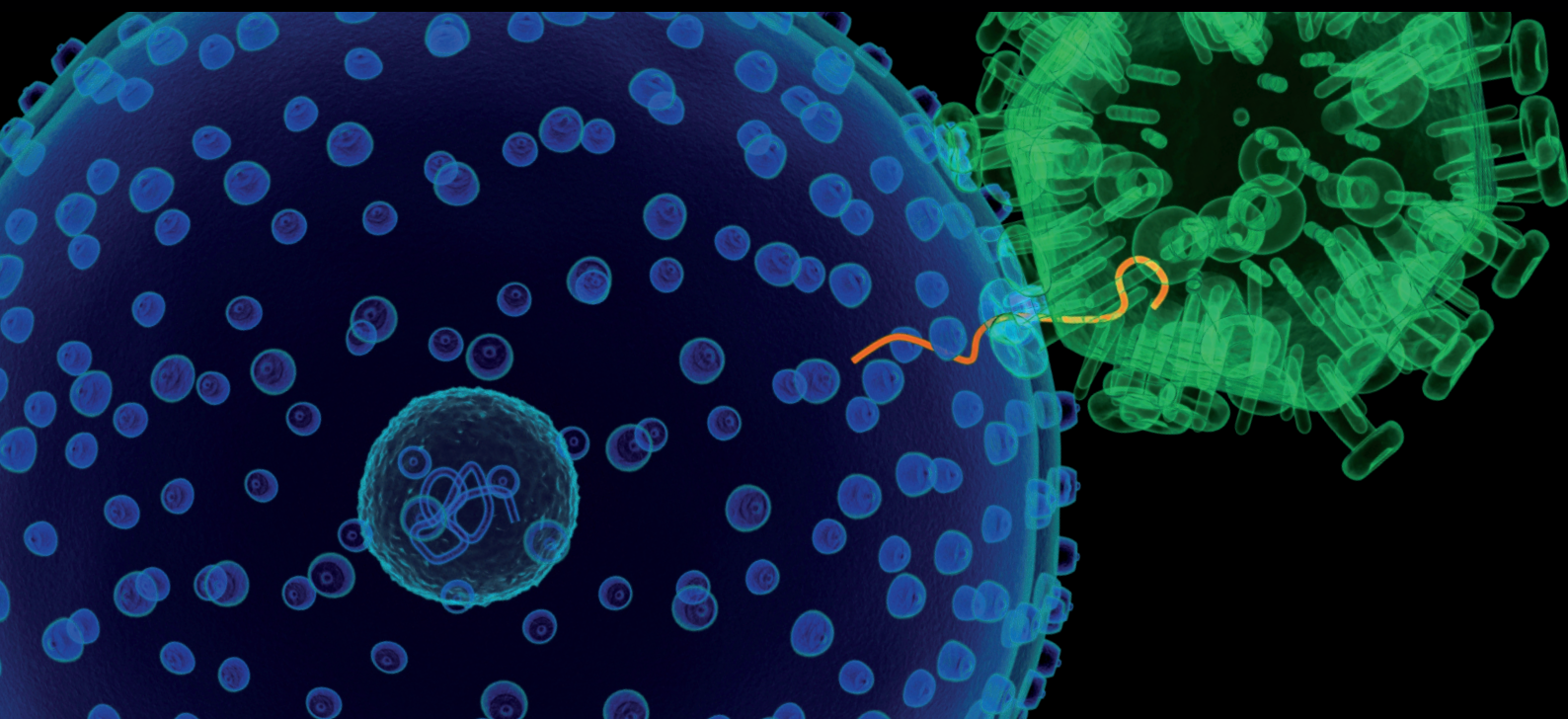


Using Mobile Health Technology to Improve HIV Care for Persons Living with HIV and Substance Abuse

GUEST EDITORS: GREGORY D. KIRK, SETH S. HIMMELHOCH, RYAN P. WESTERGAARD,
AND CURT G. BECKWITH





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Guest Editors: Gregory D. Kirk, Seth S. Himmelhoch,
Ryan P. Westergaard, and Curt G. Beckwith



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Editorial

Using Mobile Health Technology to Improve HIV Care for Persons Living with HIV and Substance Abuse

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Mobile phone technology has a growing and pervasive influence on society, with >6 billion mobile phone subscribers worldwide. Round-the-clock connectedness increasingly represents the norm and smartphones are ubiquitous in many sectors of society. As costs for these technologies decrease, expansion into populations with more limited resources is increasing. With many persons now routinely carrying a portable computing and communication device, adaptation of these mobile technologies for monitoring or improving health has been touted as a revolution in health care [1, 2]. Mobile health, or mHealth, has been broadly defined as medical or public health practice supported by mobile devices. The purpose of this special issue is to provide a research and implementation update on the incorporation of mHealth approaches to improve health outcomes among persons living with HIV/AIDS (PLWHA) and substance use.

PLWHA who are drug and alcohol users face many health challenges including delayed HIV diagnosis, delayed linkage to care, difficulty with adherence to antiretroviral treatment (ART), poorer virologic control, and difficulties with long-term retention in care, compared to nonsubstance users [3, 4]. Substance use may often be associated with other barriers to optimal care (e.g., mental illness, financial and legal difficulties, and inadequate housing and transportation) [5]. Several strategies to improve HIV care among persons with substance abuse have been identified (e.g., multidisciplinary case management, peer navigation) but often require substantial resources. Novel, affordable, and evidence-based strategies that are feasible to implement are needed to identify substance-using persons at risk for poor outcomes, promote

engagement in HIV care, enhance adherence, and improve treatment responses.

As with most chronic diseases that rely on adherence to prescribed medical regimens or lifestyle modifications, the underpinnings of optimal HIV care include enhanced capacity for self-management by patients. mHealth strategies hold great promise to transform the approach to HIV care. Real-time monitoring of PLWHA with mHealth devices can generate dynamic, individualized models of behavior and provide a foundation to inform health behavior change strategies. Technology can empower patients, with direct delivery of individualized motivation, education, and support. mHealth strategies will likely be significantly represented in evolving models of care delivery. Wireless technologies remove the barriers of time and distance between patients and providers; this is especially important for substance-using PLWHA and other populations that are hard to reach and difficult to keep engaged in care. Hopefully, mHealth approaches will facilitate HIV care providers to work more effectively and be able to collect higher quality data related to care delivery and health outcomes.

