

The Voice of Public Health

PUBLIC HEALTH PERSPECTIVES ON THE

Future of Psychedelics



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KEY MESSAGES

- Commercial investment in psychedelics research, manufacturing, and treatment is outstripping the supply of rigorous, unbiased, and comprehensive evidence about the efficacy of psychedelic-assisted therapy for mental health conditions.
- Current psychedelics research, commercialization, and practice are at risk of misappropriating traditional Indigenous cultural knowledge and practice with psychedelics.
- The potentials of psychedelics for improving population mental health can be realized only if research and treatment protocols enable the full inclusion of structurally disadvantaged populations.
- Psychedelics should be regulated under a public health-oriented framework balancing safety, accessibility, and the diverse needs of different sectors and populations.
- Public health stakeholders should be acting now to develop evidence-based harm reduction and public education strategies to respond to growing popular interest in and use of psychedelics.

WHY A PUBLIC HEALTH APPROACH TO PSYCHEDELICS?

During the past decade, observers and participants in the field of psychedelics have noted that public interest and commercial investment in these substances are far outpacing the state of scientific evidence. In 2024, a multidisciplinary group of experts calling themselves the Hopkins-Oxford Psychedelic Ethics (HOPE) Working Group produced an important consensus statement:

[T]he field of psychedelics is at a pivotal point in its history: Research, clinical applications, and policy initiatives are quickly scaling up. The use of psychedelics is expanding, and the development of new systems governing their use is already underway. These changes are happening while substantial uncertainty remains, both about the effects of psychedelics and about the ethical dimensions surrounding their use. (Jacobs et al., 2024)

With growing popular interest in the use of these substances for nonclinical, spiritual, and wellness purposes, and in light of the great need for new effective mental health treatments, countries around the world are beginning to explore various schemes of decriminalization or legalization (Chesak, 2024; Psychedelic Alpha, n.d.). Commercial interests of drug developers, investors, and facilitators of psychedelic use are aiming to shape the research, policy, and legal terrains. So too are activist advocates and non-profit organizations aimed at liberalizing access to psychedelics for the general public or for specific groups such as military veterans and first responders. Entrepreneurs are opening illegal storefront and online shops selling psilocybin and other psychedelics in many Canadian cities, which local police occasionally raid but mostly ignore (Lorinc, 2024). Indigenous Peoples in many parts of

the world maintain longstanding knowledge and use of natural psychedelics for ceremony and healing, sometimes welcoming settler engagement but also concerned about settlers misappropriating their knowledge and traditions (UNODC, 2024).

From a public health perspective, these developments raise a host of questions. For instance, therapeutic uses of psychedelics hold the potential to help Canadians who are under-served by existing clinical approaches to treating mental illness and promoting wellness. However, their potential value to populations at higher risk of mental illness due to structural disadvantage will be realized only if research into psychedelic medicine is itself shaped by equity considerations.

Another important public health consideration is the current mismatch between burgeoning consumer access to psychedelics and the preparedness of health promoters to provide evidence-based education for harm reduction. Recent decades' experience with corporate lobbies for other psychoactive substances (such as alcohol, tobacco, and cannabis) should put the public health community on alert to consider how commercial interests are shaping the research, medical, and regulatory environments for psychedelics in ways that might prioritize corporate interests over population health outcomes.

Many actors in the psychedelics terrain may have an interest in downplaying concerns about potentials for harm in therapeutic research and nonclinical use. For this reason, the editor of a recent academic symposium on 'critical psychedelic studies' warns that "nuance and harm reduction are not threats to the field's survival; rather, they are essential features for ensuring scientific rigor and increasing the likelihood of benefits" (Devenot, 2024). Implications of this warning for the public health community are

twofold. First, public health professionals must be aware both of the multiplicity of interests and actors in the psychedelics field and of the need to intervene in policymaking in the interests of population health. Second, and the more pressing, the public health community must start taking action on the mismatch between the enormous popular interest and advocacy hype around psychedelics, on one hand, and the lack of evidence-based guidance for safer usage and harm reduction, on the other.

Motivated by these considerations, in June 2023 the Canadian Public Health Association (CPHA) held a two-day virtual Forum on a Public Health Approach to Psychedelics, bringing together public health stakeholders, researchers, practitioners, and community activists. Topics discussed included clinical research and medical applications, commercial determinants of health and regulatory approaches, equitable engagement by and with structurally disadvantaged populations, and intersections with Indigenous, religious, and recreational uses of psychedelics. Out of that Forum came a report summarizing discussions in the six themed sessions and proposing directions for future consideration (Canadian Public Health Association, 2023b).

