

After a medicine session, psychedelic-assisted therapy is paired with ‘integration’, the intentional supported discussion, writing, or reflection that occurs after a psychedelic experience as a means of allowing the patient to examine their phenomenological experience, as well as to reflect upon their preexperience intentions, make meaning of their interpretations, and explore ways to incorporate them postexperience. In clinical trials, integration sessions occur after a dosing session to allow the client to further explore the experience of their psychedelic-assisted session and receive continued support for their therapist as they discuss ways to incorporate that experience into the client’s life moving forward^[3]. Techniques and number of integration sessions vary between trials. Outside of clinical trials, psychedelic integration further expands to individuals seeking this same type of processing with a health professional who was not involved in the administration of the psychedelic or oversight of the experience^[22].

A ‘psychedelic practitioner’ is a person who supports this experience through a variety of protocols or practices. We use a general term because practitioners may employ or be trained in shamanistic or traditional healing modalities, or in a variety of scientific fields such as psychiatry or psychology. There is variance among psychedelic practitioners, even in clinical trials. Johns Hopkins has used session monitors, from graduate students to psychiatrists and clinical psychologists, while MAPS, under their expanded access program, expresses that practitioners encompass a team from the medical doctor who obtains the DEA schedule 1 license to the ‘therapy pair’ in which one must be fully licensed to administer therapy according to state mandated regulations all while following a strict code of ethics^[19, 23]. Beyond professionals pursuing research, practitioners like those found through the provider network Psychedelic.Support (www.psychedelic.support), are licensed, may or may not

have worked in psychedelic research, and are empathetic to the naturalistic use of psychedelics by clients. They may be considered practitioners by way of integration or intention-setting services, but administer no psychedelic substances. The word ‘guide’ is frequently used to encompass shamans, clinical trial therapists, underground therapists, or any person who is psychedelic-informed, trusted, and competent person who assists consenting participants through preparation, integration, the psychedelic experience, and is responsible for the participant’s safety and well-being while they are under the influence of a psychedelic. This may include licensed or unlicensed practitioners, or may refer to the numerous cultures that continue to provide healing, ceremony, and spiritual guidance through a psychedelic ritual, such as the use of ayahuasca by Amazonian shamans or the use of the mescaline containing peyote cacti by indigenous tribes of the American southwest [24]. However, it does not necessitate that the guide be the giver of a psychedelic medicine or therapy. For example, Zendo Project’s ethical guidelines for peer support training require that one does not ‘guide’ a peer having a psychedelic experience at all [25], whereas clinical trial therapists are trained to specifically guide participants using a non-directive approach, and shamans pull from their cultures’ ritual and traditions to facilitate the psychedelic experience [3, 26].

‘Psychedelic harm reduction’ (sometimes referred to as ‘psychedelic risk reduction’ or ‘harm reduction and healing’) refers to the peer-to-peer or practitioner-to-participant practices and protocols that are intended to reduce the risk of mental, physical, spiritual, or social/legal harm during a psychedelic experience, and is a hallmark of safety across the field. Classically, harm reduction refers to the consideration of human rights in practice, theory, and policy meant to reduce harm to people who use drugs [27]. When considering psychedelic harm reduction, Zendo Project’s

training manual regards “creating safe spaces,” “sitting, not guiding,” “talking through, not down,” and “difficult is not the same as bad” as the key components for reducing harm in psychedelic users [25]. The approach is attentive to set and setting, and relies on human relationships to navigate challenging experiences and support open or positive experiences, while also attending to medical needs that may occur, such as those due to preexisting health issues, drug interactions, or overdose.

‘Ceremony’, in relation to psychedelic use, can describe a variety of ancient traditions that allow participants to experience facilitated psychedelic experiences, such as ayahuasca ceremonies in Peru to the use of peyote by Native American tribes of the southwest [26]. Covering a wide array of traditions, rituals and psychedelic substances, the wider purpose of a ceremony is to facilitate spiritual, and often mental and physical healing. Practitioners and guides may employ a ceremony that encompasses preparation, medicine sessions, appropriate rituals, and integration of the experience. Recent clinical trials draw on these historical traditions to help guide the development of psychedelic-assisted therapy protocols, such as MAPS’ use of therapeutic teams and integration [3]. Today, traditional psychedelic ceremonies are legally available in countries throughout the world [26].

The broader class of ‘psychoactive-assisted therapy’ is where a psychoactive substance is given as an adjunct to a modality of therapy, such as psychotherapy. Currently, psychedelic-assisted therapy falls under the larger umbrella of psychoactive-assisted therapy. The World Health Organization defines psychoactive substances as any substance that affects a person’s cognition to include not only psychedelics but also pain medications, caffeine, and nicotine [28]. Not exclusive to psychedelic-assisted therapy, psychoactive-assisted therapy may

encompass practices such as pain management and off-label use.

In clinical settings, ‘off-label use’ refers to a doctor prescribing an FDA-approved medication for an indication that was not investigated in the full battery clinical trials necessary to gain marketing approval from the FDA. Because ‘off-label prescriptions’ employ a medication outside of its primary intended use, health providers must consider the available published evidence, safety risks, and potential risk/benefit ratio and assume

legal risks in prescribing medications off-label. Ethical off-label use is intrinsically intertwined with legal frameworks and is an attempt to use medicines to promote healing outside of their intended use while still considering patient safety, legal restrictions and provider responsibility, where these considerations vary from one country to the next^[29].

