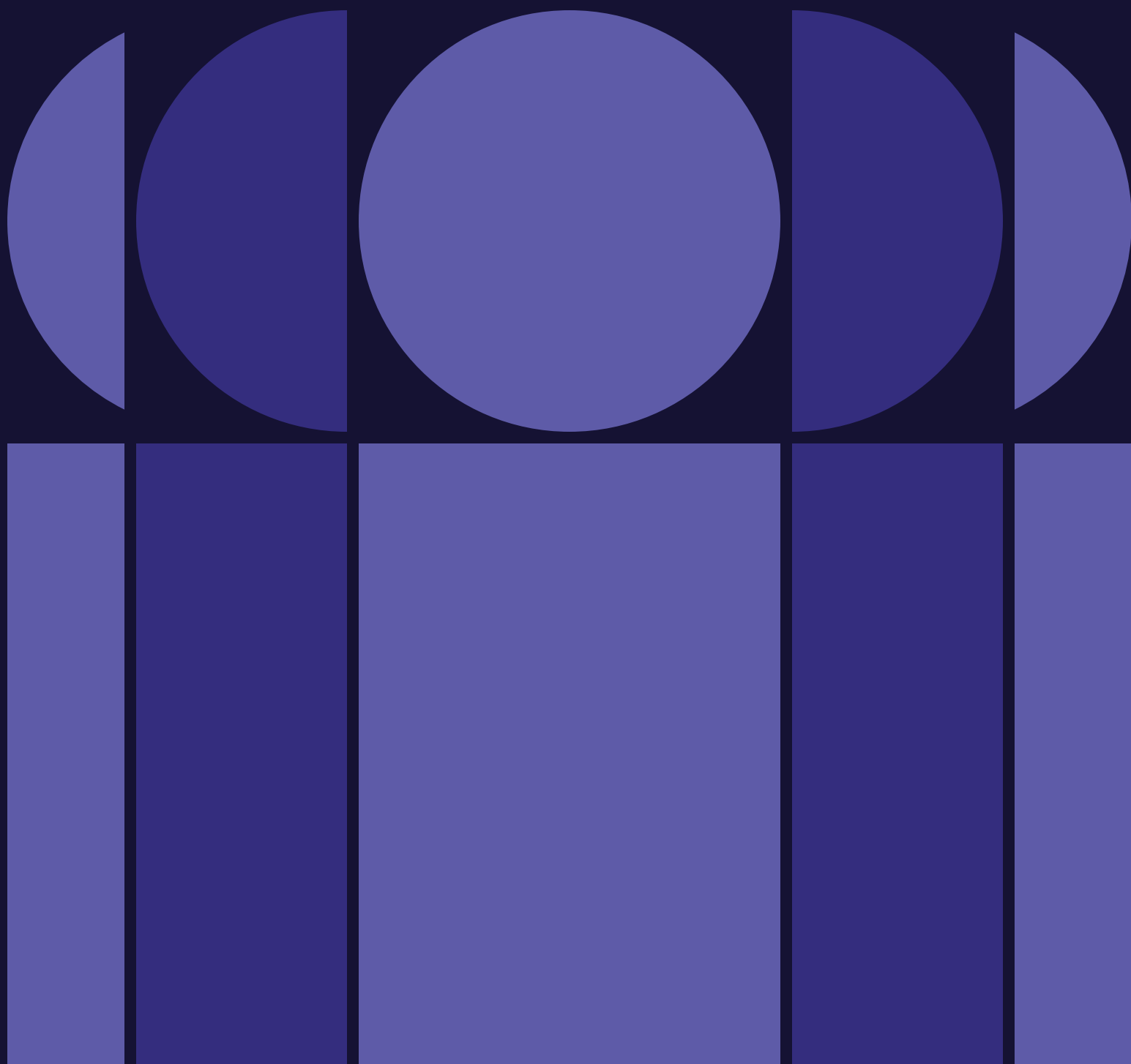


BRAIN FUTURES

PROFESSIONAL PRACTICE GUIDELINES FOR

Psychedelic-Assisted Therapy



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Professional Practice Guidelines for Psychedelic-Assisted Therapy, First Edition are a production of BrainFutures, Inc. A workgroup of researchers and trainers/educators in psychedelic-assisted therapy wrote the guidelines. Members of the writing group were: Anthony Back, MD, Mark Bates, PhD, Shannon Carlin, LMFT, Natalie Gukasyan, MD, Andrew Penn, MS, PMHNP, Jordan Slosower, MD, MSc, and Will Van Derveer, MD. Work group meeting facilitation, research, and writing support were provided by the Rockingstone Group, LLC (Jordanna Davis, MPP, and Jacqueline Lampert, MPP) and overseen by BrainFutures, Inc.

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The content contained in these guidelines does not constitute medical advice and is subject to change. Before pursuing any course of treatment for a behavioral or medical condition, including the use of psychedelic-assisted therapy, always seek the advice of your physician or other qualified health provider, and review the information together.

SPECIAL THANKS

BrainFutures wishes to acknowledge the important role the American Psychedelic Practitioners Association played in convening workgroups to provide valuable input and feedback throughout the process of developing the Professional Practice Guidelines for Psychedelic-Assisted Therapy.

Introduction

These guidelines are designed to address the evolving practice of psychedelic-assisted therapy. For the purposes of these guidelines, psychedelic-assisted therapy is defined as “a particular mode of using psychedelic substances in which the effects of the drug, both biological and psychological, play a significant role in facilitating a psychotherapeutic intervention” and is detailed more specifically in the “Definition of Terms” section (Guss et al., 2020). A growing body of evidence has demonstrated the potential value of psychedelic-assisted therapy in recent years, culminating in late-stage clinical trials of 3,4-methylenedioxy-methamphetamine (MDMA) for posttraumatic stress disorder (PTSD) and psilocybin for major depressive disorder and/or alcohol use disorder. Approval of these therapies by the U.S. Food and Drug Administration (FDA) could greatly increase interest among health-care providers and patients. These guidelines aim to educate and guide psychedelic-assisted therapy practitioners as this model of care expands to a greater number of providers and patients outside of research settings.

Research in the field of psychedelic-assisted therapy has been significantly limited by classification of psychedelics as Schedule I substances, which has constrained the development of a robust, evidence-based library of data from which to draw strong conclusions. Thus, these guidelines are informed by available studies and published articles, as well as the expert input of the guideline writing workgroup, additional contributors, and external reviewers. The literature review conducted for these professional practice guidelines included clinical trials and commonly cited publications on psychedelic-assisted therapy.

The notion of psychedelics as potential agents of healing is not novel; rather it originated in many cultures with long histories of use of psychedelic plants and fungi. Indigenous traditions have used psychedelics for healing, religious, and sacred ceremonies for centuries (Sky, 2022). Psychedelic-assisted therapy practitioners recognize that the advancement of psychedelic research and therapy would not have been possible without the millennia of practice and wisdom cultivated by Indigenous communities throughout the world. In seeking to optimize the safety and efficacy of psychedelic-assisted therapy, psychedelic-assisted therapy practitioners acknowledge that there is much to learn from Indigenous practitioners as well as pioneering scientists, clinicians, and others who possess extensive experience.

PURPOSE OF THE GUIDELINES

No comprehensive, universally-accepted guidelines currently exist for mental health providers practicing psychedelic-assisted therapy. The process of drafting these guidelines welcomed experts into discussion and debate, generating consensus around professional standards for this treatment modality. This evolving model—combining administration of psychedelic medication and therapy within the same treatment session—is significantly different from existing psychotherapy practice, and thus necessitates the development of new processes and competencies. These guidelines aim to describe the minimum standards of care, as informed by existing clinical research and expert consensus, and acknowledge that this document is dynamic and mutable.

The practice of psychedelic-assisted therapy will undergo significant evolution as research and access become more robust. Upon publication, this version of professional practice guidelines will be a static document, existing in the context of a rapidly changing landscape. It is assumed that many of these guidelines will be subject to change in the coming years, as noted in the “Status/Expiration” section below. The guidelines should be evaluated in the context of current knowledge of best practices in efficacy and safety, which are always iterative. Science is fundamentally a field of learning and adapting, and the guidelines should be viewed in that light.

Future iterations of guidelines for psychedelic-assisted therapy are intended to be incorporated into broader guidance for professionals working in the mental health field. Psychedelic-assisted therapy would not be considered separate and apart from other therapies offered to patients suffering from major depressive disorder, PTSD, or other diagnoses. Instead, it might be considered within a menu of options to relieve the suffering of patients with certain mental health diagnoses.