This discussion paper provides a public health-centred overview of the current psychedelics terrain, with the goal of introducing public health professionals, researchers, and policymakers to relevant issues and potential interventions. Because this field is relatively new and is developing with such speed, CPHA is not yet providing specific recommendations. Instead, we aim to help the public health community and wider stakeholders understand what is at stake for Canadian populations in these developments, where these might lead, and where action today is needed.

PSYCHEDELICS 101

Psychedelics are a loosely-defined group of substances "categorized by their shared subjective experience of a significantly altered state of consciousness with profound capacity to reliably induce shifts in perception, cognition, and mood" (Rush et al., 2022). The so-called 'classic psychedelics' include LSD (lysergic acid diethylamide), DMT (N, N-dimethyltryptamine), psilocybin, and mescaline, while the 'atypical' category includes ketamine, MDMA (3,4-Methylenedioxymethamphetamine), and ibogaine. Many of these substances, naturally found in plants, mushrooms, and animals, have long been used by Indigenous Peoples in traditional communal contexts for purposes of ceremony and healing. Others were artificially synthesized in the twentieth century, and new ones are being created by researchers today.

Each psychedelic substance has characteristic subjective effects on feeling, cognition, and perception, with considerable variation experienced by individuals. Collectively the acute altered states of consciousness produced by psychedelics may span "a few minutes to many hours, with the possibility of persisting effects lasting days, weeks, months, or even years" (Jacobs et al., 2024). Much about how psychedelics produce their subjective effects is still unknown. Current research suggests that unlike most other psychoactive substances, the pharmacological mechanism of psychedelics is only part of the explanation. Following Timothy Leary's terminology, the pharmacology "combines with two other factors known as 'set' (what the individual user brings to the experience in terms of expectations, personality, interpersonal support, and mental/ emotional state) and 'setting' (both the physical surroundings and the socio-cultural context of use)" (Rush et al., 2022).

The potential of psychedelics for clinical medicine and other forms of healing is thought to stem from their effect on neuroplasticity, whereby patterns of feeling, thought, and perception can be changed. The standard approach for psychedelic-assisted psychotherapy reflects this expectation of significant and subjectively meaningful change: it includes a preparatory rapport-building phase with a psychotherapist, one to several sessions of medication administration, and an integration phase of psychotherapy following each medication session.

Although psychedelics are considered less harmful than most other psychoactive substances (Nutt et al., 2010) and are not considered addictive, with the exception of ketamine (Rush et al., 2022), their consumption does come with risks that vary according to the substance, the individual, and the context of use. The acute experience (the 'trip') can include panic, anxiety, risky behaviour, and acute distress. The extended aftermath can bring "more severe problems such as psychosis, ongoing psychological problems and visual disturbance" (Canadian Public Health Association, 2023). Because of these risks, clinical trials and treatment clinics using certain psychedelic drugs typically exclude persons with psychiatric disorders such as schizophrenia or bipolar disorder, or with physical risks such as heart conditions (Smith, 2023).

To date, little is known about harms experienced by users of psychedelics and the conditions under which these harms are happening. In recent years, researchers and advocates have been raising awareness of negative effects (MacBride, 2023) and gathering reports of negative experiences following psychedelics use in order to counter the impact of psychedelic 'hype' and ignorance of potential risks (The Challenging Psychedelic Experiences Project, 2024).

Status and usage in Canada

Psychedelics are illegal for nonclinical use or possession in Canada, and can be prescribed or sold only by a qualified medical professional or pharmacy. Most fall under Schedule III of the *Controlled Drugs and Substances Act* (CDSA), although ketamine and MDMA fall under the more tightly regulated Schedule I category.

Two important exceptions permit specified psychedelic use in Canada. Since 2017, a Section 56 exemption issued by Health Canada has permitted two religious groups (the Santo Daime and União do Vegetal churches) to import and use regulated ayahuasca from Brazil for religious practice (Rochester et al., 2022). Health Canada has also approved requests for healthcare practitioners to use some psychedelic substances (psilocybin, MDMA, and ketamine) in psychedelic-assisted psychotherapy, and has approved some psychedelic pharmaceutical companies to manufacture and sell the drugs. Many clinical research trials are also underway in Canada investigating the safety and efficacy of a range of psychedelic substances for a variety of mental health disorders (prominently treatment-resistant depression, post-traumatic stress disorder (PTSD), and end-of-life distress) and substance use disorders.

