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Unlocking the Therapeutic Potential of Psychedelics: Legal and Ethical Considerations

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This article explores the rapidly growing field of psychedelic-assisted therapy. It examines the therapeutic potential of these substances while addressing the legal and ethical frameworks surrounding their use. Psychedelic substances like psilocybin and MDMA have shown promising results in treating mental health conditions such as depression, anxiety, and PTSD. Despite these advancements, legal barriers and ethical considerations pose a challenge to their integration into mainstream therapy. In a 2023 survey, the UC Berkeley Center for the Science of Psychedelics revealed that 61% of American registered voters spoke in favour of legalizing regulated access to psychedelics for therapeutic purposes. Additionally, 78% of voters supported making things easier for researchers to study these substances. This article dives into the historical and contemporary use of psychedelics, and the current legal status in India and other countries, and tries to propose necessary reforms. The matters of patient safety and informed consent are also thoroughly analyzed. The article concludes by promoting a balanced legal and ethical framework that can utilize the therapeutic benefits of psychedelic substances while ensuring patient safety.

Keywords: *psychedelic-assisted therapy, psilocybin, legal framework, mental health.*

INTRODUCTION

Psychedelics usually refer to a certain type of drug that changes a person's perception of reality. They are also commonly known as 'hallucinogens'. They have the effect of making a person see, feel and hear things that are not real. They can distort a person's interpretation of things happening around them. This state of being under the influence of a psychedelic is known as 'tripping'. Psychedelics work by targeting specific centres of the brain to alter its understanding of sensory input. Because of that, psychedelics can be very unpredictable drugs. An enjoyable trip for the first time does not guarantee that the experience will always be pleasant.

Some common psychedelics can be identified as LSD, Psilocybin, Mescaline, Ayahuasca etc. LSD usually comes in small squares of blotting paper or gelatin soaked in the substance. Psilocybin, commonly referred to as magic mushrooms, can be cooked, boiled into a drink, or even eaten raw. Mescaline is found in peyote cactus as a white powder. Ayahuasca is a plant-based hallucinogenic tea. Apart from these natural sources, synthetic psychedelics are also developed in modern times.

Psychedelics as a class of drugs cannot be fully understood without referring to some other fields of research such as anthropology, ethnopharmacology, psychiatry, psychology, and sociology, to name a few. These substances have been deeply rooted in different human cultures from very ancient times. In ancient Indian texts including the Rigveda, there are mentions of a substance known as 'Soma', known for its relation to divine revelations. In the ancient village of Eleusis, outside Athens, for over 2000 years an annual all-night secret ceremony used to take place, which involved the ingestion of a hallucinogenic brew. Psilocybin mushrooms were used by Aztec shamans for healing and various religious rituals. Ayahuasca has a long history of use by natives in South America.

In this article, first, we shall explore the therapeutic potential of these drugs. Contemporary research on psychedelics has shown promising development in treating mental health issues like depression, anxiety, PTSD etc. We shall follow the development of research on psychedelics through the 20th century until modern times. We shall also look at the potential downsides and risks of psychedelic-assisted therapy. Then, we shall take a look at the legal status of psychedelic

drugs in different countries, including India. We shall analyze the prevalent legal restrictions to the research and use of psychedelics in therapy settings, and we shall also explore potential legal reforms necessary for the advancement of this field. And finally, we shall delve into the ethical considerations of these drugs from the perspective of the therapists. We shall examine the potential ethical risks faced by both patients and therapists. We shall try to navigate the steps that could be taken to mitigate those risks.

THERAPEUTIC POTENTIAL OF PSYCHEDELIC DRUGS

In the early 1950s, psychedelics had a sudden surge of use in research and clinical practices. It is estimated to have been used to treat tens of thousands of patients for around 15 years. These drugs piqued the interest of psychologists after the discovery that they could be tools for significantly shortening psychotherapy. A recent meta-analysis of 19 studies on psychedelics that were published between 1949 and 1973 found that almost 79% of patients showed a clinically judged improvement after psychedelic-assisted therapy¹. However, due to a plethora of reasons to be discussed in the later sections of this article, psychedelic therapy research fell into a complete hiatus until its revival in the 1990s by scientists in Germany, the USA, and Switzerland.²