INTENDED AUDIENCE

These guidelines provide general recommendations for practitioners of psychedelic-assisted therapy to increase their awareness, knowledge, and skills. They may also provide assistance to those with an interest in psychedelic-assisted therapy, such as other mental health providers, legislators, regulators, third-payer payers (such as health insurers), educators, or consumers.

DEFINITION OF TERMS

Medication administration session. These guidelines use the term medication administration session to mean the session during which a patient ingests or is otherwise administered an FDA-approved psychedelic medication and is accompanied by a psychedelic-assisted therapy practitioner or practitioners until it is safe for them to leave. As used herein, medication administration is one part of a medication administration session.

Patient. These guidelines use the term patient to mean the individual who seeks or is considering psychedelic-assisted therapy services. However, published results of clinical trials may refer to a participant or volunteer and other research may use the term client. These guidelines maintain the original text when directly quoting research and use the term patient at all other times.

Psychedelic medication. For the purposes of developing these guidelines, the workgroup used a broad definition of psychedelic medications, similar to that developed by Sky (2022), as medications “that affect neurochemistry, causing shifts in experiential perception and mood often accompanied by vivid mental imagery.” The workgroup includes in this definition medications that are not considered classic psychedelics, such as MDMA, but which may be classified as psychedelics due to the subjective effects of the medications. Though ketamine meets this description,

standards of practice for subanesthetic use of ketamine already exist, and ketamine-assisted therapy is therefore not included in these guidelines (American Society of Ketamine Physicians, Psychotherapists, and Practitioners, 2020). In addition, these guidelines are agnostic with regard to medication and dose, and the workgroup encourages practitioners to use their clinical judgment in applying these guidelines to a specific patient taking a specific dose of a specific psychedelic medication. As additional evidence becomes available, the field should revise and update clinical practice guidelines to address each of these circumstances.

Psychedelic-assisted therapy. The term psychedelic-assisted therapy refers to “a particular mode of using psychedelic substances in which the effects of the drug, both biological and psychological, play a significant role in facilitating a psychotherapeutic intervention” (Guss et al., 2020). Most current studies and clinical trials involve three types of sessions—preparatory, medication administration, and integration—preceded by patient screening and assessment (Bogenschutz & Forcehimes, 2016). Uses of psychedelic medications unaccompanied by psychotherapy do not meet this definition of psychedelic-assisted therapy.

Psychedelic-assisted therapy practitioner. It is neither the purview nor purpose of these guidelines to define who is, or is not, a psychedelic-assisted therapy practitioner. As such, the term psychedelic-assisted therapy practitioner, as used in these guidelines, is necessarily broad. It reflects the wide range of healthcare professionals who may provide this care in a healthcare setting. While some use the term “psychedelic therapist” to refer to those who provide psychedelic-assisted therapy, this document uses the term psychedelic-assisted therapy practitioner to reflect that not all members of the care team may be licensed psychotherapists (Nielsen & Guss, 2018; Phelps, 2017). At the time of publication, it is unclear whether or what restrictions the FDA or other regulatory bodies may place on the types of professionals who may deliver psychedelic-assisted therapy. These guidelines are careful to acknowledge the wide-ranging scopes of practice that psychedelic-assisted therapy practitioners bring to this work.

GUIDELINE DEVELOPMENT PROCESS

In anticipation of the submission of at least one New Drug Application (NDA) to the FDA for a psychedelic-assisted therapy treatment, a workgroup of seven expert researchers and clinicians convened to develop guidelines for psychedelic-assisted therapy. The workgroup began with a discussion of the evidence available to support guidelines for psychedelic-assisted therapy and the type of guidelines that would be most appropriate for the field at this juncture. Using its assessment of the current state of evidence and guidance on guideline and standards development from other mental health practitioner associations, the workgroup decided to develop professional practice guidelines for psychedelic-assisted therapy. The workgroup consensus is that comprehensive, universally-accepted professional practice guidelines for psychedelic-assisted therapy do not exist as of this writing and that such guidelines should set a benchmark of quality to which all psychedelic-assisted therapy practitioners should aspire across different medications and therapeutic approaches.

In general, professional practice guidelines address areas of practice, in contrast with clinical practice guidelines which provide specific recommendations about treatments for a particular health condition or diagnosis (*FAQs About Clinical Practice Guidelines*, 2023). The workgroup used the work of several organizations as models for both establishing its guideline development process and drafting the guidelines and supporting information. These include, but are not limited to, the American Psychological Association, the American Psychiatric Association, the National Association of Social Workers, the International Society of Psychiatric-Mental Health Nurses, and the National Coalition for Hospice and Palliative Care (“Practice Directorate,” 2022; *Guideline Development Process*, n.d.; *NASW Practice Standards & Guidelines*, n.d.; “International Society of Psychiatric-Mental Health Nurses (author) et al.,” 2022; “National Consensus Project for Quality Palliative Care,” 2018).

The guideline writing workgroup (members identified below) met 10 times to discuss and draft guidelines, ultimately voting to approve 12 professional practice guidelines. The guidelines were shared with the con-

tributors (listed on page two) for their input and feedback. The resulting draft was shared with the guideline writing workgroup, as well as all contributors, for editing and review. Suggested changes were presented to the guideline writing workgroup for consideration and potential inclusion. A revised draft was shared with external reviewers for their review and input. Suggested changes from these external reviewers were, again, shared with the guideline writing workgroup for consideration and potential inclusion in the final version of this document.

SELECTION OF EVIDENCE AND LIMITATIONS

As is typical in the development of professional practice guidelines, the workgroup relied on “consensus and familiarity with the body of literature,” but the guidelines are not based on a systematic literature review (*FAQs About Clinical Practice Guidelines, 2023*)¹. The development of these professional practice guidelines was informed by peer-reviewed, published results of clinical trials and other peer-reviewed publications when available, supplemented by guideline development process documentation from other organizations, other approved guidelines and association policies, government reports and publications, publicly-available work from relevant research organizations, books, chapters, the consensus of experts involved in the drafting and review of these guidelines, and other sources as identified in the References.

Peer-reviewed evidence on the observed effects of various psychedelic medications in conjunction with psychotherapy is significant and growing. However, consistent with other pharmaceutical trials, the published results of randomized clinical trials for psychedelics focus on the safety and efficacy of the medication studied and do not test the effects of specific elements of the clinical intervention, including the precise role of the psychedelic-assisted therapy practitioner during the medication administration session (Cavarra et al., 2022). Despite this, expert consensus has developed

among modern researchers regarding discrete elements of care that should be provided in psychedelic-assisted therapy. Expert consensus may be viewed as one lineage of psychedelic-assisted therapy knowledge.

A dearth of evidence from randomized controlled trials is not atypical of psychiatric interventions and, using the guideline development work of the American Psychiatric Association (APA) as a model, many guidelines included herein rely on evidence such as “consensus opinions of experienced clinicians or indirect findings from observational studies rather than research from randomized trials” (“Guideline Writing Group,” 2022).

The racially homogenous and relatively small number of participants in modern clinical trials results in a limited understanding of the effect of psychedelic medications within more diverse populations (Michaels et al., 2018; Thrul & Garcia-Romeu, 2021). To help broaden the applicability of these guidelines, the workgroup sought the input of a range of experts in the psychedelic-assisted therapy space beyond the traditional research setting, as identified in the Appendix. Workgroup members heartily endorse the imperative to enhance diversity and equity, not only in psychedelic-assisted therapy research, but also in the clinical provision of psychedelic-assisted therapy when it becomes available outside of the clinical trial environment.

Another challenge workgroup members acknowledge is that “studies on MDMA and psilocybin so far have been conducted with carefully screened, highly restricted populations” (Barber and Dike, 2022). This is not atypical of randomized controlled trials, which may exclude individuals with comorbid conditions, both psychiatric and medical, in order to allow assessment of a treatment in a well-defined population (U.S. Food and Drug Administration, 2018). However, excluding certain subgroups from a clinical trial, such as individuals with comorbidities, may limit the applicability of clinical observations and inferences made during such trials to a broader patient population.

¹ Sky (2022) offers a review of the clinical research on psychedelic medications.

GUIDELINE STATEMENT SUMMARY

GUIDELINE 1

Psychedelic-assisted therapy practitioners are in good standing with the healthcare licensure and/or certification body of their professional discipline.

GUIDELINE 2

Psychedelic-assisted therapy practitioners have specialized training in psychedelic-assisted therapy appropriate to their scope of practice and strive to ensure their knowledge of the potential physical, psychological, and spiritual effects of psychedelics and core principles of psychedelic-assisted therapy.