Despite these legal restrictions, illegal-market psychedelic substances are widely available and used in Canada. They are available through storefront sales in many Canadian cities, often tacitly tolerated by local authorities though sometimes subject to raids and arrests. Underground religious and non-religious communities of practice exist; individuals use psychedelics both episodically and through microdosing of regular small amounts; and uncredentialed 'healers' or 'guides' offer facilitated psychedelic treatment for therapeutic or spiritual purposes.

The latest Canadian Alcohol and Drugs Survey found that in 2019, hallucinogenic drugs (i.e., LSD, PCP, and psilocybin) were used by 2% of all Canadians and 6% of adults age 20-24 (Government of Canada, n.d. (a)). This rate is similar to 2022 data from the United States showing that in 2022, 7.7% of adults age 18-25 (and 3.0% of all persons age 12 and older) reported hallucinogen use in the past year (Substance Abuse and Mental Health Services Administration, 2023). Another recent survey of Canadian students in grades 7-12 found hallucinogens reported to be their most-consumed illegal drug in the past year, with 16% of respondents calling it fairly easy or very easy to access (Government of Canada, n.d. (b)). In a survey of postsecondary Canadian students over the same period, far more respondents reported using hallucinogens over the previous year than any other illegal drug (Government of Canada, n.d. (c)).

CLINICAL POTENTIALS AND POPULATION HEALTH CONCERNS

The current boom in research about, and popular interest in, the clinical potentials of psychedelics reflects the lack of available and effective mentalhealth resources for conditions such as treatmentresistant depression, PTSD, end-of-life distress, and substance use disorders. Such conditions, for which existing treatments are ineffective for some people and out of reach for many others, might be transformed if psychedelic medicine could offer a relatively quick and lasting effect. If other trained professionals beyond the scope of medical practice could offer safe and effective psychedelic treatment with therapeutic benefit, an improvement in population mental health could be possible. Consequently, public health should have a keen interest in seeing how clinical research on psychedelics, and its uptake by regulators and the wider medical community, plays out.

Many dimensions of the current clinical research landscape, however, raise concerns from a public health perspective. These include:

- worries about the integrity of the research itself and whether the promise of efficacy will be borne out by evidence;
- questions about what the current psychotherapyintensive protocol for psychedelic medicine means for the accessibility of treatments; and
- concerns about how the currently non-diverse range of participants in clinical research on psychedelics might curtail accessibility and suitability of psychedelic treatment for the full range of populations that stand to benefit.

Concerns with clinical research

Various stakeholders in psychedelics research offer markedly diverse assessments of the results that clinical trials of psychedelic medicines have proven to date. Many observers acknowledge that small-scale clinical trials have shown promising but not yet conclusive evidence for the efficacy of substances such as psilocybin, MDMA, and ketamine for a range of mental health conditions (Canadian Public Health Association, 2023b).

According to some critics of this research, however, "psychedelic science is facing serious challenges that threaten the validity of core findings and raise doubt regarding clinical efficacy and safety" (Van Elk & Fried, 2023). These challenges stem from a range of methodological shortcomings that call into question the causation and generalizability of treatment effects, the explanation of effects, and the statistical validity of conclusions. Because such "problems tend to co-occur in psychedelic studies," they "[limit] conclusions that can be drawn about the safety and efficacy of psychedelic therapy" (Van Elk & Fried, 2023). Other observers acknowledge such challenges but suggest that the difficulty of producing psychedelic

research meeting the methodological 'gold standard' of a double-blinded randomized controlled trial may indicate the need to rethink methodological assumptions and consider alternative trial designs suited to the distinctive quality of the psychedelic experience and the impact of patient expectations (Aday et al., 2023; Rush et al., 2022). To date there has been little standardization of the psychotherapy component of psychedelic trials, creating another problem for interpreting and comparing trial results (Canadian Public Health Association, 2023b). All these issues fed into the high-profile decision of a U.S. Food and Drug Administration (FDA) advisory panel in June 2024 to reject the application by Lykos (a private pharmaceutical company spin-off of the Multidisciplinary Association for Psychedelic Studies (MAPS)) to approve a new drug for use in MDMAassisted psychotherapy for PTSD (Jacobs, 2024; Sinclair, 2024; Hu, J., 2024). In August 2024, the FDA formally declined to approve the Lykos application.

