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

Jeremy Sugarman[1], Brian W. Weir [1], Chen Dun[1], Roy M. Gulick[2], Timothy Wilkin[2], Kenneth H. Mayer[3], Marybeth McCauley[4], and Kevin P. Weinfurt[5]

[1]Johns Hopkins University, Baltimore, MD, USA, [2]Weill Cornell Medicine, New York, NY, USA, [3]The Fenway Institute, Boston, MA, USA, [4]FHI 360, Washington, DC, USA, [5]Duke University Medical Center, Durham, NC, USA

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.

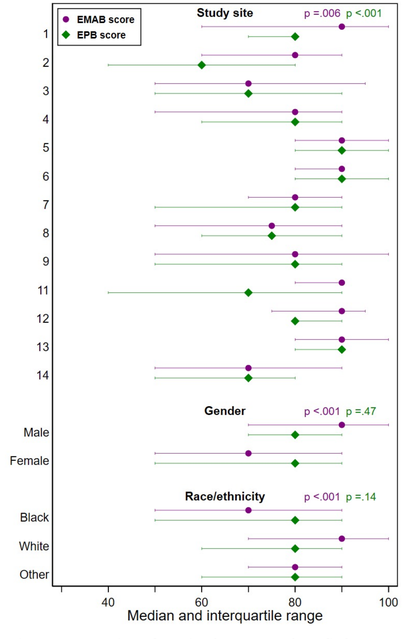

Figure. Expectation of maximal aggregate benefit (EMAB, n = 300) and expectation of personal benefit (EPB, n = 340) by site, gender and race/ethnicity.

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

Author Contact Information

Jeremy Sugarman, MD, MPH, MA
Berman Institute of Bioethics
1809 Ashland Ave
Baltimore, MD 21205
jsugarman@jhu.edu

Acknowledgements

This work was supported by grant R21MH092253 from the National Institute of Mental Health (NIMH). In addition, HPTN 069/ACTG 5305 provided support through collaboration. It was supported by the HIV Prevention Trials Network (HPTN) and by cooperative agreements from the National Institute of Allergy and Infectious Diseases (NIAID) to the HPTN Leadership and Operations Center (UM1AI068619), the HPTN Laboratory Center (UM1AI068613), and the HPTN Statistical and Data Management Center (UM1AI068617); and the AIDS Clinical Trial Group (ACTG) was supported by grant U01AI068636 from NIAID, NIMH and the National Institute of Dental and Craniofacial Research (NIDCR). The content is solely the responsibility of the authors and does not necessarily represent the official views of the National Institutes of Health.

The authors thank the study teams, sites, and the participants.

Presented at the 2022 Conference on Retroviruses and Opportunistic Infections (CROI)
16 February 2022