GUIDELINE 3

Psychedelic-assisted therapy practitioners are committed to ongoing development in fundamental therapeutic competencies, including building and maintaining therapeutic rapport, maintaining emotional and physical presence, treating patients with dignity and respect, being welcoming and compassionate, and meeting the highest levels of ethical integrity.

GUIDELINE 4

Psychedelic-assisted therapy practitioners obtain and document informed consent before commencing treatment, respect the patient's right to withdraw consent, and approach consent as an ongoing process to be addressed at multiple points over the course of therapy.

GUIDELINE 5

Psychedelic-assisted therapy practitioners specifically address the potential applications of touch in the informed consent process. Such consent includes the patient's right to refuse touch except in situations where touch is required to prevent serious injury, damage, or harm.

GUIDELINE 6

Psychedelic-assisted therapy practitioners ensure that patients have been comprehensively screened in accordance with existing evidence, guidelines, and clinical judgment.

GUIDELINE 7

Psychedelic-assisted therapy practitioners aim to build rapport and trust with patients during the preparatory period.

GUIDELINE 8

Psychedelic-assisted therapy practitioners prepare patients for a medication administration session by inviting them to share their personal histories, explaining medication administration session logistics, reviewing the range of possible experiences during the medication administration session, discussing potential therapeutic approaches that may be used, providing guidance for navigating challenging experiences that could arise, and answering patient questions.

GUIDELINE 9

Psychedelic-assisted therapy practitioners aim to facilitate a safe and therapeutic medication administration session conducted in a comfortable and confidential setting.

GUIDELINE 10

Psychedelic-assisted therapy practitioners monitor patients for adverse events both during and following the medication administration session, and ensure that complications are addressed.

GUIDELINE 11

Psychedelic-assisted therapy practitioners support patients in understanding and making meaning of their psychedelic medication experience and incorporating desired changes into their lives.

GUIDELINE 12

Psychedelic-assisted therapy practitioners communicate and coordinate with other relevant providers to ensure continuity of care.

Guidelines

GUIDELINE 1

Psychedelic-assisted therapy practitioners are in good standing with the healthcare licensure and/or certification body of their professional discipline.

Rationale

Psychedelic-assisted therapy is a specific model of care within the larger field of mental health care. It is therefore practiced by a variety of practitioners within the mental health field, with varying degrees and backgrounds. The licensure and/or certification(s) held by a practitioner in their professional discipline offers important accountability for competency, education, ethics, and other standards. Psychedelic-assisted therapy practitioners should be in good standing with the bodies offering such licensure and/or certification.

Application

Many psychedelic-assisted therapy practitioners are licensed to practice in other healthcare professions. Such licensure generally requires applicants to submit proof of education and training, provide details of work history, reveal any malpractice or criminal convictions, pass a licensing examination, and show a level of continuing education (e.g. “Federation of State Medical Boards,” n.d.; Dittmann, 2004; National Council of State Boards of Nursing, n.d.). Remaining in good standing generally requires that a license not be expired or have any restrictions or limitations in effect. Meeting such standards offers a level of accountability that practitioners are in compliance with all relevant laws and regulations, and that they have met or exceeded benchmarks for education, competency, and ethics.

Healthcare teams are often multidisciplinary, and psychedelic-assisted therapy is no different. Teams may be composed of individuals from various profes-

sional backgrounds whose credentials include licensure and/or certification for their specific scope of practice. Practitioners may earn certificates in a range of areas including Medical Assistant, Mental Health Technician, Patient Care Technician, Clinical Medical Assistant, Nursing Assistant, and more (American Medical Certification Association, n.d.). These certification programs often include important administrative, clinical, and on-the-job training, signaling that graduates have a thorough and current understanding in a specific area of healthcare delivery. Many certification programs also require recertification at specified intervals, ensuring that individuals remain current in their knowledge and experience. Like licensure, certification provides a level of assurance that individuals participating on a psychedelic-assisted therapy team have a baseline level of training and accountability.

GUIDELINE 2

Psychedelic-assisted therapy practitioners have specialized training in psychedelic-assisted therapy appropriate to their scope of practice and strive to ensure their knowledge of the potential physical, psychological, and spiritual effects of psychedelics and core principles of psychedelic-assisted therapy.

Rationale

Psychedelic-assisted therapy is practiced by individuals with varying degrees and educational backgrounds. Though a number of programs exist offering education specific to psychedelic-assisted therapy and research,

there is currently no requirement that practitioners complete such programs, nor is there an accreditation mechanism to set standards for educational programs. However, comprehensive education regarding the physical, psychological, and spiritual effects of psychedelics, as well as core principles of psychedelic-assisted therapy, is a key component of delivering high-quality care.

Application

As of the date of this publication, the psychedelic-assisted therapy field has yet to establish an accreditation mechanism to set standards for educational programs and the institutions that sponsor them. In other areas of healthcare, this function is often served by organizations such as the Accreditation Commission for Education in Nursing, the Commission on Collegiate Nursing Education, the Council on Social Work Education, the American Psychological Association Commission on Accreditation, the Commission on Accreditation for Marriage and Family Therapy Education, or the Accreditation Council for Graduate Medical Education, which use best practices, research, and educational excellence to render accreditation decisions based on compliance with the established standards.

Programs voluntarily submit to the accreditation process to demonstrate their achievement of a quality standard. Such accreditation engenders trust and confidence that a program has comprehensive curricula, adequate resources, expert faculty, appropriate facilities, and more. This is a standard to which current programs should aspire. In the meantime, many current programs offer important education in psychedelic studies, often culminating in the award of a Certificate (“Certificate Programs”).

While curricula will evolve as evidence grows and best practices emerge, at its core, specialized training should provide psychedelic-assisted therapy practitioners broad knowledge of the potential physical, psychological, and spiritual effects of psychedelics, and of the core principles of psychedelic-assisted therapy. Psychedelic-assisted therapy practitioners endeavor to understand potential physical effects of psychedelics as they might for other medications or procedures within their scope of practice. However, psychological, as well as spiritual or existential, effects can be quite unique to psychedelic-assisted therapy. Psychedelic-as-

sisted therapy practitioners aim to understand these effects so that they can appropriately guide patients as they encounter such experiences.

More specific training requirements are outside the scope of this document, and remain an area of active inquiry and development.

GUIDELINE 3

Psychedelic-assisted therapy practitioners are committed to ongoing development in fundamental therapeutic competencies, including building and maintaining therapeutic rapport, maintaining emotional and physical presence, treating patients with dignity and respect, being welcoming and compassionate, and meeting the highest levels of ethical integrity.

Rationale

Psychedelic-assisted therapy is a rapidly evolving field, with a limited but growing body of scientific evidence to support the work. As new data emerge, best practices will change. Psychedelic-assisted therapy practitioners understand this moment of rapid development and endeavor to monitor and evaluate new research and maintain familiarity with current professional guidance. Psychedelic-assisted therapy practitioners aim to remain current in fundamental therapeutic competencies such as building and maintaining therapeutic rapport, maintaining emotional and physical presence, treating patients with dignity and respect, being non-judgmental and compassionate, being patient-oriented, meeting the highest levels of ethical integrity, and other key competencies that are identified over time.

Application

Psychedelic-assisted therapy practitioners develop and maintain knowledge of fundamental therapeutic competencies through ordinary channels of professional development: attending conferences, participating in professional associations, engaging in formal continuing education, conducting their own research or reading, delivering case presentations, and seeking consultation on their own work. For many practitioners, such continuing education will also be a necessary part of maintaining licensure and/or certification, which is generally contingent upon demonstrating continuing “knowledge and skills required to provide patients the best possible care” (“American Board of Physician Specialties,” 2020). At this time, psychedelic-assisted therapy practitioner accountability lies mainly in the continuing education requirements of their professional licensure and/or certification.

Psychedelic-assisted therapy practitioners also hone their core competencies by remaining current with clinical and professional practice guidelines and recommendations for specific diagnoses and populations. Such guidelines and standards are available from the American Psychological Association, the American Psychiatric Association, the National Association of Social Workers, the International Society of Psychiatric-Mental Health Nurses, and others. Psychedelic-assisted therapy practitioners also consult clinical practice guidelines for the underlying conditions psychedelic-assisted therapy aims to treat, such as those for depression and PTSD (e.g. American Psychological Association, 2019; American Psychological Association, 2017b; American Psychiatric Association, 2004; American Psychiatric Association, 2010).

