Perceptions Of Factors That Influence The Potential Use Of

Pre-Exposure Prophylaxis (PrEP)

BY

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DISSERTATION

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This dissertation is dedicated to my parents, Gregory and Debra Pearson, without whom it would never have been accomplished.

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LIST OF ABBREVIATIONS

CDC	Centers for Disease Control and Prevention
COI	Conflict of Interest
FDA	Food and Drug Administration
GCP	Good Clinical Practice
HIPAA	Health Insurance Portability and Accountability Act
HIV	Human Immunodeficiency Virus
HVTN	HIV Vaccine Trials Network
ICD	Informed Consent Document
IRB	Institutional Review Board
MDS	Multidimensional Scaling
MSM	Men Who Have Sex with Men
OHRP	Office of Human Research Protections
OPRS	Office for the Protection of Research Subjects
PHI	Protected Health Information
PI	Principal Investigator
PrEP	Pre-Exposure Prophylaxis
STI	Sexually Transmitted Infection

SUMMARY

This study evaluated high-risk African American women's perceptions about the use of pre-exposure prophylaxis (PrEP) for human immunodeficiency virus (HIV) prevention. A descriptive survey, a video from whatisprep.org, and the concept mapping process were used to introduce and explain PrEP and a brief survey and concept mapping were used to identify salient factors affecting women's perceptions about PrEP's adoption and compare them to healthcare providers' perspectives. Forty-eight high-risk African American women completed a survey that captured their demographics, HIV risk behaviors, media use, and awareness of PrEP. For comparison, 10 healthcare providers with experience in HIV prevention or the care of individuals living with HIV participated in the concept mapping process. Concept mapping is a multi-step participatory research method that allows participants to identify and rate their perceptions about a specific topic. A detailed explanation of the concept mapping process is provided in Chapter 3. Data analysis occurred through a web application called REDCap, and concept maps were generated using the Concept Systems Incorporated software CS Global Max.

This dissertation summarizes the literature related to HIV in African American women and PrEP (Chapter 1); this is followed by two manuscripts. The first manuscript (Chapter 2) reports survey results about women's HIV risk behaviors, media and dating application use, HIV testing, and PrEP awareness. The second manuscript (Chapter 3) provides the result of the concept mapping exercise that identified and compared the factors that high-risk African American women and healthcare providers related to the use of PrEP. The appendices include the author's vita and the approval letters for this research from the University of Illinois at Chicago Institutional Review Board.

I. REVIEW OF THE LITERATURE ON HIV AND PRE-EXPOSURE PROPHYLAXIS (PrEP) IN AFRICAN AMERICAN WOMEN

Medical advances have led to reduced transmission of human immunodeficiency virus (HIV) worldwide.[1] In the United States, this reduction has not been equal across populations.[2] African Americans, who make up 12% of the United States population, account for 44% of new HIV diagnoses.[2] At 43.6 per 100,000, African Americans have the highest incident rate of HIV.[2] After the sub-population of men who have sex with men (MSM), African American women have the next highest rate of HIV.[2] Among women diagnosed with HIV in the United States, 61% of them identify as African American and most are between the ages of 25 and 39. Most African American women with HIV report acquiring the infection from condom-less sex with their main sexual partner.[2,3] Pre-exposure prophylaxis (PrEP), a medication that reduces the likelihood of acquiring HIV, could prevent new infections in at risk populations including African American women.[1] Unfortunately, PrEP is underutilized by high-risk African American women.[4] Below is a brief summary of the literature describing the factors affecting patterns of HIV infection among African American women and PrEP is reviewed.

A. Factors that contribute to HIV risk in African American women

1. Social determinants of health

The intersections of gender, race, education, and economics are a way to frame why African American women have higher HIV burdens than other sub-populations in the US.[5] Ethnicity and/or race are certainly risk factors for HIV; but United States socioeconomic structures heavily contribute to the production of disparities in HIV transmission patterning.[6] For example, 22% of African Americans live below the poverty threshold[7] and rates of HIV are highest among individuals with annual income less than $10,000. A similar pattern exists with education attainment, as those with less than a high school education have higher rates of HIV than those who graduated high school.[5] Poverty and low levels of education may limit where African American women can afford to live, and impoverished neighborhoods tend to have less

access to quality healthcare options for preventive care and treatment of HIV.[6] Impoverished individuals may also have limited access to sexual partners outside of the neighborhood due to not having a car or the costs of public transportation.[8] Small sexual networks in high-incidence areas of HIV contribute to the risk of HIV acquisition among African American women.[8] Even though HIV is one type of sexually transmitted infection (STI), having other STIs is an independent risk factor not only because of the associated risky sex behaviors, but also because these infections increase vulnerability to HIV acquisition. African American women report high rates of inconsistent condom use, which puts them at risk for STIs.[9] They are also at risk for substance use, and often report having a new partner in the past six months, partners with other partners, and having partners that have been incarcerated.[6,10–12] Below are descriptions of these factors and how they relate to patterns of HIV.

2. STIs and inconsistent condom use

In addition to HIV, African American women also have higher rates of gonorrhea, chlamydia, primary syphilis, and secondary syphilis, than females of other racial/ethnic backgrounds.[5,13] Although African American women report higher rates of condom use,[9] they still have higher rates of STIs compared to white women.[13] Using condoms less consistently than white women contributes to the rate of STIs among African American women.[9] For example, condoms tend to be used with casual sexual partners; however, condom use is less common during sex with main or trusted sexual partners, which exposes women to sexually transmitted infections.[9] Sexually Transmitted Infections (STI) increase women's susceptibility to HIV, because such infections damage the integrity of the vaginal or anal mucus membranes.[13–15] Male and female condoms act as barriers that can protect vaginal and anal membranes from HIV. However, the type of partner (main or casual) often determines whether condoms are used or not.[16,17] Women report less consistent use of condoms when having sex with their main partner than with a casual partner.[16,17] Gender power imbalances influence women's ability to negotiate condom use with male sexual partners.[16,17] A qualitative study[18] among African

American women found that, in some cases, males controlled condom use by producing the condom immediately before intercourse or by stating that condom use decreased sensation or caused irriatation.[18] The same study also found the desire to consistently use condoms during sex declines as the relationship continues and trust is established.[18] Hence, condom use is frequently reported more with casual sexual partners than main sexual partners.[16] In terms of power imbalances, African American women tolerate undesirable behaviors from their main sexual partners with the hope of sustaining the relationship.[18] These undesirable behaviors may include, verbal or emotional abuse or having other sex partners, both of which increase the risk for HIV aquisition.[18]

In addition, being under the influence of drugs or alcohol negatively impacts the ability of African American women to negotiate the use of condoms during sex with male partners.[19] African American women who have experienced intimate partner violence are more likely to have experienced sexual coercion which impairs their ability to negotiate condom use and increases their exposure to STIs.[20] These intersections of gender and poverty together make heterosexual African American women vulnerable to HIV, and these social inequities perpetuate the epidemic in this population. The untapped potential of PrEP may be one answer to overcoming some of the factors that put African American women at risk.

B. Pre-exposure prophylaxis (PrEP)

Pre-exposure prophylaxis is federally approved antiretroviral medication developed to prevent the acquisition of HIV in individuals who are HIV negative and at risk for HIV acquisition.[21] The efficacy and safety of PrEP for women has been evaluated in various forms, including vaginal gels, vaginal rings, and oral pills. However, only one oral pill, called Truvada, has been approved by the Federal Drug Administration (FDA) for the prevention of HIV.[21] Oral PrEP, which is manufactured by Gilead Pharmaceuticals, consists of a combination of two antiretroviral drugs, 300 mg of tenofovir disoproxil fumarate and 200 mg of emtricitabine (TDF-

FTC).[22–24] The brand name of this pill is Truvada. This section provides background information about oral PrEP.

1. PrEP efficacy in women

Several clinical trials have evaluated PrEP efficacy among women. The TDF2 trial,[23] conducted among heterosexual men and women in Botswana, found PrEP 62.2% effective in preventing HIV. The TDF2 study assigned 557 women to daily TDF-FTC or placebo regimens and found 49% efficacy among women.[23] Ten participants in the TDF-FTC group seroconverted and became infected with HIV, in the placebo group10 seroconverted to HIV+. Tenofovir was detected in the blood plasma of 80% of women who did not seroconvert.[23] The level of the drug detected in blood plasma was significantly lower (50%) in the women who seroconverted.[23]

Partners PrEP [25] has been the largest PrEP efficacy trial and included 4,758 heterosexual serodiscordant couples in Kenya and Uganda. All participants received risk reduction counseling, free condoms, condom training, and screening for STIs.[25] There were 1,780 HIV-negative women assigned to daily TDF (n=595), daily TDF-FTC (n=566), or placebo (n=619) regimens. Forty-five women seroconverted to HIV positive after enrollment: n=8 in the TDF group, n=9 in the TDF-FTC group, and n=28 in the placebo group.[25] The efficacy of tenofovir (TDF) and Truvada (TDF-FTC) in women was 71% and 66% respectively. Tenofovir was detected in the blood plasma of 83% of women who did not seroconvert versus 31% of women who seroconverted.[25] The Bangkok Tenofovir Study[26] was a randomized, double-blind, placebo-controlled trial that evaluated daily oral TDF efficacy in injection drug users (n=2,413, 489 women). There were 13 seroconversions among women: two in the tenofovir group (n=246), and 11 in the placebo group (n=243). Efficacy to prevent HIV was 78.6% in women who injected recreational drugs.[26]

FEM-PrEP[27] was a randomized, double-blind, placebo-controlled trial conducted in Kenya, Tanzania, and South Africa among 2,120 women assigned to take daily oral TDF-FTC or a placebo. Thirty-three women in the TDF-FTC group seroconverted to HIV+, while there

were 35 seroconversions to HIV+ in the placebo group (6% efficacy).[27] Having greater than or equal to 10ng of TDF-FTC per milliliter of plasma was indicative of taking the study drug within 48 hours. Although participants self-reported 95% adherence, plasma levels revealed that detectable levels of TDF-FTC were seen in less than 40% of participants.[27] The authors hypothesized that low adherence within their sample was attributed to low perception of risk and difficulty with following the daily pill regimen.[27]

A large placebo-controlled trial called the VOICE trial, conducted among 5,029 women across South Africa, Uganda, and Zimbabwe, evaluated oral and vaginal gel PrEP.[28] The five arms of this trial were oral TDF 300 mg and TDF-FTC placebo, oral TDF-FTC and FTC placebo, TDF placebo and TDF-FTC placebo, 1% tenofovir vaginal gel, and vaginal gel placebo.[28] All groups received STI testing, standard HIV risk reduction counseling, condoms, and adherence counseling.[28] Efficacy for each product study group was as follows: TDF 49%, TDF/FTC 4%, and vaginal gel 15%. The VOICE trial found no reduction in HIV rates in any group of the study due to low adherence to the study product regimine.[28] A qualitative study[29] that explored the experiences of a subgroup of VOICE participants (n=102) found that participants missed study doses for various reasons including; forgetting, being busy and did not have the pill on hand, or they found taking PrEP boring. Participants stated that they underreported missed doses of PrEP during face-to face study visits because it was assumed that the truth would come out in the laboratory results once their blood was tested.[29] Authors concluded that PrEP was not embraced as an HIV prevention method by their study population simply because it was needed.[29] Therefore, understanding social and structural contexts is important when introducing new HIV prevention methods order to facilitate uptake.[29]

CAPRISA-004[30], a two-arm, double-blind, randomized, placebo-controlled trial, evaluated the efficacy of vaginally administering 1% tenofovir gel using 889 South African women (Tenofovir n=445, placebo n=444). Participants were instructed to insert the gel 12 hours prior to sexual intercourse and as soon as possible within 12 hours after intercourse.[30]

There were 38 seroconversions to HIV+ in the tenofovir group and 60 seroconversions in the placebo group.[30] Efficacy was 54% when participants adhered to the study drug regimen more than 80% of the time.[30] Efficacy dropped to 28% when adherence to the study drug regimen was less than 50%.[30] Inadequate adherence was a challenge in gauging efficacy in the CAPRISA-004 trial.[30] Despite implementing an adherence support program, gel adherence remained low.[30] Authors concluded that stronger emphasis should be placed on improving and measuring adherence in future studies.[30] FACTS-001[31], another South Africa-based study with the same product regimen and a sample of 2,029, also found that 1% tenofovir vaginal gel was not effective in preventing HIV acquisition. Across vaginal gel trials, women had difficulty adhering to the daily dosing regimen and chiefly complained about the leaking sensation of the vaginal gel.[28,30]

