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VIEWPOINT

On Minimizing Risk and Harm in the Use of Psychedelics

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Objective: This article outlines recommendations from 30 psychedelic researchers on how to create a better psychedelic safety net.

Methods: A survey of 30 psychedelic researchers asked them to identify key critical research gaps around psychedelic harm and safety.

Results: The critical research gaps identified by the authors included defining the main types of psychedelic harm, the predictors of those harms, and the most effective way to treat those harms. They also call for better support for those experiencing post-psychedelic difficulties, including better online information, peer support groups, affordable therapy, and psychiatric consultation and medication. Finally, the authors call for better funding to create a psychedelic safety net, and suggest psychedelic philanthropists, investors and companies could commit 1% of their investment in psychedelics into supporting safety measures such as research and support services.

Conclusions: The authors identify several practical steps to create a better psychedelic safety net and call for more funding to psychedelic safety measures such as research and support services.

Relevance to clinical practice: The authors outline important gaps in our knowledge around the safety and risk profile of psychedelic medicines and identify practical steps forward for researchers and clinical practitioners to make this promising field safer.

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Psychedelics hold potential for health and well-being. However, they are also associated with risks. By "psychedelics" we refer to classic serotonergic psychedelic drugs including psilocybin, LSD, mescaline and DMT (1). Many of our statements are also relevant to non-classic psychedelic drugs such as MDMA, ketamine, and ibogaine, although these have additional specific risk profiles. Preliminary evidence suggests that a minority (9%) of users of psychedelics in non-clinical settings have experienced functional difficulties lasting longer than a day following the acute effects of the substances (2). On some occasions, post-psychedelic difficulties can endure for weeks, months or years (3). These risks appear to be lower in clinical trials, possibly due to controlled conditions and screening for potential risk factors, but serious adverse events (AEs) can still occur in psychedelic clinical trials, with evidence of some AEs going unreported (4–7). During larger scale rollout and implementation, variations in treatment

HIGHLIGHTS

- A consensus paper from 30 psychedelic harm researchers suggests steps to make psychedelic culture and industry safer, as rising numbers of people are taking psychedelic drugs for recreational and healing purposes.
- The authors identify critical research gaps to fill, including defining the main types of psychedelic harm, the predictors of those harms, and the most effective way to treat those harms.
- They also call for better support for those experiencing post-psychedelic difficulties, including better online information, peer support groups, affordable therapy, and psychiatric consultation and medication.
- Finally, the authors call for better funding to create a psychedelic safety net, and suggest psychedelic philanthropists, investors and companies could commit 1% of their investment in psychedelics into supporting safety measures such as research and support services.

conditions, experience and expertise of providers, levels of oversight, and population heterogeneity may result in higher rates of AEs than reported in clinical trials, necessitating robust post-marketing surveillance and support (8).

Risks and adverse drug reactions are associated with all effective drug treatments, including psychotropic medicines, though some of these are often only identified post-approval through Phase IV studies and pharmacovigilance reporting programs. Psychedelic drugs are not exceptional in this regard. Although the risks of dependency and death (through accidents or toxicity) are substantially lower for classic psychedelic drugs than for many other psychotropic drugs (9), there are psychedelic-specific risks that need to be better understood and communicated. Furthermore, psychotherapeutic treatments have known AE profiles that range from 7% to 15% of patients (4); given that psychedelics are typically co-administered alongside psychotherapy or at a minimum "psychological support," adverse responses to interpersonal components of treatment, and their interaction with drug effects, should be monitored as well (10, 11).

As usage of psychedelic drugs increases in some countries, and national and local authorities consider bills to legalize or decriminalize their access (12), it is important to learn more about psychedelic risks, communicate them more accurately, prevent them where possible, and support those who experience AEs. These steps are challenging but achievable, and will enhance the potential of psychedelic-assisted therapy to improve quality of life.

