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Vulnerable Infected Populations and Street Markets for ARVs: Potential Implications for PrEP Rollout in the USA

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Vulnerable infected populations and street markets for ARVs: Potential implications for PrEP rollout in the USA

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Widespread diversion of antiretroviral (ARV) medications to illicit markets has recently been documented among indigent patients in South Florida. The recent approval of ARVs for pre-exposure prophylaxis (PrEP) has the potential to broaden these illicit markets, as high-risk individuals seek ARVs without a prescription or medical supervision. Nonadherence among diverters and unsupervised use of ARVs for treatment or PrEP increase risks of treatment failure, drug resistance, and disease transmission. We report the scope of ARV diversion among substance-using men who have sex with men in South Florida. Structured interviews ($N = 515$) queried demographics, HIV status, mental distress, substance dependence, and sexual risks. HIV-positive participants answered questions about medical care, treatment, and ARV adherence and diversion. Median age was 39. Of 46.4% who were HIV-positive, 79.1% were prescribed ARVs. Of these, 27% reported selling/trading ARVs. Reasons for diversion were sharing/trading with friends, sale/trade for money/drugs, and sale/trade of unused medications. ARV diverters, compared to nondiversers, were more likely to be substance dependent (74.5% vs. 58.7%, $p = 0.046$) and have traded sex for money/drugs (60.8% vs. 32.6%, $p < 0.001$), and less likely to be adherent to ARVs (54.9% vs. 73.9%, $p = 0.012$). ARV diversion should be a particular concern in communities of high-risk men who have sex with men as uninfected men in such communities are likely to benefit most from PrEP but unlikely to have access to PrEP and necessary ancillary services through the health-care system. The implications of diversion for increased risks of treatment failure, disease transmission, and PrEP failure should be carefully considered in developing policy and behavioral supports to scaling up treatment as prevention and PrEP.

Keywords: ARV; PrEP; MSM; diversion

Introduction

Widespread diversion – the unlawful channeling of regulated pharmaceuticals to illicit markets (Inciardi, Surratt, Kurtz, & Burke, 2006) – of antiretrovirals (ARVs) has recently been documented in South Florida among vulnerable, indigent patients who are targeted by pill brokers to trade their ARVs for money and/or drugs (Surratt, Kurtz, Cicero, O’Grady, & Levi-Minzi, 2013). Large-scale diversion of ARVs has also been detected in several other locations (Associated Press, 1995; Dorschner, 2005; Flaherty & Gaul, 2003; Glasgow, 1999; Surratt & Kurtz, 2013), with law enforcement activities disrupting ARV diversion networks in no fewer than seven states. Beyond these organized profit-making enterprises, a few reports indicate that ARV diversion also occurs for the purposes of getting high on medications with known psychoactive properties (Grelotti, Closson, & Mimiaga, 2013; Inciardi, Surratt, Kurtz, & Cicero, 2007), or for nonprescribed pre- or post-exposure prophylaxis (PrEP/PEP) (Liu et al., 2008; Mansergh et al., 2010; Mimiaga, Case, Johnson, Saffren, & Mayer, 2009). In this regard, emtricitabine/tenofovir, the only US Food and Drug Administration (FDA, 2012)-approved medication for PrEP, is among the most frequently diverted ARV

according to recent reports by both law enforcement and patients (O’Grady, Surratt, & Kurtz, 2013; Surratt & Kurtz, 2013). The selling and trading of ARVs are associated with nonadherence among diverters (Surratt et al., 2013), increasing the risk of treatment failure and disease transmission (Bangsberg et al., 2001), as well as drug resistance and PrEP failure among nonmedically supervised end users (Hurt, Eron, & Cohen, 2011).