Vaginal rings as a mode of HIV prevention medication have shown high acceptability and adherence among women; however, their efficacy has not been proven. The ASPIRE trial,[32] a phase 3, randomized, double-blind, placebo-controlled clinical trial, evaluated the efficacy of a monthly vaginal ring containing dapivirine. Dapivirine is a non-nucleoside HIV-1 reverse transcriptase inhibitor.[32] There were 1,313 women assigned to the dapivirine group and 1,316 women to the placebo group (n=2,629). The study drug was detected in the plasma levels of 82% of participants.[32] There were 168 seroconversions to HIV+ (97 in the placebo group and 71 in the dapivirine group), and the incidence of HIV infection in the dapivirine group was 27% lower than the placebo group.[32] There was no efficacy shown in women between 18 and 21 years old due to low adherence.[32] Authors also speculated that physiologic differences in the genial tracts of women between 18 and 21 years old contributed to poor efficacy. Similarly, the Ring Study,[33] which used the same monthly vaginal ring as the ASPIRE trial, found 77 seroconversions to HIV+ in the dapivirine group (n=1,300) and 56 seroconversions in the placebo group (n=650).[33] The drug's efficacy was 31%, and there was no efficacy among women 21 years old and younger.[33] Low efficacy among women 21 years old and younger was

attributed to a combination of low adherence, genital tract differences, and higher frequency of sex than women over 21 years old.[33]

With no satisfactory vaginal gel or vaginal ring trials, the focus of PrEP has shifted toward Truvada, an oral pill, as a safe and effective option for PrEP use in populations at high risk for HIV acquisition. In following text, PrEP refers to Truvada unless otherwise specified. In terms of PrEP safety, renal function should be monitored every six months during the use of PrEP.[1] Renal dysfunction was not found in PrEP clinical trials that evaluated safety in healthy adults.[26,30,34] The VOICE trial[28] of PrEP found statistically significant decreases in bone mineral density in the hip (p=0.018) and spine (p=0.002) between the baseline and 48-week visits, and bone mineral density improved when PrEP was discontinued.[28] Dual-emission x-ray absorptiometry or other bone health assessments are not recommended prior to PrEP initiation or during monitoring.[1] Nausea, vomiting, and dizziness are common effects of PrEP.[23,35] These side effects were generally mild upon PrEP initiation and subsided over the first few months.[23,27] In the FEM-PrEP trial,[27] adverse events leading to interruption or permanent withdrawal of the study drug occurred in 5.4% and 3.2% of the TDF-FTC group (n=1,025) and placebo group (n=1033) respectively.

2. <u>Provider awareness and perceptions of prescribing PrEP</u>

In order to obtain PrEP, a person has to be HIV negative, be engaging in behaviors posing high risk for acquiring HIV, recognize high risk for HIV infection, and find a provider willing to prescribe PrEP.[1] In addition to HIV testing stigma, providers' having little knowledge about PrEP is a barrier to PrEP use.[36] A study that evaluated provider knowledge and attitudes about PrEP,[37] found that physicians prescribed PrEP for less than half of patients who requested the medication. In that study, physicians mostly prescribed PrEP to men who have sex with men (MSM). Whether physicians offered PrEP without a specific request from the patient was not evaluated. In this study, three primary influencers of whether PrEP was prescribed included having an HIV-positive partner, having multiple sexual partners, and lack of

condom use.[37] A primary reason given for not prescribing PrEP was the provider's belief that it would increase sexual risk behaviors, although there is no evidence to support this concern. To a lesser degree, physicians were also concerned about poor adherence to the medication regimen.[37]

Another study of HIV specialists,[36] found that most did not have detailed knowledge about published PrEP trials. However, most of these providers primarily considered prescribing PrEP to the HIV-negative partner of a serodiscordant couple or to MSM.[36] Physicians who completed HIV educational courses had more positive attitudes about PrEP than those who did not complete a course.[36] Across studies, physicians thought HIV testing and behavioral interventions were the most effective methods of HIV prevention, and not necessarily the use of PrEP.[36,37] Between 2012 and 2014, 10% of oral PrEP prescriptions were written by nurse practitioners, compared to 80% by physicians of various specialties; including internal medicine which had the highest proportion of PrEP prescribers at 19%.[4] Physician assistants accounted for 10% of PrEP prescribers between 2012 and 2014.[4]

At the conclusion of 2016, 153,000 people in the United States were taking PrEP for HIV prevention,[38] while it is estimated that over one million people were eligible based on risk status. Seventy-four percent of PrEP users are white men and women. In 2015, PrEP was being used by 19,344 men and 2,491 women.[39] Approximately 7,500 white men and 500 white women initiated PrEP in 2015. Overall, only 20% of PrEP users are women, thus many more women at risk for HIV could benefit from PrEP. There has been a 500% increase in PrEP use in the United States; however, this increase was not seen in African American users and especially not in African American women.[39] Only 10% of PrEP users are African American.[39] In 2015, approximately 1,000 African American men and 100 African American women initiated PrEP, which is very low considering estimates of one million people being eligible for PrEP based on risk status.[39] Between 2012 and 2015 there was a decline in the initiation of PrEP use among

women from 48.5% to 11.4%.[39] The decline in PrEP initiation among women is possibly due to a lack of culturally relevant PrEP services and HIV education.[39]

3. PrEP among men who have sex with men

Although at higher risk, some MSM self-perceive to be at low risk for acquiring HIV.[40–42] Based on the literature reviewed, MSM consider condom use as their main form of HIV prevention.[43,44] Other forms of HIV prevention for MSM include strategic positioning (HIV-positive partner is receptive to body fluids) and selecting partners of like serostatus.[43,45,46] MSM believe using PrEP will decrease fear or anxiety of contracting HIV when having sex.[43,45] Men who were under 35 years of age, who had casual sexual partners, or had condomless anal sex were more likely to express willingness to use PrEP than older men.[40,42,43,47–55] Also, visiting an STI clinic or receiving HIV counseling in the past year was significantly associated with willingness to use PrEP in MSM populations.[40,47,48,55] MSM were more likely to use PrEP if they were personally told it was effective by another user or a partner.[56,45] Overall among MSM, primary motivator for PrEP use is protection from HIV.[44,45,55,57] Thus strategies to increase PrEP use among MSM may include outreach to encourage STI clinic visits, HIV testing and peer counseling.

4. PrEP among female sex workers

Few studies have evaluated willingness and interest in PrEP use among female sex workers. The majority of these studies collected data using questionnaires administered in China.[58–60] In the studies identified,[58–60] one definition of sex work was stated: providing sexual services with the primary purpose of receiving money.[58] Across studies evaluating willingness to use PrEP among female sex workers, PrEP awareness and HIV knowledge were low.[58–60] Female sex workers were positive toward the use of PrEP once they were aware of it.[58–60] Positive responses among a sample of 1161 female sex workers in China increased from 69% to 80% when it was assumed that PrEP would be offered at no cost and that people were

already using the medication.[60] However, female sex workers thought it would be difficult to remember to take a daily pill.[61,62]

Chinese female sex workers in urban areas were more willing to use PrEP than those in rural areas.[60] Authors noted that in the female sex worker population, "willingness" to use PrEP did not necessarily translate into a person's "actually" using PrEP.[60–62] Having a history of STIs, HIV transmission knowledge, alcohol use, having received free consultation for HIV/AIDS, and use of preventive STI medications were all statistically significant positive predictors of willingness to use PrEP.[60] In female sex worker populations possible medication side-effects and cost were primary barriers to PrEP use.[58,59]

5. Costs

In 2012, the lifetime cost of treatment for an individual diagnosed with HIV at age 35 was approximately $326,500.[63] In 2009,in Illinois alone, the total lifetime treatment cost for 1,708 new HIV diagnoses was $627 million.[64] Prevention of new HIV infections is less expensive (per person) than a lifetime course of HIV treatment.[65] Thus, PrEP makes economic healthcare sense. In the United States, the cost of PrEP therapy is estimated to be $900 per month, not including the costs of counseling and HIV testing.[65] Many commercial health insurance companies have developed policies to cover PrEP costs.[66,67] Public sources of health insurance have varying coverage,[1] which can make the cost of PrEP out of reach. Since adults aged 18 to 34 are more likely to lack health insurance,[68] medication assistance programs are available to cover the cost of PrEP for individuals who do not have health insurance or are underinsured.[1] Individuals may find out about medication assistance from their healthcare provider, case worker, or a pharmacist. Information on how to access the Truvada medication assistance program is also provided on the Gilead website. Eligibility is determined after submitting an application with a copy of the prescription and documentation of income and residency.[69]

Administration of PrEP may not be necessary for the duration of a person's lifetime due to decreasing levels of risk as they age. The literature suggests that wide-scale PrEP use could

lead to “herd immunity” that would reduce HIV transmission at a population level in the United States. Due to the significant costs associated with treating every at risk adult, PrEP use is targeted to specific populations that have the highest HIV risk.[70] These populations include MSM, serodiscordant couples, and individuals with a history of infrequent condom use with partners of unknown sero status for HIV.

Gilead, the manufacturer of the PrEP medication called Truvada, offers co-pay assistance to those who do not have public or private health insurance.[69] Aetna insurance company requires pre-certification for Truvada use for PrEP.[66] To receive this medication as a covered benefit, a member must receive an HIV-negative test result immediately before PrEP initiation, be tested for HIV every three months thereafter, and as undergo biannual monitoring of creatinine levels.[66] Similarly, other major health insurance providers, such as United Health Care, approve PrEP when the member has a prescription from their physician indicating that PrEP s needed for HIV prevention.[67] Most insurance companies approve a 90-day supply of PrEP at a time and require quarterly or biannual HIV testing for the prescription to be renewed.[66,67]

6. PrEP in African American women

Two separate studies that evaluated African American women’s attitudes about PrEP reported that less than 10% of participants were familiar with PrEP.[71,72] In another study,[73] in which African American women (n=35) discussed PrEP attitudes and program preferences within focus groups, participants responded favorably to the possibility of taking an oral pill daily for HIV prevention. African American women were more likely than white women to report potential use of PrEP.[73] Women under 30 were more likely to use PrEP in combination with other prevention methods, such as condoms, than use PrEP alone.[73,74]

In Southern states, PrEP uptake is slow among African American women due to the lack of awareness, poverty, and the lack of access to healthcare.[75] The inconvenience of obtaining the medication from a healthcare provider also was a concern among African American

women.[71,76] Side-effects of PrEP and the costs associated with PrEP were also considered possible barriers.[76] The most common barrier to PrEP use reported in the literature is low perceived risk of HIV infection by persons at high risk for HIV infection.[11] Individuals at high risk for HIV infection have self-perceived risk comparable to that of individuals at lower risk.[72,76] If an African American woman believes that she is at low risk for HIV acquisition, she is far less likely to be tested for HIV,[11] seek treatment, or adhere to a daily medication regimen for HIV prevention.[77] Common explanations for low perceived HIV risk among African Americans include believing that HIV is an issue for white gay men and that HIV-infected individuals can be identified by their appearance.[11] The literature does not report that African American women increase sexual risk behaviors after initiating PrEP.[72,76] HIV testing is a necessary preface to PrEP implementation; however, one study found that HIV testing was not viewed as a barrier to using PrEP.[76] Thus, addressing the perceived risk and additional barriers will probably require a multi-faceted approach to increase PrEP usage.

In conclusion, despite a number of studies conducted to date, no studies have directly compared the PrEP-related perceptions of African American women to those of healthcare providers. To address this gap in the literature, this dissertation presents two manuscripts specifically addressing perceptions of factors that influence the potential use of PrEP among African American women. The first manuscript describes current levels of PrEP awareness, information seeking, and use among African American women in Chicago. The second manuscript compares African American women's perceptions of factors influencing PrEP use to the perceptions of healthcare providers.

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II. HIV SEXUAL RISK BEHAVIORS, HIV TESTING INTENTIONS, USE OF MEDIA, AND CURRENT LEVELS OF PRE-EXPOSURE PROPHYLAXIS (PrEP) AWARENESS AMONG HIGH-RISK AFRICAN AMERICAN WOMEN

A. Background

African American women account for 61% of human immunodeficiency virus (HIV) infections among women in the United States.[1] In Chicago, African American women account for 81% of new HIV diagnoses in 2016.[2] Heterosexual intercourse has contributed to 83% of new HIV infections in women.[3] Condomless heterosexual intercourse is the primary contributor to HIV infections in African American women, with most acquiring the infection from their main sexual partner.[4,5] Furthermore, small sexual networks, or connections between individuals and their sexual partners, which contain a high prevalence of HIV also lead to increased exposure to the virus.[4,5] Ethnicity is an important factor in the HIV epidemic for women, as social determinants of health pose risks for HIV aquisition.[6] Low socioeconomic status and life stress have associations with risky sexual practices.[7] Risky sexual practices include having multiple sexual partners, young age of sexual debut, and inconsistent condom use.[7] In African American heterosexual partnership dyads males tend to have more authority over the use of condoms during intercourse, giving the women less control over their exposure to HIV.[8,9,10,11] In light of these risk factors for African American women an oral HIV prevention method called pre-exposure prophylaxis (PrEP) is available that can help to give women control in preventing HIV, whether a condom is used or not.

