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EDITORIAL

Counting the uncountable: The critical quest to quantify psychedelic medicine's reach

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In this second issue of *Psychedelics* (1), we feature on our cover the thought-provoking study by Rab, Raison & Marseille (2). That paper presents the first rigorous estimate of the potential demand for psilocybin-assisted therapy (PSIL-AT) in the United States. As psychedelic medicine moves from the periphery of psychiatric research toward the possibility, and now the reality, of approval by national drug regulatory agencies,[1] this analysis could not be more timely (3, 4). Understanding the size of the potential patient population eligible for PSIL-AT informs pharmaceutical development and the broader healthcare ecosystem, preparing to accommodate this emerging class of therapy.

By establishing a range of estimates, the authors bring welcome nuance to their methodology, steering clear of hyperbole and undue pessimism. They avoid overly broad assumptions that would be impossible to meet and exclusion criteria so implausibly narrow they are unlikely to occur in actual clinical populations. Their approach provides a credible framework for estimating incidence in a relatively narrow yet clinically relevant setting. Rab and colleagues' finding—that between 24% (using stringent criteria) and 62% (after adjustment for comorbidities) of individuals with major depressive disorder (MDD) or treatment-resistant depression (TRD) may be eligible for PSIL-AT—offers a crucial starting point for healthcare planning, one that has been sorely needed (2).

This study advances the conversation on psychedelic medicine in several ways. First, it acknowledges that not every individual with a depression diagnosis is automatically a candidate for PSIL-AT, pushing back against overly enthusiastic claims of psychedelics as universal remedies. Second, it illustrates how exclusion criteria can act as barriers to access, highlighting that decisions about who receives treatment are not merely clinical—they are public health decisions. Third, it draws a clear line between theoretical benefit and practical implementation: the potential of a treatment cannot be separated from the real-world constraints on its delivery.

Rab et al. identify alcohol and substance use disorders as key factors limiting eligibility in clinical trials. Their analysis is particularly sharp on this point. By showing that removing these exclusion criteria would significantly expand the eligible population, they raise a critical question: Should these conditions automatically disqualify patients—especially given emerging evidence that psychedelics may help those with substance use disorders?

While methodologically strong, the study does have limitations worth noting. The assumption that demand will arise primarily from those already receiving care may underrepresent broader interest once PSIL-AT becomes widely accessible. Additionally, the analysis treats exclusion criteria as binary—present or absent—whereas, in clinical practice, these are often subject to more nuanced judgment.

The authors are careful to emphasize that they are estimating potential demand. But between potential and access lies a complex landscape: insurance coverage, provider training, geography, and cultural attitudes. As Oregon and Colorado lead the way with state-level frameworks for psilocybin therapy (5), these estimates are no longer just statistics. They are planning tools, policy triggers, and moral signposts.

Oregon became the first U.S. state to legalize psilocybin for therapeutic use through Measure 109, which was passed in November 2020. The law established a regulated system for psilocybin services, including licensed service centers where individuals aged 21 and older can access psilocybin under the supervision of trained facilitators. Colorado followed in 2022 by passing Proposition 122, which decriminalized the personal use, cultivation, possession, and sharing of psilocybin mushrooms for adults 21 and over. It also legalized psilocybin-assisted therapies at licensed healing centers.

Yet, history offers a cautionary note as the field edges toward mainstream legitimacy. New therapies—especially those imbued with the allure of innovation—tend to reach the privileged first. Inequities are not incidental; they are systemic. Equity must be engineered, not merely hoped for. Future research must explore who qualifies for PSIL-AT and who receives it.

There are urgent next steps. Longitudinal tracking of real-world implementation in Oregon and Colorado can help validate or refine these projections. Cost-effectiveness analyses stratified by patient subgroups can support rational policy and reimbursement decisions. Clinical trials must evolve to include populations historically excluded—not recklessly, but with careful oversight—so that "evidence-based" does not become a euphemism for exclusion.

Rab et al. have done more than quantify potential demand. They have mapped out a terrain that psychiatry must now navigate—not only with data but with conscience. As we face an epidemic of depression and a crisis in psychiatric innovation, we cannot afford to miscalculate either our reach or our resolve.

What's at stake is not merely regulatory approval but a reimagining of what psychiatric care could become—when informed by innovative science, shaped by society, and governed by ethics.

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[1]The Australian Therapeutic Goods Administration (TGA) approved the use of psilocybin for treatment-resistant depression and MDMA for PTSD, effective on 1 July 2023.

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