The modern resurgence era of psychedelics has seen a more controlled approach with careful experiment designs and a more critical approach to outcomes. Contemporary researchers have found rapid and enduring anti-anxiety and depression effects after treatment with psilocybin. There have also been significant improvements in obsessive-compulsive disorder symptoms. While traditional chronic antidepressant action includes reduced limbic responsiveness and emotional moderation or blunting, with psychedelics there is an emphasis on emotional release.³

¹ James Rucker et al., 'Psychedelics in the treatment of unipolar mood disorders: A systematic review' (2016) 30(12) *Journal of Psychopharmacology* <https://www.researchgate.net/publication/310585834_Psychedelics_in_the_treatment_of_unipolar_mood_disorders_A_systematic_review> accessed 17 June 2024

² Robin L. Carhart-Harris and Guy M. Goodwin. 'The Therapeutic Potential of Psychedelic Drugs: Past, Present, and Future' (2017) 42(11) *Neuropsychopharmacology* <<https://www.nature.com/articles/npp201784>> accessed 17 June 2024

³ *Ibid*

Various recent studies with psychedelic-assisted therapy have given rise to groundbreaking findings. In treatment for obsessive-compulsive disorder, all patients have shown improvements within 24 hours of the treatment. Patients with end-stage cancer dealing with anxiety and depression, have seen significant reductions in anxiety at 3 months and depression at 6 months. Even in cases of addiction like long-term chronic tobacco smoking and alcohol dependence, there has been a significant level of abstinence at 6 to 9 months follow-up.⁴

Psychedelic treatment involves micro-dosing which means administering small amounts of the substance. This is done to produce benefits without the risk of 'bad trips' or triggering intense hallucinatory effects. Because as beneficial as psychedelics can be for the treatment of mental health, studies also show that there are potential downsides when the use of mind-altering substances is concerned. The whole field of study is still very much in an early stage. While positive effects have been discovered, there have always been caveats to those findings. Let us examine the advantages and disadvantages of some common psychedelics:⁵

Psilocybin: Studies have found that therapy with the help of psilocybin has produced 'large, rapid, and sustained antidepressant effects.'⁶ However, it has also shown a higher rate of serious adverse events in participants. Side effects include anxiety, panic attacks, paranoia, feelings of fear and depression, nausea, and numbness.

MDMA: Following treatments with MDMA, almost 67% of participants no longer met the diagnostic criteria for PTSD. Researchers have concluded that 'MDMA-assisted therapy represents a potential breakthrough treatment that merits expedited clinical evaluation.'⁷ But at the same time, MDMA users are 3.5 more likely to experience adverse events, including anxiety, jaw clenching, blurred vision, nausea, sweating, and chills.

⁴ Ibid

⁵ 'The Pros and Cons of Psychedelics in Psychiatry' (*Amen Clinics*, 21 May 2021)

<<https://www.amenclinics.com/blog/the-pros-and-cons-of-psychedelics-in-psychiatry>> accessed 17 June 2024

⁶ Alan K. Davis et al., 'Effects of Psilocybin-Assisted Therapy on Major Depressive Disorder' (2021) 78(5) *JAMA Psychiatry* <<https://www.ncbi.nlm.nih.gov/pmc/articles/PMC7643046/#!po=3.12500>> accessed 17 June 2024

⁷ Jennifer M. Mitchell et al., 'MDMA-assisted therapy for severe PTSD: a randomized, double-blind, placebo-controlled phase 3 study' (2021) 27(6) *Nature Medicine* <<https://www.nature.com/articles/s41591-021-01336-3>> accessed 17 June 2024

LSD: Researchers suggest that low doses of psychedelics might lead to decreased depression by inducing cognitive flexibility. But microdosing LSD can last for weeks and potential side effects include hyperactivity, heightened aggression, and difficulty in feeling pleasure.⁸

Ketamine: Numerous studies have pointed out ketamine's positive effects on major depressive disorders, especially with treatment-resistant depression. Ketamine can very quickly trigger antidepressant effects. At the same time, ketamine may be addictive and can cause high blood pressure, dizziness, and nausea.⁹

It is evident that while the therapeutic potential of psychedelic drugs is undeniably promising, these treatments must be approached with caution as well. The potential and serious adverse effects like anxiety, and paranoia among others emphasize the need for carefully controlled and monitored applications in therapy. Moreover, further research is essential to understand the benefits and limitations of psychedelics fully.

LEGAL FRAMEWORK FOR PSYCHEDELIC-ASSISTED THERAPY IN INDIA AND INTERNATIONAL CONTEXT

The therapeutic benefits of psychedelics are slowly but surely gaining recognition worldwide. However, scholars like to argue that legal frameworks significantly get in the way of their research and clinical application.