In addition to condom use, testing for HIV has been a cornerstone of HIV prevention. A study[12] that evaluated racial and ethnic disparities in future testing intentions for HIV (n=98,971) found that the most common reason for receiving an HIV test was that the testing was part of a routine medical checkup or procedure. Rates of HIV testing are higher in African Americans than in whites; African Americans also reported higher intentions for future HIV testing than whites.[12] In high-risk populations, increased perception of risk was associated with decreased

intentions for HIV testing.[13] African American women understand the importance of HIV testing and condom use in HIV prevention;[14] however, those at high risk for HIV remain in the dark about medication that could prevent acquisition of the virus.[15–18]

In 2012, the Food and Drug Administration approved an oral pill called Truvada (emtricitabine and tenofovir disoproxil) as a form of pre-exposure prophylaxis (PrEP) for prevention of HIV.[19] Pre-exposure prophylaxis works by creating a virologic barrier that prevents the virus from attaching to CD4 cells.[20] CD4 cells, also known as T-cells, are blood cells that attack infection. Clinical trials have found that PrEP is effective in reducing the likelihood of HIV acquisition if the medication is taken daily.[21–23] According to Gilead, the manufacturer of Truvada, the number of PrEP users has increased every year since 2012; however, this increase is predominantly found among white, middle-aged men who have sex with men (MSM).[24] A possible explanation for why more African American women at high risk for HIV are not using PrEP is that they are simply unaware of the existence of the medication.

The phrase "PrEP awareness" refers to having heard of taking medication (PrEP) for prevention of HIV. The few studies that have evaluated PrEP attitudes in African American women found that PrEP awareness was low.[15,16,25] A qualitative study of 144 African American women found that participants had no knowledge of PrEP and that they expressed anger over not hearing of PrEP prior to their focus group participation.[18] Similarly, a mixed methods study of 119 African American women found that only 18% of participants were aware of PrEP.[16] In 2017, Collier, Colarossi, and Sanders found that 74% of female study participants in New York had never heard of PrEP prior to study enrollment.[15] However, in each of these three studies, once participants were informed about PrEP, the majority responded favorably to the possibility of using it for HIV prevention. A national telephone survey conducted among 1,068 African American and 441 white women found that African American women were more likely than white women to report potential use of PrEP.[26] Although awareness of PrEP is low among African American women, they are likely to consider PrEP once they are educated about this

form of HIV prevention.[18] Therefore, informing African American women at high risk for HIV about PrEP is the first step in leading them to contemplate PrEP use.

One way to direct information about PrEP to African American women is through dating applications and social media. Applications and social media are often used to meet new people, including sexual partners. It is easy to identify potential sexual partners though online dating sites or applications.[27] Risk behaviors tend to be higher in people that have used an application for dating than those who have not.[28] Dating websites, applications, and social media have advertisement space that could be used to increase PrEP awareness. In a time when most individuals living in the United States have access to the internet, a television, or a radio, awareness about PrEP remains low in one of the populations that could benefit most from it: African American women. When thinking of ways to inform African American women about PrEP we should consider various forms of media, from the radio to social media may represent important modes of information transfer.

B. Purpose

The purpose of this cross-sectional study was to describe the HIV sexual risk behaviors, use of media as a potential source of PrEP information, HIV testing intentions, and current levels of PrEP awareness of high-risk African American women in order to determine the most effective ways of informing them about PrEP.

C. Methods

Once institutional review board approval was obtained, recruitment took place in Chicago, Illinois, using flyers, palm cards, and Craigslist advertisements. For women responding to advertisements, screening forms were used to determine their eligibility. Under the study inclusion criteria, the principal investigator (PI) recruited 18- to 49-year-old cisgender women who identified as African American. Women had to be HIV-negative or of unknown status and have the ability to read and write in English. In order to align the study population with the Centers for Disease Controls and Prevention PrEP clinical practice guidelines,[29] eligible

participants had to affirm at least one of the following activities in the past six months: condom-less vaginal or anal sex with two or more men, vaginal or anal sex with a known HIV-positive man, or recreational injection drug use. Women excluded were currently pregnant, breastfeeding, or in a monogamous relationship in which their partner recently received an HIV-negative test result.

Eligible participants met with the PI for one study visit on the campus of the University of Illinois at Chicago or at a Chicago public library, whichever location was more convenient for the participant. A REDCap survey was administered using computer-assisted personal interviewing to gather information on HIV risk behavior, media use, dating site use, HIV testing, and PrEP awareness. The survey was an adaptation of a survey developed for MSM by Dr. Jo Stryker and associates [30] to "assess factors associated with current levels of knowledge, information-seeking, partner communication and use of PrEP among MSM." At the conclusion of the study visit, participants received a $20 Target gift card for their time.

A total of 89 potential participants were screened, of which 38 were not eligible. Reasons for ineligibility included not self-identifying as African American (one), being currently pregnant or breastfeeding (three), being in a monogamous relationship with a recently tested HIV-negative person (three), being over 49 years old (two), and replying "no" to all risk questions (29). Fifty-one women met the criteria for enrollment. Additional participant inclusion segmentation included one participant who reported sex with an HIV-positive person, one who reported injecting drugs to get high, and 49 who reported sex without a condom with two or more male partners in the six months preceding enrollment. Of the 51 women who were eligible, three did not enroll in the study due to scheduling conflicts. Consequently, recruitment of eligible participants resulted in a convenience sample of 48 women between the ages of 18 and 49 years. Table I describes the characteristics of the participants.

TABLE I

CHARACTERISTICS OF STUDY PARTICIPANTS (N=48)

Characteristics	**n (%)**
Age median, interquartile range	32,18-49
Gender	
Cisgender female	48 (100)
Ethnicity	
African American[a]	48 (100)
Relationship status	
Not in a relationship	19 (40)
In a relationship w/ man	25 (52)
In a relationship w/ woman	3 (6)
Concurrent relationships	2 (4)
Married to a man	4 (8)
Highest education level	
Some high school	1 (2)
Completed high school/GED	5 (10)
Some college	26 (54)
College graduate	16 (33)
Personal income	
$0–20,000	15 (31)
$20,001–30,000	5 (10)
$30,001–40,000	9 (19)
$40,001–50,000	2 (4)
50,000+	15 (31)
Prefer not to answer	2 (4)
Sexual orientation	
Heterosexual	38 (79)
Bisexual	9 (19)
Prefer not to answer	1 (2)
Current health insurance	
Yes	43 (90)
No	5 (10)
Perception of risk	
Low	34 (71)
Medium	8 (17)
High	4 (8)
Prefer not to answer	2 (4)
Country/territory born	
USA	47 (98)
Other (Tahiti)	1 (2)

[a]One participant of African American and Latino descent

D. Measures

Table II summarizes the measures used to describe sociodemographic factors, sexual risk, media use, dating application use, HIV testing, and PrEP awareness. All data was self-reported.

TABLE II

MEASURES

Construct	Operational Measure
Sociodemographic factors	
Age	Number of years lived since birth
Race/ethnicity	Self Identification of races (select all) and Hispanic/non Hispanic (yes/no)
Education	Highest grade or year of school completed
Income	Total personal income during the past year
Possession of Health Insurance	Have health insurance at time of study visit (yes/no)
Sexual Risk	
Perception of risk for HIV acquisition	In terms of sexual behaviors in the twelve months preceding enrollment; self-perception of low, medium, or high risk for HIV acquisition.
Condomless sex	In the 12 months preceding enrollment; how often were condoms used for vaginal and anal sex with main or causal male sexual partners
History of condomless sex work	In the past six months preceding enrollment exchanged sex for money, gifts, goods, drugs, shelter, or services
Use of media	
In a typical month how often do you use:	Facebook, Twitter, Instagram, YouTube, television, radio, online news print news,
Use of Dating applications	
In a typical month, how often do you use:	Craigslist, Tinder, Match.com, PlentyOfFish.com, Black People Meet, and OkCupid
HIV Testing	
Information seeking about HIV	In the 12 months preceding enrollment, looking for information about HIV prevention (condoms), how to talk to a partner about HIV, or taking medicine to reduce the chance of being HIV infected
Information seeking about HIV testing	Looking for HIV testing locations in the 12 months preceding enrollment
Intention to be tested for HIV	Intending to receive an HIV test in the six months following the study visit, twelve months following the study visit, before sex with a new partner, or testing together with a sexual partner
History of HIV tests	Number of tests in the two years preceding enrollment, location of most recent test, if applicable; reasons why never tested
PrEP awareness	
Heard of PrEP	“Prior to this study, have you ever heard of taking PrEP or Truvada before sex to prevent HIV, or have you never heard of taking PrEP or Truvada before sex to prevent HIV?”
Use of PrEP	“In the past 12 months, have you taken PrEP/Truvada before sex because you thought it would keep you from getting HIV, or have you not taken PrEP before sex?”

E. Results

Responses to survey questions were separated into the following categories: sexual risk behaviors; HIV testing; use of social media and dating applications; and PrEP awareness.

1. Sexual risk behaviors

The PI asked participants the following question: “Thinking about the sex you’ve had over the past 12 months, do you consider yourself to be at low, medium, or high risk for getting HIV?” Risk levels of low, medium, and high were subjective determinations made by each participant. Only four women (8%) perceived that they were at high risk for acquiring HIV and eight women reported medium risk (17%). Most participants perceived themselves to be at low risk for HIV acquisition (n=34, 71%). Of those 34 participants, 26 (76%) reported low risk despite reporting no (n=10, 29%) or inconsistent (n=16, 47%) condom use during vaginal sex with their main partner. A quarter of the participants who perceived themselves to be at low risk were college graduates, and 40% attended 1 to 3 years of college.

Thirty-nine participants (81%) reported having a main sexual partner. For the purposes of this study, a main partner was considered a boyfriend, spouse, significant other, or life partner. Of 39 participants with a main sexual partner, 26 (67%) reported that their main partner told them that his HIV status was negative. Three participants (8%) reported always using condoms during vaginal sex with their main partner. Typically, participants reported that they did not engage in anal sex with their main partner (n=30, 77%), however nine participants (23%) did report having anal sex with their main partner. Of those nine participants, five reported never using condoms, one reported using condoms about half the time, one used condoms most of the time, and two always used condoms. In the 12 months prior to enrollment, 23 participants (59%) discussed HIV testing and their last HIV results with their main sexual partner. Twenty-eight participants (72%) discussed using condoms with their main sexual partner. Two participants (5%) discussed PrEP with their main partner. Regarding concurrent partnerships,

25 participants (64%) reported having sex with another man during the time they were in a relationship with their main partner.

In this study, a casual partner was defined as a male sexual partner who was not considered a spouse, significant other, or life partner in the 12 months prior to enrollment. Generally, participants reported having casual partners (n=41, 85%). A range of one to six casual partners was reported, with a mean of two. Of the 41 participants who reported having a casual partner, 19 (46%) reported that their most recent casual partner stated he was HIV negative. Only nine of 41 participants (22%) reported always using condoms for vaginal sex, and three of the 41 participants (7%) reported always using condoms for anal sex with their most recent casual sexual partner. Table III compares responses given for main partners and casual partners.

TABLE III

PARTNER HISTORY AND CONDOM USE

Characteristics		**n (%)**
Partner history[a]		
Has a main partner		39 (81)
Does not have a main partner		9 (19)
Sex with another man while in a relationship with their main partner (concurrent sexual partners)[b]		
Had sex with another man		25 (64)
Did not have sex with another man		14 (36)
Number of casual partners in past 12 months mean (min, max)		2.13 (1, 6)
Partner told me his HIV status	Main partner[b]	Casual partner[c]
Yes	26 (67)	20 (49)
No/don't know	13 (33)	20 (49)
Prefer not to answer	0 (0)	1 (2)
Partner's HIV status		
Negative	26 (67)	19 (46)
Prefer not to answer	0 (0)	1 (2)
Condom use in past 12 months during vaginal sex		
Always	3 (8)	9 (22)
Most of time	12 (31)	13 (32)
About half the time	4 (10)	4 (10)
Sometimes	4 (10)	9 (22)
Never	15 (39)	6 (15)
NA: does not have vaginal sex with partner	1 (3)	0 (0)
Condom use in past 12 months during anal sex		
Always	2 (5)	3 (7)
Most of time	1 (3)	2 (5)
About half the time	1 (3)	0 (0)
Sometimes	0 (0)	0 (0)
Never	5 (13)	2 (5)
NA: does not have anal sex with partner	30 (77)	34 (83)

[a] n=48.

[b] n=39.

[c] Casual partner refers to most recent casual partner n=41.

For this study, condom-less sex work consisted of having vaginal or anal sex without a condom in exchange for money, gifts, goods, shelter, or services. In this sample, seven participants (15%) reported condom-less sex work. Of these seven participants, one (2%) was a college graduate, five (10%) attended college for 1 to 3 years, and one (2%) was high school-educated. Only three of the seven participants with a history of sex work considered themselves to be at high risk for HIV acquisition. Of the remaining four participants, two reported low risk and two reported medium risk for HIV acquisition. Four of the seven participants with a history of sex work were bisexual.