While mHealth holds great promise, this nascent field remains in early stages of development [6]. Current mHealth interventions to support HIV care have been largely centered in resource-limited countries. Strategies most widely employed have focused on supporting care providers in remote settings and providing text message support to HIV patients. A growing evidence base indicates that weekly text messages can improve ART adherence and viral suppression [7]. Text messaging appears to work best when the message

is individually tailored, context-sensitive, and associated with follow-up intervention. In response to these accumulating data, UNAIDS has recommended that mHealth approaches be incorporated into national HIV care programs. As the next step, smartphone interventions will expand the ability to collect intensive, real-time data from patients, provide tailored education or counseling, and facilitate responsive, interactive communication.

To date, mHealth studies which focus on HIV-infected populations with substance abuse have been limited. In this special issue, eight manuscripts provide an assessment of the scope of mHealth strategies employed among marginalized, substance-using PLWHA. Consistent with the current state of the field, the studies largely represent early stage evaluations of applying novel technology in diverse populations.

Conducting research studies among vulnerable populations such as persons with HIV or substance abuse raises several ethical issues. Further, mHealth approaches that collect data from and/or deliver interventions to participants during their daily routine also pose unique ethical considerations. Dr. A. B. Labrique and colleagues apply a widely accepted ethical framework to describe a range of ethical issues salient to protection of participants in mHealth research on HIV/AIDS and substance abuse.

Several manuscripts in this special issue report on the acceptability, feasibility, and implementation of mHealth approaches. Dr. C. W. T. Miller and Dr. S. Himelhoch report high levels of ownership and interest in using mobile phones among patients at an urban HIV clinic to help support and improve adherence to ART. Dr. K. J. Horvath and colleagues report that while methamphetamine-using men who have sex with men (MSM) had poorer engagement in HIV care, their use of social media and mobile phone technologies was comparable to nonstimulant using MSM, thus raising the possibility of using mHealth in this population.

A major focus of mHealth interventions among substance-using PLWHA is to facilitate ART adherence. Among methamphetamine users studied by Dr. D. J. Moore and colleagues, daily texts were sent to assess drug use and ART adherence. In the preliminary analysis, the proportion of texts responded to and both qualitative and quantitative assessments of acceptability indicate favorable responses by participants. Among HIV-infected IDUs receiving ART in China, Dr. M. B. DeSilva and colleagues evaluated real-time, wireless adherence monitoring using the Wisepill system. Overall, their findings were promising with only minor technical issues and participant feedback highlighting the need for unobtrusive technologies.

Novel intervention strategies which can capture and respond to illicit drug use in realtime can provide a framework for improving engagement and adherence to HIV care. Dr. K. A. Phillips and colleagues report preliminary data from a study of video-based, risk reduction messaging delivered through a smartphone to opioid-dependent patients in drug treatment. Nested within a larger mHealth study in this population, the authors demonstrated the feasibility and acceptability of delivering educational video content as well as capturing feedback in drug users' natural environments. Dr. G. D. Kirk and colleagues report on implementation of

ecological momentary analysis (EMA) methods using mobile devices among persons with a history of injecting drugs. During an intensive one-month study period, participants reported drug craving and use in realtime and displayed high levels of response to multiple daily EMA questionnaires regarding their mood, activity, and social and physical environment. Finally, Dr. A. Kurth and colleagues describe an mHealth intervention focused on PLWHA involved in the criminal justice system. In an ongoing randomized controlled trial, computer-delivered counseling is combined with text messaging to improve linkage, retention, and ART adherence during the critical transition following release from correctional settings.

The populations under study in this special issue are highly diverse. Several studies focus on marginalized IDU populations from urban settings in the US. Two studies evaluate mHealth approaches among MSM who abuse methamphetamine. Another study examines technology-enhanced ART adherence support among IDUs in China. Implementation into these disparate populations emphasizes the broad reach of mHealth to cross socioeconomic, racial, or geographic boundaries. Further, successful demonstration of mHealth strategies in these diverse groups bodes well for implementation into other HIV and substance-using populations.

To summarize the findings reported in this special issue, despite the field being in early stages of development, mHealth holds substantial promise for optimizing HIV care and improving adherence to treatment. These strategies appear feasible and acceptable even among challenging, marginalized populations confronted by HIV and substance use. The next steps in development of mHealth intervention strategies will be challenging [8]. Substantial work is needed to develop the theoretical frameworks underpinning mHealth interventions. Further efforts will be required to refine real-time data collection and analysis procedures, identify the best methods for delivering context-sensitive interventions, maintain patient confidentiality, and determine the most appropriate methods for defining effectiveness in mHealth. Challenges exist regarding data security, staying current with rapidly evolving technologies, and best practices for interaction with market-driven industry partners. Despite these challenges, we remain strongly enthusiastic that increasingly available and affordable mHealth tools will continue to evolve and provide successful strategies to improve HIV care outcomes among PLWHA and substance abuse.

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Research Article

The Exposure Assessment in Current Time Study: Implementation, Feasibility, and Acceptability of Real-Time Data Collection in a Community Cohort of Illicit Drug Users

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Objective. We describe the study design and evaluate the implementation, feasibility, and acceptability of an ecological momentary assessment (EMA) study of illicit drug users. **Design.** Four sequential field trials targeting observation of 30 individuals followed for a four week period. **Participants.** Participants were recruited from an ongoing community-cohort of current or former injection drug users. Of 113 individuals enrolled, 109 completed study procedures during four trials conducted from November 2008 to May 2013. **Methods.** Hand-held electronic diaries used in the initial trials were transitioned to a smartphone platform for the final trial with identical data collection. Random-prompts delivered five times daily assessed participant location, activity, mood, and social context. Event-contingent data collection involved participant self-reports of illicit drug use and craving. **Main Outcome Measures.** Feasibility measures included participant retention, days of followup, random-prompt response rates, and device loss rate. Acceptability was evaluated from an end-of-trial questionnaire. Sociodemographic, behavioral, clinical, and trial characteristics were evaluated as correlates of weekly random-prompt response rates $\geq 80\%$ using logistic regression with generalized estimating equations. **Results.** Study participants were a median of 48.5 years old, 90% African American, 52% male, and 59% HIV-infected with limited income and educational attainment. During a median followup of 28 days, 78% of 11,181 random-prompts delivered were answered (mean of 2.8 responses daily), while 2,798 participant-initiated events were reported (30% drug use events; 70% craving events). Self-reported acceptability to study procedures was uniformly favorable. Device loss was rare (only 1 lost device every 190 person-days of observation). Higher educational attainment was consistently associated with a higher response rate to random-prompts, while an association of HIV infection with lower response rates was not observed after accounting for differences in trial recruitment procedures. **Conclusion.** Near real-time EMA data collection in the field is feasible and acceptable among community-dwelling illicit drug users. These data provide the basis for future studies of EMA-informed interventions to prevent drug relapse and improve HIV treatment outcomes in this population.

