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Examining the Role of Autonomy Support, Goal Setting, and Care Coordination Quality on HIV PrEP Adherence in Black Men Who Have Sex with Men: HPTN 073

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Abstract

Autonomy support is a concept that is derived from self-determination theory. Autonomy refers to the freedom to act as one chooses. The current study aimed to examine if autonomy support was associated with dried blood spot validated pre-exposure prophylaxis (PrEP) adherence, and whether the association was mediated by PrEP adherence goal setting and progress toward PrEP adherence goals. Our sample was drawn from Black men who have sex with men (MSM) from across three cities (Chapel Hill, NC; Los Angeles, CA; and Washington, DC) in the United States between February 2013 and September 2014. We used logistic regression to evaluate associations between study variables and path analysis to test mediation effects. Participants were, on average, 28 [standard deviation (SD) = 1.12] years old and 25% were unemployed. We found that MSM who experienced high autonomy support were more likely to adhere to PrEP [odds ratio (OR) = 1.17; 95% confidence interval: 1.00–1.38]. MSM who set PrEP adherence goals were more likely to adhere to PrEP. Moreover, MSM who reported making progress toward their goals were also more likely to adhere to PrEP. Finally, client perception of coordination quality enhanced the magnitude of the association between goal setting and goal progress and

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the effect size of goal progress on PrEP adherence. Autonomy support, goal setting, goal monitoring/evaluation, and care coordination quality influenced PrEP adherence among Black MSM. Our findings indicate that while it is important to set goals for PrEP adherence, goal setting may need to be accompanied by progress monitoring to achieve the maximal effect.

Keywords: HIV prevention, Black MSM, autonomy support, PrEP adherence

Introduction

BLACK MEN WHO HAVE SEX WITH MEN (MSM) continue to have disproportionately high rates of HIV infection in the United States.¹ Between 2010 and 2018, the annual HIV incidence among Black MSM remained relatively unchanged from 10,000 to 9100.^{2–4} However, during the same time period, the HIV incidence among White MSM decreased significantly from 8200 to 5400.^{2–4} Thus, while declines in HIV incidence among Black MSM have plateaued, the racial disparity in HIV incidence has widened over time. This racial gap is occurring despite the advent of highly effective behavioral prevention tools such as HIV pre-exposure prophylaxis (PrEP).^{5,6} Racial inequities in PrEP use have been observed since the beginning of its introduction into the national prevention toolkit, with the use among Black MSM markedly lower than that of White MSM.^{1,7,8}

To date, a great deal of attention has been given to the individual-level motivational (e.g., perceived low risk), structural (e.g., costs, unstable housing) and lack of health insurance^{9,10} and sociocontextual (e.g., anti-Black racism and heterosexism)^{11–13} factors influencing PrEP adherence among Black MSM. More recently, there has been a growing interest in examining the role of health care environments as one specific type of social context that either facilitates or undermines PrEP use and adherence among Black MSM.^{14,15}

Autonomy support is a concept that is derived from self-determination theory (SDT).¹⁶ Autonomy refers to the freedom to act as one chooses.^{16,17} For example, allowing Black MSM to make decisions about their health care without their providers trying to steer the decision. Individual's autonomy can be constrained through oppressive social processes that compel, coerce, or otherwise function to control an individual's behavior.^{16–19} An individual's autonomy can also be supported through liberating social processes that promote informed decision making and nurture an individual's capacity to enact whatever decision they make or goal they set.^{16–20} Health care settings are social environments composed of an array of individuals (e.g., counselors, nurses, physicians, social workers) who collectively influence the climate within which individuals make health behavior decisions—including decisions about the use of PrEP.^{16,21} Evidence from meta-analyses indicates that interventions that use autonomy-supportive approaches positively affected behavioral and clinical outcomes across a wide range of health domains.^{22,23}

For example, the results of a randomized controlled trial of an online SDT-based intervention among adolescents in a primary care setting indicated that it produced significant increased cardiorespiratory fitness and health-related quality of life, as well as exhibited a preventive effect against increased body mass index.²⁴ Another RCT found that, higher self-reported smoking quit rates, lower levels of lung expi-

ratory carbon monoxide and saliva cotinine at 6-month follow-up, among participants receiving an SDT-based smoking cessation intervention compared with those who only received educational leaflets.²⁵ There are fewer studies of autonomy support in HIV prevention.^{14,26} This is an important limitation of the current HIV prevention research evidence base, especially because it is already well established that health care workers can play a gatekeeper role by tacitly enacting and/or supporting approaches that restrict Black MSM's access to PrEP^{12,27,28}—nullifying possibilities for PrEP use goal attainment.