Psychedelics are found to be deeply ingrained in the history of Indian culture as well. In the Vedas, there is mention of 'soma', a sacred plant associated with divine experiences. Some experts believe this could be psilocybin mushrooms. Cannabis is also well-documented in Ayurvedic texts for its medicinal qualities. This historical context put forward a legacy of traditional use, contrasting sharply with modern practices and restrictions.¹⁰

⁸ The Pros and Cons of Psychedelics in Psychiatry (n 5)

⁹ *Ibid*

¹⁰ Indra Shekhar Singh, 'Is India Missing Out On the Psychedelic Science Wave?' *The Quint* (16 July 2023) <<https://www.thequint.com/fit/india-missing-out-on-the-psychedelic-science-wave>> accessed 08 June 2024

CURRENT LEGAL FRAMEWORK IN INDIA

In India, the use and distribution of psychedelic substances are governed by the Narcotic Drugs and Psychotropic Substances Act of 1985 (NDPS Act)¹¹. Under this Act, there is no differentiation between users and traffickers. The Act also provides for severe penalties for possession of psychedelics in certain cases.¹²

Despite such strict laws, there is a growing interest in psychedelics for therapeutic purposes¹³. However, at the time of writing this article, to the best of the knowledge of the authors, there is no significant active research relating to psychedelic-assisted therapy currently being conducted in India. This lack of development highlights the need for certain legal and social reforms to enable such research and applications.

INTERNATIONAL LEGAL CONTEXT

The legal status of psychedelics varies significantly depending on the country¹⁴. Let us examine some important ones:

United States of America: Psychedelics such as MDMA, psilocybin, and LSD are usually illegal in the US under the Controlled Substances Act. This classification indicates that these drugs have a high potential for abuse and generally no medical purpose. However, the discussion and mindset around them have changed due to the evolving research. The state of Oregon has decriminalised most drugs in 2020. The state of Colorado has followed the same path for the possession and use of small amounts of psychedelics for individuals aged 21 and above.

Canada: Canada has granted some exemptions to psychedelic substances for therapeutic use in certain cases. The Canadian government has added an amendment to its Special Access Program

¹¹ Narcotic Drugs and Psychotropic Substances Act 1985

¹² Sneha Mahawar, 'NDPS Act : Narcotic Drugs and Psychotropic Substances Act, 1985' (*iPleaders*, 10 May 2022) <<https://blog.iplayers.in/ndps-act-narcotic-drugs-and-psychotropic-substances-act-1985>> accessed 10 June 2024

¹³ Kenneth W. Tupper et al., 'Psychedelic medicine: a re-emerging therapeutic paradigm' (2015) 187(14) *CMAJ* <<https://www.cmaj.ca/content/187/14/1054>> accessed 08 June 2024

¹⁴ Jennifer Chesak, 'What psychedelics legalisation and decriminalisation looks like around the world' (*BBC*, 21 March 2024) <<https://www.bbc.com/future/article/20240320-legal-status-of-psychedelics-around-the-world>> accessed 10 June 2024

(SAP), which allows physicians to request access to psilocybin, LSD, MDMA, DMT and other psychedelics for therapy.

United Kingdom: Psychedelics are still very much controlled substances in the UK. They are classified under ‘Schedule 1’, defined as having ‘no therapeutic benefit’ and requiring a license from the government. There are also considerable security and cost implications to conduct research.

Australia: In 2023 Australia made a breakthrough move and became the world’s first country to allow psilocybin and MDMA for treatment of psychiatric conditions like depression and PTSD (post-traumatic stress disorder).¹⁵

European Union: Psychedelics are still highly controlled and illegal except for some scientific or limited medical purposes. However, the European Medicines Agency, the agency's Central Nervous System Working Party and representatives from the European College of Neuropsychopharmacology recently acknowledged the renewed interest in psychedelics as potential treatments for various mental health conditions. They also called for the need for effective, safe new treatments for mental disorders.¹⁶

From these examples, we get valuable insight into the legal systems of different countries and how they balance the therapeutic value of psychedelics with their regulatory concerns.