Current research into the as-yet-unknown mechanism by which psychedelics have a beneficial effect on mental health disorders is particularly significant for the future of psychedelic medicine. Some investors and researchers in psychedelic pharmacology are keenly interested in developing altered compounds that might deliver effects on brain plasticity while shortening or eliminating the subjective psychedelic experience from the treatment, and presumably eliminating the need for psychotherapy. Such compounds would give "scalable treatments" that are much less expensive than the current protocol requiring extensive investments of clinical time for supervision and psychotherapy (Smith, 2022). By eliminating the physical and emotional stresses of the psychedelic experience, psychedelic medical treatment might be possible for patients who are currently disqualified due to risk for psychosis or cardiac conditions.

Some researchers, however, believe that the psychedelic experience is intrinsically linked to cognitive shifts with therapeutic impact, and that it could be unethical to strip that element out of psychedelic medicine for the sake of costeffectiveness. The outcome of research and drug development around this issue has substantial implications for medicine, industry, and ultimately, population health: "At stake in this debate is not only the intellectual question of how drugs that take you to hell and back can cure your depression, but also the future of how they are administered as medications and in what form they make it to market" (Smith, 2022).

Equity and population health concerns about psychedelic research

To date, subjects in clinical research trials of psychedelic drugs have been notably homogenous. Trials use narrowly selected research participants who are typically white, urban, with high levels of education, and with less likelihood to be diagnosed with treatment-resistant mental health conditions (Hayes, 2024). Given that racial and cultural identities affect the expression of mental health conditions, critics of mainstream psychedelic science note "a strong need for research demonstrating the efficacy of psychedelic-assisted therapy in people of color" (George et al., 2020). The exclusionary nature of current clinical research is also reflected in the lack of women and people of colour among the leadership of scientific research on psychedelics (Williams & Labate, 2019).

Current treatment protocols for research into psychedelic-assisted psychotherapy do not prioritize culturally sensitive medical treatment suitable for patients who are from Indigenous, Black, and other equity-deserving groups (George et al., 2020). These factors mean that the clinical significance for treatment found in psychedelic research studies

may not hold for more diverse populations needing culturally-appropriate settings, protocols, and personnel to establish trust and safety (Rush et al., 2022). It is only through deliberate efforts to develop culturally-attuned psychedelic treatment that research will produce effective treatments for populations with the greatest need (Chen et al., 2020).

Equity and population health concerns with protocols for psychedelic therapy

One of the most prominent barriers to equity in psychedelic medicine is the extensive therapeutic services associated with current treatment protocols in clinical research and practice, and the costs in time and money associated with these protocols. They include one or more preparatory sessions and post-administration sessions with a psychotherapist (10-15 hours in total), as well as supervision by two clinicians during 1 to 3 administration sessions of 6 to 8 hours each (Aday et al., 2023). Unless covered by insurance, the costs in clinical and supervisory time would be prohibitive for lower-income patients, meaning that populations most in need of treatment may be least able to access it.

This affordability barrier would be all the greater should training in trauma- and violence-informed care and cultural safety become prioritized for psychedelic therapists. As noted in an analysis of equity-oriented care in psychedelic medicine, "measures which are taken to increase safety in psychedelic medicine, such as increased psychoeducation for patients or ensuring the presence of two therapists rather than one during medicine sessions, are generally associated with increased therapy costs" (Rea & Wallace, 2021).

Current research into the mechanisms by which psychedelic medicines have their therapeutic impact has great bearing on the potential accessibility of these medicines for structurally disadvantaged populations. If psychedelic medicines could have lasting therapeutic benefits without the subjective experience of the psychedelic 'trip' (Olson, 2020), and consequently less need for extensive therapy and supervision, they could offer the prospect of easily-administered treatments with fewer barriers of cost, cultural safety, and medical exclusion. On the other hand, a two-tier level of higher- and lower-cost access to psychedelic medicine with and without the hallucinatory experience might create new forms of health inequity for patients not able to cover the expense of the hallucinatory experience and its meaning-making potential (Smith, 2022).

A public health lens on research, protocols, and policies for psychedelic medicine requires prioritizing effective treatment for populations that are structurally burdened with higher rates of preventable mental illness. As Rush et al. (2022) conclude, "[t]o ensure that psychedelic-related policy and treatments are embedded within a public health equity framework, there is a need to recognize priority populations."

PSYCHEDELICS AND INDIGENOUS PEOPLES' CONCERNS

Discussions of the contemporary psychedelics landscape often note the original use of psychedelics by Indigenous Peoples for ceremonial and healing purposes, in contexts of communal spirituality and led by qualified traditional healers or practitioners. Sometimes these discussions also include an acknowledgement that this traditional knowledge and these ongoing practices should have bearing on how non-Indigenous people engage with psychedelics today (Kilmer et al., 2024).

