The Non-Prescribed, "Informal" Use of Antiretroviral Medication for HIV Prevention among Men Who Have Sex with Men in South Florida

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BACKGROUND

- Antiretroviral medications (ARVs) are lifesaving medications used to treat HIV infection. One relatively understudied aspect of ARVs is diversion – the unlawful channeling of regulated pharmaceuticals from legal sources to the informal marketplace.
- ARV diversion has many serious consequences, both for patient safety and for public health , including HIV treatment failure, lack of viral suppression, an increased risk of HIV transmissibility, and the development or transmission of ARV-resistant strains of HIV.
- Pre-Exposure and Post-Exposure Prophylaxis (PrEP and PEP) are biomedical technologies used to prevent HIV infection. Results from the 2010 iPrEX clinical trial demonstrated the efficacy of using Truvada for PrEP in the prevention of HIV infection among men who have sex with men (MSM).
- In the U.S., the Food and Drug Administration approved the use of Truvada for PrEP in 2012 and the Centers for Disease Control and Prevention issued detailed PrEP clinical guidance for health care providers in 2014.
- The lack of broad-based public health campaigns may result in misunderstandings of the efficacious use of PrEP for HIV prevention among MSM and broaden informal markets for ARV medications for use among HIV-negative MSM for PrEP.
- Recent data collected by the authors suggests that MSM are obtaining ARVs in the informal market and taking them in an effort to prevent HIV infection.
- Despite previous studies, documenting widespread ARV diversion in Miami and emerging data suggesting that increasing awareness of PrEP is fueling the diversion of ARVs among MSM, no in-depth research of this phenomenon has been conducted.

METHODS

Purpose: The purpose of this analysis is to investigate the use of diverted ARVs among HIV-negative MSM to use for HIV prevention.

Methods: The data are drawn from a qualitative study of the scope and magnitude of the informal ARV market and the use of non-prescribed ARVs for PrEP among MSM. A total of 30 in-depth, one-on-one interviews with HIV-negative MSM were conducted between September 2015 and May 2016.

Eligibility: Eligible participants are age 18 or over and report: a) one or more anal sex partners in the past 90 days, including at least one condomless event and b) obtaining and taking diverted ARVs for HIV prevention.

Data collection and analysis: Participants were interviewed using a semi-structured protocol. A descriptive qualitative approach was being used to investigate the social ecological factors related to ARV diversion. Atlas.ti version 7 software was used for analysis.

Results

Informal use practices

Before sex
- "I take one… like maybe an hour or so [before sex], like to let it take effect." – Jay
- Russ takes ARVs "during a party session" when he would be consuming methamphetamine and engaging in sex.

After sex
- Leo and Andres described informally taking an ARV pill, given to them by their sex partners, immediately after sex.
- Paul noted that, "Usually within 24 hours I was able to procure a pill or two."

Before and after sex
- Danny said, "Let's say I'll see [sex partner] today. I would take [informal ARV] yesterday or two days before, and I'll probably take it tomorrow or a couple of days after. There's no schedule to it. I don't know exactly how to take the medication."

Daily / daily intermittent
- "I take it probably twice a week. Just you know, as a preventative measure."
- Cesar took his HIV-positive partner's extra medication daily for a time, but he eventually decided to quit using the medication and only take it if he became infected with HIV.

Concerns about sufficient protection

- Ryan said informal ARV use made him feel "bullet proof" but later in the interview he asked the interviewer, "If I actually knowingly screwed somebody with AIDS… would the [informal ARVs] actually work?
- Danny said his informal use "kind of helped me mentally," but he later said, "I don't feel like I'm taking it the right way and I don't know much about it."

Primary Motivations

Condom avoidance
- "Condoms, I don't use. The medicine is pretty much my prevention." – Emmett
- "You got this here that works 100% [ARVs] and this ain't [condoms]. So, which one you gonna pick?" – Kevin

Risk reduction
- Miguel's HIV prevention strategy consists of "rubbers and taking pills".
- Jackson uses ARVs with particularly risky activities, including sex with an HIV-positive sex partner.
- Michael uses ARVs on occasions when he engages in transactional sex to, "take extra precaution."

Feared HIV exposure
- Men reported ARV use following an "accident", a condom breakage, and the discovery of a sex partner's HIV-positive status following intercourse.

Limited knowledge about PrEP

- Five men were completely unaware of the existence of PrEP. Jay expressed it this way, "When wonder drugs come… Viagra, Cialis… it's the commercial. It gets played 24 hours a day. So if something actually worked and it is FDA-approved… there would be commercials, prescriptions, government programs." He, had never seen PrEP promoted or mentioned, even though he was taking informal ARVs for HIV prevention.
- Jim described the benefit of taking ARVs intermittently, "I would image [ARVs] work better because my body wouldn't have built up a tolerance to it."
- George stated that taking ARVs regularly could lead to the body becoming immune, "It's like penicillin. If every time you got some kind of virus or sore throat, penicillin is eventually not gonna work."