1. Introduction

Optimal HIV care requires prompt identification of HIV infection, linkage to HIV care, prolonged engagement in HIV care with regular attendance at appointments, and high levels of adherence to antiretroviral regimens in order to achieve viral suppression [1]. Illicit drug use can have negative

impacts at each stage of this HIV care continuum [2, 3]. Despite substantial research, identification of the proximate predictors of relapse to illicit drug use, nonadherence to HIV medications, or disengagement with primary HIV care among drug users remains elusive. Through data collection in near real time among persons going about their daily lives, ecological momentary assessment (EMA) methods attempt

to sample persons' real-life experiences and may capture the contextual factors which precede events such as drug use or nonadherence [4, 5].

The promise of mobile health (mHealth) technologies for strengthening HIV care delivery has been acknowledged by the United Nations Joint Programme on HIV/AIDS (UNAIDS) strategic plan [6]. Text messages have been effectively utilized to improve attendance at clinic appointments, promote adherence to antiretroviral therapy (ART), and increase rates of viral suppression [7–14]. However, most of the smartphone applications developed for use in HIV care settings, have not been widely used or reviewed favorably [15]. Further, few studies have been directed at substance-using HIV-infected populations in resource-intensive countries or have utilized EMA approaches. In non-HIV-infected populations in the USA, EMA studies centered in drug treatment settings have demonstrated a strong correlation between tobacco, cocaine, and heroin craving, and related urine-verified periods of cocaine abstinence to negative moods, stress levels, and to daily patterns of recreation and work activity [5, 16–18].

In response to the limited application of EMA approaches to out-of-treatment, high-risk populations, we sought to develop EMA methods for near real-time characterization of illicit drug use occurring in users' natural environments. In this paper, we describe the study design and participants of the EXposure Assessment in Current Time (EXACT) study. Further, we characterize implementation barriers and examine the feasibility and acceptability of using intensive EMA data collection methods among community-dwelling illicit drug users with or at-risk for HIV infection.

2. Methods

2.1. Study Participants. EXposure Assessment in Current Time (EXACT) study participants were recruited from the AIDS Linked to the IntraVenous Experience (ALIVE) study, an ongoing, community-recruited, observational cohort of persons with a history of injecting drugs in Baltimore, MD [19]. The ALIVE cohort is community-based rather than clinic-based, thereby reducing selection bias toward persons seeking or accessing care for drug use or for HIV infection. From November 2008 through May 2013, four successive field trials were conducted. Each trial followed approximately 30 participants for four weeks. ALIVE cohort participants attend regularly scheduled appointments for semiannual study visits, thus, allowing a carefully regulated environment in which to invite participation in this substudy. Eligibility criteria for EXACT included current enrollment in ALIVE, residence in Baltimore City, and the ability to understand and follow directions on a personal digital assistant (PDA) or mobile phone. Individuals were excluded if they had any medical condition that would prevent them from operating the hand held device (e.g., visual or hearing impairment) or if they failed to attend the screening appointment where they were trained how to use the device. Figure 1 shows a flow diagram of recruitment and retention in the study. Of persons that were referred, attended a screening visit, and found to

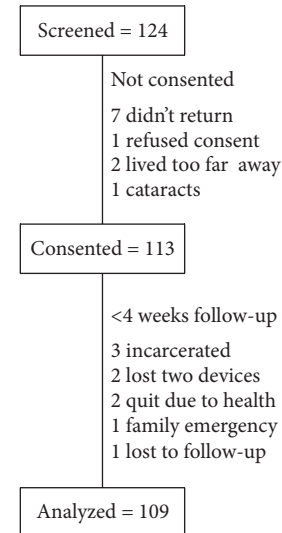


FIGURE 1: EXACT Participants flow diagram.

meet eligibility criteria, and enrolled, 93% of participants completed the four weekly study visits. In successive trials, the specific inclusion criteria regarding drug use and HIV status were varied slightly. In Trial 1, selection was made to balance the numbers of participants that reported recent heroin or cocaine use with those that were not currently using drugs. In Trial 2, all participants reported heroin or cocaine use within the prior three months. While HIV status was not a recruitment criterion in the first two trials, Trials 3 and 4 included only HIV-infected participants who reported recent heroin or cocaine use, with preference for those using on average at least three times weekly in the past month.

The Johns Hopkins School of Public Health approved the study protocol. An existing Certificate of Confidentiality through the National Institute on Drug Abuse was amended to include EXACT study procedures. All participants provided written informed consent. Participants in the EXACT study were informed that involvement (or noninvolvement) in EXACT would in no way affect their participation in ALIVE.

Funding for the study was provided through the National Institute on Drug Abuse as part of the Network on Exposure to Psychosocial Stress and Addictive Substances, a component of the NIH's Genes, Environment and Health Initiative [20].

2.2. Study Procedures. Current EMA methodology generally employs electronic diaries or mobile devices to collect data on both a random and an event-contingent schedule. For random-prompt data collection, EXACT participants responded to an alarm that sounded at a set number of randomly spaced times throughout the day by answering a questionnaire on the device. For event-contingent data collection, participants self-initiated a questionnaire in close temporal proximity to an event of interest (e.g., drug use or craving); participants were required to confirm that the event occurred within the last 30 minutes.

Measure	Week 1					Week 2					Week 3					Week 4				
EMA																				
GPS																				
ACASI																				
Sweat patch																				
Blood																				

EMA: ecological momentary assessment data

GPS: global positioning system data, Trials 2–4 only

ACASI: audio computer-assisted self-interview. Two ACASI assessments were done at the end of week 4, summarizing the past week and past month

Sweat patch: sweat patches were changed weekly

Blood: Trials 1–3 collected blood sample after week 4 only. Trial 4 collected blood weekly

FIGURE 2: EXACT data collection procedures.

EXACT participants were provided a hand-held electronic device to carry for four weeks for real-time data collection. For Trials 1–3, participants were provided PDAs (Palm Z22, Palm, Inc., Sunnyvale, CA, USA) running applications developed using Satellite Forms software (<http://www.satelliteforms.net/>). To reduce the street value of handheld devices, all PDA programs were disabled except for study-required applications. In Trial 4, participants were provided an Android smartphone (Motorola Droid X2), running the electronic Mobile Open-source Comprehensive Health Application (eMOCHA), developed at Johns Hopkins School of Medicine [21]. Previously, eMOCHA had been used to support community health workers in resource-limited settings that were heavily impacted by HIV [22] and was modified specifically for this study. Other functions of the smartphones were not disabled, although superfluous applications such as games were uninstalled whenever possible. In order to collect real-time geolocation data, participants in Trials 2 and 3 carried a global positioning system (GPS) unit (QSTARZ BT-Q1000X, Taipei, Taiwan) which recorded their latitude and longitude every five minutes or if they moved more than five yards. In Trial 4, GPS data collection was obtained from the geolocation tracking system of the smartphone.

