JIAS JOURNAL OF THE INTERNATIONAL AIDS SOCIETY

VIEW POINT

# Building effective multilevel HIV prevention partnerships with Black men who have sex with men: experience from HPTN 073, a pre-exposure prophylaxis study in three US cities

Darrell P Wheeler[1§], Jonathan Lucas [2], Leo Wilton[3,4], LaRon E Nelson[5,6], Christopher Hucks-Ortiz[7], C Chauncey Watson[8,a], Craig Hutchinson[9,b], Kenneth H Mayer[10,11,12], Irene Kuo[13], Manya Magnus[13], Geetha Beauchamp[14], Steven Shoptaw[15], Lynda Marie Emel[16], Ying Q Chen[16], Lisa Hightow-Weidman[17] and Sheldon D Fields[18]

§**Corresponding author**: Darrell P. Wheeler, Iona College, - 715 North Avenue, New Rochelle, New York, USA, Tel: +19146332602. (dwheeler@iona.edu)
[a]Please note at time of study implementation, Mr. Watson served as CRS Coordinator for the GWU site and HPTN Black Caucus Chair.
[b]Please note at the time of the study implementation, Mr. Hutchinson served as Vice-Chair of the Black Gay Research Group and a member of the HPTN Black Caucus.

**Keywords:** African American; homosexual; community engagement; PrEP research

**Received** 30 April 2018; **Accepted** 6 August 2018



The sub-population at greatest risk for HIV infection in the United States is Black men who have sex with men (BMSM), and there is an urgent need for effective HIV prevention interventions among them [1]. Despite advances in biomedical and behavioural interventions, healthcare systems continue to fail to slow the epidemic among BMSM. This is particularly the case among young men [2], who have an estimated lifetime risk of HIV infection of up to 50% [3]. It has been well demonstrated that tenfovir disiproxil fumarate (TDF) and emtricitabine (FTC) as pre-exposure prophylaxis (PrEP) are effective in protecting those at risk of HIV acquisition from sex or injection drug [4,5], but prescriptions to BMSM have sorely lagged behind other affected populations, including gay and bisexual White men [5,6].

Myriad structural characteristics, including poor health, poverty, stigma, high rates of incarceration, inadequate housing, lack of health insurance, decreased educational attainment and unemployment, impede recruitment and retention of BMSM in studies [6,7]. This constellation of factors is likely responsible for both high HIV prevalence and low uptake of PrEP (and other interventions) [8]. Clearly, effective interventions to increase PrEP uptake among BMSM are urgently needed; yet, in public health and medicine, we continue to miss the mark [5].

Just one demonstration project cannot overcome this full range of barriers. However, in the HIV Prevention Trials Network (HPTN) 073 study discussed in this view point article, we focused on what we perceived to be primary factors precluding adequate study of HIV prevention interventions among BMSM: lack of indigenous scientific leadership evident throughout the HIV prevention research field; and low BMSM enrolment in nearly all PrEP studies, including the initial iPrEX trial itself [2,9]. The key to our approach was purposefully increasing representation of Black researchers in leadership roles [10]. HPTN 073 was unique in its being led by researchers of the community under study and its thoughtful connectivity and engagement with this community at all points of study design, implementation, analysis and dissemination. This approach was grounded in the foundational work of Andrasik *et al.* [11], who identified three key themes as barriers to engage BMSM in HIV prevention research: authentic/true partnerships with community-based organizations; a real investment in the Black gay community; and the follow-up to truly inform and educate the community after the study is completed.

HPTN 073 was an open-label antiretroviral PrEP demonstration project. Eligible BMSM aged 18 years and older in three US cities were offered daily oral co-formulated FTC/TDF, with primary outcomes being PrEP uptake/initiation and adherence [12]. The majority of the HPTN 073 leadership team, including the protocol chair and co-chair, behavioural scientist, intervention developer and key staff members, worked together on a previous BMSM study (HPTN 061) [7,13,14] and had many years of significant linkages to BMSM communities and organizations across the US. In addition, along with key staff at all sites, they were also members of the BMSM community.

