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Fragile promise of psychedelics in psychiatry

Cédric Lemarchand and colleagues highlight weaknesses in the evidence on efficacy and safety of hallucinogens and question the use of expedited regulatory pathways

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The US clinical market for ketamine, estimated at $3.1bn in 2022 and expected to expand at 10.6% a year until 2030,[1] is just one of many signs of renewed interest in the use of psychedelics to treat psychiatric conditions.[2] Various mind altering drugs have already entered the market, including esketamine nasal spray, which the US Food and Drug Administration approved in 2019. And in 2022 the Australian Therapeutic Goods Administration (TGA) allowed psilocybin and 3,4-methylenedioxymethamphetamine (MDMA) to be prescribed by authorised physicians for psychiatric conditions such as depression and post-traumatic stress disorder. The decision was taken despite an independent scientific report commissioned by the TGA advising against authorisation because the certainty of evidence for benefits was low or very low.[3]

Psychedelics, the lay term for substances classified as hallucinogens, have various targets and distinct purported mechanisms of action. For instance, psilocybin is a serotoninergic agonist, whereas esketamine is a N-methyl-D-aspartate (NMDA) glutamate receptor antagonist, although its effect is also attributed to synaptic plasticity. Mystical experiences have also been reported as a mechanism of action.

Nevertheless, hallucinogens as a group are often understood as "a new paradigm of care for mental health."[4] While many countries, including the UK, Japan, Indonesia, Saudi Arabia, Singapore, Russia, and China, have maintained relatively strict regulatory standards for hallucinogens, more relaxed approaches in the US, Australia, and Europe are hindering repeated calls for a critical evaluation of the evidence.[2 4]

Regulatory challenges

The clinical use of hallucinogens began after Alfred Hofmann accidentally discovered the psychotropic effects of LSD while working at Sandoz in 1943.[5] The drug was initially hailed as a cure for mental health problems, but enthusiasm waned because of negative clinical outcomes, controversial experiments by Timothy Leary, and failed military research.[6] Sandoz stopped producing LSD and psilocybin in 1965.[7] Furthermore, the tightened standards for drug evaluation following the thalidomide scandal, the Kefauver-Harris Drug Amendments Act in 1962[8] and the Comprehensive Drug Abuse Prevention and Control Act of 1970, effectively ended research on hallucinogens in the US.

Fifty years later, the renewed interest in hallucinogens comes at a time when the big drug companies have reduced research into psychopharmacology, leaving patients and clinicians with psychotropic drugs of limited efficacy[9] and unmet medical needs that they hope hallucinogens will fulfil. Simultaneously, regulatory agencies are deploying expedited pathways more frequently,[10] resulting in a lowering of approval standards worldwide. However, the evaluation of hallucinogens comes with unique methodological and regulatory challenges. In the US, the FDA must assess efficacy through "adequate and well controlled trials." This is challenging for hallucinogens because of functional unblinding, when participants often know their group. Although blinding isn't always essential, it is a crucial safeguard, especially for subjective outcomes[11] and when there are strong participant expectations or investigator conflicts of interest. The FDA and European Medicines Agency are therefore developing guidelines to deal with pitfalls such as unblinding, suitability of control groups, and safety concerns (box 1).[12 13] Furthermore, because hallucinogens are often combined with a psychotherapy component, it is difficult to separate the effects of the drug from the therapeutic context, complicating comprehensive evaluations and product labelling (box 2).

Box 1: FDA and EMA recommendations for trials of hallucingens[12 13]

Characterisation of clinical pharmacology

- Assess potential drug-drug and drug-disease interactions
- Evaluate inter-individual variability in drug metabolism caused by age, sex, diet, etc
- Define dose-response relations
- Explore connections between acute experience and long term effects for both efficacy and safety

Study design

- Address functional unblinding by using independent and blinded raters and questionnaires to minimise bias from perceptual disturbances
- Include psychedelic-naive patients to reduce expectancy bias and regularly assess patient expectations
- Use active placebos—that is, placebos that produce effects that may convince the person being treated that they are receiving the drug under study
- Triangulate evidence using dose-response data and evidence from studies with inactive control treatments that can help to contextualise safety findings

- Evaluate effects over at least 12 weeks and monitor long term symptom recurrence over a year

Safety

- Identify and manage adverse events (eg, anxiety, headaches, tachycardia)
- Set monitoring requirements before, during, and after the studies
- Exclude patients with pre-existing conditions (valvopathy or pulmonary hypertension) and explore risks of 5-HT2B (serotonin) receptor agonists (assess valve structure and function and pulmonary artery pressure). Evaluate the potential for misuse
- Ensure the healthcare system can prevent overdose for both patients and non-patients