Also common are objections by Indigenous communities, activists, and scholars that settlers'

acknowledgement of Indigenous tradition and rights is missing or severely inadequate in practice. During the MAPS Psychedelic Science 2023 conference, an Indigenous participant criticized the lack of respect shown to sacred plants by those who use these plants for commercial purposes, and the lack of inclusion of Indigenous people in scientific research (Leite, 2023). Other representatives from Indigenous communities noted that the commodification of psychedelics is taking place without their communities' consultation or consent, resulting in poaching and over-harvesting of the peyote supply and exponentially higher costs for Indigenous practitioners to procure the sacramental plant peyote for ceremonial use (Lucid News, 2023).

Indigenous practitioners of traditional sacred medicines object to appropriation and commodification by non-Indigenous psychedelic practitioners that result in quasi-Indigenous elements of ceremony and purported connections to nature (Lekhtman, 2023). They also denounce the appropriation of Indigeneity by syncretic religious groups who claim access to peyote and other plants as a 'natural' heritage not exclusively reserved to Indigenous Peoples (McGivney, 2023). The appropriation of traditional Indigenous knowledge of psychedelic medicines for patenting and commercialization is part of the larger Western practice of 'exploitation through biocolonialism' (Tone-Pah-Hote & Redvers, 2022).

Some Indigenous communities, however, are open to their members' engagement with Westerners in using psychedelics. Various Indigenous communities in South America welcome visitors for ayahuasca retreats and ceremonies. In Canada, the Roots to Thrive program is pairing a First Nations community and Elders in British Columbia with university researchers and health officials to create a mental healthcare practice offering psychedelic-assisted

group therapy among other elements of its curriculum (Roots to Thrive, n.d.).

While the burgeoning psychedelic landscape urgently needs normative guidance in how to engage respectfully with traditional Indigenous knowledgeholders, there is little formalized consensus on what forms of acknowledgement, practice, and policy should exist. Canada's 2021 accession to the UN Declaration on the Rights of Indigenous Peoples (UNDRIP) requires it to respect and promote Indigenous rights deriving from spiritual traditions as well as rights to lands and resources (Government of Canada, Department of Justice, 2021). The Declaration's Article 11 establishes Indigenous rights to protect cultural heritage and to have redress for "religious and spiritual property taken without their free, prior and informed consent or in violation of their laws, traditions and customs." Article 31 further mandates their right to control and protect traditional knowledge and medicines.

The most in-depth effort to date to articulate normative guidance in this area was developed by a group of multidisciplinary Indigenous scholars who convened a consensus process with a global panel of Indigenous representatives in 2021. That process produced a 2023 Lancet article defining eight Indigenous ethical principles of traditional Indigenous medicine and high-level suggestions for their translation into Western psychedelic research and practice (Celidwen et al., 2023). As was noted during CPHA's 2023 Forum, Indigenous communities in Canada may not yet be able to engage easily, or may not want to participate substantively, in translating the principles into practical application. Much time for internal engagement and discussion within Indigenous communities will be required, along with the resources to do so. Many Indigenous Peoples may be reluctant to discuss any use of psychedelics outside of their traditional ceremonial context; while

they might be open to endorsing potential therapeutic uses, they may be unlikely to sanction nonclinical or commercialized use (Canadian Public Health Association, 2023b).

Current acknowledgements of the Indigenous origins of psychedelic use are far from conceding robust Indigenous rights to control over this traditional knowledge and practice; and doing so could place substantial normative limits on Western engagement with psychedelics. Canada's commitments to Truth and Reconciliation will make this complex terrain for public health and other stakeholders to negotiate.

Some of the challenges ahead may parallel Indigenous Peoples' experience to date with cannabis legalization in Canada. Recent reviews have found that insufficient governmental consultation with Indigenous communities produced a legalization framework that fails to balance communal health and safety concerns with self-determination and economic opportunity for Indigenous entrepreneurs (Health Canada, 2022; National Collaborating Centre for Indigenous Health, 2023). In the sphere of psychedelics, where deeper Indigenous concerns about spirituality, cultural knowledge, and safeguarding access to medicines are at stake, consultation and collaboration will be essential in order for policymakers to understand the diversity of perspectives within and across Indigenous communities.

To date, efforts to move beyond mere acknowledgement of Indigenous rights and interests have produced initiatives such as the Indigenous Medicine Conservation Fund, through which Indigenous activists are working to promote the conservation of sacred plants, fungi, and animals and to develop Indigenous communities' capacity to foster benefit-sharing interactions with researchers and entrepreneurs seeking knowledge and access (Siebert, 2022).