2. HIV testing

Of the 48 participants, 24 (50%) stated that they had not sought information about HIV or HIV testing locations in the 12 months prior to enrollment. Similarly, 23 participants (48%) did not seek information about HIV prevention or condoms. Notably, 42 participants (88%) had never sought information about taking medicine daily to reduce the chance of being infected with HIV. Nearly three-fourths of participants (n=35, 73%) had not sought for information about how to talk to a sexual partner about HIV.

Participants reported that they would have an HIV test every six months if the test were offered for free (n=38, 80%), if the testing location were near their home (n=39, 81%), if they would receive the results within 20 minutes (n=42, 89%), if the results would be kept confidential (n=40, 83%), if they felt comfortable with the provider (n=39, 81%), or if they could use a home-based testing kit (n=39, 81%). In terms of intentions, 20 participants (42%) reported intentions to receive an HIV test in the 12 months following the study visit, of which 16 participants (33%) reported intentions to do so in the six months following the study visit. Nineteen participants (40%) stated that they would have themselves tested for HIV before sex with a new partner; intentions to receive testing together with a sexual partner were similar, with 17 participants (35%) reporting they would receive testing together. In the two years preceding study enrollment, the mean reported number of HIV tests for the participants in the study was 1.90.

Results from questions about HIV testing history and sexual risk behavior are presented in Table IV. Forty participants (83%) reported having received an HIV test result in their lifetime. Twenty-nine participants (60%) received their most recent HIV test in a private doctor's office or clinic. Of those that had never been tested for HIV (n=8, 17%), three reported the rationale of thinking that they were at low risk for HIV infection, one reported that she did not know where to get tested, three reported no particular reason, and one preferred not to answer. One of the three participants who reported no particular reason for not being tested had a history of sex work.

TABLE IV

HIV TESTING AND RISK BEHAVIORS (N=48)

Characteristics	**n (%)**
HIV testing confidence	
Confident that I could get an HIV test	47 (98)
Prefer not to answer	1 (2)
HIV testing history	
Ever been tested for HIV	40 (83)
Location of most recent HIV test	
Private doctor's office/clinic	29 (60)
Public clinic/community health center	6 (13)
HIV testing site	1 (2)
Street outreach/mobile unit	1 (2)
Hospital (inpatient)	2 (4)
Emergency room	1 (2)
Never been tested for HIV	8 (17)
Reasons not tested	
Low perception of risk	3 (6)
Don't know where to get tested	1 (2)
No particular reason	3 (6)
Prefer not to answer	1 (2)

3. Use of media and dating applications

To determine effective ways to disseminate educational PrEP information, participants were asked how often they used various forms of media in a typical month. The options were daily, 2 to 5 times a week, once a week, 2 to 3 times a month, less than once a month, and never. For analysis, we renamed and combined some options illustrated in Figure 1, which compares avenues of possible PrEP campaign exposure according to frequency of use. Television had the highest reported use, with 32 participants (67%) using it daily. Radio and Facebook use followed with 31 participants (65%) and 30 participants (63%) respectively. Twitter had the lowest use, with 24 participants (50%) reporting that they never used the application in an average month.

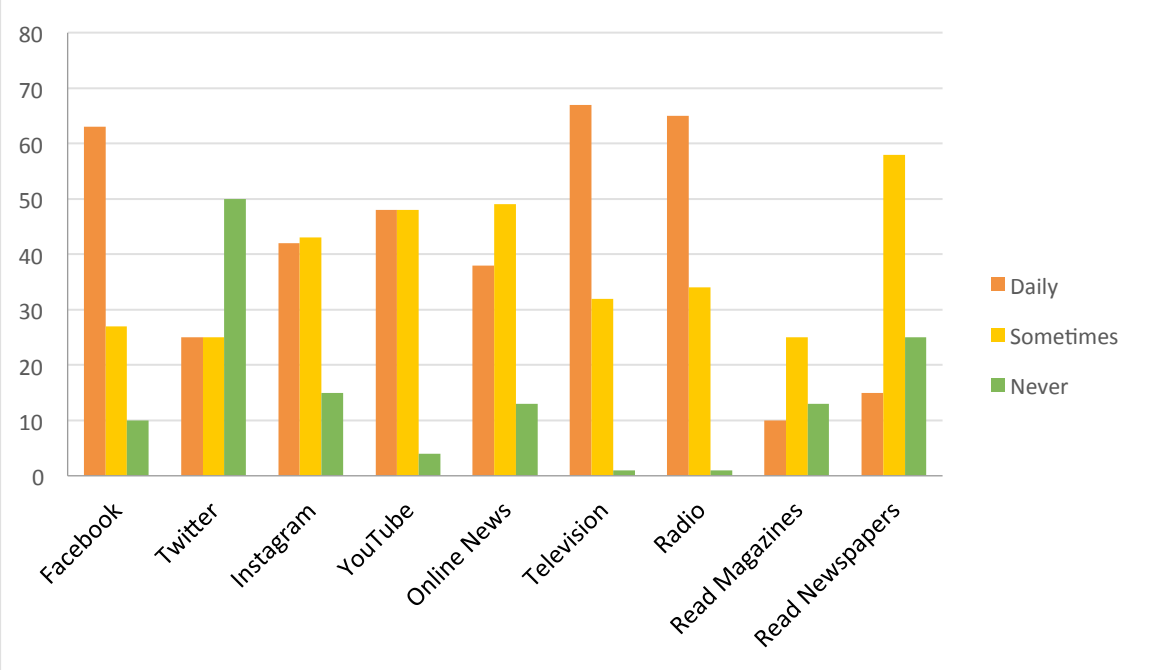

Figure 1. Use of media in an average month

General use of online dating sites and applications was low, with 34 participants (71%) reporting that they never used Craigslist for dating. In a typical month, respondents reported never using the following dating applications: Tinder (n=37, 77%), Match.com (n=43, 90%), PlentyOfFish (pof.com; n=43, 90%), and BlackPeopleMeet.com (n=44, 92%). OkCupid.com was the least used dating site in a typical month (n=47, 98%).

4. PrEP awareness

Thirteen participants (27%) reported that they were aware of PrEP prior to this study (Table V). No participants reported personal use of PrEP. Forty-six participants (96%) reported that they did not know anyone who had taken PrEP for HIV prevention. If given options for PrEP administration, 31 participants (65%) reported that they would use a vaginal ring for HIV prevention in the same way vaginal rings are used for birth control, if it were safe and effective. Similarly, 34 participants (71%) reported that they would get an injection 2 to 3 times a year for HIV prevention if it were safe and effective.

TABLE V

AWARENESS (N=48)

Characteristics	**n (%)**
PrEP awareness	
Ever heard of PrEP	13 (27)
Never heard of PrEP	35 (73)
In the past 12 months, I have taken PrEP	0 (100)
I know someone who has taken PrEP	2 (4)
I do not know anyone who has taken PrEP	46 (96)
Hypothetical PrEP methods	
Would use vaginal ring for HIV prevention	31 (65)
Would not use vaginal ring	15 (31)
Prefer not to answer	2 (4)
Would get an injection 2 to 3 times a year	34 (71)
Would not get an injection 2 to 3 times a year	14 (29)

F. Discussion

The findings of this study represent a contribution to the literature on PrEP among African American women. The most important new study findings are the following: (1) African American women who engage in high-risk behaviors perceive themselves to be at low risk for HIV acquisition; (2) African American women are not being informed about PrEP during visits for HIV tests or routine healthcare visits; (3) television, radio, and Facebook may be ideal modes for disseminating PrEP information, as these media were used frequently by participants in an average month; and (4) African American women have little awareness of PrEP, and the study participants did not know other women who had used PrEP.

Despite the fact that many of the women in this study engaged in risky sexual behaviors such as inconsistent condom use and condomless sex work, the present study found a low perception of HIV risk in this sample of women. The finding of low perception of risk is both notable and ironic because this sample is considered to be at high risk for HIV acquisition. The finding is aligned with results from studies that evaluated perception of risk among other high-risk African American women. For example, a study [31] found that 83% of women were "not worried at all" that their sexual behavior might lead to HIV. Similarly, other high-risk populations such as MSM and serodiscordant couples typically underestimate their risk for HIV acquisition.[32–34] Low perception of risk for HIV acquisition often translates into low motivation to change risky sexual behaviors such as the number of partners, lack of condom use, and lack of preventive behaviors.

Like other studies [4,32,35] that evaluated concurrent sexual partnerships, in African Americans,[32] this study found that most participants (n=39, 81%) had casual relationships outside of their current main relationship. The women in this study reported a median of two sex partners in the six months preceding study enrollment. Having two sex partners in a six month period is congruent with results from a study of high-risk women with a predominantly African American sample (n=1,387 of 1,628, 85%), which also found that the median number of

sex partners in a six-month period was two.[4] Women who have never married, are divorced, widowed, or separated are more likely to have sexual encounters with different partners during the same timeframe, or concurrent partnerships, than married women.[4] Women may engage in concurrent partnerships because they believe that their partners also have other partners,[4] and African American women are twice as likely to have concurrent partnerships than white women.[35] Moreover, 80% of concurrent partnerships are with people from the same ethnic background. Which leads to considerable risk for African American women, as their concurrent partnerships are likely to be with African American men, who have the highest incidence of HIV in the United States.[35]

The women in our study reported low rates of anal sex activity. In fact, most of the women reported not having anal sex. Although the literature states that black women are more likely to report condom use during anal sex than white women,[36] the present study found that inconsistent condom use was common among the few participants that reported having anal sex. Engaging in anal sex with a main partner has been associated with HIV infection.[37] In addition, heterosexual anal sex is more common in individuals who inject drugs,[37] but recreational injection drug use was reported by only one participant during screening. Low recreational drug use by the women in our study might account for the low reporting of anal sex.

We were interested in learning about media and dating application use among high-risk African American women. Reports of online dating in the sample were surprisingly low. Although some participants found out about this research study on Craigslist, most did not use the site's personals section for dating. In regard to media use, radio, television, and Facebook were used daily by at least 63% of participants. These forms of media could be ideal platforms for dissemination of PrEP information tailored to African American women. These women cannot use PrEP if they remain unaware of its existence. Barriers to PrEP use identified by previous studies involved its cost and accessibility;[17,18,38] however, lack of PrEP awareness also plays a sizeable role in the slow uptake of PrEP among African American women .

Of the 29 (60%) participants who received their most recent HIV test in a physician's office, only nine (19%) had heard of PrEP. Although PrEP-aware participants were not asked how they learned of PrEP, this finding is an example of a missed opportunity to educate African American women on the latest advancements in HIV prevention during healthcare visits for HIV testing. A qualitative study[18] found that African American women were likely to consider use of PrEP if it was recommended by a trusted physician, preferably a gynecologist or primary care physician. Gilead (Foster City, CA), the manufacturer of Truvada, estimated that it had not seen the same increases in PrEP use among African American women over the past 5 years that it had seen in other populations of users.[24] Gilead estimates of lacking PrEP use among African American women are supported by the study findings, as no participants reported previous PrEP use, and 96% of participants reported not knowing anyone that had used PrEP.

Low perceived risk of HIV acquisition has been associated with low PrEP uptake.[33] High-risk African American women may be able to better understand their susceptibility to HIV if the information is delivered to them after the collection of their sexual histories during medical appointments. Providers should aim to develop a trusting rapport with African American female patients before initiating a conversation about PrEP. Messages that provide PrEP information should be targeted to high-risk African American women through Facebook, television, and radio, as these media are frequently used by this population in a typical month. Because this sample of women did not report frequent use of online dating applications or sites, it would be worthwhile to investigate how high-risk African American women meet their sexual partners.

Future research should evaluate the HIV acquisition risk perceptions of African American women who are PrEP users to determine whether their motivation for PrEP use is fueled by their perception of risk. In addition, future research should compare the risk behaviors and willingness to use PrEP of middle-class African American women to those of African American women of lower socioeconomic status to provide a broader picture of this understudied population. Finally, certain findings in this study have not been linked with causes; for example,

three participants reported that they always used condoms during sex with their main partner, but whether the consistent use of condoms was for prevention of sexually transmitted diseases or for birth control is unknown. Research on the motivation for consistent condom use versus the motivation for consistent PrEP use among African American women would provide better understanding of HIV prevention preferences in this population.

G. Limitations

Our study has several limitations. First, this study used a small convenience sample, and data collection took place in one geographical area of Chicago. Thus, the results are not necessarily generalizable to African American women throughout the United States. In addition, participants self-reported their HIV status, and recall bias is sometimes observed in self-reported data. Because the PI asked participants survey questions in person, it is also possible that participants provided socially favorable responses, creating social desirability bias. Moreover, to further gauge risk for HIV acquisition, a more detailed survey could have assessed previous diagnoses of sexually transmitted infections, whether sexual partners had a history of incarceration, and condom negotiation skills. Furthermore, as this study was cross-sectional, there was no way to determine whether participants' willingness to use PrEP translated into actual use of the medication. Finally, toward the end of the data collection period, the World Health Organization changed the guidelines for PrEP use to include HIV-negative pregnant and lactating women, a subset of women that was excluded from this study.

