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The Demand for Antiretroviral Drugs in the Illicit Marketplace: Implications for HIV disease management among vulnerable populations

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Abstract

The diversion of antiretroviral medications (ARVs) has implications for the integrity and success of HIV care, however little is known about the ARV illicit market. This paper aimed to identify the motivations for buying illicit ARVs and to describe market dynamics. Semi-structured interviews (n=44) were conducted with substance-involved individuals living with HIV with a history of purchasing ARVs on the street. Grounded theory was used to code and analyze interviews. Motivations for buying ARVs on the illicit market were: to repurchase ARVs after having diverted them for money or drugs; having limited access or low quality health care; to replace lost or ruined ARVs; and to buy a back-up stock of ARVs. This study identified various structural barriers to HIV treatment and ARV adherence that incentivized ARV diversion. Findings highlight the need to improve patient-provider relationships, ensure continuity of care, and integrate services to engage and retain high-needs populations.

Keywords

HIV; ARV; diversion; adherence; substance use; qualitative

INTRODUCTION

Prescription drug diversion is defined as the unlawful channeling of regulated pharmaceuticals from legal sources (e.g. legitimate prescriptions filled by patient) to the illicit market (1). The Centers for Disease Control and Prevention (CDC) has classified prescription drug diversion and abuse as one of the nation’s fastest growing public health problems and it has reached epidemic levels (2). Although most drug diversion research focuses on controlled prescription drugs with high abuse potential, like opioids (3), the diversion of antiretroviral drugs (ARVs) has been documented in at least seven U.S. states (4–10), with substantial ARV diversion recently revealed among highly vulnerable HIV-positive patients in South Florida (11).

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ARV diversion has serious implications for the integrity of HIV care and prevention, making it a critical public health concern. ARV diversion has been associated with regimen non-adherence among people who divert their medications (11). Non-adherence is directly linked to HIV treatment failure, the lack of viral suppression, and an increased risk of HIV transmissibility (12). ARV non-adherence is also associated with the development of ARV resistance and transmitting ARV resistant strains of HIV (13). People taking illicit ARVs without medical supervision may be under-dosing or not adhering to regimen protocols, which would further elevate the risk for treatment failure, ARV resistance, and onward HIV transmission. Additionally, ARV diversion may compromise the pharmaceutical supply given that ARVs purchased in illicit markets may be illegitimate, expired, or compromised by mishandling, and are sometimes recycled into the formal medication supply chain (10, 14).

The diversion of controlled substances can occur at all points in the drug delivery process from the original manufacturer to the wholesale distributor, the physician's office, the retail pharmacy, or the patient (15). In a similar way, the diversion of ARV medications appears to involve numerous participants, including physicians who prescribe ARVs in exchange for payment, local pharmacies that recycle and resell ARVs, ARV pill brokers, and people living with HIV who divert their ARVs (10, 14). Research on ARV diversion in South Florida indicates that pill brokers target indigent people living with HIV to divert their medication for money due to financial hardship, to support their substance use, or because of adherence problems due to side effects or regimen complexity (11, 14).

Despite documented ARV diversion, little is known about the *demand* for ARVs in the illicit marketplace. Who purchases ARVs on the illicit marketplace and what are their motivations? Prior research in Miami identified several types of potential illicit ARV buyers, including people living with HIV who wish not to disclose their status and large-scale brokers who ship ARVs to countries in Latin American and the Caribbean with supply shortages (14). A few reports suggest that diverted ARVs may be sought after for their psychoactive properties (8, 14, 16–18) or for their non-prescribed use as pre-/post-exposure prophylaxis (8, 19–21). However, the demand side of the ARV illicit market remains largely undocumented.

Using data from in-depth qualitative interviews with purchasers, this paper examines ARV illicit market dynamics, and describes the health and social risk profiles, as well as the motivations, of those who buy diverted ARVs. We situate ARV diversion and purchase from illicit markets within the broader context of socioeconomic marginalization, substance use, and structural barriers to care.

METHODS

Data were drawn from a larger mixed methods study that was designed to describe the dynamics of ARV medication diversion to local illicit markets and to examine the patterns and predictors of ARV diversion among people living with HIV in South Florida. The qualitative research component of the study targeted four groups of people central to understanding ARV diversion, including: 1) HIV-positive individuals who divert their

ARVs, 2) HIV-positive individuals who do not divert their ARVs, 3) HIV-positive individuals who illicitly purchase ARVs, and 4) ARV pill brokers. Interviews gathered detailed information on the dynamics of ARV medication diversion and the local illicit ARV marketplace. The current analysis utilizes interview data from group three only – HIV-positive individuals who illicitly purchase ARVs.

Study sampling and recruitment

This study utilized targeted sampling approaches for recruitment. Targeted sampling is a systematic method to identify and recruit hard-to-reach populations (22–25) in which a set number of participants are recruited within specific geographical districts. Recruitment target areas were identified by key informants (KIs; e.g. treatment professionals, community outreach workers, HIV service providers, and a variety of street-based substance users) who presided or worked in communities with high HIV prevalence and concentrated poverty (26).