CORPORATE INTERESTS IN PSYCHEDELICS AS A DETERMINANT OF POPULATION HEALTH

Corporate involvement in both the medical and nonclinical uses of psychedelics is already following paths similar to its involvement with legal psychoactive substances such as alcohol, tobacco, and cannabis. With the psychedelic drug market estimated at USD \$4.9 billion in 2022 - and expected to reach USD \$11.8 billion by 2029 (Brand Essence Research, n.d.) – enormous potential profits are at stake for the substances themselves as well as for providers of psychedelic psychotherapy and facilitators of nonmedical uses. Although much of the current boom was sponsored at first by advocates interested in using medical research as a wedge to open up use of psychedelics for wellness and spiritual growth, venture capital investment and biotech companies are now steering the terrain in search of patents and profits (Perrone, 2024).

The current boom in for-profit psychedelics is being tempered by the realities of start-up financing for drug developers and treatment clinics, the difficulties of patenting naturally-derived substances and long-practiced methods, and the uncertain prospects of profiting from a drug that is envisioned to be taken in a limited number of treatment sessions rather than long-term (Perrone, 2024). At least one high-profile start-up, a chain of ketamine clinics, has already collapsed three years after its launch (Gunther, 2023).

Commercial actors and interests are confusingly intertwined with non-profit actors and advocates in the psychedelic space. For instance, the Psychedelic Association of Canada simultaneously represents the advocacy interests of grassroots psychedelics users, researchers, and therapeutic practitioners seeking to open up the regulatory landscape for both medical

and nonmedical uses. The non-profit coalition TheraPsil, which advocates for Canadians' access to legal medical psilocybin, accepts donations from commercial psychedelic and biotech organizations.

These corporate interests and their entanglement with non-profit advocates raise the need for public health stakeholders to be aware of corporate interests overtly and covertly shaping the research and regulatory landscape in Canada. As with other powerful industries such as alcohol, cannabis, tobacco, and pharmaceuticals, the corporate psychedelic lobby is likely to exert influence through channels including the knowledge environment (i.e., research and training), the political environment (through lobbying), and the legal environment (by influencing law and regulations), and by preference shaping (i.e., advertising and marketing) (Madureira Lima & Galea, 2018).

Public health has a strong interest in seeing impartial assessment of psychedelic research to counter the influence of corporate funding and of some researchers' own financial stakes in the field (McNamee et al., 2023). Given that there is already "substantial evidence of population health hazards due to industry influence," public health stakeholders will want to protect the public good by advocating for structural and systemic measures to limit industry influence, as well as for more publicly-funded psychedelic research (Rosenbaum & Buchman, 2023).

REGULATORY APPROACHES

The public health community has a clear interest in seeing psychedelics legalized and regulated. As CPHA noted in its 2017 position statement on the decriminalization of personal use of psychoactive substances, criminalization fails as a tool to control the use of illegal substances (Canadian Public Health Association, 2017). A public health approach to legalizing and regulating psychedelics – along the

lines of the federal legalization and regulation of cannabis – is preferable. This general principle is particularly evident in the case of psychedelics, given that these substances are mostly non-addictive and have a relatively low risk level compared to other psychoactive substances (Nutt et al., 2010).

Learnings from cannabis legalization

The experience of cannabis legalization in Canada holds important learnings for how a public health approach to legalized psychedelics should be structured. Although the impacts of cannabis legalization as implemented in different provinces and territories are far from fully understood, some important public health lessons are already evident. As a health-focused evaluation of the first five years of cannabis legalization concludes, "success in meeting policy objectives has been mixed, with social justice benefits appearing to be more tangibly substantive than health benefits" (Fischer et al., 2023).

A key takeaway for future regulation of psychedelics is the need to approach any regulatory change with a commitment to gathering comprehensive data from the outset. A widespread "frustration and disappointment with the dearth of evidence and a lack of progress in the cannabis research field in many areas," is noted in the federal government's summary of stakeholder feedback from the legislative review of the *Cannabis Act* (Government of Canada, 2023). Major issues of public health concern on which data are lacking include the impacts of cannabis legalization on young people, population awareness of cannabis risks to health, and the relative market share of the regulated and illegal cannabis supplies (Berg & Jesseman, 2023).

