EXPECTATIONS OF PREVENTIVE BENEFITS & HIV-RELATED RISK BEHAVIORS IN HPTN069/ACTG5305

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BACKGROUND

- When clinical trial participants hold a **preventive misconception** (PM), i.e., expectations that experimental interventions will confer protection from HIV infection, they may engage in behaviors that might increase their risk of acquiring HIV.
- We evaluated these issues in HPTN069/ACTG A5305 [NCT01505114], a double-blind, phase 2 study that compared 3 potential preexposure prophylaxis (PrEP) regimens [maraviroc (MVC); MVC + emtricitabine (FTC); MVC + tenofovir (TDF)] with TDF + FTC. The study enrolled at-risk cisgender men and cisgender and transgender women.
- At the time of the study there was clear evidence of preventive efficacy of TDF/FTC PrEP among men who have sex with men (MSM), but limited data for women, and no data about whether MVC was protective.

METHODS

- Key PM components, were measured at the week 40 study visit:
  - **EMAB, Expectation of maximal aggregate benefit** = Participant's estimate of the percentage of people in the most efficacious study arm will have their chance of getting HIV reduced; and
  - **EPB, Expectation of Personal Benefit** = Participant's confidence that the medication(s) they are taking in this study will prevent them from getting HIV.
- Associations of EMAB and EPB with study site, self-reported gender and race/ethnicity were evaluated using Kruskall-Wallis multi-sample rank-sum test; associations with sexually transmitted infections (STIs), self-reported adherence, and condomless anal intercourse were evaluated with logistic regression with random intercepts for study site.

Preventive misconception is often considered to be a personal characteristic, but we observed ***significant site differences*** that may indicate different messaging among sites or communities.

RESULTS

- 375 participants had valid EMAB or EPB scores:
  - 65% were male, 35% female;
  - 20% Hispanic, 31% non-Hispanic Black, 41% non-Hispanic White and 7% other race/ethnicity.
- On a scale from 0 to 100, participants thought on average that 76.6% (SD = 22.7%) of those on the most effective arm would have their chance of getting HIV reduced (EMAB); and were on average 71.9% confident (SD = 25.1%) the medication(s) they received would prevent HIV infection (EPB).
- EMAB (p = .01) and EPB (p = .001) differed significantly across sites; EMAB varied significantly by race/ethnicity and gender, with non-Hispanic Whites and males having higher scores. (See Figure.)
- A 20-point increase in EMAB was associated with 57% higher odds of condomless anal intercourse in the last 6 months (95% CI = 22% – 103%); neither EMAB or EPB was associated with STIs.

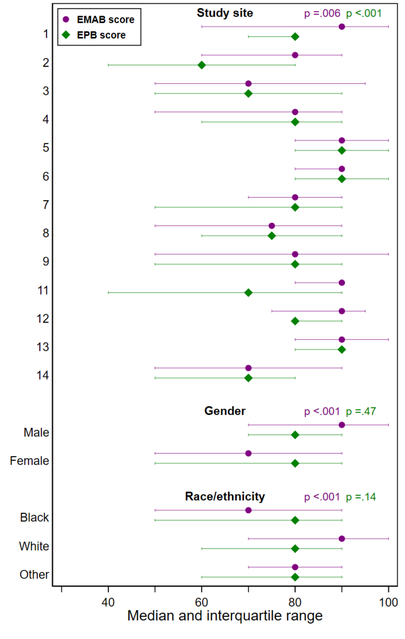


Figure. Expectation of maximal aggregate benefit (EMAB, n = 300) and expectation of personal benefit (EPB, n = 340) by site, gender and race/ethnicity.

CONCLUSIONS

- Despite the lack of evidence of efficacy for PrEP regimens besides TDF/FTC in MSM at the time of the study, average EMAB and EPB were high, but women had lower expectations of protection than men.
- Although PM is often considered to be a personal characteristic, we observed significant site differences (not explained by differences in site demographic characteristics) despite using a common informed consent document that may indicate different messaging among sites or communities, which warrants careful future examination.

ADDITIONAL KEY INFORMATION

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