Clinical practice guidelines focusing on specific populations may help psychedelic-assisted therapy practitioners be sensitive to how a patient’s race, ethnicity, gender, sexual identity, gender identity, or other categories of identity may affect their experience. Because not all research has prioritized diversity and inclusion in recruitment, many clinical trial populations are quite homogeneous in terms of race (Michaels et al., 2018), socio-economic background, education, and other factors. Results from such studies may not be generalizable to all patients, particularly those not

represented among trial participants. It is important to note the efforts of researchers to make clinical trial recruitment more inclusive of diverse populations, including Williams et al. (2019) and MAPS (Leighton & Harrison, 2022).

Finally, part of a psychedelic-assisted therapy practitioner’s ongoing development includes remaining up-to-date on the developing infrastructure of this field, which should include a universally-adopted Code of Ethics. The ethical transgressions of psychedelic-assisted therapy practitioners already published in news accounts (e.g., Goldhill, 2022; MacBride, 2021; Rosin, 2022), strongly reinforce the need for a universally-adopted and enforceable Code of Ethics for the field. Such a Code may draw on the work of Taylor (1995), MAPS PBC (2021), the Organization of Psychedelic & Entheogenic Nurses (*Code of Ethics* | OPENurses, 2020), and the American Society of Ketamine Physicians, Psychotherapists, and Practitioners (2021), among others.

GUIDELINE 4

Psychedelic-assisted therapy practitioners obtain and document informed consent before commencing treatment, respect the patient’s right to withdraw consent, and approach consent as an ongoing process to be addressed at multiple points over the course of therapy.

Rationale

Informed consent enhances patient protection by ensuring patients receive enough information to understand any risks associated with, have the opportunity to ask questions about, establish comprehension of, and make an educated decision about their treatment. It is a key component of the ethical guidelines of nearly all healthcare practitioner associations (e.g., American Psychiatric Association, 2013; American Psychologi-

cal Association, 2017a; National Association of Social Workers, 2021).

Application

Psychedelic-assisted therapy practitioners understand informed consent to be an ongoing process involving, at a minimum: disclosing to the patient information needed to make an informed decision about participating in treatment, facilitating the patient's understanding of what has been disclosed, and promoting the voluntariness of the patient's decision to participate in treatment (Shah et al., 2022) while the patient is in an ordinary state of consciousness. Practitioners obtain signed informed consent from patients before commencing with any treatment.

Psychedelic-assisted therapy practitioners disclose, in accessible language, all relevant information about experiences and adverse events that may result from psychedelic-assisted therapy including: "changes in perception, sense of time and space, and emotion (possibly including anxiety, fear, panic and paranoia)," ontological shock (Gorman et al., 2021), and longer-term (though typically considered rare) risks of psychosis (Thomas & Malcolm, 2021), suicidality (Mithoefer, 2017), and hallucinogen persisting perceptual disorder (HPPD) (Johnson et al., 2008). Psychedelic-assisted therapy practitioners also clearly convey the more objective aspects of the medication session, such as the anticipated duration of medication effects, any information about the medication's toxicity profile, and the incidence and severity of adverse effects (Johnson et al., 2008). Finally, psychedelic-assisted therapy practitioners clearly convey information about how physical touch may be used in psychedelic-assisted therapy so that patients can make an informed decision about their preferences. (Patient consent for touch is discussed as a separate guideline below.)

The informed consent process for psychedelic-assisted therapy may be more involved relative to other drug classes, and psychedelic-assisted therapy practitioners aim to allow sufficient time to account for the challenge of explaining the subjective effects of psychedelic medications (Johnson et al., 2008). Additionally,

if more than one medication administration session is included in treatment, patients may wish to change their consent (e.g. regarding types of support they would like to receive) between medication administration sessions. As such, psychedelic-assisted therapy practitioners endeavor to begin the informed consent process at the earliest stages of screening and/or preparation and discuss consent with the patient throughout the model of care.

This guideline acknowledges the tension between respecting a patient's right to withdraw consent at any time and the critical need to maintain patient safety, particularly when patients are experiencing the effects of the psychedelic medication. Safety guidelines emphasize the importance of preparing for the possibility of a patient attempting to leave the treatment site while under the influence of a psychedelic medication and the safety imperative to minimize the chance of and prevent this from occurring (Johnson et al., 2008). Psychedelic-assisted therapy practitioners endeavor to ensure patients understand that while they may withdraw their consent to treatment at any time, such withdrawal does not supersede the need to remain onsite until it is safe for them to leave.

This guideline also acknowledges that an informed consent process specific to psychedelic-assisted therapy should be more thoroughly explored in a Code of Ethics. Until such a Code is adopted, this guideline aims to emphasize the critical importance of informed consent to the provision of psychedelic-assisted therapy, as in the provision of all healthcare services.

GUIDELINE 5

Psychedelic-assisted therapy practitioners specifically address the potential applications of touch in the informed consent process. Such consent includes

the patient’s right to refuse touch except in situations where touch is required to prevent serious injury, damage, or harm.

Rationale

Optional supportive or reassuring touch during medication administration sessions is a common component of treatment protocols in contemporary clinical trials involving psychedelic medications (e.g. Guss et al., 2020; Mithoefer et al., 2017). The specific risks and benefits of touch in this setting have yet to be determined. Psychedelic-assisted therapy practitioners understand that patients deserve information about the use of touch in psychedelic-assisted therapy so that they may express their preferences regarding touch and have those preferences respected by the practitioner.

While ethical guidelines for many mental health professions clearly prohibit sexual or intimate touch, they generally do not identify or describe other forms of touch that may be permissible and, in some cases, promote patients’ healing. The difficulties in discussing appropriate and therapeutic forms of touch persist despite the field’s acknowledgement of both the importance of touch in human communication and the presence of touch in psychotherapy from the field’s beginning (Berendsen, 2016; Montagu, 1986; Smith, 1998). Furthermore, several publications offer ethical and clinical guidelines for the use of touch in psychotherapy (Hunter & Struve, 1997; Smith et al., 2001).

As of the date of this publication, a Code of Ethics for psychedelic-assisted therapy has not been universally adopted by the field. Guidelines for the use of touch in psychedelic-assisted therapy should be more thoroughly explored in such a Code. Until a Code of Ethics is available, this practice guideline aims to emphasize the importance of addressing the potential use of supportive or reassuring touch in psychedelic-assisted therapy during the informed consent process.

Application

Psychedelic-assisted therapy practitioners recognize the importance of informed patient consent in the

provision of psychedelic-assisted therapy, as in the provision of all healthcare services. As part of this process, psychedelic-assisted therapy practitioners endeavor to ensure that patients understand how and when touch may be used in psychedelic-assisted therapy and understand their right to refuse touch other than that required to ensure the physical safety of themselves, others, and the environment.

Supportive forms of touch have been incorporated into many clinical trials of psychedelic-assisted therapy and one trial manual notes that touch “can be an important catalyst to healing” (Mithoefer et al., 2017). Johnson et al. (2008) note that if clinical trial participants become anxious during the medication administration session, “a supportive touch to the arm or shoulder” or “simply holding the hand of the participant,” can provide reassurance.

Mithoefer et al. (2017) also offer a framework for discussing touch with patients, stating that providers should make clear there is no expectation that the patient be touched at all, that the patient is always in control regarding touch and, if the patient has given consent for physical touch, discussing appropriate ways for the participant and provider to start, stop, and communicate about touch during the session.

Psychedelic-assisted therapy practitioners may find it useful to describe to patients the forms of touch relevant to psychedelic-assisted therapy and may find a taxonomy from Zur and Nordmarken (2011), based on the work of Downey (2001) and Smith et al. (1998), helpful in this endeavor. Six forms of touch classified by Zur and Nordmarken (2011) are likely most relevant to psychedelic-assisted therapy: consolation touch, reassuring touch, grounding or reorienting touch, touch intended to prevent a client from hurting his/her self, touch intending to prevent someone from hurting another, and self-defense. A seventh form of touch, task-oriented touch, such as occurs when taking a patient’s blood pressure or wiping a chin, is also relevant in this context. This guideline aims to distinguish between the first three forms of touch, which patients have the right to refuse, and the last four forms of touch, which may be necessary to ensure the safety of

the patient, providers, others in the vicinity, and the clinical environment.

Finally, psychedelic-assisted therapy practitioners understand that certain forms of touch are prohibited because they are inappropriate, unethical, counter-clinical, and in many states, illegal. These include sexual touch, hostile or violent touch, and punishing touch. Penn et al. (2021) state, “touch between therapists and patients is always intended to steady and comfort and is never sexual in nature.” Further, sexual touch or intimacy with a former patient or with any person over whom the psychedelic-assisted therapy practitioner has supervisory, evaluative, or other authority is unethical and unacceptable. Practitioners should refer to the most protective standard within the ethics requirements of their professional disciplines for guidance and accountability (e.g., American Psychiatric Association, 2013; American Psychological Association, 2017a; National Association of Social Workers, 2021). These issues should be more comprehensively discussed in a Code of Ethics.