Aside from the device provided, the study procedures and data collection in the trials were essentially identical (Figure 2). Random-prompts were delivered four times daily between 9:00 am and 9:00 pm, with a fifth prompt, set for 9:01 pm each day (end-of-day questionnaire). Alarms would repeat every three minutes up to a maximum of five times. Participants were required to complete the questionnaire within 15 minutes or the prompt was considered missed. Twice each week, in Trials 1–3 using the PDA, participants returned to the clinic for device maintenance and to upload their data to a secure server. All participant data was then erased from both the PDA and GPS units. In Trial 4, EMA and GPS data were continuously transmitted in encrypted fashion to the eMOCHA secure server for storage.

EMA studies provide the ability to collect data in participant's natural settings. EMA questions were developed to assess the social, psychosocial, physical, and activity context of the participants' current environment. Survey instruments

were adapted from prior EMA studies conducted by collaborators working with drug using populations [5, 16, 23]. Participants were asked to self-report each time they either craved (but refrained from using) or used heroin or cocaine; these self-initiated responses constitute the event-contingent data collection.

In all trials, at the end of each week, participants answered an audio-computer assisted standardized interview (ACASI)-based version of the end-of-day questionnaire modified to reflect activities, behavior and events during the prior week. Similarly, at the conclusion of each trial, participants completed an ACASI-based questionnaire designed to reflect the entire four week study period. Hair and/or sweat patch samples were collected weekly for measurement of illicit substances, and blood samples were collected at the end of the trial period to be tested for potential biomarkers of psychosocial stress. Participants received remuneration for attendance at study visits, for providing adequate responses to weekly random-prompts, and for returning devices upon study completion. Participants were informed at entry that loss of two study devices would result in dismissal from the study.

2.3. Data Analysis. Baseline sociodemographic (e.g., age, sex, race, education, marital status, employment, income, homelessness, and health insurance status), behavioral (e.g., self-reported alcohol, tobacco, and illicit drug use), and clinical (e.g., HIV/antiretroviral therapy status, CD4 T-cell count, and HIV RNA levels) characteristics were obtained from the existing ALIVE database. Depressive symptoms were assessed using the Center for Epidemiologic Studies Depression Scale (CES-D) for the 6 months prior to EXACT study entry.

Characteristics of participants, days of followup, random-prompt response rates (overall and by week), and device loss rate were examined by trial number. Using a response rate of $\geq 80\%$ to weekly random-prompts as a dichotomous outcome variable, logistic regression models with generalized estimating equations (GEE) were evaluated to identify the sociodemographic, behavioral, clinical, and trial-related correlates of higher response rates. Analyses were performed using Stata statistical software (version 11).

TABLE 1: Characteristics of EXACT participants by trial.

Characteristic	All trials (N = 109)	Trial 1 (N = 31)	Trial 2 (N = 28)	Trial 3 (N = 28)	Trial 4 (N = 22)
Sociodemographic variables					
Median age, yrs (IQR)	48.5 (43.3–52.9)	48.5 (41.8–52.3)	47.4 (40.8–50.4)	47.9 (43.5–53)	51.6 (45.6–55.7)
African American (%)	90	90	79	100	91
Male (%)	52	42	43	64	64
High school education (%)	41	39	50	33	41
Ever married (%)	39	42	32	41	41
Income, yearly <\$5000* (%)	78	83	89	71	64
Had insurance* (%)	85	71	79	96	100
Homeless* (%)	8	6	14	4	9
Substance use variables*					
Cigarette use (%)	83	77	75	93	91
Alcohol use (%)	65	61	61	68	73
Marijuana use (%)	25	39	21	14	23
Heroin or cocaine use (%)	61	55	46	89	55
Cocaine use (%)	46	42	36	64	41
Heroin use (%)	46	52	36	57	36
Speedball (%)	24	21	15	38	23
Clinical variables					
Depressive symptoms (CESD > 23) (%)	24	29	25	21	18
Methadone treatment* (%)	24	16	21	21	41
Hepatitis C virus seropositive (%)	86	84	79	89	95
HIV positive (%) [†]	59	16	32	100	100
Median CD4 (IQR) [†]	360.5 (239–529)	451 (380–529)	328 (242–404)	327.5 (244–437)	414.5 (166–612)
HIV viral load > 500 copies/mL (%) [†]	55	60	78	61	36

* Represents self-reported exposure during the prior 6 months.

[†] HIV+ status was an inclusion criteria for Trials 3 and 4; CD4 and viral load tested on HIV-positive participants only.

3. Results

We analyzed data from 109 participants who had at least one week of follow-up. Nine participants were followed less than the full four weeks possible (Figure 1). For 109 EXACT participants with evaluable data, the median age was 48.5 years, 90% were African American, and 52% were male (Table 1). A majority of participants had not completed high school, had never been married, and had an annual formal income of <\$5000. At study entry, a majority of participants reported recent substance use, including the consumption of cigarettes (83%), alcohol (65%), and heroin or cocaine (61%). Among the 59% of participants that were HIV infected, the median CD4 cell count was 361 cells and 55% had an HIV RNA level >500 copies/mL.

Overall, the 109 participants provided 3,047 days of observation (median of 28 days per person; IQR 26–29) with little variability between trials (Table 2). A total of 11,181 random-prompts were delivered, which represented 78% of planned prompts. In particular, delivery of random-prompts was lower in Trial 3 (60%) due to technical problems. Delivery was not completed and data were lost if the Palm devices reset accidentally (a common occurrence) or if the battery

ran out. In Trial 4 using the eMOCHA smartphone platform, random-prompt delivery was notably more efficient at 98%.

The overall proportion of random-prompts responded to was 78%, which translated to an average of 2.84 random-prompt responses per day. The response rate was relatively consistent in Trials 1 and 2 but was lower in trials which targeted more intense, recent drug users (Trials 3 and 4). Despite the lower response proportion in Trial 4, the more efficient delivery of prompts by smartphone translated into a greater average number of prompts answered daily (3.45 compared to the overall estimate of 2.84). Problems in the PDA studies including technical problems, battery outage, and device loss or damage resulted in the loss of several days' data collection. Further, the data collection software required that the data be manually uploaded using a USB cable from the PDA to the computer where the database was located. The eMOCHA software eliminated this requirement by transmitting the data wirelessly and securely to a server approximately every 15 minutes.