Goal setting is a collaborative strategy by which health care providers and their clients outline shorter term objectives that are useful for attaining long-term HIV prevention objectives. Goal setting has been shown to have a statistically significant positive effect on a wide array of health behaviors²⁹ [$d=0.44$; 95% confidence interval (CI): 0.31–0.56] and among diverse populations and cultural contexts.²⁹ Moreover, goal setting can also be autonomy supportive if it is grounded in informed decision making, centers the client's preferences, and minimizes external pressure. Goal setting, with progress monitoring and feedback, also helps to ensure both congruence and sufficiency between the goal and the steps one plans to take to accomplish it.²⁹ Nonetheless, to date, limited research has studied whether goal setting and goal progress monitoring affects PrEP adherence among Black MSM. Additionally, there can be economic, legal, social, material, and logistical challenges to Black MSM attaining PrEP use goals.³⁰

Overcoming these challenges may require a constellation of services and resources that, if not available or not well coordinated, could result in service discontinuities that then become de facto structural impediments to PrEP use for Black MSM.³¹

Care coordination models were widely used in the first few decades of the domestic HIV epidemic.^{32–36} Their focus was on reducing disease progression, disability, and mortality among people living with HIV who also experienced economic, legal, and social hardships that complicated their medical care.^{32–36} Today, it is understood that economic, legal, and social hardships also complicate the paths that Black MSM take to attaining their HIV prevention goals.³⁷ Care coordination models have recently begun to be used as a tool for HIV prevention with Black MSM.²⁶ High-quality care coordination can potentially buffer the negative impact of hardships on Black MSM's ability to make progress toward their PrEP use goals; however, this proposition has not been empirically tested.

Building on prior research,^{14,15,26,38,39} the purposes of this study were to test our hypotheses that (H₁) health care provider autonomy support was associated with PrEP adherence, (H₂) health care provider autonomy support was associated

with PrEP through a mediating pathway of PrEP adherence goal setting (AGS) and making progress toward achieving the PrEP adherence goal, (H₃) care coordination quality moderates the relationship between AGS and progress toward the PrEP adherence goal, and (H₄) care coordination quality moderates the relationship between progress toward the PrEP adherence goal and PrEP adherence.

Methods

Design

This was a secondary analysis of data collected in a parent study: HPTN 073, which was an open-label, vanguard, clinical demonstration study to assess feasibility and acceptability of PrEP in a sample of Black MSM in three US cities: Chapel Hill, NC; Los Angeles, CA; and Washington D.C. Full details of the parent study are published elsewhere.²⁶ The parent study consisted of PrEP-eligible, Black MSM ($N=226$) who were offered oral PrEP and a Client-Centered Care Coordination (C4TM) intervention over the course of 52 weeks. C4TM was developed using SDT whereby participants in the study guided their engagement with service providers in accessing HIV prevention and other health-related services.^{15,26} HPTN 073 was approved by the Institutional Review Boards of the University of California, Los Angeles; the University of North Carolina at Chapel Hill; and George Washington University. The current study was exempt from IRB review because it only utilized deidentified data from HPTN 073 following the HIPAA Safe Harbor guidelines.