A second major learning is that superior public health outcomes may be produced by Quebec's relatively strict approach to cannabis legalization, which avoided the commerce-promoting slant of other Canadian jurisdictions and focused on limiting youth consumption. Quebec imposed a single state-owned cannabis retailer rather than private ones, with profits going mostly to a fund for cannabis use prevention and research; it set a minimum age of 21 for purchase and consumption, as opposed to 18 or 19 in the rest of Canada; and it banned the sale of cannabis in the form of candy, chocolate or desserts (Malsch et al., 2023). This restriction on child-enticing edible formats is reflected in a lower rate of post-legalization cannabis poisonings among children in Quebec than among children elsewhere in Canada (Canadian Centre on Substance Use and Addiction, 2023).

Proposals for regulatory approaches

From a public health perspective, it is relatively clear what the contours of a sound regulatory approach to psychedelics would be. As outlined at CPHA's 2023 Forum on a Public Health Approach to Psychedelics, it would:

- recognize a spectrum of potential use from beneficial or non-problematic casual use to chronic problematic use, and consider population use levels and risk/benefit ratios of psychedelic substances in order to assess population-level risks and benefits;
- ensure a regulated legal supply for beneficial and non-problematic use;
- mitigate demand for psychedelic substances through restrictions on commercial marketing and promotion, and through health promotion education about risks and benefits;
- encompass diverse control approaches relevant to medical/therapeutic uses, sacred and social contexts, and individual use;
- assess appropriate modes of supervised access to psychedelics, whether medical or traditional, as well as appropriate harm reduction measures for unsupervised individual access;

- consider needed measures to address health inequities with the aim of advancing overall population health and well-being; and
- ensure robust research, population health assessment, and monitoring (Canadian Public Health Association, 2023b).

As noted by Rush et al. (2022), medical and public health science about psychedelics is not yet developed enough for even the first element of such an approach to be determined: "Overall, there is wide variation in stakeholder-specific assessment of the benefit-risk ratio, at both clinical and population levels, and more evidence-based consensus on this equation is no doubt a fundamental requirement for moving the field forward."

Nonetheless, advocates in the psychedelic space are already putting forward regulatory proposals that anticipate an eventual legal regime permitting uses beyond medical and recognized spiritual ones. A group of expert advocates in Canada has offered a detailed proposal for the credentialing, education, and regulatory bodies needed to support facilitated and therapeutic use of psychedelics (Rochester et al., 2022). In the United Kingdom, an advocacy group has proposed a regulatory regime for the non-medical use of classic psychedelics, involving "a flexible fourtiered model that seeks to manage both the variety of preparations of these psychedelics (both plant-based and synthetic), as well as the various ways in which they are used" (Transform Drug Policy Foundation, 2023).

Ultimately, regulation of psychedelics should align with a sound public health approach to substance use more broadly (Canadian Public Health Association, 2024). As recommended in 2021 by the Health Canada Expert Task Force on Substance Use, this broader regulatory approach would consist in "a single public health framework with specific regulations for all psychoactive substances, including currently illegal

drugs as well as alcohol, tobacco, and cannabis" (Government of Canada, 2021). That recommendation is echoed in the 2024 report of the Royal Society of Canada Task Force on COVID-19 that found that Canadian drug law reform should go beyond decriminalization toward a comprehensive legislative framework that seeks to reduce substance-related harms through harmonized regulation of psychoactive substances (Gruben et al., 2024).

PUBLIC HEALTH ACTIONS

In June 2024, the Toronto Ketamine Clinic sponsored what was billed as the 'world's first psychotherapy expo', a two-day event aimed at "the uninitiated, the curious consumers" encountering a "lack of information" from mainstream healthcare providers (Vega, 2024). The current level of popular interest in psychedelic wellness is evidenced by the presence at this event of approximately 30 speakers and 50 exhibitors, as well as 2000 general-public attendees who were offered an online platform to book on-site informational meetings with psychedelic retreat facilitators, clinic owners, therapists, coaches, and advocates (OPEN:MINDS EXPO, n.d.).

This level of interest points to a significant information gap to which commercial providers are responding. It is time for the public health community to do as other health professions are already doing (Nutt et al., 2024): provide the public with an alternative to commercial messaging, in the form of proactive public health education that is evidence-based and focussed on harm reduction rather than commerce.

While it is important for public health professionals to be aware of, and advocate on, the prospects for medical use of psychedelic therapies within a unified regulatory framework for all psychoactive substances, the more pressing and central priority for public health to address is the nonclinical use of

psychedelics. The rapid expansion of nonmedical use of psychedelics provides the public health community with the opportunity to shape research, policies, and practices in ways that will lead to improved population health outcomes. As the recent Hopkins-Oxford group statement notes, "Nonclinical uses of psychedelics are and will likely remain the vast majority of psychedelic use.... Developing a better understanding of how to reduce harms in these contexts should be a priority" (Jacobs et al., 2024).