Recognizing concerns that exhaustion with responding to device prompts may occur, we examined the response rates and average daily number of prompts answered by week of trial (Figure 3). Overall, there was no meaningful difference

TABLE 2: Feasibility measures by trial*.

Measure	All trials (N = 109)	Trial 1 (N = 31)	Trial 2 (N = 28)	Trial 3 (N = 28)	Trial 4 (N = 22)
Total days followup	3047	919	817	757	554
Median days of followup (IQR)	28 (26–29)	29 (28–32)	29 (27–33)	28 (25–28)	27 (26–28)
Daily EMA responses					
Random-prompts delivered (N)	11181	3462	2317	2654	2748
Random-prompts delivered (%)	78%	80%	60%	73%	98%
Random-prompts answered (N)	8655	2816	1940	1985	1914
Random-prompts answered (%)	77%	81%	84%	75%	70%
≥80% response	46%	58%	61%	32%	27%
≥60% response	86%	94%	93%	79%	78%
Random-prompts answered (daily mean)	2.84	3.06	2.37	2.62	3.45
Drug using and craving events					
Participant-initiated events (N)	2798	656	836	425	881
Median events initiated (IQR)	11 (3–24)	20 (6–26)	12.5 (1–36)	9 (4–20)	6.5 (1–15)
Craving events initiated (IQR)	8 (5–14)	9 (3–17)	5.5 (0–23)	4 (1–10)	4 (1–11)
Using events initiated (IQR)	3 (0–9)	4 (0–12)	1 (0–11)	4 (1–8)	0 (0–3)
Device retention					
Device loss (1 per × days)	190.4	306.3	204.3	108.1	277.0
PDA/smartphones issued	140	38	33	43	26
PDA/smartphones lost	15	3	4	6	2
GPS issued	61	0	30	31	0
GPS lost	1	0	0	1	0
Participant incentives					
Total \$ paid	\$46,579.00	\$12,186.00	\$11,986.00	\$12,737.00	\$9,670.00
Cost/participant	\$427.33	\$393.10	\$428.07	\$454.89	\$439.55
Cost/person-day	\$15.29	\$13.26	\$14.67	\$16.83	\$17.45

* During one-month followup.

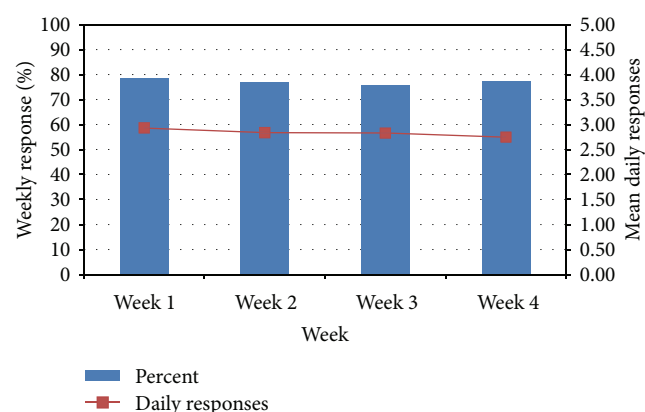


FIGURE 3: Responses to random-prompts by week of trial (% answered; daily mean number of responses).

in either the response proportion or average number of responses between weeks. Similar to the overall four-week response rate data, we did observe tapering of response rates in Trial 4 in later weeks, although the average number of prompts answered daily remained higher than other trials.

Regarding event-contingent data, there were 2,798 participant-initiated events reported, representing 70% drug craving and 30% drug use events (Table 2). Drug craving events appeared to be reported most commonly in Trial 1, while drug use events were reported more commonly in Trials 1 and 3.

Of 201 devices issued to participants, 15 were lost or damaged which translates to the loss of a device once every 190 days of observation. Only two participants (1.8%) were excluded from continuing in the study because they lost two devices. Monetary incentives were provided for active participation, which averaged about \$15 per day of observation.

In assessment of participant acceptability (Table 3), favorable responses were uniformly reported regarding ease of use of the devices (98% reported easy or very easy), the burden of reporting (93% reported just right or not enough), the understandability of the questions (89% reported most or all make sense), and confidence in privacy protections (91% reported mostly or extremely confident). Twenty-nine percent of respondents agreed that carrying the devices made them behave differently.

To understand what factors may contribute to higher levels of active participation in EMA studies, we examined correlates of responding to ≥80% of weekly random-prompts

TABLE 3: Participant acceptability.

Question	Trials 2–4 (N = 55)
<i>In general, how easy is it to use the PDA/phone?</i>	
Very easy	73%
Easy	25%
Difficult	2%
<i>What do you think about the number of times that your PDA/phone beeps every day?</i>	
Not enough	20%
Just right	73%
A little too much	7%
<i>Do the questions on the PDA/phone make sense to you?</i>	
All make sense	56%
Most make sense	33%
Some do not make sense	11%
<i>Does carrying the device(s) make you behave differently than if you didn't have it?</i>	
Yes	29%
No	71%
<i>Do you feel comfortable carrying the GPS unit?</i>	
Extremely comfortable	53%
Mostly comfortable	31%
Somewhat comfortable	15%
Not too comfortable	2%
<i>Do you feel confident that the information collected by the GPS unit will only be seen by researchers and not used against you?</i>	
Extremely confident	69%
Mostly confident	22%
Somewhat confident	9%
Not Too confident	0%
<i>Did you have any problems with the GPS unit?*</i>	
Yes	15%
No	85%
<i>How easy is it to carry both the GPS unit and PDA at the same time?*</i>	
Very easy	68%
Easy	24%
Difficult	9%

*GPS survey questions completed from Trials 2 and 3 only (N = 34).

(Table 4). Of 405 total weeks included in the analysis, 199 (49%) were weeks with $\geq 80\%$ response rate. Among sociodemographic variables, educational attainment was strongly and consistently associated with higher response rates; there was no association with age, gender, race, or homelessness. Neither recent history of heroin or cocaine use prior to study entry nor heroin or cocaine use reported by EMA during the same week was associated with decreased odds of a $\geq 80\%$ response rate.

Trials 3 and 4 were associated with lower responses (Table 4, Model B). Because of selection criteria for Trials 3 and 4 in which recruitment targeted only HIV-infected persons with attempts to enroll for more active drug users, the variables of HIV status and trial were related to each other resulting in collinearity in the models. Therefore, it is difficult to establish what factors explain the lower responses. When not accounting for trial characteristics (Table 4, Model C), we observed a dose-response association with increasing odds of lower responses in HIV-infected persons with undetectable HIV RNA levels and even poorer responses in those persons with detectable viral load in comparison to HIV-uninfected persons. However, after accounting for trial characteristics (Table 4, Model D), HIV infection was no longer associated with poorer responses.

