From Today's Observations to Tomorrow's Standards in Women's Psychiatry

To the Editor: In their recent JCP article, Ammerman and colleagues[1] offer findings on how race ethnicity is related to treatment utilization and stated preferences among 2,877 women with mood disorders. By focusing on cultural context, apart from a specific medication development program, the study directly addresses a pressing knowledge gap regarding preference-sensitive mental health care for women. Key findings are noteworthy: psychotherapy was favored across all groups; Black women were less likely to use medication; Hispanic women were more likely to use complementary approaches; and public insurance was associated with greater participation in multiple treatment modalities.[1]

Several methodological issues, many of which were acknowledged by the authors, deserve to be emphasized. First, outcomes and diagnoses were self-reported and not verified by physicians, which may lead to recall bias and misclassification. Second, the participating population was heterogeneous in terms of care setting, with recruitment dominated by obstetrics/gynecology (79.8%) and only 2.2% by psychiatry (n = 63); this mix could shape both access to options and respondents' framing of preference. Third, age was considered as a potential covariate but was not associated with treatment use or preferences; models included race, ethnicity, and insurance as predictors and were adjusted for one another. Marital/partner status and reproductive status, both of which were measured, could plausibly influence preferences and utilization, particularly if family support, burden of care, or perceptions of perinatal risk were related to treatment decisions. Sensitivity analysis adjusting to these factors would further improve the conclusions.

Conceptually, the article invites a sharper articulation of preferences. Preferences elicited in surveys may differ from revealed preferences (actual choices when options are offered). Provider behavior also plays a role: differences in medications recommended or provided, shaped by clinical heuristics, concerns about side effect profile, or implicit bias, may shape what patients later report as "preferred." As the authors note, the current data cannot distinguish whether some women were offered fewer options or declined them; documenting offer rates and reasons for refusal is therefore critical.

These considerations can be applied directly to the design of clinical trials. Prior to approval, sponsors should establish a strategy to promote diversity, with recruitment targets disaggregated by race/ethnicity, sex, and age, and, importantly, incorporate prospectively collected measures of patient preferences. This would allow for a planned analysis of the interaction between preferences and treatment and help to examine whether efficacy and acceptability differ between preference strata. The recent US Food and Drug Administration (FDA) guidance describes the content and submission of Diversity Action Plans and provides a clear framework for such approach.[2] In addition, in its guidance on patient-centered drug development, the FDA describes methods to find out what is important to patients (eg, qualitative interviews or structured surveys) and how these data can be integrated into development programs.[3] ICH E8(R1) further emphasizes that the quality of studies must be considered across the life cycle and that outcomes must be guided by what is meaningful to patients, principles that support the measurement of preferences and the inclusion of patients (including gender perspectives beyond biological sex) in psychiatric studies.[4] Finally, expanding participatory design with patient communities is consistent with the National Academies' recommendations to improve representation and equity in research.[5]

After approval, when pivotal trials cannot fully characterize preference-dependent efficacy, sponsors should commit to real-world studies that track both choice and offer rates and model socioeconomic and system factors (network adequacy, cost-sharing, disability eligibility, and payer type). The higher utilization observed among publicly insured women warrants analysis by payer and should not be attributed solely to cost-sharing. In the US, public coverage is often associated with disability eligibility and a greater clinical and socioeconomic burden. Differences in insurance plan design, including cost-sharing, can influence clinician offers, patient acceptance, and treatment adherence.[6]

In summary, Ammerman et al[1] provide valuable, real-world evidence and a compelling rationale for moving beyond the "access or no access" question and rigorously measuring preferences, offers, and real-world choices, so that the most clinically beneficial option is the option that every woman truly has.

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