GUIDELINE 6

Psychedelic-assisted therapy practitioners ensure that patients have been comprehensively screened in accordance with existing evidence, guidelines, and clinical judgment.

Rationale

As with any treatment, psychedelic-assisted therapy is not indicated for all patients with mental health, behavioral health, or substance use disorder diagnoses, and may in fact be contra-indicated for patients with specific conditions or who take specific medications. Nearly all recent randomized clinical trials of psychedelic-assisted therapy use exclusion criteria related to physical health, psychiatric health, medication use, or a combination of these (Carhart-Harris et al., 2021; Mitchell et al., 2021; Griffiths et al., 2016; Carhart-Harris et al., 2016; Mithoefer et al., 2019; Jerome et al.,

2020). Such exclusion criteria have been even more rigorous in trials of cancer patients with diagnoses of acute stress disorder or anxiety disorder related to their cancer diagnosis (Grob et al., 2011). The rigorous screening criteria used in modern research trials may be amended after FDA approval to give a broader patient population access to psychedelic-assisted therapy, but screening will nonetheless remain a critical and potentially challenging component of this model of care (Bradberry et al., 2022; Sky et al., 2022). As Reiff et al. (2020) and Johnson et al. (2018) note, administration of psychedelic medications should include patient screening to increase patient safety and minimize the potential for adverse events.

Application

This guideline endeavors to ensure that patients do not receive psychedelic-assisted therapy when it is not indicated or when the risks of treatment outweigh the benefits. In addition, this guideline recognizes that comprehensive patient screening includes many different elements which may vary by medication. Some of these screening elements may include conducting appropriate medical and psychiatric evaluations, weighing potential risks and benefits, assessing for contraindications, and determining the appropriateness of the potential practitioner and site of care for each patient. This guideline also acknowledges that exclusion criteria in clinical trials may be more restrictive than in future clinical practice and more research is needed into specific screening best practices for psychedelic-assisted therapy.

As noted above, modern clinical trials have largely used rigorous screening and exclusion criteria. In such a rapidly evolving field, psychedelic-assisted therapy practitioners endeavor to ensure their knowledge of patient screening requirements, exclusion criteria, and contraindications remains up to date for each medication with which they work. Even for patients who meet all criteria for psychedelic-assisted therapy, psychedelic-assisted therapy practitioners must use their clinical judgment to weigh the potential risks and benefits of a particular medication for a particular patient. Part of this judgment includes determining whether the practitioner team and site of care is best suited for the patient. This may include ensuring that the team’s

therapeutic approach will serve the patient's needs and that the site is able to handle any issues or complications that may arise.

Psychedelic-assisted therapy practitioners are also aware that cultural humility and sensitivity are particularly important during screening. Legacies of mistreatment and experiences of discrimination breed broad and persistent mistrust of the healthcare system, and psychedelic-assisted therapy practitioners are therefore highly attuned to the importance of both capturing a full health history and creating an open, respectful, culturally-sensitive environment in which patients can feel safe expressing various aspects of their life experiences and identity. A full health history can be particularly important for certain patients, given that institutional and systemic bias against marginalized groups places individuals at greater risk for poor health outcomes: higher rates of chronic disease; lower levels of healthcare coverage, access, and use; and disparities in social determinants of health (Hafeez et al., 2017; Hill et al., 2022; *Racism and Health*, 2021).

Finally, psychedelic-assisted therapy may be provided by a multidisciplinary team consisting of healthcare providers with scopes of practice that vary based on each provider's credential as well as state and local laws and regulations. While it is, therefore, challenging to determine precisely which member of the psychedelic-assisted therapy team should be responsible for conducting patient screening, this guideline aims to clarify that each person involved in the delivery of this care is responsible for ensuring that appropriate, comprehensive screening is complete.

GUIDELINE 7

Psychedelic-assisted therapy practitioners aim to build rapport and trust with patients during the preparatory period.

Rationale

As Murphy et al. (2022) note, "The importance of the therapeutic relationship in psychedelic-assisted ther-

apy has long been treated as a matter of conventional wisdom," and recent studies confirm its connection to improved patients outcomes. Johnson et al. (2008) describe developing rapport and trust as "the main purpose of" the preparatory sessions and key to "minimiz[ing] the risk of fear or anxiety reactions" during the medication administration session. Barone et al. (2019) offer many examples of patients who describe the combination of the medication and rapport with the therapy team as creating an environment for healing, and integral to the success of their treatment.

Psychedelic-assisted therapy practitioners also understand that the importance of trust and rapport go well beyond the medication administration session. The quality of the relationship between the patient and the practitioner "is a major determinant of psychotherapeutic effectiveness" (Saunders et al., 1989). The "outcome of a psychotherapeutic process" is often influenced by "a positive therapeutic climate" (Ardito & Rabellino, 2011). Trust and rapport are undoubtedly part of this overall positive climate, and a key element of treatment efficacy.

Application

Psychedelic-assisted therapy practitioners are aware that while building rapport can be a learned and practiced skill, trust must be earned and can only be given at the discretion of the patient. However, certain activities help develop such trust, including "discussions of the volunteer's childhood, romantic life, current relationships with family and friends, and the volunteer's philosophical and/or spiritual beliefs" (Johnson et al., 2008). Johnson et al. (2008) note that such an interaction conveys that "all aspects of the person are welcome, from the petty to the noble, from embarrassments to achievements, and from sorrow to joy."

Research on practitioner-patient relationships from outside the psychedelic-assisted therapy field also offers clues to reducing patient anxiety and building trust. Helpful behaviors include providing reassurance to patients, encouraging them to ask questions, showing and explaining test results (if applicable), avoiding language and behaviors that are judgmental of patients, and asking patients about their treatment goals and preferences (Dang et al., 2017).

Practitioners also understand that cultural humility and sensitivity is a key element in building rapport and trust with patients. Practitioners aim to embody cultural humility and sensitivity by understanding, respecting, and responding to a patient's experiences, values, and beliefs. Practitioners understand that true cultural humility and sensitivity has a strong backbone of ongoing curiosity and exploration and is "defined not by a discrete endpoint but as a commitment and active engagement in a lifelong practice" (Tervalon & Murray-García, 1998). Further, psychedelic-assisted therapy practitioners aim to maintain awareness of cultural appropriation: the unacknowledged or inappropriate use of the cultural elements of one population by members of another people or society. In psychedelic-assisted therapy, this may include use of certain iconography, music, therapeutic traditions, or other elements. The use of such elements must be approached with caution and consideration to ensure appropriate cultural acknowledgement, recognition, appreciation, and deference.

Maintaining professional boundaries is another crucial element of building and sustaining trust. Key elements include maintaining a professional therapeutic relationship, managing transference and countertransference, upholding confidentiality, and preventing and addressing confusion or ambiguity about the parameters of a professional therapeutic relationship and the role of the practitioner.

Psychedelic-assisted therapy practitioners are also aware that if rapport and trust cannot be developed during the preparatory sessions, as determined by either the practitioner or the patient, the patient should not proceed to the medication administration session (Johnson et al., 2008). In fact, studies routinely screen for patients with "suspected or known presence of a preexisting psychiatric condition that could jeopardize rapport between the patient" and practitioners (Carhart-Harris et al., 2021). In such circumstances, psychedelic-assisted therapy practitioners seek to determine whether the patient should be referred to a different practitioner(s), clinic(s), or center(s) where rapport and trust might be established, or whether psychedelic-assisted therapy may not be indicated for a particular patient.

GUIDELINE 8

Psychedelic-assisted therapy practitioners prepare patients for a medication administration session by inviting them to share their personal histories, explaining medication administration session logistics, reviewing the range of possible experiences during the medication administration session, discussing potential therapeutic approaches that may be used, providing guidance for navigating challenging experiences that could arise, and answering patient questions.

Rationale

Psychedelic-assisted therapy practitioners understand the importance of using the preparatory period to comprehensively orient patients to the medication administration session. Such orientation allows patients to understand logistical details of the session, understand the range of possible experiences during the session, discuss various therapeutic approaches that may be used, and hear guidance on how to navigate challenges that may arise. This orientation can significantly reduce stress and anxiety both leading up to, and during, the medication administration session.