CHALLENGES AND BARRIERS TO REFORM

It is an undeniable fact that the interest in the therapeutic benefits of psychedelics is rapidly growing every day, as is the evidence to support it. And yet, these substances continue to face strong barriers on the path to becoming mainstream in the field of therapy:

¹⁵ Rich Haridy, ‘Australia to prescribe MDMA and psilocybin for PTSD and depression in world first’ (*Nature*, 30 June 2023) <<https://www.nature.com/articles/d41586-023-02093-8>> accessed 08 June 2024

¹⁶ Florence Butlen-Ducuing et al., ‘The therapeutic potential of psychedelics: the European regulatory perspective’ (2023) 401(10378) *The Lancet* <[https://doi.org/10.1016/S0140-6736\(23\)00264-7](https://doi.org/10.1016/S0140-6736(23)00264-7)> accessed 12 June 2024

Political Influence: India, along with a significant number of other countries, are signatories to certain international drug treaties¹⁷¹⁸ that influence their drug policies. These treaties were led by the USA and can be found to be deeply rooted in the global ‘war on drugs’ declared by former American President Richard Nixon. Many experts like to point out the fact that this war was perpetuated by Nixon as a means to stifle his political opponents¹⁹, and had very little to do with the actual nature of the drugs themselves. This global influence has given rise to strict regulations that get in the way of research and therapeutic use of psychedelics.

Social Stigma: Psychedelics, or drugs in general, have certain social and cultural stigmas attached to them. This further complicates any efforts to reform drug policies. The perception of the general public often associates such substances with illicit usage and even violence. Such perception tends to overshadow or ignore any potential medical benefits that psychedelics might have.

PATHWAYS FOR LEGAL REFORM

India and other countries must consider several legal reforms to fully unlock the field of psychedelic-assisted therapy. There must be a strong focus on developing a regulatory framework that clearly distinguishes between the medical use and recreational use of psychedelics. There must also be provisions for controlled use in therapy settings. Additionally, research institutions like the Indian Council of Medical Research (ICMR) and the National Institute of Mental Health and Neurosciences (NIMHANS) must be encouraged to explore further research in the policy initiatives. Finally, there must be established ethical guidelines to ensure informed consent and patient safety in psychedelic use under therapy settings. Therapists must be given comprehensive training and the clinical trials must be strictly monitored to mitigate potential risks.

¹⁷ UN Convention on Psychotropic Substances 1971

¹⁸ UN Convention on Illicit Traffic in Narcotic Drugs and Psychotropic Substances 1988

¹⁹ German Lopez, ‘Nixon official: real reason for the drug war was to criminalize black people and hippies’ (Vox, 24 March 2016) <<https://www.vox.com/2016/3/22/11278760/war-on-drugs-racism-nixon>> accessed 11 June 2024

ETHICAL CONSIDERATIONS

Ethical considerations in psychedelic therapy are of utmost importance. These substances can have a profound impact on the mental state of patients. Ensuring patient safety and autonomy can only be achieved by ensuring a rigorous informed consent process, a harm reduction approach, and a clear understanding of the potential risks.

Psychedelics induce an altered consciousness in patients, which effectively makes the state of mind vulnerable by increasing suggestibility. The patient may be less likely to refuse sexual advances that they might consider abuse once the effect of psychedelics wears off. Therefore, informed consent is crucial for patient safety during psychedelic therapy.²⁰ It is necessary to safeguard the autonomy of patients.

Clients who seek guidance for psychedelic therapy, tend to have little or no experience and knowledge regarding these substances. To ensure IC, the therapist does not advocate for or against the use of psychedelics but instead analyses the client's goals to help the client decide for themselves.²¹ However, IC in the field of psychedelics is still very much a developing area.²²

Certain possible requirements of informed consent must be adhered to in psychedelic treatment:²³

- IC should be obtained from every patient, regardless of their prior experience with psychedelics.
- The therapist should clarify the realistic expectations of the psychedelic experience
- IC must encompass all kinds of decisions following psychedelic intake, including physical boundaries, risk of self-harm, violent events, and property destruction

²⁰ M.W. Johnson et al., 'Human hallucinogen research: guidelines for safety' (2008) 22(6) *Journal of Psychopharmacology* <<https://doi.org/10.1177/0269881108093587>> accessed 13 June 2024

²¹ Brian Pilecki et al., 'Ethical and legal issues in psychedelic harm reduction and integration therapy' (2021) 18(1) *Harm Reduction Journal* <<https://doi.org/10.1186/s12954-021-00489-1>> accessed 13 June 2024

²² David S. Mathai et al., 'Mapping consent practices for outpatient psychiatric use of ketamine' (2022) 312 *Journal of Affective Disorders* <<https://www.sciencedirect.com/science/article/abs/pii/S0165032722006966>> accessed 13 June 2024