Measures

Clinical outcome

PrEP adherence. Adherence to PrEP was assessed at 26 weeks and defined as meeting the 90% sensitivity threshold for ≥ 4 oral doses per week of combination emtricitabine (FTC)/tenofovir disoproxil fumarate (TDF) in a dried blood spot (DBS). This threshold was measured by concentrations of tenofovir diphosphate (TFV; a byproduct of TDF metabolism) and FTC: ≥ 4.2 ng/mL for TFV and ≥ 4.6 ng/mL for FTC in plasma; 9.9 fmol/ 10^6 for TFV diphosphate and 0.4 fmol/ 10^6 for FTC triphosphate in PBMCs.^{40,41} Levels \geq either of these thresholds were classified as adherent and those below the thresholds on both TFV and FTC were categorized as nonadherent.²⁶

Predictors

Autonomy support. The Healthcare Climate Questionnaire (HCCQ)^{14,18,42} is a 15-item measure, with strong internal consistency ($\alpha=0.96$) that assessed the extent to which a client experienced support in the health care environment across three theoretically grounded^{21,43} domains: autonomy (freedom and choice), competence (individual agency), and relatedness (closeness).^{14,18,19} The HCCQ was administered through self-report computer-assisted self-interview (CASI) survey starting at week 4, and then at weeks 8, 13, and 26. Participants were asked to indicate the degree to which they agreed with a series of statements regarding interactions with individuals in the health care environment. Sample scale items included: “I feel that the team accepts

me,” “The team listens to how I would like to do things,” and “The healthcare team encourages me to ask questions.” Response options were on a 7-point Likert-type scale that ranged from 1=strongly disagree to 7=strongly agree. Higher mean scores correspond with a higher perception of autonomy support.

PrEP AGS. This item was documented using a case report form (CRF) completed by the C4TM counselor.¹⁵ The CRF instructed the counselor to provide a binary response (yes/no) to the following item, “Did the participant set a PrEP adherence goal at this visit?” This item was assessed at all study visits. AGS was assessed at each study visit; however, the current analysis does not include AGS documentation from weeks 39 to 52 because those are after the 26-week PrEP adherence outcome measurement time point.

PrEP adherence goal progress. Progress toward a PrEP adherence goal was also measured using a CRF completed by the C4TM counselor. The CRF instructed the counselor to provide a binary (yes/no) response to the following item: “Did the participant make progress toward his PrEP adherence goal(s) set at last study visit?” This was an external assessment made by the counselor that included the client’s subjective understanding of whether they have made progress and the counselor’s evaluation of any evidence that the client has made steps toward any goals that were set. Adherence goal progress (AGP) was assessed only if the participant set a PrEP adherence goal at the previous study visit. AGP was assessed at each study visit; however, the current analysis does not include AGP documentation from weeks 39 to 52 because those are after the 26-week PrEP adherence outcome time point.

Care coordination quality. The Client Perception of Coordination Quality (CPCQ) assessed the extent to which the client perceived that their care services were well coordinated in four domains: quality, coherence, satisfaction, and impact.⁴⁴ The 15-item measure had good internal consistency (0.84) in the current sample and was administered through CASI starting at week 13, and then at weeks 26, 39, and 52.¹⁵ However, the current analysis does not include CPCQ ratings from weeks 39 to 52 because those are after the 26-week PrEP adherence outcome time point. Sample items included: “How often have service providers responded appropriately to changes in your needs?” “How often did providers seem to be unnecessarily repeating tests or assessments?” and “How often were you confused about the roles of different providers?”⁴⁴ Response options were on a 5-point Likert-type scale that ranged from “1=never to 5=always.” Items indicating poor coordination quality were reverse coded. The CPCQ was scored using the mean, with higher mean scores corresponding with greater quality.

Covariates

Several covariates were included in the multiple regression analysis. Age was used as a continuous variable. Both education attainment, and income were entered in the model as continuous variables.

Data analyses

All analyses were conducted on observations that included nonmissing data for the outcome, PrEP adherence. Table 1 presents sample characteristics of Black MSM who initiated PrEP. Next, we conducted a logistic regression analysis to evaluate the association between independent variables and PrEP adherence (Table 2). We also evaluated a moderation effect of CPCQ on the associations between AGS and AGP on PrEP adherence (Table 3). The moderator was mean centered. Lastly, we conducted a mediation (path) analysis to examine direct and indirect pathways to PrEP adherence and to test our hypotheses that autonomy support effects PrEP adherence through goal setting, goal progress, and care coordination quality (Table 4). Figure 1 shows the direct and indirect pathways to PrEP adherence. The mean and