H. Conclusion

Our study aimed to describe sexual risk behaviors, HIV information seeking, and HIV testing intentions among African American women to better understand possible ways to provide PrEP information to this demographic. Both PrEP awareness and the perception of HIV risk were low among high-risk African American women. However, the women were open to the idea of using PrEP once they were informed about it. Educating African American women about their risk for HIV acquisition and the benefit of PrEP use is the first step in increasing PrEP

uptake. The findings of this study support use of television, radio, and Facebook to disseminate information about PrEP to African American women. Public health groups focusing on HIV prevention should strive to increase PrEP awareness in populations of women at high risk for HIV acquisition in the United States. Additional research would benefit the development and placement of quality educational materials that promote PrEP to African American women.

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III. COMPARISON OF PERCEPTIONS FROM AFRICAN AMERICAN WOMEN AND HEALTHCARE PROFESSIONALS REGARDING FACTORS THAT INFLUENCE THE LIKELIHOOD TO USE PRE-EXPOSURE PROPHYLAXIS (PrEP) FOR HIV PREVENTION

A. Background

Among women in the United States, African Americans have the highest rates of human immunodeficiency virus (HIV).[1] Eighty-six percent of African American women living with HIV contracted the virus through heterosexual contact.[1] As of 2015, African American women were three times more likely than their white counterparts to contract HIV[1]. Since the beginning of the ongoing HIV epidemic, the public health focus has been on identifying interventions that curtail HIV risk behaviors. Methods of HIV prevention have primarily been intended to discourage condomless sexual intercourse and increase the number of individuals who are regularly tested to determine their HIV status.

There have been several advancements in biomedical HIV prevention methods over the past 10 years. HIV vaccination trials have been disappointing due to the diverse ways in which the virus impacts the immune system make HIV vaccine development difficult.[2–7] Safe vaginal microbicides for HIV prevention exist, they have shown poor efficacy.[8,9,10] Women had difficulty adhering to the dosing regimen and complained chiefly about the leaking sensation of the vaginal gel.[9,11–13] Vaginal rings as a mode of HIV prevention medication have shown high acceptability and adherence among women,[14,15] however, the rings' efficacy and safety are still under evaluation.

Pre-exposure prophylaxis (PrEP) is a biomedical intervention that reduces the acquisition of HIV in high-risk populations.[16–19] In 2012, the Food and Drug Administration approved the use of Truvada as a form of oral PrEP.[20] PrEP consists of a combination of two antiretroviral drugs, 300 milligrams (mg) of tenofovir disoproxil fumarate and 200 mg of emtricitabine (TDF-FTC).[16–18,21] In September 2015, the World Health Organization published the following recommendation: "Oral PrEP containing TDF should be offered as an additional

prevention choice for people at substantial risk of HIV infection as part of combination HIV prevention approaches."[20]

PrEP works by creating a virologic barrier that prevents the virus from attaching to CD4 cells [22] The virus is unable to attach and replicate, which causes it to die.[23] Oral PrEP has shown high efficacy when an individual shows medication adherence.[16,17] A high serum drug level is necessary for PrEP to remain effective, and thus adherence to the once-a-day drug regimen is vital. However, nausea, vomiting, and dizziness are common side-effects of PrEP.[18] To reach protective levels in vaginal tissues, PrEP should be taken daily for at least three weeks prior to possible exposure to HIV. Although intermittent dosing of PrEP was considered as an alternative to daily pills,[23] adherence and effectiveness have been shown to be higher with daily dosing regimens.[24–26] Intermittent use of PrEP has shown lower protective effects and increased rates of drug resistance, which is a common concern among healthcare providers.[25]

A qualitative study[27] that evaluated healthcare providers' perceived barriers and facilitators for prescribing PrEP found that patients' adherence to the PrEP regimen was a major concern. Providers feared that patients would only use the drug intermittently, a practice that might lead to antiretroviral resistance.[27] In addition, unknown long-term adverse effects caused providers to hesitate when deciding whether to prescribe PrEP to individuals with no other health issues. [27,28,29,] Another school of thought among healthcare providers that creates a barrier to prescribing PrEP is the belief that taking preventive HIV medications would increase patients' risky sexual behaviors. An increase in high-risk behavior is referred to as risk compensation. Although risk compensation was not found to be significant among participants in PrEP clinical trials,[24,25,30–33] it remained the main concern for healthcare providers across studies.[27–29]

The perceptions of healthcare providers may influence whether a client is considered eligible to receive and will receive a prescription for PrEP. A survey conducted among 360 healthcare providers[28] that evaluated knowledge of, perceptions of, and willingness to adopt

PrEP found that PrEP knowledge was lower in non-physicians, public health providers, and those of ethnicities other than white. A similar study conducted among 189 HIV specialists that evaluated PrEP knowledge, attitudes, and prescribing practices found that most providers were aware of PrEP but that only 28% (n=10) had previously prescribed PrEP to heterosexual women.[29] Providers reported a patient's having an HIV-positive partner as the most influential factor when deciding whether to prescribe PrEP.[29] Providers perceived HIV testing as more effective than PrEP in reducing HIV acquisition.[29] Having a patient who reports frequent condomless sex was the second most influential factor when deciding whether to prescribe PrEP.[29] Consequently, performing a sexual behavior risk assessment is a necessary component of determining PrEP eligibility. However, HIV specialists face challenges when discussing sexual risk behaviors with patients.[27] Providers also doubt the comprehensiveness and authenticity of responses they receive from patients about their sexual risk behaviors.[27]

Another influential factor in providers' deciding to prescribe PrEP is knowing colleagues who are prescribing the medication for HIV prevention, as providers highly value the opinions and experiences of provider colleagues.[27] Conversely, a practitioner's view of the likelihood that an HIV-negative person would adhere to PrEP could be negatively influenced if other providers shared experiences with HIV-positive patients who did not adhere to antiretroviral treatment.[27]

African American women are more likely than white women to report potential use of PrEP.[34] However, PrEP awareness and uptake still remain low among African American women.[35–38] Racial disparities, including poverty and structural barriers such as lacking health insurance or reliable transportation, challenge access to PrEP.[37] The convenience of obtaining the medication is important to African American women who consider using PrEP.[38,39] Therefore, having access to a healthcare provider and a pharmacy may influence their likelihood of using PrEP. Testing for HIV is a necessary prerequisite to PrEP implementation, but study findings suggested that HIV testing was not viewed as a barrier to using PrEP.[39]

Few studies have evaluated the PrEP perceptions of either African American women or healthcare providers. Moreover, no study to date has used concept mapping to compare African American women's and healthcare providers' perceptions of factors likely to influence PrEP use among African American women.

B. Purpose

The study had two aims. The first was to determine which factors influence African American women's likelihood of using PrEP for HIV prevention. The second was to compare African American women's perceptions of factors influencing PrEP use to perceptions of healthcare providers.

C. Methods

This study used concept mapping and its associated quantitative analysis (CS Global Max Concept System® Incorporated, Ithaca, New York) to bring qualitative and quantitative data together to generate, categorize, and compare factors that African American women and their healthcare providers feel influence a woman's likelihood of PrEP use. Concept mapping is a "structured conceptualization process" developed by William Trochim and colleagues, producing a conceptual framework that describes how a group perceives a subject.[40–42] Multidimensional scaling is used to generate dimensional figures to present the sorted and rated data. Because PrEP is a relatively new approach to prevention of HIV, the Principal Investigator (PI) chose the concept mapping method because it combines the qualitative aspect of participatory research with quantitative data analysis using software. The concept mapping process allows participants to identify and rate the importance of their perceptions.[41,42] To compensate for low awareness about PrEP, the 48 African American women who participated in this study watched a five-minute educational video produced by *whatisprep.org* prior to initiating the concept mapping process.

1. Recruitment

After study approval by the institutional review board at the PI's university, the PI used online and posted advertisements to recruit 48 cisgender, African American women between the ages of 18 and 49 at high risk for HIV acquisition. High risk for HIV was defined as a "yes" response to at least one of the following questions: "In the past six months have you had vaginal or anal sex without a condom with two or more men?", "Have you had vaginal or anal sex with an HIV-positive man?", and "Have you injected recreational drugs to get high?" Women excluded were currently pregnant, breastfeeding, or in a monogamous relationship in which their partner had recently received an HIV-negative test result.

In addition to high-risk African American women, the PI also recruited 10 healthcare providers via email. The healthcare providers met the following enrollment criteria: at least one year of experience in HIV prevention or in the care of individuals living with HIV and familiarity with the current Centers for Disease Control and Prevention (CDC) PrEP recommendation.

2. Data collection

Data collection took place during one study visit with each participant in Chicago, Illinois. According to Trochim,[41] the concept mapping process has six steps: preparation, generation of statements (brainstorming), structuring of statements (sorting and rating), representation of statements (generation of maps), interpretation of maps, and utilization of maps, with the final three steps comprising data analysis. In the first step, preparation, the PI selected a focus statement to guide the direction of brainstorming. The focus statement used for this study was "Some factors that might influence a woman's likelihood to use or not use PrEP are…."

a. Brainstorming

During the second step, brainstorming, the first 15 women enrolled generated short responses to the focus statement. The oral responses were compiled into an anonymous list using CS Global Max. Participants generated 53 statements that were edited for relevance and redundancy, resulting in 41 statements. Four additional statements were created because the

original statement contained two ideas, resulting in 45 statements. The randomization function in CS Global Max (Concept Systems, Ithaca, NY) shuffled the order of and numbered the statements prior to the third step, sorting and rating.

b. Sorting and rating

In the third step of the concept mapping process, sorting and rating, the 45 statements from the brainstorming session were individually printed on laminated cards. The next 30 enrolled women and the 10 healthcare providers used the cards to group similar statements into piles in a way that "made sense to them."[41,42] Participants sorted the statements using the following stipulations: not all statements could be in one pile, each statement could belong to only one pile, and not all statements could be placed in their own individual piles.[41] Immediately after sorting the statements into piles, participants labeled each pile with an overall theme. Participants then used a rating sheet to rate each of the 45 statements using this five-point Likert scale: 1=not at all influential, 2=slightly influential, 3= moderately influential, 4=very influential, and 5=extremely influential. All sorting and rating responses were entered into CS Global Max for data analysis.

3. Data analysis

In the fourth step, multidimensional scaling is used to generate dimensional figures based on a composite of the ratings. The figures included the cluster map, the pattern match, and the go zone. The cluster map shows groups of statements produced by a hierarchical cluster analysis.[43] The pattern match is a graph that compares the average cluster ratings between two variables[43] (in this case, African American women and healthcare providers). Bivariate scatter plots of the pattern match data, called go zones, are displayed on an X/Y graph divided into four quadrants.[43] Each type of figure is further discussed below.

A small focus group completed the fifth step of the concept mapping process, interpretation of maps. The focus group met in a private room at a Chicago Public Library. Interpretation of maps is a participatory process that involves presentation of maps to a small

number of participants. In this case, the women communicated their understanding of whether the items and clusters of items in the diagrams were related to PrEP use. The women shared their opinions about diagrams that compared women's and healthcare providers' perceptions of factors that influence PrEP use. Six women originally agreed to participate in this step, but on the day of the focus group meeting, two participants canceled and one participant did not show up. Consequently, the three remaining women completed the interpretation of maps. For this study, the sixth step, utilization of maps consisted of generating two publications that provide results to health care providers and stakeholders for the use of informing interventions aimed to increase PrEP uptake in African American women.

D. Results

1. Participant characteristics

The study participants included 48 African American women and 10 healthcare providers (N=58). Table VI shows participant demographic characteristics.

TABLE VI

CHARACTERISTICS OF STUDY PARTICIPANTS

Characteristics	African American Women[a]	Healthcare Providers[b]
Age (years, median, interquartile range)	32 (18-49)	50 (29-62)
Gender		
Female	48 (100)	8 (80)
Male	0 (0)	2 (20)
Ethnicity		
African American	47 (98)	8 (80)
African American/Latino	1 (2)	0 (0)
White	0 (0)	2 (20)

[a] n=48.

[b] n=10.

The healthcare providers included six nurses, one clinic coordinator, one HIV research coordinator, and two outreach workers. Their years of experience in HIV prevention and care ranged from one to 35. All 10 providers completed the rating; however, only nine completed the sorting because one study visit was inadvertently interrupted. The provider was called away, and thus she was unable to complete the sorting portion of the study visit. Rescheduling attempts with the provider failed.