Box 2: Steps to establish trial effects are not due to psychotherapeutic components[12 13]

- Avoid using in-session therapists or monitors in post-session psychotherapy to prevent them deducing treatment assignments and inducing performance bias
- Manage high expectancy by limiting the potential for psychotherapeutic interventions to increase expectations and performance biases
- Compare psychedelic drugs with psychotherapy or psychological support alone, possibly using factorial designs
- Explore the maintenance of effects and the need for repeated sessions and follow-up psychotherapy, with or without adjunctive pharmacological treatment

Changing authorisation standards

To address the unmet need for severe and treatment resistant mental illness, the FDA has encouraged research on hallucinogens by designating some as breakthrough therapies. The designation was introduced to allow an expedited review process for drugs "intended to treat a serious condition [where] preliminary clinical evidence indicates that the drug could demonstrate substantial improvement over available therapy on a clinically significant endpoint(s)."[14] This means that even a low level of evidence suggestive of efficacy is deemed sufficient to consider the treatment as promising for an unmet medical need. Companies often use expedited development and regulatory review pathways to accelerate regulatory approval of expensive cancer drugs despite a lack of robust evidence of their efficacy and safety. However, in a 2016 survey of around 700 physicians, a quarter wrongly believed that drugs receiving breakthrough designation were safer than previously approved treatments.[15]

The FDA granted esketamine breakthrough designation for "treatment resistant depression," even though there was no consensual definition of the condition. In addition, the FDA lowered the regulatory threshold by not enforcing its decades old requirement for at least two positive initiation trials.[16] Of the three short term (four week) initiation trials, only one showed a significant benefit over placebo. For the first time, a maintenance trial was accepted in place of a second positive initiation trial, despite the risk that such trials overestimate treatment effects.[9]

Esketamine is not an isolated example. The FDA used the breakthrough therapy pathway to approve bupropion plus dextromethorphan for major depressive disorder and also for assessment of MDMA for post-traumatic stress disorder, LSD for anxiety, and psilocybin for depression. In Europe, although the EMA followed the FDA's decision on esketamine, several European health technology assessment bodies, including the French National Authority for Health and UK National Institute for Health and Care Excellence (NICE), refused authorisation because of important gaps in the evidence (such as questionable clinical added value or insufficient data on long term efficacy and safety). Of note, NICE's decision not to recommend esketamine nasal spray for treatment resistant depression was based on both clinical efficacy and cost effectiveness,[17] highlighting that agencies include other considerations beyond clinical evidence.

Inconsistencies in reporting

Given the hopes it has raised, research into hallucinogens has been a hot topic, with many new players. Alongside prominent drug companies such as Janssen (esketamine), many smaller companies are sponsoring studies, including Compass Pathways (psilocybin), Axsome Therapeutics (dextromethorphan), and Lykos Therapeutics, which was established by the non-profit advocacy organisation Multidisciplinary Association for Psychedelic Studies. The research agenda is rapidly growing. A search of interventional studies registered on ClinicalTrials.gov shows trends typical of products in the early phases of development with registered study information often poorly described and inconsistent, small sample sizes, and short follow-ups.[18]

Inconsistencies are also evident in published articles on hallucinogens. For instance, *JAMA Psychiatry* published an open label psilocybin study without a control group as a "non-randomized controlled trial"[19]; a study published in *eClinical Medicine* used "double blind" in the title, while the text reported clear and strong evidence of unblinding[20]; and a meta-analysis on psilocybin published in *The BMJ* received an expression of concern just three days after publication because of likely inconsistencies and errors.[21]

Adequacy of blinding is often not properly assessed in pivotal studies. For esketamine, functional unblinding was not specifically assessed, even though esketamine has been shown to increase the risk of dissociation sevenfold.[22] Functional unblinding was also not formally assessed in the first pivotal study of MDMA assisted psychotherapy used for a new drug application to the FDA.[23] However, the presented data suggest that 81/90 (90%) participants may have correctly guessed which treatment they received at the end of the intervention.[24] In the second pivotal study used for FDA approval, the article misleadingly stated that the trial was "double blind" and that "not all participants correctly identified the treatment that they received." However, the supplementary data show that 94% of the patients assigned to MDMA correctly guessed their treatment assignment, versus 20% who thought they received MDMA in the placebo group.[25] In addition to the problem of functional unblinding, a report from the Institute for Clinical and Economic Review, which conducts independent assessments of health interventions in the US, concluded that it was "not able to assess the frequency of misreporting of benefits and/or harm and thus the overall net benefit balance with MDMA." It also noted that "concerns have been raised by some that therapists encourage favourable reports by patients and discourage negative reports including reports of substantial harm, potentially biasing the recording of benefits and harm."[26]