TABLE 1. DEMOGRAPHICS OF PARTICIPANT WHO INITIATED PRE-EXPOSURE PROPHYLAXIS (N=179)

	Frequency (%)
Age	
Range	18–69
Mean (SD)	29.4 (9.9)
Ethnicity	
Black non-Latino (e.g., African American, African Caribbean)	161 (90%)
Black Latino	14 (8%)
Other	4 (2%)
Education	
Some high school	8 (4.42)
High school graduate or equivalent	36 (20.3)
Vocational/trade/technical school	8 (4.42)
AA or other 2-year degree	8 (4.4)
BA/BS degree	35 (19.9)
Masters or other advanced degree	17 (9.7)
Annual income	
<\$20,000	82 (46%)
\$20,000 to \$40,000	45 (25%)
≥\$40,000	49 (27%)
No response	4 (1%)
Employment status	
Employed full time	67 (37.6)
Employed part-time	53 (30.1)
Self-employed	9 (5.3)
Disabled	4 (2)
Unemployed or in between jobs	38 (21.2)
Other	7 (4)
Marital status	
Single/divorced/widowed	149 (83)
Married	30 (17)
Study location	
Washington, DC	59 (33)
Los Angeles, CA	61 (34)
Chapel Hill/Durham, NC	59 (33)
CAI with HIV+ or unknown causal male partner	
No	102 (57%)
Yes	77 (43%)
STI prevalence at 6 months	
No	146 (82%)
Yes	33 (18%)

SD, standard deviation; STI, sexually transmitted infection.

TABLE 2. LOGISTIC REGRESSION ON INDIVIDUALS WHO INITIATED PRE-EXPOSURE PROPHYLAXIS AND ADHERENCE (N=179)

PrEP adherence	OR	SE	95% CI
Autonomy support	1.17*	0.06	1.00 to 1.38
Age	0.61***	0.07	0.47 to 0.78
Income	1.24***	0.09	1.07 to 1.44
Education	1.17*	0.09	1.00 to 1.37

*p < 0.05, **p < 0.01, ***p < 0.001.

CI, confidence interval; OR, odds ratio; PrEP, pre-exposure prophylaxis; SE, standard error.

variance-adjusted weighted least squares estimator was used instead of maximum likelihood estimation because this is the preferred estimator when the dependent variable is categorical and not normally distributed.⁴⁵

The percentage of missing data was <5%.⁴⁵ Full information maximum likelihood was used to handle missing data.⁴⁶ Model fit indices were not included in the report, as the models were just identified.⁴⁵ Instead, beta coefficients and p-values are included and used to examine associations among key study variables. All analyses were done in M-plus 8.4.

Results

Table 1 describes the characteristics of the sample of Black MSM who initiated PrEP (N=179). The average age of the participants was 29.4 (SD=9.9); ~46% reported having income below \$20,000 in the previous 12 months. Thirty-seven percent reported being employed full-time and ~20% of the sample reported having a BS/BA degree. Most (69%) reported having health insurance in the past 12 months. The majority (83%) of the sample reported being single, divorced, or widowed. Eighteen percent of the sample reported receiving an sexually transmitted infection (STI) diagnosis in the 6 months before enrollment.

Logistic regression

Autonomy support was associated with PrEP adherence [odds ratio (OR)=1.17; 95% CI: 1.00–1.38], indicating that individuals who reported higher autonomy support from their

TABLE 3. ASSOCIATIONS BETWEEN PRE-EXPOSURE PROPHYLAXIS ADHERENCE GOAL SETTING AND PROGRESS TOWARD PRE-EXPOSURE PROPHYLAXIS ADHERENCE GOAL OF BLACK MEN WHO HAVE SEX WITH MEN WHO INITIATED PRE-EXPOSURE PROPHYLAXIS (N=179)

	Main effects		Moderating effects	
	OR	SE	OR	SE
CPCQ	0.87*	0.57		
AGS	0.43**	0.12		
AGP	0.60*	0.12		
CPCQ x AGS			1.09*	0.04
CPCQ x AGP			1.06*	0.03

*p < 0.05, **p < 0.01.

AGS = setting a PrEP adherence goal.

AGP = progress toward PrEP adherence goal.