Study recruitment was carried out by a team of professional field staff and outreach workers who conducted direct outreach. Study information cards and flyers were distributed in a variety of street venues and community-based HIV service organizations within the identified communities. Study recruiters gave potential participants the project contact information and asked them to participate in telephone screening for eligibility. Participants were eligible for inclusion if they were 18 years of age or older, had a documented HIV-positive serostatus, and had purchased ARV medications from illicit markets at least once in the prior six months. To capture variability in the phenomenon of ARV diversion, participants were purposively recruited for equivalence across gender and race. Eligible participants were scheduled for appointments at the field site, where they were re-screened.

A total of 44 buyers of illicit ARVs met the eligibility criteria and were enrolled in the study between November 2009 and July 2011. After informed consent was obtained, a semi-structured interview was conducted (either in Spanish or English based on participants' desires) and averaged 45 minutes in length. The interview guide included questions about the person's history living with HIV, their access and quality of HIV care, their involvement in the illicit buying and selling of ARVs, concerns and consequences of buying ARVs from illicit markets, and characteristics of the illicit ARV marketplace (e.g. structure, stability, elasticity and pressures of the illicit ARV market). Participants were paid a \$30 stipend upon completion of the interview, and were offered a variety of educational and risk reduction materials. Each interview was transcribed verbatim by the interviewer, all identifying information was removed from the transcripts, and interviews conducted in Spanish were translated and back-translated for accuracy. All project staff completed the required web-based certification for protection of human subjects and study protocols were approved by the Institutional Review Boards of University of Delaware (predecessor institution) and Nova Southeastern University. An NIH Certificate of Confidentiality was also obtained and a copy was offered to participants.

Data Analysis

A grounded theory approach was used to analyze the qualitative data and, consistent with this methodology, constant comparison was conducted across each stage of the research process for a dynamic process (27–29). The recruitment of participants was designed to achieve saturation across gender and racial groups, such that additional data no longer provided new information on the phenomenon of illicit ARV purchases by people living with HIV (28, 30). The primary qualitative analyst began by open coding the first four interviews to identify initial patterns, and then employed axial coding to group initial codes into higher level categories. Each additional interview was coded and constantly compared to analyzed interviews to develop new categories, expand existing categories, and to explore relationships between categories.

Two methods were used to establish rigor and minimize researcher bias throughout data analysis. First, the primary analyst wrote memos to document the analytic process. Memos served to elaborate categories, specify their properties, define relationships between categories, and to identify gaps in the data (27). Throughout the process of memo-writing, quotes were identified to ensure codes and categories were grounded in the data. Second, coding review and debriefing was conducted in a team with two additional researchers who were trained in grounded theory. Team members individually engaged in open coding of the first four interviews to identify initial codes. Then, as a team, initial codes were compared to memos and categories to confirm findings, resolve discrepancies, and identify analytical codes.

RESULTS

Table I describes our sample (n=44) of people living with HIV who reported buying ARVs from the illicit marketplace at least once in the prior six months. The sample averaged 45.8 years old (range=26 to 62 years), was 59% male, and 43% Black/African-American, 39% Hispanic/Latino, and 18% non-Hispanic White. Most participants had the Ryan White program cover their ARV medications (50%) or had public insurance (34%; e.g. Medicaid, Medicare, etc.), with a few participants reporting no insurance coverage (7%). Most interviews were conducted in English (75%) and almost a third of participants had a history of homelessness (30%). Participants were living with HIV for an average of 13 years (range=1–27 years). More than a third of the sample used multiple substances (39%), 27% used one substance, 14% mentioned substance use but did not elaborate, 18% did not mention substance use, and 2% did not use any substance. Of those who mentioned substance use, 36% reported alcohol, 34% crack cocaine, 27% powder cocaine, and 23% marijuana.

Table II outlines the primary motivations for buying ARVs from illicit markets. The majority of participants purchased illicit ARVs because they had diverted their legitimately obtained prescription for money for drugs (61%) or for personal needs (57%; e.g. bills, rent, food, childcare, etc.). Almost half (41%) of participants accessed the illicit marketplace for ARVs because they had limited access to health care and/or low perceived quality of care, with 14% of participants reporting a lack of insurance coverage for their prescriptions because they had been assigned to Florida's AIDS Drug Assistance Program (ADAP)

waitlist. More than a tenth of the participants mentioned buying illicit ARVs because they had to replace prescribed medications that had been lost, stolen, or ruined (11%). Seven percent purchased illicit ARVs to have a back-up supply.

The ARV Illicit Marketplace

Participants emphasized the ease of accessing the illicit ARV marketplace, despite notions of the market's hidden nature, the fear of HIV stigma, and the danger of prosecution. Participants consistently mentioned that South Florida has a large population of people living with HIV, and that social networks are formed quickly among them given the regular exposure to one another at hospitals, doctors' offices, pharmacies, support meetings, and on the street. As one participant stated:

Once you've found out that you're HIV and you know the circle of people that you're dealing with, it's quite easy...There's a lot of people out there that's HIV, a lot. You go to the places, doctors and stuff that they go to and you get to know 'em...a lot of them are drug users...and they wanna sell their bottles to get high ... There is a profit, but there's also a danger.