There is also evidence that the media have overstated the benefits of hallucinogens. An example is an article in the *Guardian* suggesting that psilocybin was "a more successful treatment for depression than a typical antidepressant,"[27] although the study it was reporting on found no significant difference on its primary outcome.[28] In Maryland there were misleading, possibly false, claims in online direct-to-consumer advertising for the off-label use of

ketamine.[29] Industry influence is a risk even in the scientific literature. For example, a *Nature* Outlook on psychedelic medicine published in 2022 was sponsored by the biotechnology company Atai Life Sciences, which conducts research into several hallucinogens and novel 5-HT2A receptor agonists; it comprised 12 news features, one editorial, and a "sponsor feature."[30]

Safety concerns

In contrast to well established drug classes, hallucinogens have various proposed mechanisms of action, and their long term effects are not fully understood. The potential for harm and serious adverse events from long term use of hallucinogens would not be evident in short term trials. Pharmacovigilance suggests that esketamine could be linked to suicidal behaviours.[31] A similar signal is observed for psilocybin, suggesting that it could increase serious adverse events, especially suicidal ideation and behaviours.[32] Cardiovascular problems are to be expected, especially in vulnerable populations, as esketamine increases the risk of hypertension. While some of these events were observed during drug development, suboptimal reporting of safety issues in journal publications may have led to underestimation.[33] Furthermore, 5-HT2B agonists such as psilocybin increase the risk of valvular disease.[12] Ketamine and its derivatives are known to increase the risk of urinary disorders, and severe ulcerative cystitis has been documented.[34] The potential for abuse or misuse must also be considered. For example, recreational use of ketamine is increasing in the US, alongside poisoning[35] and legal seizures.[36]

Beyond the drug related adverse events, the psychotherapeutic component of "psychedelic assisted psychotherapy" introduces additional safety concerns. Mind altering drugs place patients in a state of heightened vulnerability and potentially increased risk of harm. For example, legal proceedings are under way involving therapists accused of sexual assault in a clinical trial of MDMA.[37] That such events occurred in closely monitored clinical trials, where best practices are theoretically ensured, is particularly concerning and raises serious concerns about the potential risks of use in everyday clinical practice. Despite these risks, insufficient safeguards have been put in place since Australia legalised psilocybin and MDMA to treat depression and PTSD.[3 38]

Moving forward

Growing numbers of hallucinogenic drugs are being marketed for treatment resistant disorders. According to a 2023 narrative review in *World Psychiatry*,[39] treatment resistance could now affect up to 55% of people receiving antidepressants. In the context of a global shortage of clinicians, ensuring widespread availability of treatment facilities with appropriately trained and licensed professionals to guarantee medical oversight and safety precautions is a challenge. In addition, these new treatments will probably require multiple therapy sessions at considerable cost—estimates in Australia are around $25 000 (£13 000; €15 000; $17 000) per treatment[40]—which is likely to limit accessibility and exacerbate (mental) health inequalities.

Because the stakes are so high, it is imperative that the benefits of hallucinogens outweigh the risks associated with relying on low quality evidence. To guarantee that hallucinogens are rigorously vetted before endorsing them as safe and effective treatments, medical journals must appraise the evidence more critically, fully account for limitations, avoid spin and unsubstantiated claims, and correct the record when needed. For example, *Psychopharmacology* retracted three studies on MDMA because of data integrity concerns and lack of transparency about some of the authors' conflicts of interest.[41] Health authorities must require standard regulatory pathways over accelerated ones. Otherwise, they set a concerning precedent and encourage research of degraded quality, whose numerous inconsistencies are not up to standards. Regarding MDMA assisted therapy, the FDA turned down the application.[41] It remains to be seen whether this decision will prompt the generation of higher quality evidence in hallucinogen research.

Key messages

- There has been renewed interest in the use of psychedelics for treating mental health problems
- Regulatory agencies have approved several psychedelics using accelerated procedures that require lower levels of evidence
- Published studies often have problems such as overstated benefits, small sample sizes, and short follow-ups
- Additional problems include conflicts of interest, lack of standardisation on safety outcomes, and functional unblinding
- More rigorous research and higher ethical standards are needed to protect patients

Contributors and sources: Our group comprises senior experts with different clinical expertise—psychiatrists (FN, ET), psychologists (LC, IC, EIF), and one addiction specialist (AB)—plus three students (CLM, RC, MP) who compiled a large clinical studies database on psychedelic treatments in psychiatry. CLM and FN wrote the first draft. All the other authors contributed to revising it critically and have agreed on the final content. FN is the guarantor.

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