4. Discussion

Illicit drug users are considered a challenging population to identify, recruit, and retain in epidemiological, behavioral, or clinical research. Consequently, many issues of primary concern to this population remain poorly understood, such as why some active drug users are able to maintain cessation and do well on HIV treatment while others have difficulty with drug relapse, ART nonadherence, and virological failure. By employing multiple methods to maximize retention, including strong rapport among clinic staff and participants, mailed appointment reminders, phone calls, tracing through contacts, street tracing, transportation vouchers, and minimal financial remuneration for participation, the ALIVE study has demonstrated the ability to successfully follow an IDU population over >25 years in a design incorporating study visits conducted every six months. Further, ALIVE represents a community-recruited cohort following IDUs outside of the provision of clinical care in research clinics situated in residential and commercial sections of East Baltimore rather than physically colocated in buildings of the Johns Hopkins Medical Institutions. Despite these successes, there clearly is potential for extremely valuable information on the proximate influences of drug users' behavior to be gained by refining the data collection window to minutes instead of months and of locating data collection to occur wherever persons may be, rather than relying on retrospective reporting in a formal clinic setting. The primary objective of the EXACT study was to develop EMA methods for real-time characterization of illicit drug use occurring in users' natural environments.

In this paper, we provide strong data supporting the feasibility and acceptability of using EMA methods for data collection among illicit drug using populations. Our recruitment and referral process from ALIVE was highly efficient. With inclusion of a dedicated screening visit, which served to ensure attendance at an additional study visit prior to enrollment and to gauge potential participants' comfort level with the technology, we had a 93% rate of study completion. During the process of implementing the study, we were frequently met with healthy skepticism from other researchers regarding the likelihood of success in meeting our objectives. Our study protocol included 5 daily random-prompts, which represents a higher participant burden than many EMA studies.

TABLE 4: Sociodemographic, behavioral, clinical, and trial characteristics associated with ≥80% weekly EMA response rates.

Variable	Model A			Model B			Model C			Model D		
	OR	95% CI	P value	OR	95% CI	P value	OR	95% CI	P value	OR	95% CI	P value
Sociodemographic variables												
Age, 50+	0.99	(0.55–1.79)	0.974	1.22	(0.66–2.25)	0.527	1.03	(0.56–1.89)	0.918	1.14	(0.61–2.10)	0.686
Male	1.4	(0.80–2.46)	0.239	1.21	(0.68–2.15)	0.516	1.34	(0.76–2.37)	0.305	1.24	(0.70–2.20)	0.463
African American	0.81	(0.32–2.07)	0.665	1.23	(0.45–3.38)	0.689	0.86	(0.33–2.22)	0.749	1.18	(0.42–3.29)	0.754
High school education	2.07	(1.15–3.67)	0.012	2.06	(1.15–3.66)	0.015	1.82	(1.03–3.25)	0.040	1.94	(1.08–3.47)	0.026
Used heroin or cocaine [†]	0.89	(0.65–1.42)	0.633	0.85	(0.51–1.40)	0.523	0.79	(0.49–1.29)	0.352	0.84	(0.51–1.40)	0.503
Used heroin or cocaine, past 6 months	1.18	(0.64–2.15)	0.599	1.72	(0.89–3.33)	0.106	1.19	(0.65–2.18)	0.576	1.73	(0.88–3.44)	0.114
Viral load												
HIV negative								Reference			Reference	
Viral load undetectable							0.50	(0.26–1.00)	0.046	1.61	(0.56–4.63)	0.378
Viral load detectable							0.31	(0.16–0.60)	0.000	0.89	(0.34–2.35)	0.821
Week												
1					Reference						Reference	
2				1.10	(0.67–1.81)	0.712				1.09	(0.66–1.82)	0.724
3				1.43	(0.80–2.54)	0.223				1.43	(0.80–2.56)	0.225
4				1.65	(0.90–3.03)	0.103				1.66	(0.90–3.06)	0.105
Trial												
1					Reference						Reference	
2				1.19	(0.55–2.53)	0.661				1.18	(0.56–2.52)	0.665
3				0.24	(0.11–0.53)	0.000				0.22	(0.07–0.69)	0.009
4				0.38	(0.17–0.85)	0.019				0.29	(0.09–0.92)	0.035

[†] Used heroin or cocaine that week, reported by EMA.Bold indicates statistically significant associations with *P* value < 0.05.

A recurring question from colleagues and IRB reviewers was whether illicit drug users would really answer all those questions. Overall, EXACT participants answered 78% of random-prompts, a response rate comparable to EMA studies performed using similar technologies in varied settings. Prior EMA studies in diverse populations including illicit drug users, chronic pain patients, and smoking cessation or obesity intervention participants achieved response rates to random-prompt surveys ranging from 70–80% [5, 24–26]. In questioning upon completion of the study, participants were very clear in reporting that study procedures were not overly burdensome. Although we did not conduct formal qualitative evaluations, our informal debriefs were consistent with our quantitative assessment of participant acceptability indicating that participants held strongly positive sentiments regarding the study procedures and their participation.

We examined correlates of higher response rates and found that higher educational level was a strong and consistent predictor, while age, race, gender, and income level were not associated. Our study population had low overall educational attainment with only 41% completing high school or equivalency. It is unclear whether this association represents more ease or familiarity with the technology among more educated persons or whether education status is a surrogate marker for other factors which may facilitate high responses. In a recent survey conducted in ALIVE, we found that participants with greater education reported increased ownership of smartphones and an increased willingness to receive health-related communications through various technologies. Educational attainment is strongly associated with health literacy, defined as the ability to obtain, process, and understand the basic health information and services needed to make appropriate health decisions [27, 28]. These data highlight the need for mHealth interventions to be sensitive to the educational and health literacy levels of participants. Technologically-based platforms have significant potential to address the health needs of low health literacy individuals [29]. Formal evaluation of health and/or communication technology literacy may be appropriate with the provision of additional training and monitoring to persons with lower literacy and efforts focused on developing literacy-adapted interventions. Although underdeveloped to date, the concept of eHealth literacy merits further investigation, including the need for development of standardized and valid scales for its measurement [30].

We provided modest weekly incentives to participants for providing more complete responses to EMA questioning. Our lack of association of response rates with income and the finding that higher educational attainment (which would be expected to be associated with higher income) were associated with higher responses provides indirect evidence suggesting that the level of incentives was not coercive to vulnerable participants with limited income. Future studies will need to examine further the efficacy and ethics of providing incentives for improving EMA responses and to establish what type and level of incentives may be most appropriate. One EMA study has supplemented response-weighted incentives with weekly sessions between participants and research staff to review their individual response

rates and emphasize compliance to obtain even higher levels of response [31].