The behavioural intervention developed for this study was client-centred care coordination (C4), which incorporated

theoretical and public health approaches from comprehensive risk counselling and self-determination theory [15] tailored specifically for BMSM supporting participants' evaluation of their risk for HIV and personal ability to accept and adhere to PrEP if they elected to take it [16,17]. The study sites included Washington, District of Columbia; Los Angeles, California; and Chapel Hill, North Carolina.

HPTN 073 included standardized and rigorously evaluated site development activities to assist study teams in assessing and enhancing their readiness to work with BMSM, including a comprehensive cultural competency component designed by the HPTN Black Caucus [presence/place at the table (PAT)], specifically manualized for the study. Intrinsic to this approach was the concept that the study itself was not objectifying disconnected community members, but rather partnering members of the community with esteemed academic experts. This allowed participants to realize from the outset that the results of this study were intended to impact the lives of men in their communities in real time. This comprehensive approach embraced all facets of study, allowing brisk recruitment, strong retention and collection of high-quality data. In addition, emerging from this demonstration project are new scalable approaches for engaging historically under-represented researchers in leadership roles in the future.

HPTN 073 sites successfully recruited and screened 344 people and ultimately enrolled 226 BMSM between February 2013 and September 2014, retaining 92% of participants for the 12-month follow-up]. The findings from the HPTN 073 study suggest that behavioural and biomedical interventions can be used in combination to support BMSM acceptance of, adherence to and benefit from oral PrEP [16,17].

It is already known that PrEP works when taken and that removing barriers helps uptake. This study went further showing the critical importance of meaningful engagement between the community and researchers who embody the priorities of the participants. BMSM leaders of the study ensured that all facets of HPTN 073 were rigorously performed to support the needs of the BMSM themselves, and not just to prepare an article read only by researchers. The depth of community support, from recruitment to evaluation and analysis, were consistent in all sites. Study participants and community members identified the significance of having BMSM leadership. By supporting staff's awareness of and ability to engage in active listening, critical examination of barriers to service delivery and attention to understanding multilevel needs of BMSM, the HPTN 073 staff created supportive environments in which men could develop HIV prevention approaches, including PrEP tailored to their needs.

The researchers used a culturally tailored PrEP programme for BMSM with intentional indigenous scientific leadership and ongoing codified efforts to ensure adequate training and cultural competency; this led to numerous positive outcomes [12]. The role of knowledge in the form of BMSM leadership is a key factor in supporting future research efforts. Those in control of access to, and interpretation of knowledge and research processes can and do shape what is validated and what is not. As Tunde Wey writes, "It is about who gets to create us and what those representations mean for our lives… The world has a way of turning on the careless words of fools." (2018, March 11, SF Chronicle) [18].

## AUTHORS' AFFILIATIONS

[1]Iona College, New Rochelle, NY, USA; [2]Science Facilitation Department, FHI 360, Durham, NC, USA; [3]Department of Human Development, State University of New York at Binghamton, Binghamton, NY, USA; [4]Faculty of Humanities, University of Johannesburg, Johannesburg, South Africa; [5]School of Nursing, University of Rochester, Rochester, NY, USA; [6]Centre for Urban Health Solutions, Li Ka Shing Knowledge Institute, St. Michael's Hospital, Toronto, ON, Canada; [7]John Wesley Community Health Institute, Inc., Commerce, CA, USA; [8]Gilead Sciences-333 Velocity Way, Foster City, CA, USA; [9]Westside Community Mental Health Center, San Francisco, CA, USA; [10]The Fenway Institute, Fenway Health, Boston, MA, USA; [11]Harvard Medical School, Boston, MA, USA; [12]Beth Israel Deaconess Medical Center, Boston, MA, USA; [13]Department of Epidemiology and Biostatistics, Milken Institute School of Public Health, George Washington University, Washington, DC, USA; [14]Statistical Center for HIV/AIDS Research & Prevention (SCHARP), Vaccine and Infectious Disease Division (VIDD), Fred Hutchinson Cancer Research Center, Seattle, WA, USA; [15]Department of Family Medicine, David Geffen School of Medicine, University of California Los Angeles (UCLA), Los Angeles, CA, USA; [16]Fred Hutchinson Cancer Research Center, Seattle, WA, USA; [17]Division of Infectious Diseases, University of North Carolina at Chapel Hill, Chapel Hill, NC, USA; [18]School of Health Professions, New York Institute of Technology, Northern Boulevard, NY, USA

## COMPETING INTERESTS

The authors declare that they have no competing interests.