The recent approval by the FDA of ARVs for PrEP (FDA, 2012), together with the earlier issuance by the US Centers for Disease Control and Prevention (CDC) of interim guidance for the clinical administration of PrEP (CDC, 2012; Smith et al., 2011), has the potential to broaden illicit markets for ARVs, as at-risk individuals – many lacking financial resources or health coverage (Curran & Crosby, 2013) – seek them without medical supervision or behavioral support. Although ARV diversion is also potentially a concern for unsupervised use by uninsured HIV-positive patients in search of ARVs for self-treatment, the widespread availability of low-cost treatment for HIV-positive patients in the USA, together with the multiple and often complex treatment regimens for HIV infection, would appear to limit the use of diverted medications for this purpose. On the other hand, the approved

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PrEP regimen consists of a single well-recognized product, and the nonprescribed use of emtricitabine/tenofovir for prevention (e.g., “Methamphetamine, Truvada and Viagra [MTV] party packs,” “disco dosing,” “taking a T”) has been documented among high-risk men who have sex with men (MSM) since at least 2009 (Philpott, 2013; D. Fawcett, personal communication, June 1, 2013).

Here, we describe the diversion of ARVs among a highly vulnerable sample of HIV-positive substance-using MSM as reported in interviews conducted during the period November 2008 through October 2011 as a part of their participation in an intervention trial.

Methods

The MSM study is a randomized clinical trial of a behavioral intervention targeted to high-risk substance-using MSM in South Florida. Eligible men were aged 18–55 and reported recent (in the past 90 days) unprotected anal intercourse (UAI) with a nonmonogamous partner(s), and met one or more of three substance use inclusion criteria: binge drinking (five or more drinks) or drug use, excluding marijuana, at least three times, or marijuana use at least 20 days, in the past month.

Data reported here are drawn from standardized interviewer-administered baseline assessments ($N = 515$)

conducted between November 2008 and October 2011 that included measures of demographics, self-reported HIV status, sexual risk behaviors, and Diagnostic Statistical Manual IVR (DSM-IVR) clinical measures of mental distress and substance dependence (Dennis, Titus, White, Unsicker, & Hodgkins, 2002). HIV-positive participants also answered questions about medical care and treatment; self-reported past month ARV adherence; and ARV diversion history. Reasons for diverting ARVs were assessed with open-ended responses that were coded into well-defined categories. Research protocols were approved by the University of Delaware’s (predecessor institution) and Nova Southeastern University’s Institutional Review Boards.

For the analyses presented here, descriptive statistics were used to characterize the study sample. Chi-square and analysis of variance tests examined the differences between HIV-positive participants with ARV prescriptions who had sold or traded their ARV medications compared to those who had not done so.

Results

Characteristics of the total sample and the sample of HIV-positive men with ARV prescriptions are shown in Table 1. Mean age of the full sample was 38.9

Table 1. Baseline characteristics of substance-using MSM.

	Total sample ($N = 515$)		HIV + w/ARV prescription ($N = 189$)	
	N	%	N	%
<i>Demographics</i>				
Age (mean; SD)	38.9 (9.6)		43.4 (7.2)	
Education (mean; SD)	13.8 (2.4)		13.7 (2.3)	
<i>Race/Ethnicity</i>				
Hispanic	133	25.8	40	21.1
African-American/Caribbean	108	21.0	47	24.9
Caucasian	250	48.5	93	49.2
Other	24	4.7	9	4.8
Homeless in the past year	133	25.8	52	27.5
<i>Sex-risk behavior (past 90 days)</i>				
Anal sex partners (mean; SD)	13.3 (18.6)		15.6 (19.8)	
UAI times (mean; SD)	22.6 (35.4)		26.1 (34.9)	
Traded sex (past 12 months)	176	34.2	76	40.2
<i>Health-risk measures</i>				
Severe mental distress	298	57.9	122	64.6
DSM-IVR substance dependence	156	62.1	119	63.0
Victimized before age 18	282	54.8	101	53.4
<i>Health-care coverage</i>				
HIV-negative	276	53.6	–	
Health-care coverage	117	42.4	–	
HIV-positive	239	46.4	–	
Health-care coverage	206	86.2	–	
Receiving HIV medical care	219	91.6	–	
Prescribed ARV medications	189	79.1	–	