In addition to higher educational attainment, our analysis of response rates to the random-prompts indicated that the later trials that selectively recruited HIV-infected participants with more intense recent substance use had lower response rates. This raises concern that the targeted population of out-of-care HIV-infected persons with detectable viremia and active illicit drug use may be less likely to actively participate in similar studies or interventions. However, it should be noted that after accounting for the differential recruitment criteria between trials, the association with HIV infection was no longer observed. Further, the mean number of daily responses was actually higher among HIV-infected participants. Ultimately, larger and longer trials will likely be needed to refine how those populations at greatest risk will engage and respond to EMA studies.

Another challenge to using technological devices among drug user populations is concerned that participants might simply sell the devices. To mitigate this potential problem, we clearly delineated to participants during screening and enrollment procedures that the loss of two devices (whether reported as damaged, lost, or stolen) would result in their exclusion from the study. Further, we provided a small incentive for return of the devices upon completion of the study. Remarkably, only two persons (representing <2% of all participants) were excluded for lost devices. Overall, we averaged only one lost device per every 190 days of observation, which we feel represents an effective utilization of these technologies. We acknowledge that the street value for the PDAs is less than for the smartphones; however, in our limited data, there was not a substantial difference in the device loss rate between trials using the different devices. While the PDAs had nonstudy features locked out, we did not implement similar restrictions with the smartphones. Current technologies allow the remote inactivation of smartphones if they are stolen or misplaced which could represent an important deterrent, although this capability was not disclosed to participants nor employed in our study. Contemporary mHealth technologies are evolving at a rapid pace. In our study, the PDA model we used at study initiation was no longer being manufactured after 10 months of study recruitment and was largely obsolete by the date of study completion. Rapid transitions in technology, therefore, represent a significant barrier to successful implementation of mHealth programs, often limiting the interpretability and applicability of data from these studies. Our smartphone platform resulted in more efficient delivery, a higher average number of daily responses, and provided automatic data transfer which both enhanced security and minimized data loss. In moving forward with advancing technology, alternative approaches to trial design must be considered, including designs fitted to the stage of technology or intervention development and adaptive trials that allow for evolving technologies or intervention optimization [32].

In addition to the challenges described above, our study had other limitations. In these field trials designed to provide information on feasibility and acceptability, we followed a limited number of persons for approximately four weeks.

It has been well recognized that many intensive data collection interventions may plateau or reach exhaustion within weeks or months, diminishing the level of participation and success of these strategies. Importantly, in our examination of weekly response rates, we did not find evidence for exhaustion. In the future, the broader goal of EMA studies would be to provide longer-term monitoring or intervention through trials that extend beyond our limited time frame. Despite our study being nested within an IDU cohort, many participants were not actively using drugs. In these early studies, we selected for a range of drug use intensity and the resulting cohort overall would not be considered heavy users. Therefore, our findings may not extend to drug users with more intense drug use patterns.

Finally, EXACT participants were largely African American from a single urban center, raising concerns regarding the generalizability of our findings. However, our IDU population represents among the most disadvantaged and vulnerable drug using populations, and our demonstration of successful implementation of EMA methods in this population bodes well for efforts to apply these methods to less challenging populations. Further, the aging, African American IDU epidemic in Baltimore is similar to many other urban IDU epidemics in the USA, from Newark to St Louis to Detroit. It is these populations that are at greatest risk for limited access to appropriate drug treatment or HIV care that are most in need of innovative and tailored interventions to improve outcomes.

In conclusion, findings from the EXACT study demonstrate that EMA methods are feasible and acceptable approaches for data collection among illicit drug users. As the next important step, interventions that leverage the predictive value of intensive EMA data collection to allow real-time tailored interventions in drug users' natural environments (i.e., ecological momentary interventions [EMI]) will need to be developed and rigorously evaluated. The translation of intensive EMA data into tailored EMI holds promise for improving our understanding and our ability to reduce relapse, improve engagement in care, enhance ART adherence, and to intervene on other difficult issues surrounding drug use and HIV care.

Conflict of Interest

RCB and LWC are minor shareholders and advisors of eMOCHA Solutions.

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Review Article

Ethical Issues in mHealth Research Involving Persons Living with HIV/AIDS and Substance Abuse

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We aim to raise awareness and stimulate dialogue among investigators and research ethics committees regarding ethical issues that arise specifically in the design and conduct of mHealth research involving persons living with HIV/AIDS and substance abuse. Following a brief background discussion of mHealth research in general, we offer a case example to illustrate the characteristics of mHealth research involving people living with HIV/AIDS and substance abuse. With reference to a well-established systematic general ethical framework for biomedical research with human participants, we identify a range of ethical issues that have particular salience for the protection of participants in mHealth research on HIV/AIDS and substance abuse.

1. Introduction

In the past decade, mobile phone technology has become nearly ubiquitous in most developed country contexts, crossing socioeconomic boundaries and in some populations displacing traditional landline infrastructure. Similar trends have been noted globally, as current estimates suggest that nearly 6.1 billion mobile subscriptions exist in 2013 [1]. The pervasive growth of this technology has resulted in innovations across sectors of agriculture, education, and even health, focused around a new domain of research and implementation science termed “mHealth” or mobile health. Classical medical information systems and technologies have, for decades, been centered on the highly tethered, facility-based patient record, and other management systems. The advent of mHealth has led both researchers and patients to explore the potential for mobile technologies to improve health outcomes and lower costs by increasing patient engagement, improving provider quality, and optimizing efficiency in health care. mHealth opens new avenues for

research insight, as this ubiquitous technology allows much more frequent data collection about participants’ behavior, location, and physiology, sometimes in real time [2].

In the past 5 years, a growing body of mHealth research has emerged, exploring the role of these technologies in improving preventive and curative care. In HIV, a number of research projects have explored how mobile phones can be used to improve adherence to antiretroviral treatment in low-resource settings [3, 4] to provide decision support to frontline health workers [5, 6] and to introduce the benefits of continuous care in places where this was previously impossible. mHealth strategies have been used to improve patient care and self-efficacy by improving adherence to complex antiretroviral regimens, reducing missed appointments, and connecting individuals to care when and where they need it. Governments and program agencies have used mHealth approaches to mobilize awareness of HIV prevention and treatment, promote testing, and advocate for support for persons living with HIV/AIDS [7–9].