## AUTHORS' CONTRIBUTIONS

All authors have contributed substantially to the conception and design of the manuscript or acquisition, analysis or interpretation of the data for this work. Each author has participated in the drafting or revision of the content. Additionally, DPW was the chair of the HPTN 073 study and SDF was the co-chair of the study. LW was the lead behavioural scientist and LEN was the lead implementation scientist for the study. JPL provided scientific leadership in all phases of community engagement for the study. MM, LHW and SS were the site investigators for the study in their respective cities. KHM, DPW, SDF, LW, LEN, MM, LHW and SS provided scientific leadership in the conceptualization, development and implementation of the study. GB and YQC provided statistical analysis for the study. LME supervised data management for the study. KHM served as a protocol team member and provided scientific-, medical- and health-related expertise for the study. IK provided research, data analysis and interpretation for the study and was also a co-PI for her respective site. CCW served as the chair of the HPTN Black Caucus. CHO and CH served as HPTN Black Caucus Vice Chairs and provided socio-cultural expertise for the study. All authors contributed to the writing of the manuscript. All authors have read and approved the final manuscript.

## ACKNOWLEDGEMENTS

The authors thank the study team and participants at the following research sites: University of North Carolina at Chapel Hill (UNC) (CTU: AI069423-08/CTSA: 1UL1TR001111); George Washington University, Milken Institute School of Public Health (5UM1AI069053); and University of California Los Angeles (UCLA). The authors also acknowledge the support from the HPTN Leadership and Operations Center (LOC), FHI 360; HPTN Laboratory Center Quality Assurance, Johns Hopkins University; HPTN Laboratory Center Pharmacology, Johns Hopkins University; HPTN Statistical and Data Management Center, Statistical Center for HIV/AIDS Research and Prevention (SCHARP); and Division of AIDS (DAIDS) at the U.S. National Institutes of Health (NIH); Gilead Sciences, Inc: Staci Bush, Lindsey Smith, James Rooney, Brenda Ng; Other HPTN 073 contributors include: Black Gay Research Group, HPTN Black Caucus, and District of Columbia Center for AIDS Research, an NIH-funded programme (AI117970). Finally, and most importantly, the authors acknowledge and thank the many local organizations and study participants who made this work possible.

## FUNDING

Overall support for the HIV Prevention Trials Network (HPTN) is provided by the National Institute of Allergy and Infectious Diseases (NIAID) of the National Institutes of Health (NIH) under award numbers UM1AI068619 (HPTN Leadership and Operations Center), UM1AI068617 (HPTN Statistical and Data Management Center), and UM1AI068613 (HPTN Laboratory Center). Additional support was provided by the National Institute on Drug Abuse and the National Institute of Mental Health, of the National Institutes of Health, U.S. Department of Health and Human Services. The study product, TDF/FTC, was donated by

Gilead Sciences, Inc. The content is solely the responsibility of the authors and does not necessarily represent the official views of the National Institute of Allergy and Infectious Diseases nor the National Institutes of Health.