(SD = 9.6); mean years of education, 13.8 (SD = 2.4). Race/ethnicity: 48.5% White, 25.8% Hispanic, 21.0% African-American/Caribbean, and 4.7% other. More than one-quarter (25.8%) reported the past year homelessness. Participants reported high levels of sexual risk behaviors, including an average of 13.3 (SD = 18.6) anal sex partners and 22.6 (SD = 35.4) UAI events in the past 90 days; 34.2% had traded sex for money or drugs in the past year. Majorities met clinical criteria for severe mental distress (57.9%) and substance dependence (62.1%), and had been victimized as minors (54.8%). Almost half (42.4%) were HIV-positive. HIV-positive men with ARV prescriptions reported demographic and health-risk profiles that were similar to the full sample.

Fewer than half (42.4%) of HIV-negative men had health-care coverage, defined as any type of insurance or program to pay health expenses. Of the HIV-positive men, the large majority reported health-care coverage (86.2%) and were receiving medical care at that time (91.6%); 79.1% were prescribed ARV medication. Of the latter group ($n = 189$), 27.0% ($n = 51$) reported having ever sold and/or traded their ARVs (diverters); 19.0% had done so in the past year. Reasons for diversion were (more than one reason was permissible) share/trade with friends ($n = 32$; 62.7% of diverters); sale/trade for money and/or drugs ($n = 19$; 37.3%); donated leftover medications to a clinic or organization ($n = 10$; 19.6%); and, sale/trade of medications that were no longer used ($n = 5$; 9.8%). Two participants (3.9% of diverters) who donated their leftover medications to a clinic or organization did not engage in any other types of diversion

activities. Such donations would not likely find their way into illicit markets, although the nature of the donee organizations is unknown.

Characteristics of participants with ARV prescriptions by diversion status are shown in Table 2. ARV diverters, compared to nondiversers, were more likely to be substance dependent (74.5% vs. 58.7%, $p = 0.046$) and to have recently traded sex for money/drugs (60.8% vs. 32.6%, $p < 0.001$), and less likely to be 90% adherent to their ARVs (54.9% vs. 73.9%, $p = 0.012$).

Discussion

The diversion of ARVs is a largely unrecognized problem in the USA, but has been documented in no fewer than seven states (Surratt & Kurtz, 2013). ARV diversion was also reported by more than one-quarter of HIV-positive participants with prescriptions in our intervention trial for high-risk, substance-using MSM. HIV-negative men in these high-risk networks are among the highest priority for PrEP rollout (Smith et al., 2011), the most likely to benefit from PrEP (Curran & Crosby, 2013), and, if successfully targeted, the most likely to produce population-level improvements in the US HIV epidemic in a cost-effective way (Jusola, Brandeau, Owens, & Bendavid, 2012). Moreover, MSM are known to be early adopters of new behavioral and biological HIV prevention technologies (Kippax, 2012). Indeed, the nonprescribed use of emtricitabine/tenofovir for prevention has been documented among high-risk MSM since at

Table 2. Correlates of ARV diversion among MSM with prescriptions ($N = 189$).

	Diverters ($N = 51$)		Nondiversers ($N = 138$)		p
	N	%	N	%	
<i>Demographics</i>					
Age (mean; SD)	42.3 (6.9)		43.8 (7.2)		0.211
Education (mean; SD)	13.6 (2.1)		13.7 (2.3)		0.932
<i>Race/Ethnicity</i>					
Hispanic (ref.)	9	17.6	31	22.5	
African-American/Caribbean	18	35.3	29	21.0	0.067
Caucasian	22	43.1	71	51.4	0.644
Other	2	4.0	7	5.1	0.881
Homeless in the past year	17	33.3	35	25.4	0.276
<i>Sex-risk behavior (past 90 days)</i>					
Anal sex partners (mean; SD)	14.7 (21.3)		16.0 (19.3)		0.695
UAI times (mean; SD)	21.4 (23.8)		27.9 (38.1)		0.255
Traded sex (past 12 months)	31	60.8	45	32.6	<0.001
<i>Health-risk measures</i>					
Severe mental distress	34	66.7	88	63.8	0.712
DSM-IVR substance dependence	38	74.5	81	58.7	0.046
Victimized before age 18	30	58.8	71	51.4	0.367
90% adherent to ARVs	28	54.90	102	73.9	0.012

least 2009 (Philpott, 2013; D. Fawcett, personal communication, June 1, 2013).