2. Statements

Forty-five statements were generated during the brainstorming process. Table VII lists the statements and the average rating scores provided by the women and healthcare providers. Among the women, the factor most likely to influence potential use of PrEP, with an average rating of 4.74, was “Knowing that PrEP will prevent me from getting HIV when my partner won’t use a condom.” Among the healthcare providers, the factor most likely to influence potential use of PrEP in African American women was “Having an HIV positive partner,” with an average rating of 5.0. The lowest-rated statement among African American women and healthcare providers alike was “Being bisexual,” with average ratings of 2.05 and 2.67, respectively.

TABLE VII

CLUSTERS

Cluster Name	#	Statement	Women's Rating Average	HCPs' Rating Average
Access			**4.63**	**4.61**
	44	Easy to obtain the medicine from a pharmacy	4.70	4.44
	26	Being easy to get a prescription from a doctor	4.57	4.78
Financial			**4.48**	**4.46**
	36	Costing too much money out of pocket	4.67	4.78
	25	Being affordable	4.57	4.89
	11	Being covered by health insurance	4.60	4.78
	21	Being provided for free at healthcare clinics	4.70	4.33
	17	Cost of PrEP without insurance	4.53	4.78
	3	Not having to pay a copayment	4.47	4.89
	10	The cost of the HIV testing	3.80	2.78
Best benefits			**4.55**	**4.14**
	4	Knowing that PrEP will prevent me from getting HIV when my partner won't use a condom	4.77	4.67
	23	Being easy to use	4.60	4.56
	1	Being non-painful	4.67	4.11
	40	It protects you from getting the virus as long as used properly	4.53	4.44
	14	Low number of side-effects	4.73	4.14
	42	Taking the pill only once a day	4.23	4.22
	5	Helping to strengthen the immune system	4.33	3.22
Protection			**4.37**	**4.36**
	33	Protecting myself from HIV	4.67	4.78
	45	Protection for my partner	4.63	4.33
	37	Not wanting to risk infection	4.47	4.22
	20	Another form of protection If I don't want to use a condom	3.70	4.11
Medication			**3.65**	**3.89**
	19	Possible long-term side-effects that could make me sick	4.43	3.89
	29	Make me sick after use	4.30	4.11
	24	Possible allergic reactions	4.10	4.00
	8	Having to remember it every day	3.65	3.89
	38	Possibility of upset stomach	3.70	3.78
	2	Size of the pill	3.53	3.89
	7	Dislike of taking pills	3.17	4.11
	12	Getting tired of swallowing a pill every day	3.00	4.11
	13	Having a nasty aftertaste	2.93	3.11
Setbacks			**3.52**	**3.81**
	34	Having to take forever even if not at risk every day	3.73	4.11
	18	Hard to find the medication	3.60	4.11
	15	Preference to use a condom	3.44	4.00
	22	The number of days you take PrEP	3.27	3.00
Network			**3.46**	**3.49**
	28	Having an HIV-positive partner	4.27	5.00
	41	Being sexually risky	4.33	3.78
	31	Having more sexual partners	3.87	4.00
	32	The ability to educate friends about the medication	3.50	3.11
	27	Having family or friends that use PrEP	3.40	3.33

Cluster Name	#	Statement	Women's Rating Average	HCPs' Rating Average
Network	39	High rates of HIV in my neighborhood	3.43	3.11
	43	Personally knowing someone that has HIV	3.20	3.44
	35	Being around people that have HIV	3.30	3.00
	16	Being bisexual	1.87	2.67
Fear			**2.64**	**3.89**
	9	Thinking PrEP is not necessary for me	2.97	4.11
	30	Scared of being tested for HIV	2.50	3.78
	6	Being scared that I already have HIV	2.47	3.78

HCP=Healthcare provider

HIV= Human Immunodeficiency Virus

PrEP=Pre-exposure Prophylaxis

3. Concept maps

A cluster, based on the sorting and rating, represents a group of statements that share a similar meaning. Clusters are groups of statements that were frequently placed in similar piles by participants during sorting. Each cluster has a label that summarizes the statements contained within. The sorting of statements yielded eight clusters: access, financial, best benefits, protection, medication, setbacks, network, and fear. The smallest cluster (access) contained two statements, and the largest clusters (medication and network) contained nine statements. The three types of concept maps used in this study were the cluster map, the pattern match, and the go zone.

a. Cluster map

Clusters are groups of statements that were frequently placed in similar piles by participants during sorting. Each cluster has a label that summarizes the statements contained within. The cluster map (Figure 2) illustrates how multi-dimensional scaling arranged the 45 statements. Each number represents the average influence rating on a scale of one (not at all influential) to five (extremely influential). Smaller clusters are more coherent than larger clusters, which are widely spaced. More layers indicate a higher level of influence, as indicated by the cluster legend. The access cluster contains statements about obtaining PrEP medication from healthcare providers; it is the smallest and most influential cluster. The financial cluster contains statements concerning the costs associated with use of PrEP, and statements in the best benefits cluster describe perceived benefits of using PrEP. Side effects and ideas about the actual PrEP pill are included in the medication cluster. The medication cluster is the largest; however, it is not extremely influential, as is evidenced by its having only three layers. The setbacks cluster contains statements of reasons that participants did not want to use the PrEP medication. Statements surrounding use of PrEP by people who frequently socialize with participants are contained in the network cluster. Fear, the least influential, one-layer cluster, contains statements about being frightened of HIV and HIV testing.

Kruskal and Wish (1978) identified the stress index, an important diagnostic statistic frequently used in multidimensional scaling.[44] A stress value indicates the fit of the map to the input similarity matrix. The final stress value for this study's concept map is 0.2492. According to Kane and Trochim (2007), this stress indicator is within the range of most concept maps.[42]

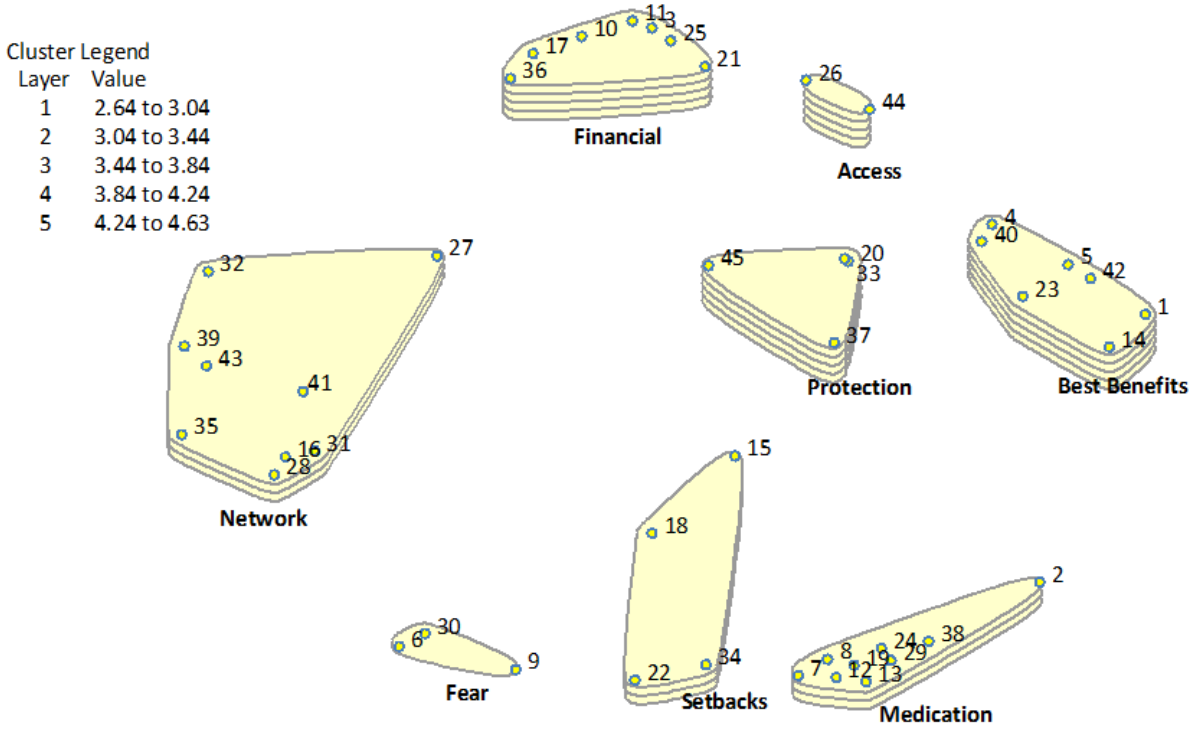


Figure 2. Cluster Map. A cluster is a group of statements that were frequently placed in the same pile during sorting. Each cluster has a label that summarizes the statements contained within. The cluster legend represents the average influence rating using layers on a scale of one (not at all influential) to five (extremely influential). Smaller clusters are more coherent than larger clusters that are widely spaced. More layers indicate a higher level of influence, as indicated by the cluster legend. *Access* contains statements about obtaining PrEP medication from healthcare providers and is the smallest and most influential cluster. The *Financial* cluster contains statements concerning costs associated with use of PrEP. Statements in the *Best Benefits* cluster describe perceived benefits of PrEP use. PrEP side-effects and ideas about the actual pill are included in the *Medication* cluster; this is the largest cluster, but it was not extremely influential, as evidenced by its having only three layers. The *Setbacks* cluster contains reasons that participants did not want to use the medication. Statements about PrEP use among people who frequently socialized with participants are contained in the *Network* cluster. *Fear,* the one-layer and least influential cluster, contains statements about being frightened of having HIV and of HIV testing.

b. Pattern matches

In addition to generating the study's concept map, graphs called pattern matches are produced to facilitate comparison of the average cluster ratings of the two types of participants. Figure 3 compares the average ratings obtained from African American women and healthcare providers on a scale ranging from one (not at all influential) to five (extremely influential). Diagonal lines represent differences in the average cluster ratings for the two groups, while horizontal lines show cluster-rating values that were similar for the groups. The values at the top of Figure 3 represent the highest average rating for each group, with healthcare providers on the left (4.61) and African American women on the right (4.63). For both groups, access to PrEP was the most influential cluster. The values at the bottom of the figure represent the lowest average rating for each group, with healthcare providers on the left (3.49) and African American women on the right (2.64). Providers perceived network to be the least influential cluster with an average rating of 3.49, while African American women perceived the fear cluster as the least influential with an average rating of 2.64. The fear cluster was perceived to be more influential by healthcare providers than by African American women. Notably, although the network cluster received a lower rating from providers than other clusters, the average rating of 3.49 was considered moderately influential. The best benefits cluster received high ratings from African American women, while it received the fourth-highest rating from providers. The correlation of ratings between healthcare providers and African American women was 0.76.

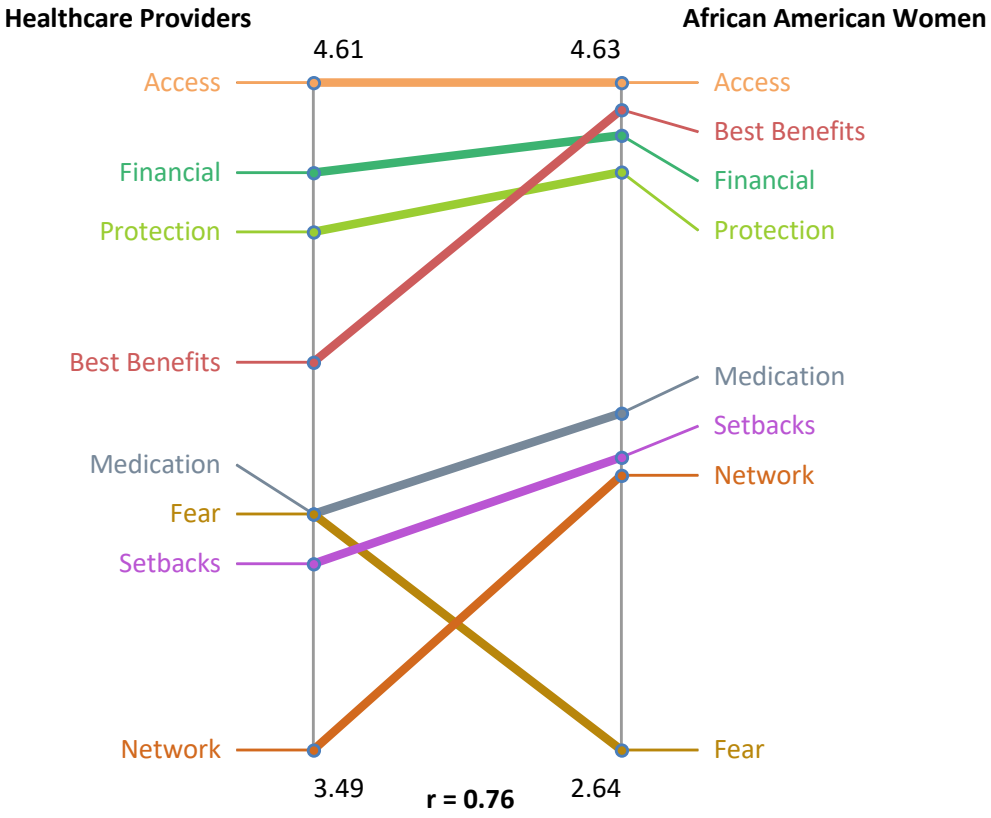
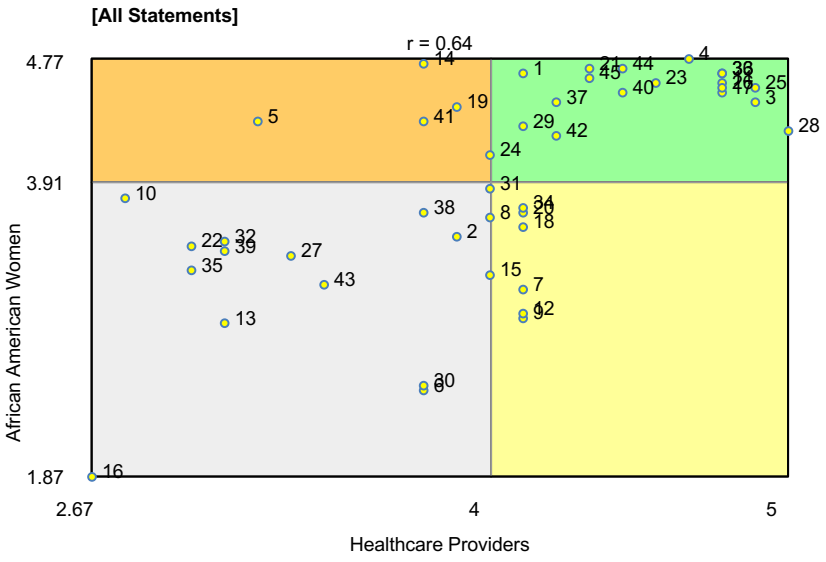