(Non-Hispanic Black Male, 51, living with HIV for 6 years)

Participants described a system that incentivized vulnerable individuals to sell "clean" bottles of their legitimately obtained ARVs and then re-purchase the same regimen at a lower price in "marked" bottles from the streets. "Clean" bottles are distributed by pharmacies in sealed and unmarked containers that include the information booklet, and participants frequently mentioned that ARVs in clean bottles can sell for hundreds of dollars on the streets. However, participants also explained that many pharmacies distribute ARVs in marked bottles to dissuade patients from diverting the medication. Marked bottles have broken seals and the bottle is usually marked with a black marker to prevent re-use. Some pharmacies even distribute ARVs in entirely different bottles from that used by the manufacturer. According to participants, marked bottles carry much lower street values. Participants also noted that novel or popular ARVs (e.g. Truvada, Kaletra, and Atripla) were worth more money and were more in demand than older regimens.

My wife and I are on the same regimen...I would end up selling it...and I would have to buy it...back...I'd make a profit...it's like a little juggling, you know?...I would normally sell my Truvada...for \$120–140 a bottle...and the Kaletra, like \$100–120 a bottle...The seals aren't broken, they're capped. They have the booklet and everything...(I would pay) \$20 dollars for a bottle of Truvada...(and) Kaletra's the same...the people that I get them (back) from, get 'em from the health department and...they put this black ink all over them and they open the top.

(Non-Hispanic Black Male, 51, living with HIV for 6 years)

Purchasing ARVs after Diverting Prescription for Financial Need

Participants mentioned that a key motivation for the illicit purchase of ARVs was the desire to take their medication after having diverted due to financial need. Participants often sold

their ARVs for money to supplement their very low incomes and meet subsistence needs (e.g. money for rent, food, transportation, phone bill, transportation, family-related expenses, emergency expenses etc.). Many cited that poor health precluded them from working for a steady income and relied on money from selling their ARVs to subsist.

I was in need of some money...I had to eat. I had to survive...to buy personal hygiene...I was used to doing some type of work...and since I've been sickly...I haven't been able to function right...I was going and getting my prescriptions and I heard some people talking and they...gave me \$140 (for Atripla) and this bottle (Kaletra) goes for \$200...you're able to purchase them...but it be a less(er) price. Of course, you're gonna get a discount

(Non-Hispanic Black Female, 46, living with HIV for 19 years)

I go and buy medication to last until it's time for me to put my 'script back in...I have a female child...Some out there like me, when we get jammed up and need money; we sell 'em. And I never sold my medicine to get high, but I have sold my medicine because I needed the money for a bill or for something for my child.

(Non-Hispanic Black Female, 43, living with HIV for 3 years)

Unfortunately, I needed some funds for something personally, and I didn't have the funds. So, by word of mouth, I found a person that buys medication... I was able to sell my meds and, later on...go back to him and buy medication that he couldn't get rid of...living on a disability income is not a whole lot of money... I'm thankful, but it doesn't go a whole...I have some transportation and I have to maintain it...keep the insurance...So that's something that I had to sacrifice, to keep my transportation.

(Non-Hispanic Black Male, 53, living with HIV for 23 years)

Purchasing ARVs after Diverting Prescription for Substance Use

Another primary motivation for illicit ARV purchases was the desire among participants to take their medication after having diverted their ARVs due to substance abuse problems. Most participants regretted diverting their ARVs and several expressed remorse and guilt for having relapsed into substance use. These participants felt they could not disclose their dilemma to their doctor or to other providers and, thus, sought to re-purchase their ARVs from illicit markets:

I smoked (crack) over the weekend and I had sold my meds, and then I felt stupid...Because nobody is knowing that I'm getting high, my doctor and all them don't know that I relapsed...I had been clean for so long, I (had) started taking my medicine on a regular basis like I was supposed to...and so I had to turn around and...get medicine.

(Non-Hispanic White Female, 47, living with HIV for 16 years)

Participants often mentioned having access to illicit ARVs through friends, street acquaintances, and pharmacy contacts. Some participants made arrangements with friends who were on the same regimen to buy and/or share medication. As one woman explained:

We just go to a friend that is taking the same medicine...give them a couple of dollars, they'll give you some pills... In the morning, the Truvadas...and Kaletras at night...after you come down off of the drugs...go to feeling guilty about it and trying to buy it back, you know, buy at least a couple of pills to last me...until I get my next prescription.

(Non-Hispanic Black Female, 37, living with HIV for 4 years)

Heavily involved substance users were often mentioned as a source for buying cheap ARVs, and some participants reported trading ARVs directly for illicit drugs. Several participants had a connection with a pharmacy or pharmacist from whom they could illicitly obtain additional ARV medications.