Although there is wide agreement among governmental agencies and scientists that individuals taking PrEP require frequent testing, regular health monitoring, and ongoing behavioral support (Koenig, Lyles, & Smith, 2013; Smith et al., 2011; Weber, Tatoud, & Fidler, 2010), MSM at highest risk for HIV infection are likely to have difficulty accessing these services. Data from our sample confirm others' concerns (Curran & Crosby, 2013; Koenig et al., 2013) that MSM who would most benefit from PrEP suffer high rates of substance use and have limited access to health care. Only 42.4% of HIV-negative men in our study had any type of health-care coverage. These vulnerabilities render them less likely to have access to prescribed PrEP, medical supervision, and ancillary services. Nevertheless, this population of sexually active men is likely to have a high level of interest in PrEP (Krakower et al., 2012; Liu et al., 2008; Mimiaga et al., 2009), and, because their health and social vulnerabilities, to be at risk for attempting access to PrEP through nonmedical channels.

Several limitations of the study design must be considered in evaluating the findings. First, the data rely on self-report, and some respondents may have refrained from reporting socially undesirable behaviors. In the present case, however, that would likely mean underreporting of diversion. Also, the prevalence of diversion among HIV-positive MSM found here is not necessarily generalizable to the overall population of HIV-positive MSM because of the eligibility requirements, requiring recent substance abuse and UAI. Importantly, we did not collect data from HIV-negative men on their use of diverted ARVs; as such, our data confirm only the supply side of illicit markets. We do not know the characteristics of the end users of the diverted medications, nor their reasons for use.

Our findings indicate that street markets for ARVs approved for PrEP are already active. We have focused our analysis on the risks posed by ARV diversion to the successful rollout of PrEP rather than self-treatment for several reasons: (1) nonprescribed use of emtricitabine/tenofovir for prevention has been documented among high-risk MSM since well before the issuance of CDC guidance or FDA approval; (2) the great difference in access to health care between HIV-positive and HIV-negative MSM; over 90% of the HIV-positive men in our high-risk sample were in care; (3) the simplicity of the PrEP regimen compared to regimens for the treatment of HIV infection and PEP; and (4) the lack of evidence for diverted ARVs being used for self-treatment. At the same time, the scale-up of treatment as prevention will potentially increase the supply of divertable ARVs.

As high-risk MSM become more aware of the use of ARVs for PrEP, illicit markets may expand based on this

new source of demand. In this informal illicit market sector, knowledge gaps, inconsistent ARV supplies and adherence, and lack of frequent testing and ongoing behavioral support may lead to sporadic use, unmonitored restarts, use when unknowingly infected, and, potentially, the use of counterfeit, ineffective, or compromised ARVs. Confusion over which drugs and dosages are approved for PrEP is also a concern (Weber et al., 2010). For PrEP to succeed in reducing HIV infections among at-risk populations, expanded health-care coverage, robust outreach programs, and access to services not directly related to HIV, including mental health and substance-abuse treatment, will be critical.

Our findings point to the need for more research on the scope and magnitude of ARV diversion, with a particular focus on how the rollout of treatment as prevention and PrEP impacts illicit markets for these medications. Moreover, it is important that clinicians be aware of ARV street markets, and the potential for such markets to result in patients' low adherence and increased risk for health problems, ARV resistance, and onward disease transmission. At the same time, care must be taken not to restrict patients' supplies such that office visits are too frequent to be manageable, or that patients are at risk for nonadherence because of running out of medication. Most importantly, ARV diversion – and related risks of treatment failure, resistance, disease transmission, and PrEP failure – should be considered in developing policy and behavioral supports to scaling up treatment as prevention and PrEP.

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