Demographics and Informal ARV Use Characteristics (N=30)

ID	Age	Race/ethnicity	Primary use practices	Medications used	Primary motivations
Eduardo	25	Hispanic	Before sex	Truvada[a]	Condom avoidance
Michael	22	Black	Daily intermittent; before sex	Truvada[a]	Risk reduction
Danny	35	Hispanic	Before / after sex	Truvada[a]	Condom avoidance
John	25	Black	After sex	Truvada[a]	Feared HIV exposure
Gio	28	Hispanic	Before sex	Truvada[a]	Condom avoidance
Carlos	53	Hispanic	After sex	Truvada[a]	Feared HIV exposure
Jackson	34	White	Before sex	Videx[b]; unknown	Risk reduction
Nelson	18	Hispanic	Daily	Truvada[a]	Condom avoidance
Manny	45	Hispanic	Before sex	Truvada[a]	Condom avoidance
Juan	24	Hispanic	Before sex	Truvada[a]	Risk reduction
Ryan	22	White	Before sex	Truvada[a]	Risk reduction
Richard	34	White	After sex	Unknown	Risk reduction
Russ	52	White	Before sex	Truvada[a]; unknown	Condom avoidance
Jay	42	Black	Before sex	Truvada[a]; unknown	Condom avoidance
Mark	27	Black	Before sex	Truvada[a]; unknown	Condom avoidance
Jim	52	White	Daily	Truvada[a]	Risk reduction
Cesar	23	Hispanic	Daily	Atripla[c]	Condom avoidance
Paul	62	White	After sex	Truvada[a]	Feared HIV exposure
Will	41	White	After sex	Truvada[a]; Isentress[d]	Feared HIV exposure
David	42	Hispanic	After sex	Truvada[a]; Isentress[d]	Feared HIV exposure
Robert	46	Black	Daily	Truvada[a]; Crixivan[e]; Stribild[f]; Viracept[g]; Combivir[h]; unknown	Condom avoidance
Leo	22	Hispanic	After sex	unknown	Feared HIV exposure
Andres	23	Hispanic	After sex	Stribild[f]	Feared HIV exposure
Miguel	51	Hispanic	Before / after sex	Stribild[f]	Risk reduction
Emmett	21	Black	Before / after sex	Stribild[f]; Crixivan[e]	Condom avoidance
George	57	White	Daily intermittent; before / after sex	Stribild[f]; Crixivan[e]	Condom avoidance
Kevin	50	White	Before sex	Truvada[a]; Combivir[h]; AZT[i]	Condom avoidance
Andy	45	Black	After sex	Combivir[h]; Zerit[j]	Risk reduction
Chris	50	White	Daily	Truvada[a]	Risk reduction
Sean	48	White	Daily; before sex	Truvada[a]; unknown	Condom avoidance

[a] tenofovir disoproxil fumarate and emtricitabine (TDF-FTC); [b] didanosine; [c] efavirinz, TDF-FTC; [d] raltegravir; [e] indinavir sulfate; [f] TDF-FTC, elvitegravir, cobicistat; [g] nelfinavir mesylate; [h] lamivudine, zidovudine; [i] azidothymidine; [j] stavudine

DISCUSSION AND CONCLUSIONS

This is the first apparent study to examine the use of informal ARVs for HIV prevention among MSM. Although participants describe their attempts to prevent HIV infection, they are not engaged in frequent testing, regular health monitoring and ongoing behavioral support, which is recommended with prescribed PrEP use. Moreover, few participants described informal ARV use practices which cohere with PrEP or PEP regimens or CDC guidance. Participants also used a range of medications not approved for PrEP. Intermittent or sporadic use of ARVs, inconsistent access to medication and the use of medications not approved for PrEP may potential leave men with less protection against HIV infection, contribute to HIV transmission, resistance or adverse effects.

Some limitations must be noted. Participants were drawn from a convenience sample in South Florida and the findings are not generalizable to other locations or populations. There is a potential for interviewer effects and the underreporting of socially undesirable behaviors. The interviewers' training, experience, and use of a semi-structured interview guide likely mitigated these effects.

Given the potential of PrEP to prevent HIV infection, efforts should be made to enhance access. As more MSM begin using PrEP, informal ARV use and related concerns – including adherence, diversion, and ARV resistance – must be considered. Public health officials and community and social service agencies must increase PrEP awareness and acceptability and decrease informal use and diversion.

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