AGP, adherence goal progress; AGS, adherence goal setting; CPCQ, Client Perception of Coordination Quality.

TABLE 4. DIRECT AND INDIRECT EFFECTS ON INDIVIDUALS WHO INITIATED PRE-EXPOSURE PROPHYLAXIS ($N=179$)

	<i>B</i>	<i>SE</i>	95% <i>CI</i>
Direct effects			
AGS			
Autonomy support	0.15	0.01	-0.01 to 0.04
Progress toward adherence goal			
AGS	1.55***	0.03	1.50 to 1.61
PrEP adherence			
Progress toward adherence goal	1.57***	0.03	1.51 to 1.68
Indirect effects			
Progress toward adherence goal			
Autonomy support	-0.24	0.27	-0.78 to 0.28
PrEP adherence			
AGS	0.00	0.00	-0.01 to 0.00
Autonomy support	0.00	0.00	0.00 to 0.00

*** $p < 0.001$.

AGS = setting a PrEP adherence goal; AGP = progress toward PrEP adherence goal.

health care providers were more likely to have DBS levels that were consistent with PrEP adherence. Care coordination quality was associated with PrEP adherence (OR = 0.88; 95% CI: 0.76–0.98). Age was statistically significant and associated with PrEP adherence (OR = 0.61; 95% CI: 0.47–0.78). Younger Black MSM were more likely to adhere to PrEP than older Black MSM. Black MSM with a higher income were more likely to have DBS levels that were consistent with PrEP adherence than lower income individuals (OR = 1.24; 95% CI: 1.07–1.44). Lastly, participants with a higher education were more likely to have DBS levels that were consistent with PrEP adherence compared with individuals with lower education (OR = 1.17; 95% CI: 1.00–1.37).

Moderation

We tested CPCQ as an interaction term. The variable CPCQ was entered into the model to examine if it exerted a moderating effect on our two goal-related variables: AGS and AGP. The results are displayed in Table 2. Black MSM who

experienced high quality in the coordination of their care services were more likely to set a PrEP adherence goal at their study visit. Similarly, Black MSM who experienced high-quality care coordination were also more likely to make progress toward their PrEP adherence goals (Table 2).

Mediation

The hypothesized path model for how autonomy support effects PrEP adherence is displayed in Fig. 1. The coefficients for the path model are presented in Table 3. Setting a PrEP adherence goal was significantly and directly associated to making progress toward achieving a PrEP adherence goal ($\beta = 1.55$; $p < 0.001$). Making progress toward achieving a PrEP adherence goal was significant and directly associated with DBS levels consistent with PrEP adherence ($\beta = 1.57$; $p < 0.001$).

Discussion

The support MSM receive in health care facilities has been shown to influence their sexual health behaviors, including condom use, HIV testing, and HIV PrEP adherence.^{47–50} Among Black MSM in the United States, the underlying mechanism by which a supportive health care environment is associated with HIV PrEP adherence is not fully known. This is particularly important given the fact that PrEP use remains low among the general Black racialized populations in the United States.⁵¹ This study investigated the hypotheses that autonomy support was associated with greater odds of PrEP adherence, and that the association was mediated by setting a PrEP adherence goal and making progress toward the PrEP adherence goal. We also investigated the hypotheses that high-quality care coordination increases the magnitude of the association between setting a PrEP adherence goal and making progress toward the goal and of the association between making progress toward the adherence goal and observed biomarker-validated PrEP adherence. The results of the analyses provided support for all the hypotheses that we tested.

The finding that autonomy support was associated with increased odds of PrEP adherence is consistent with results from other cross-sectional studies among MSM, which found that autonomy supportive health care environments increased the odds of sexual health promotive behaviors, including PrEP use, condom use, and linkage to care.^{14,48} Provision of

