Vulnerable Infected Populations and Illicit Markets for ARVs: Potential Implications for PrEP Rollout in the US

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BACKGROUND

The widespread diversion – the unlawful channeling of regulated pharmaceuticals to illicit markets – of antiretroviral (ARV) medications has recently been documented in South Florida among vulnerable, indigent patients who are targeted by pill brokers to trade their ARVs for money or drugs.[1] Large scale diversion of ARVs has also been documented by law enforcement in at least seven states.[2] Emtricitabine/tenofovir is among the most frequently diverted ARV according to recent reports from both law enforcement and patients.

The recent approval of emtricitabine/tenofovir for pre-exposure prophylaxis (PrEP) has the potential to broaden illicit markets for this medication, as high risk individuals seek access without a prescription or medical supervision. Non-adherence among diverters and unsupervised use of ARVs for PrEP increase risks of treatment failure, drug resistance, and disease transmission. We report the scope of ARV diversion among substance using MSM.

RESEARCH DESIGN

Methods: Data are from assessments completed by participants in a behavioral intervention trial during the period November 2008 through December 2011. Eligibility: MSM ages 18-55, regular substance use (including heavy alcohol) and recent unprotected anal intercourse (UAI). Surveys (N=515) queried demographics, health insurance coverage, self-reported HIV status, sexual risk behaviors, and clinical measures of mental distress and substance dependence. HIV-positive participants also answered questions about medical care, treatment, self-reported past month ARV adherence, and ARV diversion history.

Analyses: Descriptive statistics were used to characterize the study sample. Chi square and analysis of variance tests examined differences between HIV-positive participants who had sold or traded their ARV medications compared to those who had not.

SAMPLE CHARACTERISTICS

Table 1. Baseline characteristics of MSM (N=515)

	N	%
Demographics		
Age (mean; SD)	38.9 (9.6)	
Education (mean; SD)	13.8 (2.4)	
Race/Ethnicity		
Hispanic	133	25.8%
African American	108	21.0%
Caucasian	250	48.5%
Other	24	4.7%
Homeless in the past year	133	25.8%
Sex risk behavior (90 days)		
Anal sex partners (mean; SD)	13.3 (18.6)	
UAI times (mean; SD)	22.6 (35.4)	
Traded sex (past 12 months)	176	34.2%
Health risk measures		
Severe mental distress	298	57.9%
DSM-IVR subst dependence	156	62.1%
Victimized before age 18	282	54.8%
Health care coverage		
HIV-negative	276	53.6%
Health care coverage	117	42.4%
HIV-positive	239	46.4%
Health care coverage	206	86.2%
Receiving HIV care	219	91.6%
Prescribed ARV meds	189	79.1%

ARV DIVERSION

Table 2. Correlates of ARV Diversion among MSM with ARV Prescriptions

	Diverters (N=51)	Non-diverters (N=138)	
	%	%	p
Demographics			
Education (mean; SD)	13.6 (2.1)	13.7 (2.3)	0.932
Homeless in the past year	33.3%	25.4%	0.276
Sex risk behavior (90 days)			
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 mos)	60.8%	32.6%	<0.001
Health risk measures			
Severe mental distress	66.7%	63.8%	0.712
DSM subst dependence	74.5%	58.7%	0.046
Victimized before age 18	58.8%	51.4%	0.367
90% adherent to ARVs	54.9%	73.9%	0.012

Of the 46.4% of men in the sample who were HIV-positive, 91.6% were receiving medical care; 79.1% were prescribed ARVs. Of these, 27.5% reported ever selling/trading ARVs; 19.0% in the past year. Reasons for diversion (more than one reason was permissible) were

- sharing/trading with friends (n=32, 62.7% of diverters)
- sale/trade for money/drugs (n=19, 37.3% of diverters)
- donated leftover medications (n=10, 19.6% of diverters)
- sale/trade of leftover medications (n=5, 9.8% of diverters)

ARV diverters, vs. non-diverters, were more likely to be substance dependent and have recently traded sex; and had lower ARV adherence.

DISCUSSION

Limitations: MSM in our sample reported recent substance use and UAI, limiting the generalizability of the findings to other HIV-positive MSM. Also, our data are limited to diversion by HIV-positive MSM with prescribed ARVs, and as such confirm only the supply side of illicit markets.

ARV diversion is potentially a concern for unsupervised use by uninsured HIV-positive patients in search of ARVs for self-treatment as well as for HIV-negative people seeking ARVs for PrEP The widespread availability of treatment for HIV-positive patients in the US, together with the expensive, multiple, and often complex treatment regimens for HIV infection, would appear to limit the use of diverted medications for self-treatment, however.

On the other hand, our data indicate that MSM who would most benefit from PrEP suffer high rates of substance use and have limited access to health care. These vulnerabilities render them less likely to have access to prescribed PrEP, medical supervision and ancillary services, and to achieve the high adherence levels necessary for PrEP to be effective.

Nevertheless, this population of sexually active men is likely to have a high level of interest in PrEP, to receive and transmit street folklore about PrEP, and, because of this knowledge and their health and social vulnerabilities, to attempt access to PrEP through non-medical channels. Moreover, the approved PrEP regimen consists of a single well-recognized product. In fact, the non-prescribed use of emtricitabine/tenofovir for prevention has been documented among high risk MSM since at least 2009.[3,4]

The implications of diversion for increased risks of treatment failure, drug resistance and disease transmission should be carefully considered in developing policy and behavioral supports to scaling up PrEP

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