Application

Given the evolving nature of the psychedelic-assisted therapy field, evidence does not yet point towards specific best practices for the preparatory period. However, expert consensus exists around a number of key elements. First, practitioners use the prepara-

tory sessions to invite patients to share their personal histories. During a medication administration session, patients may experience “intense thoughts, feelings, and visions related to his or her personal history or world-view” (Belser et al., 2017; Johnson et al., 2008). Psychedelic-assisted therapy practitioners understand that their ability to offer interpersonal support in such circumstances is improved by a more comprehensive knowledge of the “emotional and autobiographical material that is likely to emerge during the psychotherapy” (Penn et al., 2021).

Second, practitioners orient patients towards the possible range of experiences that may be encountered during the medication administration session. This allows patients to anticipate both the potential physical sensations, such as nausea or “heightened awareness of physiological processes such as breathing and heartbeat” (Johnson et al., 2008), and the range of unusual or challenging psychological, emotional, and mystical-type experiences that may be encountered (Belser et al., 2017). Practitioners then provide guidance on how to manage any challenging experiences that arise. Strategies might include verbal or nonverbal reassurance, surrendering to the experience, interacting with it, trusting that a usual state of consciousness will return, and many others.

Third, psychedelic-assisted therapy practitioners aim to use the preparatory period to establish alignment between their own therapeutic approach or potential therapeutic approaches and the patient’s desires. Some researchers call this a “therapeutic alliance” and identify it as the “focus” of preparatory sessions (Mitchell et al., 2021). Others call such discussion of therapeutic approach core to the informed consent process, as it allows patients to have a full understanding of the process and treatment in which they are consenting to participate.

Finally, offering patients detailed logistical information about the medication administration session, including basic elements such as timing, location, diet, and transportation, as well as how and when practitioners will communicate with a patient’s support person or emergency contact(s), can ease anxiety and improve safety of the overall experience.

Additional research into best practices for the preparatory period of psychedelic-assisted therapy is strongly encouraged. In the absence of such data, however, this guideline remains agnostic as to how psychedelic-assisted therapy practitioners ensure that patients are prepared for the medication administration session. In fact, psychedelic-assisted therapy practitioners understand that some variation in preparation may actually contribute to the work of identifying best practices in the field.

GUIDELINE 9

Psychedelic-assisted therapy practitioners aim to facilitate a safe and therapeutic medication administration session conducted in a comfortable and confidential setting.

Rationale

Psychedelic-assisted therapy practitioners maintain focus on the provision of a safe and therapeutic patient experience throughout the medication administration session. Detailed guidance regarding how psychedelic-assisted therapy practitioners may endeavor to ensure a safe and therapeutic patient experience is most appropriate for inclusion in clinical practice guidelines, as particular practice considerations will likely vary based on the patient’s diagnosis and the psychedelic medication being utilized. Therefore, this guideline aims to provide high-level guidance for practitioners that may be generalizable across most psychedelic medications and diagnoses.

By ‘safe’, this guideline refers to both physical and psychological safety. As such, the physical setting for the medication administration session is key—it serves as “the container in which the treatment will take place” (Penn et al., 2021). Psychedelic-assisted therapy practitioners are particularly mindful of setting because patients experiencing medication effects may be more sensitive to, or influenced by, the environment.

Application

Psychedelic-assisted therapy practitioners are aware that a safe and therapeutic patient experience during the medication administration session begins with a safe, comfortable, confidential, and therapeutic setting. Research has not yet connected particular elements of a medication administration setting to particular treatment outcomes. In the absence of such data, many practitioners continue to rely on settings used in early models of psychedelic-assisted therapy. Psychedelic-assisted therapy practitioners understand the importance of using creativity and innovation to test new setting designs as the field evolves. This guideline is intended to encourage flexibility in setting construction within the boundaries of a safe, comfortable, confidential, and therapeutic environment, understanding the significance of the space.

A comfortable setting may vary by condition. This guideline is written in the context of ongoing clinical trials, when medication administration sessions can extend for six hours or more. Future developments in the field could result in medication administration sessions of varying length, depending on the medication type and dose. What is comfortable over a six-hour period may be very different from what is comfortable over a two- or twelve-hour period, and this guideline should be reevaluated in such a context.

This guideline is not intended to limit a setting to one patient. The use of “confidential” is intended to imply that medical and personal information shared within the context of a medication administration session will not be disclosed to others without the patient’s explicit consent. This limitation can be drawn around a single patient and a practitioner(s), or around multiple patients and a practitioner(s), as might be the case in a group therapy session.

Practitioners also understand that the foundational elements of a safe and therapeutic overall patient experience include providing a consistent therapeutic presence, supporting patients in managing anxiety and distress, and ensuring for safe discharge and after-care. A patient’s definition of “safe and therapeutic” may vary based on their personal history, cultural background, gender, age, or many other factors.

Psychedelic-assisted therapy practitioners are sensitive to, and curious about, these differences and adapt their practice as necessary to provide a safe and therapeutic experience for each patient.

At a minimum, psychedelic-assisted therapy practitioners endeavor to provide a consistent therapeutic presence by ensuring the patient is attended to throughout the medication administration session (Johnson et al., 2008). Research has not conclusively determined how many providers must be present throughout the preparatory, medication administration, and integration sessions. The relative efficacy of the presence of one, two, or more practitioners throughout the psychedelic-assisted therapy model of care is currently unknown. In the absence of a best practice, this guideline reinforces that patients should not be unattended during the medication administration session.

Supporting patient management of anxiety and distress may include, as noted by Mithoefer et al. (2017), encouraging patients to stay with these feelings and experience them fully and responding “with strong personal support and reassurance, conveying a sense of calm and security, while empathizing with what the patient may be experiencing” (Johnson et al. 2008). Further, psychedelic-assisted therapy practitioners recognize that behavior which might appear pathological outside of a medication administration session should not necessarily be characterized in the same way when a patient is experiencing the effects of the medication. This may be particularly true of patients working through trauma.

Finally, psychedelic-assisted therapy practitioners endeavor to facilitate safe after-care by ensuring the patient has been assessed for discharge from the treatment location. Such assessment may include a mental status exam, assessment of physical safety (including vital signs, coordination, gait steadiness), and inquiring about any lingering effects (Guss et al., 2020).

Psychedelic-assisted therapy practitioners monitor patients for adverse events both during and following the medication administration session, and ensure that complications are addressed.

Rationale

Psychedelic-assisted therapy practitioners are principally concerned with patient safety. Providing for such safety includes readiness to address any treatment-emergent adverse events (TEAEs) that may arise, including persisting TEAEs. Adverse events noted in clinical trials include, but are not limited to, anxiety, depressed mood, irritability, panic attack, transient confusion or thought disorder, nausea, headache, dizziness, lack of appetite, sensory disturbances, and fatigue (Bradberry et al., 2022; Carhart-Harris et al., 2016; Mithoefer et al., 2019). These adverse reactions can last for hours or for days, and can include mood, psychotic, and anxiety disorders (Johnson et al., 2008). Johnson et al. (2008) note “rare reports in which hallucinogen exposure appears to cause, accelerate, or precipitate the onset of significant or lasting psychiatric illness.” Psychedelic-assisted therapy practitioners are therefore prepared to address such events to help ensure optimal patient outcomes.

Application

Many safety considerations for a medication administration session mirror those for other medical procedures: ensuring that a physician is available for any medical complications that arise; systematically monitoring for adverse events; ensuring that medication is available for specific adverse events like sustained and severe hypertension, tachycardia, or allergic reactions; planning for the safe and private use of a restroom; and planning for unforeseen events like a fire alarm.

Some TEAEs may be more specific to the use of psychedelic medications, including anxiety, depressed

mood, irritability, panic attack, and transient confusion or thought disorder. For psychedelic medications, safety concerns are “largely psychological rather than physiological in nature” (Johnson et al., 2008). Psychedelic-assisted therapy practitioners have specific behavioral strategies for supporting patients through challenging experiences: monitoring the patient for signs of discomfort, offering strong psychological support and reassurance, conveying a sense of calm and security, and empathizing with the patient’s experience (Johnson et al., 2008). Johnson et al. (2008) note that adverse reactions will be minimized in scenarios that “provide strong interpersonal support to the participants.” If it is within their scope of practice, psychedelic-assisted therapy practitioners are also prepared to use emergency medications as indicated (e.g. benzodiazepines or antipsychotics) for patients in severe, prolonged distress who are unresponsive to reassurance or other forms of interpersonal support. Such medications, however, have their own psychological side effects, and psychedelic-assisted therapy practitioners aim to limit their use to circumstances where behavioral strategies have failed.