In order to develop an evidence-based understanding of population health needs in the sphere of nonclinical use, public health researchers must investigate various aspects of current psychedelic use:

- populations using these substances, including ethnic, cultural, and other sub-populations;
- types of psychedelics being used;
- the contexts and protocols of use;
- the harms and benefits during and after use; and
- risks of poisoning associated with synthetic psychedelics from the toxic unregulated drug supply.

Researchers should also be engaging with longestablished communities of psychedelic practice – such as Indigenous and religious groups as well as underground psychedelic networks – to learn what protocols those communities use for safe and beneficial practice, and what health impacts they report.

Better research requires more detailed ongoing pan-Canadian public health surveillance of psychedelics use as part of the Canadian Alcohol and Drugs Survey. As Rush et al. (2022) suggest, monitoring emergency departments for psychedelics-related presentations is important along with gathering such data from primary care physicians. As well, more robust capacity for policy evaluation is needed to understand the population-level impacts of different regulatory models across Canada. The development of harm reduction approaches might include those already common in the substance use field, including low-risk use guidelines and drug testing (both in-community and at festivals). Certification programs could be developed to train people how to supervise peers through psychedelic experiences.

In addition to gathering research on practices and impacts, and translating the findings into harm reduction practices, public health organizations should be deploying suitable public awareness, education, and social marketing initiatives to counter the cultural and wellness hype about psychedelics. Given recent research findings about negative experiences in nonclinical use of psychedelics (Simonsson et al., 2023) and the fact that little is yet known about negative impacts of psychedelic use that can extend over months and even years (Evans et al., 2023), the challenge for public health communicators is to convey risks and harm reduction practices that reflect the generally low-risk profile of these substances and their potential benefits. Public health organizations should also develop culturally appropriate information and harm reduction guidance for populations interested in using psychedelics for mental health and wellness, both episodically (via therapeutic practitioners and retreats) and on an ongoing basis through microdosing.

Efforts to educate the public must be accompanied by education for public health professionals as well. A 2023 report surveying more than 1000 public health professionals in Canada about their general knowledge of various psychoactive substances found respondents rating their knowledge of psychedelics as 'none' or 'very little' more often than they did for any other class of substances. Respondents mentioned psychedelics as one of the substances for which they would like further education or information, in both nonclinical and potential therapeutic uses (Canadian Public Health Association, 2023a). This is an obvious

starting point for public health stakeholders to begin focusing their efforts.

KEY QUESTIONS FOR CONSIDERATION

The following questions aim to guide the development of a holistic and inclusive public health approach to psychedelics, ensuring that both potential benefits and risks are carefully considered.

Research and Evidence Base

How can public health stakeholders contribute to ensuring that clinical research on psychedelics is rigorous, unbiased, and comprehensive, given the rapid expansion of interest and commercial investment?

Regulatory Framework

What would a public health-focused regulatory framework for psychedelics look like? How can regulations balance safety, accessibility, and the diverse needs of different user groups?

Equity and Inclusion

How can psychedelic research and treatment protocols be more inclusive and culturally sensitive to ensure that marginalized and structurally disadvantaged populations benefit equitably? What steps are necessary to include these groups in clinical research and policy-making processes?

Harm Reduction and Public Education

What harm reduction strategies are needed to address the growing non-clinical use of psychedelics? How can public health professionals develop and disseminate evidence-based educational materials to inform safer use practices?

Indigenous Rights and Knowledge

How should the public health community engage with Indigenous knowledge and practices related to psychedelics? What ethical frameworks and policies are necessary to respect Indigenous rights and prevent the misappropriation and commercialization of traditional knowledge?

Commercial and Corporate Influence

What can the public health community do to ensure that commercial interests and influences in the psychedelics field do not overshadow public health interests?

Long-term Monitoring and Evaluation

What public health tracking systems are needed to monitor emerging practices, trends, and health outcomes of both clinical and non-clinical psychedelic use?

CONCLUSION

The psychedelics field is rapidly evolving, presenting both opportunities and challenges for the public health community. While these substances offer potential therapeutic benefits, careful consideration of ethical, cultural, and regulatory issues is crucial. A balanced, inclusive approach that prioritizes public health, equity, and respect for Indigenous knowledge can help navigate this complex landscape, ensuring that the promise of psychedelics is realized responsibly.

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