²³ Nuno Azevedo et al., 'Ethics of Psychedelic Use in Psychiatry and Beyond – Drawing upon Legal, Social and Clinical Challenges' (2023) 8(5) *Philosophies* <<https://www.mdpi.com/2409-9287/8/5/76>> accessed 12 June 2024

- IC should include potential long-term side effects, including changes in moral, political, philosophical, and religious beliefs.
- IC should account for cultural differences between the patient and the therapist to avoid misunderstandings during the therapy session.
- There should be provision for the patient's decision to leave the session during the altered hallucinogenic state.
- IC could include surrogate decision-making in case the patient is rendered unable to decide under psychedelic effects.
- IC must also be tailored for patients with physical and mental impairments.

Therapists carry an ethical duty to try and reduce the risk of harm among clients who seek to explore the use of psychedelics for therapeutic reasons. A harm reduction approach respects the client's autonomy and helps them understand the potential risks and benefits of psychedelic use. Being educated about psychedelics is an important part of clients forming their informed consent. Therapists can either provide resources for clients to do their own research, or they can directly educate the clients themselves. The safety of the clients can be further promoted by helping them think through plans involving support from someone they trust, a safe and familiar environment, and having their physical needs taken care of including diet and hydration.²⁴

The risks involved in psychedelic therapy can be mitigated through a strategic approach. The ethical considerations here are complex and multifaceted. Therapists must stay informed about both the strengths and limitations of these drugs. A thorough informed consent process, a harm reduction approach, and awareness of associated risks are crucial to ensure patient safety and maximize therapeutic benefits. Therapists must also understand relevant laws, licensing board regulations, and community attitudes towards psychedelics. By following these practices, the ethical domain of psychedelic therapy can be navigated safely and effectively.

²⁴ Pilecki (n 21)

CONCLUSION

The exploration of psychedelic-assisted therapy reveals a huge potential in the field of mental health treatment. The modern resurgence of interest in these substances is highly supported by intriguing research, which shines a light on their effectiveness in treating conditions such as depression, PTSD, anxiety, and addiction. These positive discoveries play a significant role in shifting the perception of psychedelics as mere hallucinogenic drugs to powerful tools for therapy, capable of providing a rapid and long-lasting solution where conventional therapy and medication often fail.

It is evident from modern studies that psychedelics can have a profound impact on mental health. Clinical trials with these substances have shown promising results. For instance, psilocybin has a rapid and sustained antidepressant effect, while MDMA significantly reduces symptoms of PTSD. But despite such results, the applications of these drugs are not without risks. Several adverse events like anxiety, paranoia, and physical side effects can accompany psychedelic-assisted therapy. Therefore, continuing research is important to understand the benefits and limitations of such substances.

The legal status of psychedelic-assisted therapy is as complicated as it is different across various countries. In India, the NDPS Act of 1985 has strict regulations that pose a roadblock to both research and therapeutic use of psychedelics. In contrast, countries like Canada and Australia have made considerable progress by allowing therapeutic use of these substances in a controlled manner. These clear variations in legal frameworks across the international landscape underscore the need for a balanced approach. It is important to study and recognize the therapeutic potential of psychedelics while ensuring safety protocols.

A well-structured legal framework is necessary to integrate psychedelic substances into mainstream therapy. Such a framework should clearly distinguish between recreational and therapeutic use, and facilitate controlled and monitored clinical research. It should also provide for the medical use of psychedelics with strict guidelines for informed consent, patient safety, and ethical integrity. Such a framework would make it possible to maximize the benefits of psychedelic substances while minimizing potential risks.

Ethical issues in psychedelic-assisted therapy are paramount, especially those regarding informed consent, patient safety, and the responsibilities of mental health professionals. Those professionals must ensure that patients are fully aware of the risks and benefits, maintain rigorous safety standards, and adopt a harm reduction approach to uphold the ethics of this domain. Therapists must be provided adequate training to navigate the ethical complexities of psychedelic therapy.

In conclusion, psychedelic-assisted therapy represents an exciting new frontier in mental health treatment. It offers hope for those suffering from heavy psychological ailments. With an informed and balanced understanding of the legal, ethical, and practical challenges, we can create the path for these substances to be seamlessly integrated into the field of mental health treatment with therapy. An achievement that may very well transform the lives of millions for the better.