Figure 3. Pattern Match: Healthcare Providers vs. African American Women
Influence ratings assigned by healthcare providers (n=9) and African American women (n=45) are compared above. Among healthcare providers, the average cluster ratings ranged from 4.61 (extremely influential) to 3.49 (somewhat influential). The average cluster ratings among African American women ranged from 4.63 to 2.64. For both groups, *Access* was the most influential cluster. There was a notable difference in the ratings of the *Best Benefits* cluster, with African American women considering it the second most influential cluster and providers rating it fourth in terms of influence. Providers perceived the *Fear* cluster to have more influence than did African American women, who perceived it to have the least influence. On the other hand, African American women perceived the *Network* cluster to have more influence than did providers, who perceived it to have the least influence.

c. Go zone

A go zone is a bivariate scatter plot composed of pattern match data.[43] As shown in Figure 4, each quadrant on the go zone for this study contains points representing statements rated by healthcare providers and African American women. Figure 4 depicts these statements as points marked with the corresponding statement numbers. Only the most and least influential statements are represented in the figure; other statements can be viewed in Table VI. The x- and y-axes in the figure present rating results for healthcare providers and African American women, respectively.

Each quadrant of the go zone has a color. The green quadrant contains statements rated highly to extremely influential by both groups. Across clusters, both providers and women rated 18 statements as highly to extremely influential. The green box in the top right corner of the orange quadrant contains five statements rated highly to extremely influential only by African American women. The yellow quadrant contains six statements rated highly to extremely influential only by healthcare providers. The grey quadrant contains 16 statements rated as having the least influence on potential use of PrEP.



1. Being non-painful
3. Not having to pay a copayment
4. Knowing that PrEP will prevent me from getting HIV when my partner won't use a condom
11. Being covered by health insurance
17. Cost of PrEP without insurance
21. Being provided for free at healthcare clinics
23. Being easy to use
25. Being affordable
26. Being easy to get a prescription from a doctor
28. Having an HIV positive sexual partner
29. Make me sick after use
33. Protecting myself from HIV
36. Costing too much money out of pocket
37. Not wanting to risk infection
40. It protects you from getting the virus as long as used properly
42. Taking the pill only once a day
44. Easy to obtain the medicine from a pharmacy
45. Protection for my partner

Figure 4. Go Zone: Healthcare Providers vs. African American Women
Mean influence ratings assigned by healthcare providers (n=9) and African American women (n=45) are compared above. Each point represents a numbered statement that was rated in terms of level of influence on a 5-point Likert scale. The median is illustrated by the crossbar. Each color represents a different quadrant. The green quadrant contains statements that both African American women and healthcare providers perceived as the most influential for PrEP use. (The statements corresponding with green quadrant statement numbers are shown above; all other statements are listed in Table VI.) The grey quadrant contains statements that both healthcare providers and African American women perceived to be the least influential for PrEP use. The orange quadrant contains statements perceived to be highly influential by African American women only. The yellow quadrant contains statements perceived to be highly influential by healthcare providers only.

d. Interpretation of concept maps

The focus group participants agreed that the fear cluster was not influential because they did not believe that they had HIV, so they were not afraid to receive HIV tests. The participants also stated that they were not surprised that the access cluster was rated highest by healthcare providers. In general, participants stated that they understood the importance of the cluster map, but they preferred to look at the pattern matches and go zone because they found these items easier to interpret. The focus group indicated that the statement list included factors they found influential. Women reported that the pattern match data was very easy to understand.

E. Discussion

This study identified 45 factors likely to influence use of PrEP among African American women. These factors were compared, rated, and sorted, by African American women at high risk for HIV and by healthcare providers. To our knowledge, no published studies have used concept mapping to identify these factors and compare perspectives.

There were four key findings in this study. Three were different when comparing women and healthcare providers while one was shared. First, the statement “Knowing that PrEP will prevent me from getting HIV when my partner won’t use a condom” was the most likely to influence potential use of PrEP among African American women, whereas healthcare providers perceived “Having an HIV positive partner” to be the most influential statement. Second, both African American women and healthcare providers found the access cluster, which contained statements about the ease of obtaining a PrEP prescription from a doctor and pharmacy, to be the most influential cluster for likelihood to use PrEP. Third, healthcare providers perceived fear of already having HIV or testing for HIV to be influential for African American women; however, the fear cluster received the lowest ratings among African American women. Fourth, healthcare providers underestimated the influence of social interactions with family, friends, and sexual partners on the likelihood to use PrEP among African American women.

The most influential statement for African American women, “Knowing that PrEP will prevent me from getting HIV when my partner won’t use a condom,” speaks to a desire for the autonomy that PrEP provides to people wanting to protect themselves from the virus, especially women who may exhibit poor condom negotiation skills with male sexual partners. In addition, the literature reports HIV stigma to be a barrier to PrEP use in African American women.[38] However, no statements about fear of being judged for using PrEP were made by participants during the brainstorming portion of the study. Also, although it was not explicitly stated by participants, taking a pill once per day may have been considered a discreet enough activity that the women did not fear anyone finding out about their potential PrEP use.

In a previous study, African American women were found to believe that primary care physicians and gynecologists with whom they had established trusting relationships were the best sources of information on PrEP.[38] In our study, 81 percent of African American women reported that they would get an HIV test every six months if they had a provider who made them feel comfortable. Healthcare providers are key to increasing PrEP awareness, knowledge, uptake, and adherence in high-risk populations.[45] However, many healthcare providers are cautious about prescribing PrEP to populations other than MSM.[45] In this study, the providers were familiar with PrEP and the associated “strong” CDC recommendation: “Oral PrEP containing TDF should be offered as an additional prevention choice for people at substantial risk of HIV infection as part of combination HIV prevention approaches.”[20] However, other studies have found that providers are not comfortable prescribing PrEP because of their low knowledge of the drug and difficulty discussing patient sexual histories in depth.[45,46,35,47] One study found that among providers who did prescribe PrEP, the determination of eligibility was a decision the provider made together with the patient.[46] Considering this finding, the likelihood of a provider’s prescribing PrEP for HIV prevention may depend on the type of patient involved.[48]

In other studies, African American women considering use of PrEP have viewed the frequency of required HIV testing as a burden.[36] However, women in this study reported having

access to HIV testing and not being afraid to be tested. In contrast to the perception of healthcare providers in this study, fears of being tested for HIV and of having HIV were not influential for women considering PrEP use. Thus, healthcare providers should not hesitate to offer HIV testing or to initiate discussions about PrEP with African American women at risk for HIV acquisition. Providers who do initiate conversations about PrEP with high-risk African American women should evaluate the patients' access to HIV testing, pharmacies, and insurance coverage. The conversation should also emphasize patient autonomy as a benefit of using PrEP to prevent HIV acquisition.

Although healthcare providers and African American women agreed that access was the most influential cluster, providers missed the mark on other factors considered influential by African American women. For example, providers underestimated the influence of the network cluster, which contained statements about social interactions with family, friends, and sexual partners. The provider's underestimated value of the women's network is interesting, because the literature shows that healthcare providers highly value the opinions of their own peers.[27] African American women may value the opinions of their peers similar to how healthcare providers value the opinions of other colleagues.

Findings of this study underscore the importance of autonomy to African American women. PrEP messages that focus on autonomy and self-care or those containing phrasing such as "I can protect me" may be favorably viewed by urban African American women, as opposed to messages that use undertones of fear to promote HIV prevention. In addition, when healthcare providers speak with African American women at high risk for HIV, the autonomy of using PrEP verses relying on sexual partners to use condoms every time they engage in intercourse should be part of the HIV prevention discussion. In this discussion, providers should focus on how PrEP can protect women from HIV even when her partner does not want to use a condom.

Healthcare providers are responsible for ensuring that patients have the access and information needed to obtain and properly use PrEP. Providers may also want to emphasize that the once-a-day pill is easy to use and has a low number of side effects. In addition, providers should assess patients' ability to attend regular healthcare visits, undergo HIV testing, and access a pharmacy. The cost of PrEP is also an important consideration, and thus having or not having insurance coverage for PrEP may be a determining factor for some patients. With this in mind, patients will need additional assistance with obtaining pre-certification from health insurance companies or with paying for prescriptions if they are uninsured.

A unique characteristic of this study is that eight of the healthcare providers were African American women. To our knowledge, this is the only PrEP-related study in which most of the participating providers were African American women and in which providers had their perceptions compared to those of high-risk African American women. In other studies [29,49,50] that evaluated healthcare provider perceptions of PrEP, participants were predominantly white. The PrEP-related perceptions of African American healthcare providers merit further inquiry. For instance, the pattern match findings of this study could be used to support future research that compares PrEP perceptions between subsets of healthcare providers such as nurses and outreach workers. Additionally, African American women living in urban areas across the United States may identify similar factors likely to influence use of PrEP for HIV prevention. A large epidemiologic study could be generated to determine whether the factors found to influence use of PrEP in African American women are similar in Southern states having higher HIV incidence among African American women.

F. Limitations

One of the strengths of qualitative descriptive research is collection of large amounts of rich data. In this study, participant brainstorming yielded 45 statements representing factors influencing potential PrEP use among African American women, but the study sample may not have identified every influential factor. Among other study limitations, participants were not

required to explain the “why” behind their brainstorming, sorting, and rating decisions. In addition, the focus group used to interpret the maps was very small, and in the future, using a greater number of larger groups would strengthen research outcomes. Moreover, participant responses on all levels were subjective, and thus varying types of bias may have occurred. Finally, the only PrEP information provided to the women in this study was presented in a video, and thus the nature and quality of that video may have played a role in the decisions made during their participation.

G. Conclusion

Five years after the FDA’s approval of PrEP, awareness and knowledge of this biomedical HIV prevention medication remain low among African American women. In response, the number of research studies evaluating how to increase PrEP uptake in this population is beginning to increase. In this study, concept mapping, a participatory process, provided insight into the PrEP perceptions of an understudied population of women and healthcare providers. This study found that autonomy and access are the most influential factors for African American women considering use of PrEP. However, further research is needed to evaluate whether the influential factors identified can be translated into increased PrEP use among high-risk African American women. The findings of this study reveal points of interest that can facilitate initial PrEP discussions between healthcare providers and patients. Such discussions are the first step in the path toward PrEP use and increased protection from HIV.

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APPENDICES

APPENDIX A

UNIVERSITY OF ILLINOIS
AT CHICAGO

Office for the Protection of Research Subjects (OPRS)
Office of the Vice Chancellor for Research (MC 672)
203 Administrative Office Building
1737 West Polk Street
Chicago, Illinois 60612-7227

Approval Notice
Initial Review (Response To Deferred)

December 6, 2016

Triniece Pearson, BSN
Women, Child, & Family Health Science
845 S. Damen Ave
M/C 802
Chicago, IL 60612
Phone: (312) 413-8966

RE: Protocol # 2016-0731
"Perceptions of Factors that Influence Pre-Exposure Prophylaxis (PrEP) Use for HIV Prevention in African American Women"

Dear Ms. Pearson:

This research has been determined to be no greater than minimal risk by the convened IRB but will require convened review for Continuing Review and all substantive amendments.