Participants described a range of levels of adherence to their ARV regimens. In order to ensure they could properly adhere to their regimens, some participants made arrangements to repurchase illicit ARVs before they sold their legitimately obtained prescription. Nevertheless, some participants mentioned having to go for several days, or even weeks, without their ARVs because either they ran out of money to re-purchase their entire prescription, the deal fell through, or the deal involved repurchasing only a few pills:

Well, I sold my medication because...I started using drugs...but I already had somebody who was going to sell me his medication...the same medication that I was taking...I wanted the money to use the drugs...if I sold mine for \$250...I buy for \$120...I have the medication back, plus \$130... I went without medication about three days and I was worried because the doctor told me once you start taking this medication you cannot stop taking...daily doses because the virus can get resistant... (but) when I tried to get the medication, the person already had sold it... that's why it took me three days...I went with him to the pharmacy... when he came out...I got the medication.

(Hispanic White Male, 49, living with HIV for 12 years)

Although most participants were aware of the importance of ARV adherence to avoid developing resistance, many encountered barriers to strict adherence and used their "numbers" (e.g. CD4+ count and viral load) as a gauge to reassure themselves that they were on track:

I had sold my medication one month and I was out...So I had a friend...taking the same medication...I purchased some from her...I been buying it...off and on from her...or she'll give me some and I'll pay her when I get my check...I try not to go too long without taking my meds...I have skipped a lot...And I have had..., resistance or whatever, rashes...but somehow my CD4 builds back up and I get back on track...I also call my pharmacist to tell him that I lost my medication and send some more...we have a good connection.

(Non-Hispanic Black Male, 44, living with HIV for 22 years)

Access to and Quality of Healthcare

Almost one-third of participants noted barriers in access to healthcare or receiving inadequate care as motivations for buying ARVs from illicit markets. Several participants indicated that physicians rushed through appointments, were not thorough, appeared not to care, and were not approachable or open to discussion.

(I've been with this doctor) for about four months...I see him for two minutes... He'll come in, look at the labs...'Bah, bah, bah, okay'...Then write whatever and then bounce...But I've got an appointment coming this time, and...I'mma talk to him this time...I've got some issues going on, so...I'll give him another couple of months, but...I've had doctors before that would come in and sit down with you... They ask all types of questions, and spend at least, you know, 10, 15 minutes with you.

(Non-Hispanic White Male, 37, living with HIV for 7 years)

Participants often mentioned having to buy illicit ARVs to adhere to their regimen because they missed a doctor's appointment and did not have back-up pills to hold them over until the new appointment date. Likewise, some participants needed a few extra pills to hold them over until their pharmacy was able to fill their prescription or they could pick up their prescription.

I had missed a doctor's appointment, and I couldn't get back in until, like, two weeks later, so I didn't have no medication, so I had a friend that had some Atripla, and he let me buy some of his...he said he didn't take it right away, so he had some extras...And then the other time I missed the doctor's appointment, and so I had to wait until I got back in to see the doctor to get a new prescription, and then I had to wait a few days to get the pharmacy to fill it.

(Non-Hispanic White Male, 46, living with HIV for 11 years)

A number of participants were motivated to buy ARVs from illicit markets because they were not being prescribed ARVs by their physician, they wanted to take a different regimen than they were being prescribed, or their blood tests were normal according to their physician but they felt sick or did not trust that they should wait to take medication. Participants decided to take control of their health, rather than relying on their physician, by purchasing their ARV regimens from illicit markets. In these instances, participants would either buy a regimen that they were previously prescribed, a regimen recommended by a pharmacist, or a regimen that was successful with someone they knew. In addition, some participants noted that they "self-prescribe" extra doses in order to protect their health:

I bought it at \$60, Sustiva, Combivir, and Kaletra. [The pharmacist] explained to me, 'You take one with breakfast and on with lunch...Now (2009), I am trying Truvada and Kaletra...I pay about \$80 for both...(My doctor) doesn't know I buy

them because I don't want to tell him, you know? I don't want to have a problem. I don't want to go to jail for buying [illicit ARVs]. I'm doing well (taking meds w/o Rx), but it's a lot of money, I want to see if this [new] doctor prescribes them to me because I'm not about paying every month... (My current doctor) says that right now he can't, that he doesn't want to give them to me. Why? I don't know. He gives me an excuse.

(Hispanic White Male, 44, living with HIV for 15 years)

I got sick again in 2010 and I thought it was the HIV and I started to buy pills. Supposedly my numbers are good, they are normal. I bought Isentress, Lexiva y Reyataz...because a friend of mine has HIV, so she told me that is what she takes...she says that those keep your viral load and t-cells normal...She...takes them once a day. I take them twice...I don't want the viral load to go up.