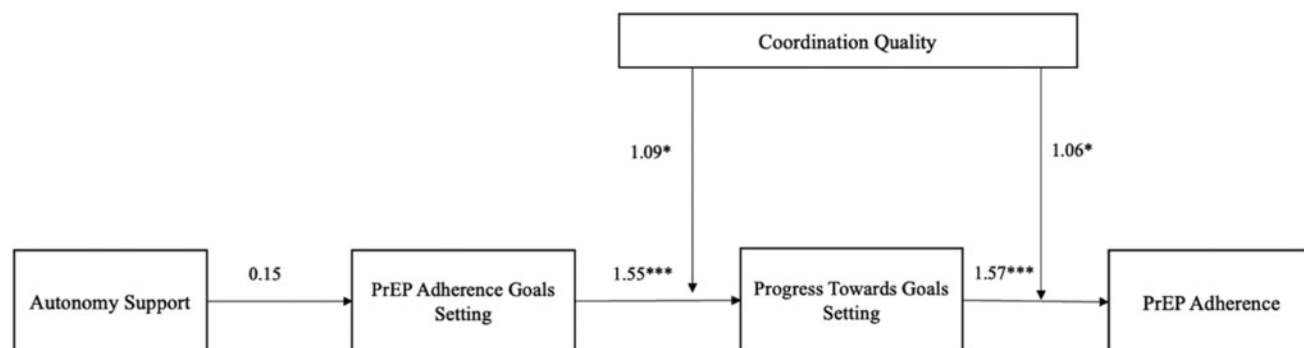


FIG. 1. Pathways to PrEP adherence, indirect and direct effects, moderating effects, and betas reported. PrEP, pre-exposure prophylaxis.

autonomy support means that health care providers do not impose their ideas on MSM but rather engage in open discourse, provide MSM with useful information and support them to make informed decisions on their own volition.¹⁵ SDT suggests that people's innate propensity to make healthy life decisions (including PrEP adherence) can be stimulated and nurtured by supporting their need for autonomy. Autonomy support enhances client's intrinsic motivation and helps to sustain behavior change.^{21,52} The influence of autonomy support on health behaviors and health outcomes has been demonstrated across a range of health domains and demographic groups.^{22,53–55} For example, our results in this study are also corroborated by a meta-analysis that found an overall medium effect size ($d_+ = 0.47$; 95% CI = 0.44–0.83) of autonomous motivation on health behavior change across 67 intervention studies.⁵⁶

In a qualitative study among Black cisgender women living with HIV, autonomy support was identified as a key element for long-term engagement in HIV testing and care, including medication adherence.⁵⁷ Autonomy support is an ideal approach to implement in health care environments because its effects are robust and not likely to be isolated to only MSM, but have residual impact on other patient groups and health conditions that were not the original intervention target.

The result supported our hypotheses that the association between autonomy support and PrEP adherence was explained, at least in part, by setting a PrEP adherence goal and making progress toward that adherence goal. In the current study, clients were allowed to determine whether they wanted to set adherence goals. The clients continued to receive support and services from the counselor and health care providers regardless of their decision to set a goal or not. This noncontingent support meant that clients "owned" the goals that they set and thus were likely to commit to them. Goal setting when done out of client's volition, and without the pressure of health care provider-imposed contingencies, is likely to lead to goal progress.¹⁵ Further, goal setting in HPTN 073 was a collaborative endeavor between client and C4™ counselor. There was attention to set goals that were feasible and always centering the client's autonomy. Goal progress was determined by the external appraisal of the trained C4™ counselor, which was informed by the MSM client's self-report but not solely determined by their self-report. Goal setting, when accompanied with progress appraisal and provision of relevant feedback, helps to ensure congruence between the goal and action plan.²⁹

Goal setting and monitoring of progress also promotes positive behavior change.²⁹ Goal progress appraisal provides an avenue to remind clients of their commitments and to identify and mitigate barriers impeding progress as well as optimize facilitators that are accelerating progress. Appraisal of goal progress has been linked to goal attainment.⁵⁸ Even though appraising the progress of client's goals is useful, the dichotomous grading (yes/no) of PrEP adherence progress does not capture the extent of the progress made. This highlights the need for more methodological innovation in the development of measures to assess how much progress clients make toward achieving their PrEP adherence goals.