This guideline is careful to note that while psychedelic-assisted therapy practitioners ensure that complications are addressed, psychedelic-assisted therapy practitioners are not expected to be equipped to handle all complications themselves. Throughout the course of a medication administration session, a patient may be monitored by several members of a multidisciplinary care team, who should have the ability to engage in real-time communication via telephone or messaging about the patient. Given that monitors may operate within different scopes of practice, not every monitor will be equipped to address every issue that arises during a medication administration session. The guideline allows for additional providers to be consulted and directed to attend to a patient, including the use of an emergency department if necessary.

This guideline also acknowledges that treatment groups in clinical trials conducted to date have been carefully screened for preexisting psychiatric and medical conditions. As Carhart-Harris et al. (2021) acknowledge, “this exclusion criterion may have biased the trial sample towards patients who could receive

psilocybin without unacceptable side effects.” Psychedelic-assisted therapy practitioners are aware that FDA approval of a psychedelic-assisted therapy may widen the patient population with access to such treatment, and that the profile of adverse events seen in trials may not reflect the experience of the broader population, as may occur when any pharmaceutical is approved by the FDA.

Lastly, this guideline intentionally does not define the frequency of contact between the psychedelic-assisted therapy practitioner and the patient after a medication administration session, given the inadequacy of existing data to define a best practice. Some studies included four telephone contacts over the seven days following medication administration, but even these studies suggest this number may be higher than is necessary (Mithoefer et al., 2019). More research into best practices in this area is needed.

GUIDELINE 11

Psychedelic-assisted therapy practitioners support patients in understanding and making meaning of their psychedelic medication experience and incorporating desired changes into their lives.

Rationale

Psychedelic-assisted therapy practitioners understand the psychedelic medication experience (or experiences) as “a step in an ‘ongoing process’ rather than simply a completed cure” (Mithoefer et al., 2012). The experience is not an end in and of itself. The goal of the integration sessions, therefore, is for the patient to implement and incorporate “the key insights and awareness gained in the psychedelic experience into their life” and to “maximize the likelihood that the psychedelic experience will lead to greater self-insight and personal development” (Amada & Shane, 2022; Bathje et al., 2022). Psychedelic-assisted therapy practitioners

support patients as they explore the thoughts, feelings, and sensations that arose during their experience, cultivate insights from that experience, and support any changes patients seek to make in their life based on that experience. Without integration, “insights gained are likely to fade without actualizing meaningful change” (Bathje et al., 2022).

Application

The psychedelic-assisted therapy literature references multiple mechanisms for allowing the process of integration to unfold. Johnson et al. (2008) discuss integration as “an opportunity for the patient to discuss thoughts or feelings” while Mitchell et al. (2021) describe it as allowing “the participant to understand and incorporate their experience.” Griffiths et al. (2016) focus on the “novel thoughts and feelings that arose during sessions.” Bathje et al. (2022) describe “ten well-elaborated approaches to integration,” some developed “with consideration to altered states of consciousness and psychedelic experiences, while others were developed for general psychotherapy.”

Recent years have seen the development of a number of thoughtful therapy manuals and protocols used for clinical trials of psychedelic-assisted therapy. At some point, these may form the foundation for a more universally-accepted, evidence-based therapy protocol going forward. Even in this future environment, however, integration will remain a patient-directed process. While psychedelic-assisted therapy practitioners may inspire, instruct, and coach patients, they bring curiosity about a patient’s “innate knowledge and tendency to orient toward healing, growth, and wholeness” (Bathje et al., 2022).

In facilitating a patient’s processing of a psychedelic medication experience, psychedelic-assisted therapy practitioners aim to contextualize the experience within the broader fabric of a patient’s personal history, strengths, challenges, and goals. As Bathje et al. (2022) describe, psychedelic medications do not offer healing on their own, but “may give us an experience of and orientation toward wholeness, along with insight into the barriers and misalignments that will need to be addressed to continue toward or maintain wholeness.”

Similarly, the use of “understanding” in this guideline is not intended to imply finality or achievement. Psychedelic-assisted therapy practitioners understand that integration is not complete when sessions end; it can be an ongoing process. The psychedelic medication experience is intended to inspire understanding that unfolds and evolves over time. The relevance of the experience may even change over time, as patients move through their lives. Ideally, this evolving understanding spurs a set of ongoing practices that support the patient in fulfilling their treatment goals.

Likewise, psychedelic-assisted therapy practitioners understand that only patients can decide if their treatment has catalyzed a desire for incorporating behavioral changes into their life. While the practitioner may remind a patient of their original intentions for psychedelic-assisted therapy and/or query potential options for the patient to consider, the patient themselves decides what is a significant and meaningful outcome for them. Belser et al. (2017) describe patients who made “a shift in their life priorities away from the busy demands of modern work life,” others who “put up boundaries against various stressors,” and still others who committed to dietary and health goals. For some patients, however, such concrete change(s) may not be a treatment goal, and psychedelic-assisted therapy practitioners are sensitive and responsive to such differing goals.

GUIDELINE 12

Psychedelic-assisted therapy practitioners communicate and coordinate with other relevant providers to ensure continuity of care.

Rationale

Care coordination involves “deliberately organizing patient care activities and sharing information among all participants concerned with a patient’s care to achieve safer and more effective care” (*Care Coordination*, 2018). Care coordination is “increasingly recognized as

fundamental to the success of healthcare systems and improved patient outcomes” and is therefore of concern to every psychedelic-assisted therapy practitioner (“Care Coordination Standing Committee,” 2014). As the Care Coordination Standing Committee of the National Quality Forum (2014) writes, “poorly coordinated care regularly leads to unnecessary suffering for patients as well as avoidable readmissions and emergency department visits, increased medical errors, and higher costs.”

In psychedelic-assisted therapy, coordination with primary care and specialty physicians during screening could offer access to physical examination and laboratory testing information without needing to repeat such testing. Coordination with a patient’s other mental health providers, if applicable, could be significantly instructive for both screening and preparation, helping the psychedelic-assisted therapy practitioner understand the patient’s history and goals. Such coordination could also allow a patient to transition smoothly back to their usual source of mental health care after a course of psychedelic-assisted therapy (if their usual provider does not offer psychedelic-assisted therapy), potentially offering that provider more understanding of the nature of psychedelic-assisted therapy and ways to support the patient.

Application

Care coordination is essential to providing safe and effective screening prior to initiating psychedelic-assisted therapy for a number of reasons. First, patients with behavioral health diagnoses have a high prevalence of comorbidities. For example, depression occurs in 40 to 65 percent of patients who have experienced a heart attack, 10 to 27 percent of stroke survivors, roughly 25 percent of those suffering from cancer, and 25 percent of individuals with adult onset diabetes (*Co-Occurring Disorders and Depression*, n.d.). Second, psychedelic medication may interact with other medications the patient may be taking, which are prescribed by care providers outside of the psychedelic-assisted therapy team. Finally, psychedelic medications can produce side effects, necessitating careful care coordination with the multidisciplinary team members who manage various aspects of the patient’s overall care. Coordinated treatments for patients with such comorbidities and

concurrent medication use is vital to ensuring positive outcomes on all health metrics. When engaging in care coordination that involves sharing patient information, psychedelic-assisted therapy practitioners protect and respect patient privacy by complying with all relevant state and federal privacy laws regarding the confidentiality, use, and disclosure of clinical records for care and treatment.

Care coordination is particularly important within a patient's team of mental health providers. While not all patients will have been referred to psychedelic-assisted therapy from another source of mental health care, coordination is key when such relationships exist. Provider-level coordination across mental health treatment modalities can offer consistent therapeutic guidance for a patient, consistent support for self-management, reinforcement of trust and rapport between patient and provider, and better opportunities for long-term success.

Psychedelic-assisted therapy practitioners recognize that many patients may already be part of a coordinated care structure. These structures function as a healthcare "home," or the central point for managing continuity of care, the patient's plan of care, and importantly, policies and procedures for collaborations between primary care and specialist providers. Psychedelic-assisted therapy practitioners recognize the importance of coordinating their work with these broader healthcare structures to support high-quality patient care.

STATUS/EXPIRATION

These guidelines expire two years from the date of publication. Several factors contribute to the brevity of this time frame. First, research on psychedelic medications—and particularly on psychedelic-assisted therapy—is limited. These guidelines were written based on a relatively small pool of evidence, buoyed meaningfully by the consensus of experts in the field. Future guidelines will be improved by the proliferation of new research, adding impartial insights on safety and efficacy. Second, the psychedelic-assisted therapy field is early in the development of potential infrastructure to support its work. These might include: an independent certification for psychedelic-assisted therapy practitioners, accreditation for educational programs

in psychedelic-assisted therapy, and a universally-accepted Code of Ethics. Creation of such infrastructure could change the landscape in which these guidelines exist. Third, the field is hopeful that the FDA will grant approval for at least one psychedelic-assisted therapy within the next two years. That regulatory change will drastically alter the landscape for psychedelic-assisted therapy and merit a review of these guidelines.