(Hispanic White Female, 24, living with HIV for 2 years)

Several participants found the difficulty in finding a good doctor so burdensome that they decided to forgo formal HIV healthcare altogether. Although rare, one female participant reported being solicited for sex in exchange for an ARV prescription. As a way to avoid these situations, she opted to purchase her ARVs from illicit markets:

I'm not going to see no doctor at all... I just been buying it off the street...I'm not disabled or I don't have no type of income...it's real stressing 'cause...I do want to do good, (but) I have a bad record. Nobody wants to give me a job... they're not even hiring...underneath the table...I have to...sell my medications and it's most of the time...I'm always worried about paying my phone bill or just paying somebody to let me...sleep and take a shower in their house...I just don't like the way the doctor talks to me...I've been through a lot of doctors...I just go when it's an emergency...There's doctors that are really harsh and they just don't know how to talk to somebody that's suffering with this disease...I had a doctor that I liked before, but then I came to find out that all he wanted to do was have sex with me, even though he knew that I was HIV positive... Yeah. And it really broke me down even worse... I've had very bad luck...I even had a doctor close his office and tell me... that he'll prescribe me any type of medication on the market, 'cause he knew that people were selling their shit. So he told me...'Look, I'm not stupid. I know you haven't been taking your medication, that's why you're here. So if you need help, I'll give you the most expensive medication that's out on the market and... just let me put on a condom and lay you over on the table and let me have sex with you'...and because of my financial needs, I really literally have to do it and feel disgusting afterwards, but...at least I'll have a hotel to sleep in and somewhere to eat, you know?... Never again. Ever again. I got so hurt to see somebody with such a lucky, healthy life that's... a doctor and...It just turned me down so bad because I was, like wow...he's even taking advantage of females with HIV...That really, it crushed me so bad that it's, like, that's why I feel like I don't care about seeing the doctor no more...I...he took very much advantage that I was young, that I was pretty and that I also had AIDS.

(Hispanic White Female, 26, living with HIV for 4 years)

Numerous participants mentioned access barriers to obtaining and filling their ARV prescription as motivations to buy ARVs on the street. Participants often mentioned having to wait for weeks to get an appointment and for hours or even days to have their prescriptions filled. These long wait times appear to reflect an under-resourced and taxed system of care:

I had ran out (of ARVs) and dude was giving away cheap, and I didn't wanna go down there, go see the case worker and wait in them long waits. You might go 8 o'clock in the morning and get out there 5 o'clock... I know where to get the same medicine...I just bought it...Sometimes dude sell it for like \$30. And they be on drugs... Yeah, I done bought two bottles that I need for \$30.

(Non-Hispanic Black Male, 50, living with HIV for 9 years)

Numerous participants mentioned their lack of access to ARV prescription insurance as a primary motivation for purchasing ARVs on the illicit marketplace. At the time data were collected, Florida's ADAP had a lengthy waiting list for enrollment because of lack of funding. Numerous participants were dropped from ADAP, and subsequently waitlisted, because they missed one or more doctor's appointments, failed to pick up a filled prescription, or moved from state to state:

The whole thing with ADAP was I guess you had to keep up your appointments and there was some sort of notice in the doctor's office and...I missed the appointment...so right now I'm in the process of trying to get on that waiting list.

(Non-Hispanic White Male, 39, living with HIV for 21 years)

When I got out of the hospital...I went back to ADAP to fill the prescriptions, they threw me off the program, because I didn't pick up the medication...so that's why I had to go out and buy medication...

(Non-Hispanic White Male, 52, living with HIV for 24 years)

Without access to ADAP services, participants found ARVs through other means but reported unreliable access to their ARV regimens, therefore making ARV adherence difficult. One participant mentioned having a connection with a nurse who ran an underground business that distributed ARVs at a discounted price to people with a low-income who were in need. Several participants found out about the Patient's Assistance Programs (PAP) run by pharmaceutical companies to ensure access to their drugs in the event of losing insurance or access to medication. However, participants mentioned that information on PAP was hard to find, becoming enrolled in PAP required extensive paperwork, and prescription coverage from PAP may only last several months. In some of these cases, participants opted to purchase their ARVs from illicit sources:

There's an underground network out there....I was going to (name of place), and I used to get medication there...and then give them to a..., a nurse, because she was involved in something that made sure people got it....that didn't have any money... they used to have a storefront...but they're gone...she's not hooked up in the medical profession no more.... there's one place I know where you get the medication for free every day: prison....(also) the Patient's Assistance Program....each drug company has a different set of rules... where if you can't afford it, you're not supposed to just die...But...there's a bunch of paper work... you have to jump through a lot of hoops.

(Non-Hispanic White Male, 52, living with HIV for 24 years)

I (had) just been complaining about the whole (ADAP) list and one of my friends... hadn't been taking his meds so he had 2 or 3 stockpiled. So I just offered him some money...But then the next month, I didn't do it. Then the following month...I bought them again....Then I'm like 'Well, I'm not really doing myself any favors because if I'm taking them for a month and then I'm not taking them...I might screw up the whole thing'...And I don't know how old they were (illicit ARVs) and all that kind of stuff...I don't have any opportunistics, haven't had any...I'll wait again...if something traumatic happens, I'm gonna end up in the emergency room.