Please note that stamped and approved .pdfs of all recruitment and consent documents will be forwarded as an attachment to a separate email. OPRS/IRB no longer issues paper letters and stamped/approved documents, so it will be necessary to retain the emailed documents for your files for auditing purposes.

Your Initial Review (Response To Deferred) was reviewed and approved by the Convened review process on December 1, 2016. You may now begin your research

Please note the following information about your approved research protocol:

Protocol Approval Period: December 1, 2016 - December 1, 2017
Approved Subject Enrollment #: 70
Additional Determinations for Research Involving Minors: These determinations have not been made for this study since it has not been approved for enrollment of minors.
Performance Sites: UIC
Sponsor: None
PAF#: Not applicable

Research Protocol(s):

a) Protocol for Perceptions of PrEP Study; Version 3; 11/13/2016

Recruitment Material(s):

a) Non-provider Screening Form; Version 1; 06/01/2016
b) Provider Screening Form; Version 1; 06/01/2016
c) Recruitment Email (Email for Provider Recruitment); Version 1; 06/01/2016
d) Recruitment Phone Script; Version 3; 11/13/2016
e) Recruitment Palm Card; Version 2; 11/13/2016
f) Recruitment Flyer #2; Version 2; 11/13/2016
g) Recruitment Flyer #1; Version 2; 11/13/2016
h) Mass Email and Ad Text; Version 2; 11/13/2016

Informed Consent(s):

a) Consent Provider Group; Version 3; 11/13/2016
b) Consent Nonprovider Group; Version 4; 12/05/2016
c) A waiver of documentation of informed consent has been granted under 45 CFR 46.117 and an alteration of consent has been granted under 45 CFR 46.116(d) for recruitment purposes only; minimal risk; verbal consent to screening/eligibility questions will be obtained; written consent will be obtained at enrollment.

Your research meets the criteria for expedited review as defined in 45 CFR 46.110(b)(1) under the following specific category(ies):

(FCR) Research has been determined to be no greater than minimal risk by the convened IRB and requires convened Continuing Review.

Please note the Review History of this submission:

Receipt Date	Submission Type	Review Process	Review Date	Review Action
07/15/2016	Initial Review	Expedited	08/08/2016	Modifications Required
09/15/2016	Response To Modifications	Expedited	10/06/2016	Referred To Convened With

				Modifications
10/10/2016	Response To Modifications	Convened	10/20/2016	Deferred
11/18/2016	Response To Deferred	Convened	12/01/2016	Approved

Please remember to:

→ Use your **research protocol number** (2016-0731) on any documents or correspondence with the IRB concerning your research protocol.

→ Review and comply with all requirements on the OPRS website at,
"UIC Investigator Responsibilities, Protection of Human Research Subjects"
(http://tigger.uic.edu/depts/ovcr/research/protocolreview/irb/policies/0924.pdf)

Please note that the UIC IRB has the prerogative and authority to ask further questions, seek additional information, require further modifications, or monitor the conduct of your research and the consent process.

Please be aware that if the scope of work in the grant/project changes, the protocol must be amended and approved by the UIC IRB before the initiation of the change.

We wish you the best as you conduct your research. If you have any questions or need further help, please contact OPRS at (312) 996-1711 or me at (312) 355-0816.

Sincerely,

Alison Santiago, MSW, MJ
Assistant Director, IRB # 2
Office for the Protection of Research Subjects

Enclosure(s) will be sent in a separate email:

1. **Informed Consent Document(s):**
   a) Consent Provider Group; Version 3; 11/13/2016
   b) Consent Nonprovider Group; Version 4; 12/05/2016
2. **Recruiting Material(s):**
   a) Non-provider Screening Form; Version 1; 06/01/2016
   b) Provider Screening Form; Version 1; 06/01/2016
   c) Recruitment Email (Email for Provider Recruitment); Version 1; 06/01/2016
   d) Recruitment Phone Script; Version 3; 11/13/2016

e) Recruitment Palm Card; Version 2; 11/13/2016
f) Recruitment Flyer #2; Version 2; 11/13/2016
g) Recruitment Flyer #1; Version 2; 11/13/2016
h) Mass Email and Ad Text; Version 2; 11/13/2016

cc: Barbara McFarlin, Women (Faculty Advisor), Child, & Family Health Science, M/C 802

APPENDIX B

Approval Notice
Continuing Review

October 20, 2017

Triniece Pearson, BSN
Women, Child, & Family Health Science
845 S. Damen Ave
M/C 802
Chicago, IL 60612
Phone: (312) 413-8966

RE: **Protocol # 2016-0731**
"Perceptions of Factors that Influence Pre-Exposure Prophylaxis (PrEP) Use for HIV Prevention in African American Women"

Dear Ms. Pearson:

Your Continuing Review application was reviewed and approved by the Convened review process on October 19, 2017. You may now continue your research.

Please note the following information about your approved research protocol:

The Board has determined that this research presents minimal risk to subjects but will require full review at a convened meeting for future continuing reviews and all substantive amendments.

Please note that stamped .pdfs of all approved recruitment and consent documents have been uploaded to OPRSLive, and you must access and use only those approved documents to recruit and enroll subjects into this research project. OPRS/IRB no longer issues paper letters or stamped/approved documents.

Protocol Approval Period: October 19, 2017 - October 19, 2018
Approved Subject Enrollment #: 70 (46 subjects enrolled)
Additional Determinations for Research Involving Minors: These determinations have not been made for this study since it has not been approved for enrollment of minors.
Performance Site: UIC
Sponsor: None
Research Protocol:

b) Protocol for Perceptions of PrEP Study; Version 4; 03/22/2017

Recruitment Materials:

i) Recruitment Email (Email for Provider Recruitment); Version 1; 06/01/2016
j) Non-provider Screening Form; Version 1; 06/01/2016

k) Provider Screening Form; Version 1; 06/01/2016
l) Recruitment Phone Script; Version 3; 11/13/2016
m) Mass Email and Ad Text; Version 2; 11/13/2016

Informed Consents:

d) Consent Provider Group; Version 4; 03/22/2017
e) Consent Nonprovider Group; Version 5; 03/22/2017
f) A waiver of documentation of informed consent has been granted under 45 CFR 46.117 and an alteration of consent has been granted under 45 CFR 46.116(d) for recruitment purposes only; minimal risk; verbal consent to screening/eligibility questions will be obtained; written consent will be obtained at enrollment.

Please note the Review History of this submission:

Receipt Date	Submission Type	Review Process	Review Date	Review Action
10/05/2017	Continuing Review	Convened	10/19/2017	Approved

Please remember to:

→ Use your **research protocol number** (2016-0731) on any documents or correspondence with the IRB concerning your research protocol.

→ Review and comply with all requirements on the OPRS website under:
"UIC Investigator Responsibilities, Protection of Human Research Subjects"

Please note that the UIC IRB has the prerogative and authority to ask further questions, seek additional information, require further modifications, or monitor the conduct of your research and the consent process.

Please be aware that if the scope of work in the grant/project changes, the protocol must be amended and approved by the UIC IRB before the initiation of the change.

We wish you the best as you conduct your research. If you have any questions or need further help, please contact OPRS at (312) 996-1711 or me at (312) 996-2014.

Sincerely,
Sandra Costello
Assistant Director, IRB # 2
Office for the Protection of Research Subjects

Please note that stamped .pdfs of all approved recruitment and consent documents listed below have been uploaded to OPRSLive, and you must access and use only those approved documents to recruit and enroll subjects

into this research project. OPRS/IRB no longer issues paper letters or stamped/approved documents.

3. Informed Consent Documents:

c) Consent Nonprovider Group; Version 5; 03/22/2017
d) Consent Provider Group; Version 4; 03/22/2017

4. Recruiting Materials:

i) Recruitment Email (Email for Provider Recruitment); Version 1; 06/01/2016
j) Non-provider Screening Form; Version 1; 06/01/2016
k) Provider Screening Form; Version 1; 06/01/2016
l) Recruitment Phone Script; Version 3; 11/13/2016
m) Mass Email and Ad Text; Version 2; 11/13/2016

cc: Barbara McFarlin (faculty advisor), Women, Child, & Family Health Science, M/C 802

Triniece Pearson, MBA, BSN, RN
Curriculum Vitae
triniece.pearson@gmail.com

EDUCATION

Saint Xavier University MBA 2009
Lakeview College of Nursing BSN 2006

RESEARCH EXPERIENCE

UNIVERSITY OF CHICAGO

2/2017-present Clinical Research Nurse

Research Nurse for the Clinical Research Center responsibilities including study drug administration, conducting study visits in accordance with the research protocol, and collecting lab specimens.

LOYOLA UNIVERSITY

3/2016- 2/2017 Clinical Research Nurse and Study Coordinator for multiple pulmonary and hepatology Phase III clinical trials. Responsible for participant recruitment, retention, conduction study visits, specimen collection and shipping, adverse event reporting, participating in site and monitoring visits.

Pulmonary

Title: A Double Blind, Randomized, Placebo-controlled Trial Evaluating the Efficacy and Safety of Nintedanib Over 52 weeks in Patients with Progressive Interstitial Lung Disease PI: Dr. Daniel Dilling

Title: Safety and Efficacy of Saracatinib In Subjects with Lymphangioleiomyomatosis PI: Dr. Daniel Dilling

Hepatology

Title: A Phase 3, Double-Blind, Randomized, Long-Term, Placebo-Controlled, Multicenter Study Evaluating the Safety and Efficacy of Obeticholic Acid in Subjects with Nonalcoholic Steatohepatitis PI: Dr. Nastasha Von Roenn

UNIVERSITY OF ILLINOIS AT CHICAGO

7/2013-3/2016 Study Coordinator

Infectious Disease

Title: Strategic Timing of Anti-Retroviral Therapy Insight 19-CH-008-0907-3 PI: Dr. Richard Novak

Title: HVTN 505 NIH/NIAID/DAIDS, Subaward from Fred Hutchinson Cancer Research Center ended 12/31/2013, continued under DAIDS Grant No. 5 UM1 AI068614 PI: Dr. Richard Novak

Research Nurse

Title: Merck MK0518-292 “A Phase III Multicenter, Double-Blind, Randomized, Active Comparator-Controlled Clinical Trial to Evaluate the Safety and Efficacy of Reformulated Raltegravir 1200 mg Once Daily Versus Raltegravir 400 mg Twice Daily, Each in Combination With TRUVADA™, in Treatment-Naïve HIV-1 Infected Subjects” PI: Dr. Richard Novak

Title: Genocea GEN-003-002 Therapeutic HSV-2 Protein Subunit Vaccine A Randomized, Double-Blind, Factorial Study to Compare the Safety and Efficacy of Varying Combinations of GEN-003 and Matrix-M2 in Subjects with Genital HSV-2 Infection PI: Dr. Richard Novak

Title: Pathogenesis2 "HIV Susceptibility and Pathogenesis in the Female Genital Tract" NIH/NIAID/DAIDS, Subaward from Rush University 5P01AI082971-04 PI: Dr. Richard Novak

Title: HVTN 092 NIH/NIAID/DAIDS Subaward from Fred Hutchinson Cancer Research Center ended 12/31/2013, continued under DAIDS Grant No. 5 UM1 A1068614-07 PI: Dr. Richard Novak

PROFESSIONAL EXPERIENCE

7/2008-7/2012 Registered Nurse Case Manager
Blue Cross Blue Shield of Illinois, Chicago, Illinois

8/2007-5/2008 Post-Partum Registered Staff Nurse
Norwegian American Hospital, Chicago, Illinois

CERTIFICATIONS AND LICENSURE

Illinois Registered Nurse Licensure
Basic Cardiac Life Support Provider

TEACHING EXPERIENCE

UNIVERSITY OF ILLINOIS AT CHICAGO
6/2014-7/2014 Co-Instructor Seminar for Excellence in Nursing Science: Clinical Skills
6/2013-7/2013 Teaching Assistant, GEP Integrated Health Care Lecture and Laboratory
8/2012-5/2013 Teaching Assistant, Fundamentals of Nursing Lecture, Laboratory, Clinical

HONORS AND AWARDS

2017-2018 Diversifying Higher Education in Illinois Fellow
2017 Marguerite A. Dion Award
2014-2016 Jonas Nurse Leader Scholar
2014-2015 Diversifying Higher Education in Illinois Fellow
2013-2014 Albert Schweitzer Chicago Area Fellow
2012 Sigma Theta Tau International, Edith Anderson Leadership Education Grant
2006 Dean's List, Lakeview College of Nursing

PROFESSIONAL ACTIVITIES

2017-Present Association of Nurses in AIDS Care (ANAC**)**
2017-Present Midwest Nursing Research Society (MNRS)
2014-Present Urban Health Program UIC College of Nursing Student Association
2012-Present Sigma Theta Tau International Honor Society- Alpha Lambda Chapter
2008-Present Chi Eta Phi Professional Nursing Organization- Alpha Eta Chapter