## REFERENCES

1. Millett GA, Peterson JL, Wolitski RJ, Stall R. Greater risk for HIV infection of Black men who have sex with men: a critical literature review. Am J Public Health. 2006;96:1007–19.
2. Watson CC, Lucas JP, Fields SD, Wheeler DP. Identifying research gaps for Black men who have sex with men: a way forward (HPTN Black Caucus Scientific Report). Washington, D.C.: FHI360; 2014.
3. CDC. Lifetime risk of HIV diagnosis by race/ethnicity. 2016. Available from: https://www.cdc.gov/nchhstp/newsroom/images/2016/croi_lifetime_risk_msm_race_ethnicity.jpg [cited: 20 July 2018]
4. Molina J-M, Capitant C., Spire B., Pialoux G., Cotte L., Charreau I., et al. On-demand preexposure prophylaxis in men at high risk for HIV-1 infection. N Engl J Med. 373 (23), 2237–46. 10p. https://doi.org/10.1056/NEJMoa1506273.
5. Mera R, Magnuson D, Trevor H, Bush S., Rawlings K, McCallister S. 2016. Changes in truvada (TVD) for HIV pre-exposure prophylaxis (PrEP) utilization in the United State: (2012-2016). Oral Presentation Conference of the International AIDS Society. Durban, South Africa. Available from: http://programme.ias2017.org/Abstract/Abstract/1614 [cited: 20 July 2018]
6. Smith DK. 2018. By Race/Ethnicity, Blacks Have Highest Number Needing PrEP in the United Sates, 2015. March 6, Presentation at the 25th Conference on Retroviruses and Opportunistic Infections. Boston, MA. Available from: http://www.croiwebcasts.org/console/player/37188?mediaType=slideVideo&&crd_fl=0&ssmsrq=1520376619407&ctms=5000&csmsrq=5000 [cited: 20 July 2018]
7. Mayer KH, Wang L, Koblin B, Mannheimer S, Magnus M, del Rio C.. Concomitant socioeconomic, behavioural, and biological factors associated with the disproportionate HIV infection burden among Black men who have sex with men in 6 U.S. cities. PLoS ONE. 2014;9:e87298. Available from: https://www.ncbi.nlm.nih.gov/pmc/articles/PMC3909083/pdf/pone.0087298.pdf
8. Brewer RA, Magnus M, Kuo I, Liu TY, Mayer KH. Exploring the relationship between incarceration and HIV among Black men who have sex with men in the United States. J Acquir Immune Defic Syndr. 2014;65:218–25.
9. Wheeler DP. Exploring HIV prevention needs for nongay-identified Black and African American men who have sex with men: a qualitative exploration. Sex Transm Dis. 2006;33:S11–6.
10. Wyatt GE, Williams JK, Henderson T, Sumner L. On the outside looking promoting HIV/AIDS research initiated by African American investigators. Am J Public Health. 2009;99 Suppl 1:S48–53.
11. Peake Andraski M, Chandler C, Powell B, Humes D, Wakefield S, Kripke K, et al. Bridging the divide: HIV prevention research and black men who have sex with men. Am J Public Health. 2014;104(4):708–14.
12. Wheeler D, Fields S, Nelson L, Hightow-Weidman L, Magnus M, Beauchamp SG, et al. Correlates for levels of self-reported PrEP adherence among Black men who have sex with men in 3 U.S. cities. AIDS 2016, 21st International AIDS Conference, Durban, South Africa. Available from: www.aids2016.org/Portals/0/File/AIDS2016_Abstracts_LOW.pdf?ver=2016-08-10-154247-087%20
13. Magnus M., Franks J., Griffith S., Arnold MP, Goodman K, Wheeler DP; for the HPTN 061 Study Group. Engaging, recruiting, and retaining black men who have sex with men in research studies: don't underestimate the importance of staffing-lessons learned from HPTN 061, the BROTHERS study. J Public Health Manag Pract. 2014;20(6): E1–9.
14. Koblin BA, Mayer KH, Eshelman SH, Wang L, Mannheimer S, del Rio C, et al. Correlates of HIV acquisition in a cohort of black men who have sex with men in the United States: HIV prevention trials network (HPTN) 061. PLoS ONE. 2013;8(7):e70413.
15. Calabrese SK, Earnshaw VA, Krakower DS, Underhill K, Vincent W, Magnus M, et al. A closer look at racism and heterosexism in medical students' clinical decision-making related to HIV pre-exposure prophylaxis (PrEP: implications for PrEP education. AIDS Behav. 2017;2017:https://doi.org/10.1007/s10461-017-1979-z [Epub ahead of print].
16. Kennedy S, Goggin K, Nollen N. Adherence to HIV medications: utility of the theory of self-determination. Cognit Ther Res. 2004;28:611–28.
17. Nelson LE, Wilton L, Agyarko-Poku T, Zhang N, Zou Y, Aluoch M, et al. Predictors of condom use among peer social networks of men who have sex with men in Ghana, West Africa. PLoS ONE. 2015;10(1):e0115504. Available from: https://www.ncbi.nlm.nih.gov/pmc/articles/PMC4312093/pdf/pone.0115504.pdf
18. Wey T. 2018. The white gaze of America: Who gets to tell the stories? Here's why it matters more than ever. San Francisco Chronical, p. L12.