

Best Practices for Assessing Sexual Orientation and Gender Identity in Psychedelic Clinical Trials: A Proposed Assessment

SCOTT MCKERNAN, MA | ALEX BELSER, PHD¹

DOES TREATMENT WITH PSYCHEDELIC MEDICINE WORK FOR SEXUAL AND gender minority people? Unfortunately, given the lack of any hard data, we must answer as follows: *we do not know*. To date, investigators in psychedelic clinical research trials have largely neglected to implement affirming practices for sexual and gender minority (SGM) people. In our clinical practices, for example, this has included a failure to ask study participants for their pronouns and preferred names upon intake. In our research practices, investigators have often neglected to assess for sexual orientation and gender identity at screening or enrollment. They have not reported these data in their published analyses. Without this information, we are unable to answer the basic question: do psychedelic treatments work as well for sexual and gender minority people as their heterosexual, cisgender peers?

To address these challenges, we propose a uniform assessment of sexual orientation and gender identity in psychedelic clinical trials as a step towards addressing the treatment needs for this underserved population. Subgroup analyses are required to systemically look for treatment differences between groups, but cell sizes for SGM participants are often too small in a single trial. This means the community has to agree on standards for how to report results across trials. However, meta-analyses are uniquely challenging, as assessments of sexual and gender identity are often inconsistently defined and rarely reported in peer-reviewed publications, thus limiting the quality of evidence.

¹ Note: the authors contributed equally to the work.

The psychedelic research community should collaborate on a uniform assessment and reporting standard. This would enable systematic reviews and meta-analyses across multiple psychedelic trials to determine treatment effects for sexual and gender minority people. Here, we provide a rationale for a standard assessment to be incorporated into emerging best practices for assessing sexual orientation and gender identity in psychedelic clinical trials.

WHY ASSESS SEXUAL ORIENTATION AND GENDER IDENTITY?

Sexual and gender minority people are a diverse population and come from a variety of cultural, racial, ethnic, and economic backgrounds. In addition to general life stressors that everyone must manage, SGM people experience stigma, prejudice, harassment, discrimination, and identity-based violence (Hatzenbuehler and Pachankis, 2016; Meyer, 2003). This extra layer of stress is called “minority stress” and has been linked to a number of mental health problems, including depression, anxiety, substance misuse, and posttraumatic stress disorder (Hatzenbuehler, 2009; Keating and Muller, 2020; Reisner et al., 2016). Key to the minority stress model is the proposition that it is not homosexuality itself that leads to mental health distress and pathology, but rather, the stigma and stressors of being a sexual minority individual in a heterosexist culture that precipitate higher rates of mental illness, including suicidal ideation and attempt (Meyer, 2003; Meyer, Frost, and Nezhad, 2015). Minority stress may perpetuate symptoms of mental illness and reduce treatment efficacy (Livingston et al., 2019). Current interventions do not adequately address minority stress (Livingston et al., 2020), and many current interventions propagate sexual minority stress by using heteronormative assessment procedures.

WHAT, WHEN, AND HOW TO ASK

Social stigma may prevent accurate reporting of sexual orientation and gender identity. We recommend that questions be asked with self-administered questionnaires (not clinician-administered assessments) to provide respondents with the most anonymity and allow for the most candid responses. Questions about SGM identities should, ideally, be placed in the demographics section as its own battery; however, this may vary depending on

the structure of the survey. If providers prefer interviewing respondents, training on how to ask questions about sexual orientation and gender identity and appropriate terms to use should be provided.

FACTORS TO CONSIDER WHEN ASKING

Ethnicity

Ethnic and cultural background influence what terms people choose to identify with. Additionally, some individuals may participate in same-sex behavior, but not choose to identify as a sexual minority. The suggested survey items below include a spread of culturally diverse terms and ask about sexual behavior in order to capture the breadth of sexual and gender identities.

Gender Identity

When looking at a small subset of the population, such as gender-diverse persons, false positives are more likely to affect data. To reduce the risk of a false positive, we suggest using the “two step” approach: first, ask about sex assigned at birth and then about gender identity.

How to Report the Data

We recommend reporting subgroup data by gender identity and sexual identity for all primary and secondary outcomes. Some of the suggested categories below may be aggregated for data reporting purposes.

A PROPOSED ASSESSMENT OF SEXUAL ORIENTATION AND GENDER IDENTITY IN PSYCHEDELIC CLINICAL TRIALS

Note: these measures are derived and adapted from published guidelines developed at UCLA’s Williams Institute (The GenIUSS Group, 2014; Badgett, M. L., et al., 2009).

What is your preferred name?	-----
<p>A pronoun is a word that substitutes for a noun; in this case a word that substitutes for your name. We want to know what to call you! Examples: he, she, they</p>	
<p>Check one or more options for the set(s) of pronouns you want people to use to refer to you.</p>	<p><input type="checkbox"/> He, him, his <input type="checkbox"/> She, her, hers <input type="checkbox"/> They, them, theirs <input type="checkbox"/> Sie, hir, hirs <input type="checkbox"/> Other: -----</p>
<p>1. What sex were you assigned at birth? [Only check one]</p>	<p><input type="checkbox"/> Female <input type="checkbox"/> Male <input type="checkbox"/> Intersex</p>
<p>2. What best describes your current gender identity? [Check all that apply]</p>	<p><input type="checkbox"/> Female <input type="checkbox"/> Male <input type="checkbox"/> Transgender <input type="checkbox"/> Trans female/Trans woman <input type="checkbox"/> Trans male/Trans man <input type="checkbox"/> Nonbinary <input type="checkbox"/> Gender fluid <input type="checkbox"/> Genderqueer <input type="checkbox"/> Gender nonconforming <input type="checkbox"/> Indigenous or culturally-specific gender identity (e.g., two-spirit, Hijra, etc.) <input type="checkbox"/> Different identity (please specify): -----</p>

<p>Sexual Identity: Do you consider yourself: [Check all that apply]</p>	<ul style="list-style-type: none"> <input type="checkbox"/> Heterosexual or straight <input type="checkbox"/> Lesbian <input type="checkbox"/> Gay <input type="checkbox"/> Bisexual <input type="checkbox"/> Pansexual <input type="checkbox"/> Queer <input type="checkbox"/> Questioning <input type="checkbox"/> Asexual <input type="checkbox"/> Same gender loving <input type="checkbox"/> My sexual orientation is not listed here: _____
<p>Sexual Behavior: In the past five years whom have you had sex with? [Check all that apply]</p>	<ul style="list-style-type: none"> <input type="checkbox"/> Men <input type="checkbox"/> Women <input type="checkbox"/> Men and women <input type="checkbox"/> Gender-diverse persons <input type="checkbox"/> I have not had sex in the past 5 years
<p>Sexual Attraction: People are different in their sexual attraction to other people. Which best describes your feelings? Are you: [Only check one]</p>	<ul style="list-style-type: none"> <input type="checkbox"/> Only attracted to females <input type="checkbox"/> Mostly attracted to females <input type="checkbox"/> Equally attracted to females and males <input type="checkbox"/> Mostly attracted to males <input type="checkbox"/> Only attracted to males <input type="checkbox"/> Attracted to gender-diverse persons <input type="checkbox"/> Not sure