(Non-Hispanic White Male, 39, living with HIV for 21 years)

To Replace Lost, Stolen, or Ruined ARVs

A handful of participants mentioned that they purchased ARVs from illicit markets because their legitimately obtained ARVs were lost, stolen, or ruined. Although one participant simply forgot his ARV prescription on the bus, other participants had their ARVs stolen or ruined in a manner that reflects the instability of their living situations. Participants mentioned that their ARV medications were misplaced while they were high, were stolen from their home or shelter, were left out in the elements when they were evicted, and were thrown away in the heat of an argument. Although this was a less common motivation for purchasing ARVs from illicit markets, the need to find replacement medication often introduced them to or strengthened their connections in the illicit ARV marketplace.

I lost my medicine that the doctor prescribed me. I was on the bus and I left the whole package there. So I came and I bought half from someone else to cover me every other day.

(Hispanic White Male, 61, living with HIV for 12 years)

My medications were ruined and rained on...the heat, just left out in the elements...So, even though I was paying the rent...I went back to the place and my stuff was on the side of the apartment...on the lawn on the side of the building. He packed everything nice and neatly, but people went through it. It was just a nightmare. I lost pretty much everything except for clothes...I bought 15 at one

shot the first time...and it wasn't cheap...\$150...It probably was his own medication, and he probably just wanted to get high.

(Non-Hispanic White Male, 45, living with HIV for 27 years)

I was living somewhere, and I had a prescription bottle of medication, and me and that person got into a fight, so they threw all my stuff away, so they threw my medications away. So I ended up having to buy some from a friend.

(Non-Hispanic White Male, 46, living with HIV for 11 years)

Buying for back-up

An additional, although rarely mentioned, motivation for purchasing ARVs from illicit markets was to have an extra stock, or back-up, of ARV medications. Some individuals spoke of keeping a back-up in case there is storm, they run out of medication, or they lose access to medication or healthcare insurance coverage. Participants often mentioned missing doctor's appointments and some kept back-up ARVs to hold them over until the new appointment date. Likewise, some participants needed a few extra pills to hold them over until their pharmacy was able to fill their prescription or they could pick up their prescription. Participants that solely accessed their ARV medications from illicit markets mentioned keeping a backup to enable adherence in case they had a hard time finding their regimen on the street. Many participants noted that individuals will stockpile ARV medications when they experience undesirable side-effects or are non-adherent and then sell them (or give them) to friends, acquaintances, or loved ones to use. Having a back-up stock of ARVs was also deemed important because most participants can only fill their prescriptions on a month-to-month basis, depending on the pharmacy. Other participants reported that they sometimes fill their prescription at multiple pharmacies to gather a back-up stock.

I do have an extra stock...of my medication for back up...in case we get a storm, in case I can't get to the pharmacy. And I always, well, you can get your medicine only on a month to month basis on the time that it's due...But it's pretty much up to the pharmacy. Sometimes some pharmacies make exceptions...If you go to some specific pharmacy you can go to another pharmacy and if they don't investigate and research...they'll give you another.

(Non-Hispanic Black Male, 53, living with HIV for 23 years)

DISCUSSION

Our qualitative analysis elucidates the demand for the purchase of ARVs in illicit markets and is among the first to situate illicit ARV sales and purchases within a broader context of socioeconomic marginalization, substance use, and structural barriers to HIV care.

Our street-level data reveal new dimensions of the ARV illicit marketplace. This study documented an incentivized price structure for "clean" ARV medication bottles that

explicitly connects individual or patient-level diversion to a higher level system of ARV diversion. “Clean” bottles of expensive ARV medications are desirable because they can be recycled back into the formal medication supply chain and re-sold, a process that potentially involves pill brokers, health care and pharmacy professionals, insurance fraud, and distributors. A recent case in New York is indicative of a similar operation in which Medicaid recipients were paid to divert their ARVs, which were later resold to unsuspecting patients (10). This particular episode of fraud cost Medicaid some \$500 million, compromised the pharmaceutical supply with mishandled and expired ARVs, and targeted socioeconomically disadvantaged people (10). For people who are marginalized by poverty, substance use, and HIV, this “clean” bottle versus “marked” bottle dispensing system creates a market where individuals try to meet their medication needs and subsistence needs by selling their “clean” ARV medications and repurchasing the ARVs in opened and “marked” bottles; a process that often compromises adherence.

This study found that barriers to accessing HIV care and low quality of care were two key motivations for buying illicit ARVs. At the time of our study, Florida’s ADAP fell \$14 million short of their budget and severely restricted eligibility criteria, which led to a wait list that peaked in 2011 of 4,068 people in need of ARVs (31). Our study puts a face to the ensuing shortage in access and exemplifies structural barriers to HIV care that are often overlooked. Patients using public insurance are vulnerable to gaps in insurance coverage. One nationally representative study found that people with no or sporadic insurance coverage were less able to achieve viral suppression (32). Another study found that receiving the Medicare Part D prescription drug benefit was associated with a seven times greater odds of interruptions in ARV treatment in hard-to-reach populations, which was likely due to an increase in out-of-pocket costs and documentation delays (33). The cost of HIV care and the range of services needed to keep people engaged in care and on treatment may prove prohibitive to many people living with HIV (34). Continuity of care is critical for people living with HIV because even short lapses in care may have significant negative repercussions for viral suppression, drug resistance, and HIV transmissibility (35). It is noteworthy that, although the state of Florida was able to clear the ADAP waiting list as of 2013 (36), 949 people remained waitlisted in 2012 – two years after the list began (37).