Finally, we found that care coordination quality increased the association of AGS on goal progress, and it also increased the association of AGP on PrEP adherence. These findings supported our study hypotheses. While there is very little

research to date that has investigated associations between care coordination and antiretroviral medication for HIV PrEP, there is existing research that examined care coordination and adherence to antiretroviral medication adherence for HIV treatment. Care coordination has been shown to improve medication adherence among people living with HIV.⁵⁹ In a retrospective cohort study in the United States, participants living with HIV who engaged in an HIV care coordination program had 11% higher likelihood of having suppressed viral load compared with those who did not participate (Relative Risk = 1.11; 95% CI: 1.08–1.14).⁶⁰

Finally, it is our proposition that the enhancing effects of high-quality care coordination functions by removing social and structural barriers to PrEP adherence among MSM.¹¹ An example of this is the barrier that financial costs pose to PrEP access for many Black MSM. Our finding that income was associated with more PrEP adherence highlights the potential impact of this known social determinant of health on the sexual health behaviors of Black MSM.²⁶ Consistent with our finding, in another study among young MSM in California, the odds of PrEP adherence were four times higher for participants with higher income [adjusted odds ratio (aOR) = 4.13; 95% CI: 1.87–9.12].⁶¹ This raises concerns about the affordability of PrEP, which costs an average of \$8000 a year.⁶² For MSM who either have no or insufficient insurance coverage (69% of study participants had health insurance), the cost of PrEP may serve as an economic barrier for adherence. Even among MSM with income, the cost of PrEP may still be prohibitive and/or a lower relative priority compared with more immediate day-to-day needs that also require a share of an individual's finite income.

It may also indicate a need for greater awareness of the available programs that are designed to expand access to PrEP for individuals who have limited incomes.⁶³ Care coordination interventions approach these issues through a tripartite focus on case management, resource utilization management, and brokering services between a network of local agencies based on the client's needs. For example, if a client did not have access to insurance to cover payments for required medication, laboratory monitoring (e.g., kidney function tests), or clinic visits, care coordination activates to arrange a solution with other service providers to bridge the service gap caused by insurance insufficiency. This could result in linkage to a clinic that provide services at no cost to the client or identifying and registering the client with programs for which they may be eligible, such as manufacturer drug assistance/discount programs, Veteran's Affairs benefits, or Medicaid. In this study, we showed the care coordination quality is a key service metric that has an important impact on PrEP adherence for Black MSM.

Limitations

The study has some limitations that should be considered in the interpretation of our findings. First, AGP was assessed using a binary measure (yes or no), which likely obfuscates variability in the degree of progress made among Black MSM in the study; however, this limitation is overcome by several design features. The measurement of PrEP AGP was informed both by the self-assessment of the study participant and the external appraisal of the C4™ counselor. The C4™ counselor made the final determination regarding whether or

not progress was made toward a PrEP adherence goal. Additionally, we collected biomarker data on PrEP adherence by measuring serum concentrations in DBSs. The results of our mediation analysis indicated a positive relationship between DBS-measured PrEP adherence and report of progress toward PrEP adherence goals. These strengthen our confidence in the validity of our measure of the progress toward PrEP adherence goals. Second, the study was conducted with a nonprobability-based sample thereby limiting the external validity of the findings from this study.

Nonetheless, HPTN 073 was a vanguard study designed to determine the implementation feasibility and acceptability of a PrEP program among Black MSM. While the results cannot be generalized to the entire national US population of Black MSM it provides important proof-of-concept evidence regarding a model for PrEP services and the pathway by which the activities in the model may lead to increased PrEP adherence. Last, the observational design used for this study limits our ability to assert causal relationship between study variables. This limitation notwithstanding, our results provide important preliminary data to support the scientific premise of future studies and the generation of hypotheses that can be investigated in longitudinal randomized controlled trials with probability-based samples of Black MSM.

Conclusions

Autonomy support, goal setting, goal progress, and care coordination quality influence PrEP adherence among Black MSM. Our findings indicate that while it is important to set goals for PrEP adherence, high-quality care coordination can enhance its impact on goal progress and ultimately on PrEP adherence. The C4™ intervention is an evidence-based service platform that integrates all these important elements that contribute to the enhancement of PrEP adherence among Black MSM.

Data Access Statement

Data are publicly available from the HIV Prevention Trials Network at https://www.hptn.org/resources/concept_ancillarystudy.

Author Disclosure Statement

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