CONCLUSION AND RECOMMENDATIONS FOR FUTURE WORK

Development of these guidelines was constrained by the limited research in the field of psychedelic-assisted therapy, which is itself challenged by the classification of psychedelic medications as Schedule I substances (as of spring 2023). Furthermore, the largely homogenous population of clinical trial volunteers makes it difficult to develop guidelines that reflect the experience of the more diverse group of patients who will hopefully access these therapies following FDA approval. In addition, the focus of modern clinical trials on the safety and efficacy of the medication, while understandable, limits the available data on how different elements of the entire model of care contribute to a successful patient outcome.

Moving forward, the field is strongly encouraged to generate research on psychedelic-assisted therapy with a keen focus on the inclusion of diverse trial volunteers subject to expanded screening parameters to provide data that accurately identifies the patients who are likely to benefit. In addition, researchers are urged to report on diverse populations in subgroup analyses by population. Further, the field is encouraged to generate research that tests the discrete elements of the model of care to inform best practices that support optimal patient outcomes.

Despite these limitations and the need for additional research and field infrastructure, the establishment of foundational guidelines for this evolving treatment modality is important and necessary. Additional research and additional guidance for the field in the form of a Code of Ethics, inclusion of psychedelic-assisted therapy in clinical practice guidelines, and more, will build upon and revise this initial effort aimed at establishing a benchmark for the provision of safe, high-quality psychedelic-assisted therapy.

Appendix

GUIDELINE WRITING WORKGROUP MEMBER BIOGRAPHIES AND CONFLICT OF INTEREST DISCLOSURES

The guideline writing workgroup was composed of the following individuals who reported these disclosures during development and approval of the guidelines:

Anthony Back, MD, is Professor of Medicine at the University of Washington in Seattle, where he practices Palliative Medicine and was the founding co-director of the Cambia Palliative Care Center of Excellence. He was also co-founder of VitalTalk, a nonprofit. Dr. Back currently receives research funding from The John A Hartford Foundation, the Cambia Health Foundation, the Steven and Alexandra Cohen Foundation, the Rita and Alex Hillman Foundation, the Riverstyx Foundation, and Cybin, Inc., and has been paid for educational and facilitation work by the California Institute for Integral Studies and the Synthesis Institute. His prior research funding includes the National Cancer Institute, National Institutes of Health, the Patient-Centered Outcomes Research Institute, and other foundations. He reports no other conflict of interest with his work on these guidelines.

Mark Bates, PhD, is a clinical psychologist and psychedelic-assisted therapy therapist and researcher with Sunstone Therapies. He was previously in a leadership position at the Department of Defense Psychological Health Center of Excellence for nine years as well as a training director for an Air Force clinical psychology internship program. His work supporting psychological health in the military included helping review, create, and implement psychological health guidelines and training programs. He reports no other conflict of interest with his work on these guidelines.

Shannon Carlin, LMFT, is a psychedelic therapist and researcher with a focus on therapy training, ethics, and organizational development. For 12 years, Ms. Carlin worked at the Multidisciplinary Association for

Psychedelic Studies (MAPS) and MAPS Public Benefit Corporation (MAPS PBC) developing psychedelic therapy training and supervision programs, therapeutic approaches, harm-reduction services, and ethical standards. As Chief of Therapy Training and Supervision, Ms. Carlin led training programs to prepare clinicians around the world to deliver MDMA-assisted therapy. As a member of senior leadership, she facilitated organizational development projects to improve and integrate company values, diversity, inclusion, belonging, conscious leadership, and mental health awareness. Ms. Carlin is committed to elevating work culture to empower people and communities. Ms. Carlin was a co-therapist on two MAPS-sponsored Phase 2 trials researching MDMA-assisted therapy and has previously worked with the California Center for Psychedelic Therapy and Kadima Neuropsychiatry Institute delivering ketamine-assisted psychotherapy. Ms. Carlin practices transpersonal psychotherapy and psychedelic integration with a client-centered orientation. She received her master's degree in Integral Counseling Psychology from the California Institute of Integral Studies and a bachelor's degree in Cultural Anthropology from the University of California, Santa Cruz. Today, Ms. Carlin serves in consulting and advisory roles with MAPS PBC and other psychedelic therapy and harm-reduction organizations. Ms. Carlin receives compensation as an independent contractor with MAPS PBC. She reports no other conflict of interest with his work on these guidelines.

Natalie Gukasyan, MD, is a psychiatrist and Assistant Professor at Johns Hopkins University. Dr. Gukasyan completed a National Institute on Drug Abuse T32-funded research fellowship in behavioral pharmacology under the mentorship of Dr. Roland Griffiths, focusing on safety and efficacy of psilocybin-assisted therapy for people with mood and eating disorders. Dr. Gukasyan now serves as the Medical Director of the Johns Hopkins Center for Psychedelic and Consciousness Research, where she has continued to research novel treatment approaches involving psychedelics.

Dr. Gukasyan is a co-investigator on a multi-site study of psilocybin for major depressive disorder, funded by Usona Institute (a non-profit organization). She has received salary support from philanthropic contributions from the Steven and Alexandra Cohen Foundation, Tim Ferriss, Matt Mullenweg, Craig Nerenberg, and Blake Mycoskie. She previously received salary support from the National Institute on Drug Abuse T32DA07209. She reports no other conflicts with her work on these guidelines.

Andrew Penn, MS, PMHNP, is a Clinical Professor of Nursing at the University of California, San Francisco. He is an attending NP at the San Francisco VA and a member of the UCSF Translational Research Program in Psychedelics (TRPR) lab. He has received research funding from the Multidisciplinary Association for Psychedelic Studies (MAPS), Usona Institute, and Filament. He is on the community advisory board of Tactogen and Osmind and has been a consultant to Compass Pathways, MindMed, and the Alexander Shulgin Research Institute. He has received compensation for teaching with the North American Center for Continuing Education (NACCME) and the California Institute for Integral Studies Center for Psychedelic Therapies and Research (CIIS-CPTR). He reports no other conflicts of interest with his work on these guidelines.

Jordan Slosower, MD, MSc., is co-director of West Rock Wellness, PLLC and a clinical instructor in the Yale Department of Psychiatry. Dr. Slosower is also a clinical investigator in MAPS' Expanded Access Program for MDMA-assisted therapy of PTSD and a consulting trainer with Usona Institute and Cybin. Reflecting his commitment to ethical stewardship of psychedelic medicines, Jordan serves on the Board of Directors of, and is a paid consultant with, the American Psychedelic Practitioners Association and is a member of Chacruna Institute's Council for the Protection of Sacred Plants. He reports no other conflicts of interest in his work on these guidelines.

Will Van Derveer, MD is co-founder of the Integrative Psychiatry Institute (IPI), LLC, course director for the IPI psychedelic-assisted therapy training, and medical director of the Integrative Psychiatry Center of Boulder, LLC. He reports no other conflicts of interest in his work on these guidelines.

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BRAINFUTURES

BrainFutures was launched in 2015 by the nation's second oldest mental health advocacy organization, the Mental Health Association of Maryland (MHAMD). For more than 100 years, MHAMD has addressed the mental health needs of Marylanders of all ages through programs that educate the public, advance public policy, and monitor the quality of mental healthcare services. Building on this success, and bolstered by a cross-disciplinary advisory board of leading experts, BrainFutures brings together diverse stakeholders, policy-makers, funders, and influencers to accelerate and scaffold national adoption of effective practices targeting four main areas: youth, workforce, mental health treatment, and older adults. Breakthroughs in our understanding of the brain have the potential to improve learning outcomes for children, optimize functioning at work, enhance treatment for mental health or substance use problems, and maintain sharp thinking as we age.

BrainFutures writes evidence-based issue briefs and releases recommendations that fill knowledge gaps related to brain-focused applications targeting the above segments of society. These educational resources highlight the latest advances in brain plasticity and how their application is transforming quality of life for people of all ages. Through this process, we not only gain insight from experts and innovators, we also foster support for change, building coalitions and cross-disciplinary collaborations to advance both adoption and access to new breakthrough applications. Ultimately, by informing the public, cultivating influential relationships, and connecting communities of diverse advocates we help propel the change that is needed to make meaningful progress.

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