In the present study, participants purchased ARVs from illicit markets to secure treatment after a gap in formal care caused by missed appointments or a poor patient-provider relationship. Although research consistently supports the links between quality of the patient-provider relationship and improved engagement in HIV care, patient satisfaction in HIV care, and improved adherence to ARV regimens (38–41), retention efforts often fall short for patients with high levels of competing needs. Most importantly is the ability of HIV care providers to empathize with the patients’ lives (41), allowing patients to disclose the reality of lost pills, imperfect adherence, side-effects, and substance use. Future research should emphasize structural health care system interventions to improve patient-provider relationships and promote the complete engagement and retention of high-needs populations in HIV care (42).

Our study also documents an HIV treatment disparity for substance users (43). Participants were reluctant to divulge substance use or relapses to their healthcare providers for fear of

being taken off their ARV regimen. Likewise, several participants purchased illicit ARVs because they were not prescribed treatment by their healthcare provider. Although clinical guidelines are explicit that providers should not withhold ARV therapy from substance users (44), research finds that provider judgment of likely adherence (43) and negative attitudes toward substance users are important factors in whether or not ARVs are prescribed (45). A recent study finds that 98% of providers would initiate ART to patients with a low CD4+ cell count (e.g. 200 cells/mm³) but only 48% would initiate ART to injection drug users in the same condition (46). Although there is a clear link between substance use and poor treatment outcomes (e.g. low adherence, treatment failure, and ARV resistance) (47–50), this association may be due to broader structural deficits in the healthcare system that result in late diagnosis, delayed ART initiation (51–53), and poor retention in HIV care (54, 55). A recent study in Miami found that most substance using women living with HIV were capable of attaining adherence rates of 90% or more and undetectable viral loads (56). To receive adequate HIV care, this high-needs population requires providers with expertise in HIV medicine (57–60), a substance use stigma-free setting, good patient-provider relations, and care that is integrated with other services (61). Fragmented care increases the risk for limited retention in care, poor adherence, treatment cessation, and adverse clinical outcomes (62). In the current care environment where funding streams are shifting away from traditional HIV clinics, the challenges faced by health care providers in delivering sensitive, tailored HIV services to high-needs patients are likely to grow.

ARV adherence patterns in our sample ranged from complete adherence to behaviors such as skipping pills due to drug use, and stretching pills across days or weeks by limiting doses; a range that reflects both competing needs and low HIV literacy. Periodic adherence has serious risk for treatment failure, ARV resistance, and HIV transmission (12). Furthermore, medical guidance is necessary to dictate the dosage, regimen, and monitor for resistance. Participants who indicated “self-prescribing” ARVs from illicit markets are placing themselves, and others, at risk for treatment failure and ARV resistance. The extensive practice of ARV diversion revealed in this study indicates a level of ARV non-adherence that may exacerbate South Florida’s already alarming HIV epidemic.

Our study findings should be interpreted in light of some limitations. One limitation is that interviews relied on retrospective reports of illicit ARV purchase history, HIV disease progression, substance use, and access and quality of HIV care. Recall deficits could have biased participants’ ability to provide an objective account of their experience and some may have provided accounts they perceived to be socially desirable. Further, generalizability may be limited in terms of geographical area and study sample. South Florida is both a high HIV prevalence and high drug use area, with an active ARV diversion market that may not be present in other locations (11). In addition, our data were collected from indigent, substance-involved people living with HIV who experienced high levels of financial need, which often motivated their involvement in ARV illicit markets. Other types of illicit ARV buyers, with different motivations, likely exist but were not represented in our sample.

Despite these limitations, our study on the demand for ARVs from illicit markets has important implications for the HIV disease management of vulnerable populations. First, our findings emphasize the need to enact structural-level changes to reduce ARV diversion. We

recommend uniform standards of dispensing ARVs across payers and systems; this would in effect eliminate the “clean” versus “marked” bottle disparity, curtail the demand for high-value, unmarked ARVs among pill brokers, and thereby reduce diversion pressure on vulnerable patients. Second, our findings suggest policy that ensures continuous access to health and prescription coverage from public programs and that establishes provisions for the emergency access to short-term supplies of ARVs; changes that could dramatically improve ARV adherence in high-needs populations. Lastly, our findings highlight critical future steps for research. As the Affordable Care Act rolls out, and states opt to expand Medicaid (or not), future research can help us better understand how policy decisions affect the health care of people living with HIV (63). Although most participants expressed the desire to adhere to ARVs, reduce their substance use, and remain engaged in HIV care, these goals were often too difficult to attain when juxtaposed with unstable socio-economic contexts and inadequate HIV care. Future research should also test structural interventions aimed to enhance the patient-provider relationship, provide systems navigation assistance (e.g. for increased access to promptly reschedule missed appointments or to obtain urgent care), and provide stigma-free integrated care (e.g. substance use treatment, mental health services, and other wrap-around services). It is clear from this study that we will not eliminate disparities in the HIV cascade without focus on structural changes to policy and HIV care frameworks to ensure quality, long-term care for vulnerable populations.