LEARNING MORE ABOUT HARMS

Through an online survey, we asked 30 psychedelic researchers, included as co-authors of this paper, to identify key research gaps around psychedelic safety, harms, and harm reduction. The most common responses were:

× *Identifying and understanding psychedelic harms*: Emerging data suggests several types of potential harms that can potentially occur during and after psychedelic use (2, 3, 13). Harms that might possibly persist beyond the acute stages of a psychedelic experience according to emerging evidence, include (1) emotional problems including anxiety, depression, and affective dysregulation, (2) manic/hypomanic and/or psychotic episodes (14), (3) increased feelings of social disconnection (15), (4) prolonged existential confusion, (5) intense or extended derealization and/or depersonalization, and (6) Hallucinogen Persisting Perception Disorder. In addition, psychedelics can sometimes increase vulnerability to interpersonal harms such as negligence, exploitation, or boundary violations on the part of friends, therapists, facilitators, or other members of a psychedelic community (10, 16–18). Although we don't yet have a clear picture of the prevalence of these harms, it is clear they can cause intense and sometimes enduring suffering (19). There is very little research on these and other types of harms, how often they occur, or what helps people cope with them (4, 20). In addition, we need to learn more about risks unique to each individual psychedelic within various contexts.

× *Defining and understanding predictors of adverse outcomes*: More needs to be known about the circumstances and individual differences that might predict when therapeutic use of psychedelics can lead to harms. What biological, mental, social, contextual or other predictors might account for adverse reactions, why do AEs sometimes persist after dosing sessions, and why do post-psychedelic difficulties appear to last a few days for some and months to years for others? When might challenges be part of a healing process, and when are they simply harmful? When are harms the result of suboptimal or improper care, and what practices, standards, and safeguards could prevent or reduce those harms? Some prior empirical work exists on predicting responses to psychedelics (21–24), including worsening mental health outcomes (19) but more research is needed to improve our ability to screen and otherwise safeguard against risk, a priori.

× *Post-psychedelic "integration" psychotherapy and support*: There is consensus on the value of post-psychedelic "integration" psychotherapy or support, referring to various practices that serve to minimize harms and maximize benefits. However, research on integration is very scarce, which makes it impossible to describe the available models or practices as evidence-based (25, 26).

× *Harm reduction and safety measures*: There is a need to better understand how to minimize harm in extra-medical and extra-legal contexts, including at retreats, festivals, churches, or when taken in private settings; the types of harms that can occur across these contexts; and specific behavior strategies, interventions, and regulations that may improve safety, including harm reduction interventions and public health education. It is of course difficult to influence people's drug-taking behavior in naturalistic settings, but certain measures might help, such as public health campaigns and better ethics and safety guidelines for retreats.

Coordinated and collaborative research is needed to address these and other research gaps regarding psychedelic risks. Several research teams are developing psychometric instruments to evaluate psychedelic-specific AEs (4, 27, 28); we encourage clinical trials and legal treatment programs to implement and further validate these instruments and, where possible, lengthen periods of monitoring to promote comparability of long-term data.

BETTER SUPPORT

We also see a need for improved support services that are responsive to different contexts of psychedelic use. This includes better online information, peer support groups, affordable therapy, and psychiatric consultation and medication, as well as better government-funded public health education. People recovering from post-psychedelic difficulties say they are helped by non-judgmental and non-dogmatic therapeutic support, whereas they sometimes feel less supported by psychedelic integration therapists who see psychedelics as spiritual agents and tell them to "trust the medicine" or similarly dogmatic statements (29). Findings that describe common psychedelic-related problems should be shared with therapeutic and psychiatric professions, including emerging evidence on efficacious remedies.

MORE ACCURATE COMMUNICATION

Finally, there is a need for more accurate communication regarding the potential benefits and risks of psychedelic drugs by researchers, companies, academic institutions, investors, campaigners, and media. As with other forms of medicine, practitioners must strive to obtain informed consent, which includes accurately and transparently conveying the risk of symptoms worsening, adverse effects, or unexpected changes (e.g., in metaphysical beliefs) (30), without negatively priming the client/patient (31, 32). It is incumbent upon all stakeholders to find a balance between inadequate and excessive caution, which can be challenging in a complex media environment oriented towards simplistic narratives.

Some of these harm reduction issues are exacerbated by systemic barriers, such as the continued illegality of most psychedelic drugs in most jurisdictions, and the lack of significant government investment in psychedelic research or public health communication. In the absence of significant funding toward psychedelic safety from government bodies, pharmaceutical companies developing psychedelic therapies and/or leading psychedelic philanthropists could commit as little as 1% of their investments to funding research, education, and support services to support psychedelic safety initiatives. One precedent for this is the 3% of total funding from the U.S. National Center for Human Genome Research, which is committed to Ethical, Legal, and Social Implications Research (33).

These measures would constitute important steps toward developing a psychedelic "safety net" to inform the public of risks, support those who experience post-psychedelic difficulties, and maximize the potential benefits of psychedelic medicines.

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