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Table I

Characteristics of Participants who Purchased ARVs from Illicit Markets within Six Months of Interview (N=44)

Characteristic	N	%
Age (range, average)	(26–62, 45.8 years)	
18–25	7	16%
26–40	21	48%
40+	16	36%
Male	26	59%
Race/Ethnicity		
Black/African-American	19	43%
Hispanic	17	39%
Non-Hispanic White	8	18%
Education		
No High School	4	10%
Less than High School	12	29%
High School	11	26%
More than High School	6	14%
Missing	9	21%
Insurance cover ARVs		
Ryan White	22	50%
Other Public Insurance (e.g. Medicaid, etc.)	15	34%
No Insurance	3	7%
Other (Local homeless charity)	2	5%
Combination (Public & Private)	2	5%
Interview in English	33	75%
History of Homelessness	13	30%
Length of time HIV+ (range, average)	(1–27, 13.1 years)	
1–3 years	3	7%
4–10 years	10	23%
10+ years	31	70%
History of substances used ^a		
Alcohol	16	36%
Crack Cocaine	15	34%
Powder Cocaine	12	27%
Marijuana	10	23%
Heroin	4	9%

^aNote: Percentages do not add to 100% because 39% (n=17) used multiple substances

ARV: Anti-retroviral medication

Table II

Primary Motivations for Buying ARVs from Illicit Markets (N=44)

Motivations for Buying Illicit ARVs	N	%	Example Quotations
Sell for Drugs	27	61%	<p>“a lot of them are drug users...and they wanna sell their bottles to get high”</p> <p>“I smoked (crack) over the weekend and I had sold my meds, and then I felt stupid”</p> <p>“after you come down off of the drugs...go to feeling guilty...and trying to buy it back”</p> <p>“I sold my medication because...I started using drugs...but I...had somebody...sell me his medication”</p>
Sell for Money for Bills/ Personal Needs	25	57%	<p>“There is a profit, but there's also a danger”</p> <p>“I would end up selling it...and I would have to buy it...back...I'd make a profit”</p> <p>“I was in need of...money...to eat...to survive...to buy personal hygiene...they...gave me \$140 (for Atripla) and...(Kaletra)...for \$200...you're able to purchase them...but...a less(er) price.”</p> <p>“sold my medicine because I needed the money for a bill or for something for my child”</p> <p>“I needed some funds...I was able to sell my meds and, later on...buy medication that he couldn't get rid of”</p> <p>“I had sold my medication one month and I was out...So I had a friend...taking the same medication...I purchased some from her”</p> <p>“I also call my pharmacist to tell him that I lost my medication and send some more.”</p>
Access to and Quality of Care	18	41%	<p>“I had missed a doctor's appointment, and I couldn't get back in until, like, two weeks later...so I had a friend that had some Atripla, and he let me buy some of his”</p> <p>“(My doctor) doesn't know that I buy them...I don't want to have problems[My doctor] says that he can't, that he doesn't want to give them to me”</p> <p>“I started to buy pills. Supposedly my numbers are good...I bought Isentress, Lexiva y Reyataz”</p> <p>“I'm not going to see no doctor at all... I just been buying it off the street... I just don't like the way the doctor talks to me... I just go when it's an emergency”</p> <p>“I had ran out (of ARVs) and dude was giving away cheap, and I didn't wanna go down there, go see the case worker and wait in them long waits.”</p> <p>“The whole thing with ADAP...I missed the appointment...now I'm...trying to get on that waiting list.”</p> <p>“ADAP...threw me off the program, because I didn't pick up the medication...I had to go out and buy”</p> <p>“I (had) just been complaining about the whole (ADAP) list and one of my friends...hadn't been taking his meds...So I just offered him some money”</p>
Lost/Stolen/Ruined	5	11%	<p>“I lost my medicine that the doctor prescribed me. I was on the bus and I left the whole package there. So...I bought half...to cover me for half of the time.”</p> <p>“My medications were ruined and rained on...the heat, just left out in the elements”</p> <p>“Me and that person got into a fight, so they threw all my stuff away, so they threw my medications away. So I ended up having to buy some from a friend”</p>
Back-up	3	7%	<p>“I also call my pharmacist to tell him that I lost my medication and send some more.”</p> <p>“I...have an extra stock... for back up...in case we get a storm, in case I can't get to the pharmacy.”</p>

Note: Participants often cited multiple reasons for purchasing ARVs from illicit markets.