Still more sophisticated wearable mobile devices (e.g., accelerometers to measure physical activity and sensors to measure heart rate, blood pressure, or other biological processes) can harness the capacity of built-in geographic sensing and the ability to connect to other wireless devices. Such systems enable health programs and research studies to define profiles of behavior and risk exposure with more granularity than ever before in real time. Noninvasive sensors allow an individual's physiology to be monitored continuously, with little engagement by that individual, while text message or app-driven prompts can inquire about behaviors, mood, or even ideation frequently throughout the day. This emergent space, described as *ecologic momentary assessment* (EMA), offers exciting epidemiologic potential, while introducing new ethical concerns and caveats.

2. Case Example

In order to set the stage for our discussion of ethical issues, we present a case example illustrating typical characteristics of mHealth research involving persons living with HIV/AIDS and substance abuse. The example is based on an ongoing study led by 2 of the authors (RPW and GDK) at Johns Hopkins University.

Trial of Technology-Enhanced Peer Health Navigation. Investigators are following a cohort of injection drug users (IDUs) who are living with HIV. This pilot study aims to test the feasibility and acceptance of an intervention featuring peer health navigation in combination with a smartphone application to improve medication adherence and attendance at clinic appointments. Previous research with this population has shown that patients who inject drugs are often engaged in HIV care sporadically, and HIV viral suppression resulting from antiretroviral therapy may be short-lived. HIV treatment is often interrupted by relapses into drug use, incarceration, and other psychosocial stressors. The investigators hypothesize that individualized psychosocial support (including assistance with overcoming logistical barriers to care) provided by peer health navigators will improve the likelihood that IDUs living with HIV will remain engaged in HIV care over 12 months of followup. They further hypothesize that because peer health navigation is time- and resource-intensive, incorporating an mHealth application into the intervention will improve its efficiency and scalability. The research team has developed a customizable smartphone application that facilitates communication among patients and support staff and collects real-time data describing common risk factors for nonadherence such as negative-mood states and drug and alcohol use.

The study is recruiting people living with HIV/AIDS who have a history of problematic drug or alcohol use and who are not consistently engaged in care. The trial design specifies that participants will be randomly assigned to usual care (HIV-oriented primary care with clinic-based medical case management) or the technology-enhanced peer navigation intervention. Participants in the intervention arm will be assigned a peer health navigator and will be given a smartphone running the study application. They will be

expected to carry the phone at all times and may use it for personal calls, web applications, or to contact their peer navigator or clinic nurse as needed. The application will also prompt participants to respond to brief questionnaires 1-2 times daily that ascertain the level of stress they are experiencing, drug use or cravings, and anticipated barriers to keeping clinic appointments or adhering to their prescribed antiretroviral regimen. The data will be reviewed daily by research staff and the peer navigators, who will initiate contact with participants whose responses indicate they may be at high risk of disengaging from care. Participants in the usual care and intervention groups will be compared over 1-year followup with regard to missed appointments and to achieving and sustaining viral suppression in response to antiretroviral therapy.

3. A Framework to Address Salient Ethical Issues

In order to articulate the salient ethical issues raised by this example, we organize our discussion with reference to the systematic general ethical framework for biomedical research developed by Emanuel and colleagues and now well-established in the literature [10]. The framework, a critically reflective synthesis and elaboration of the most important existing ethical guidelines, presents 8 principles as necessary for the ethical justification of biomedical research with human participants: collaborative partnership, social value, scientific validity, fair participant selection, favorable risk-benefit ratio, independent review, informed consent, and respect for participants. For each principle, the framework specifies several benchmarks meant to indicate what its fulfillment requires in practice. All the principles are generally applicable to any sort of biomedical research with human participants. In what follows, we highlight three principles (and related benchmarks) as salient to the use of mHealth technology in research involving persons living with HIV/AIDS and substance abuse: scientific validity, fair participant selection, and favorable risk-benefit ratio. These are the principles that appeared most salient to us based on our experience of conducting mHealth research (ABL; GDK; RPW) and performing ethical review of mHealth research protocols (MWM). Depending on one's background and experience, other principles may also assume prominence, and we recommend to interested readers the exercise of applying the Emanuel et al. framework in full to their own research.

3.1. Scientific Validity. In order to justify the exposure of human participants to the burdens and risks of biomedical research, the research must be designed and conducted so as to produce scientifically valid results that are "interpretable and useful in the context of the health problem" [11]. In our case example, the eventually intended beneficiaries are IDUs living with HIV who are served by health systems relevantly similar to the one under study. The hope is that some form of smartphone "patient support" application will

enhance the population-level impact (efficiency and scalability) of an otherwise resource-intensive peer health navigation intervention. Eventually, it is hoped that individual IDUs living with HIV could use such technology to benefit from antiretroviral therapy and other aspects of HIV care to a significantly greater degree than they would otherwise have been able to do in the absence of the technology. Data to be generated by the study, then, should be capable of interpretation and use in the context of the behaviors and risk factors that place members of the intended beneficiary population at high risk of treatment failure.

The application of this point to mHealth technologies raises the ethical issue of responsibility for doing high-quality formative research. By the time any mHealth technology reaches the stage of being studied in the context of biomedical research, it should have gone through a foundational design process that promotes simplicity and ease of use, thereby minimizing its burdens for intended users. Formative research that engages with end users is a key part of the design process, increasingly recognized as a necessary process component, or “best practice” in mHealth design. End users should be engaged not only in the interface design but also in pre-testing and in providing feedback on whether a technology is excessively cumbersome or burdensome. To ensure that the data generated and communicated through mHealth research are useful and interpretable to end users, information access portals need to be designed for navigability, quality, presentation, and accuracy. The study protocol described in the case example resulted from several years of interaction between the study investigators and target participant groups through performance of a series of iterative field trials using similar methodologies. The investigators conducted formal assessments of feasibility and participant acceptability, which informed the design and implementation of the subsequent research.

Once an application of mHealth technology has gone through the design process and is suitable for study in the context of biomedical research, there should be a clear scientific justification for all data elements being collected. As detailed below in the discussion of risks, mHealth data collection may introduce or increase risks of various harms including social marginalization, psychological stress, invasion of privacy, or breach of confidentiality. For each variable on which data are collected and for each of the proposed interactions with the participant, there should be an *a priori* hypothesis justifying its inclusion; for example, that the data collected will improve clinical insight, the engagement strategy will improve adherence, or the patient feedback loops will increase quality of care. For example, geolocation data should not be collected merely as part of metadata for future data mining; if they are to be collected, relevant justifying hypotheses are required.

Additional care is required to take into consideration disparities in socioeconomic status and life circumstances between technical designers and end users. In the case example, formative research suggested that a minority of IDUs participating in the cohort study had used a smartphone. Conversely, smartphone ownership is widespread in the social and professional networks of investigators. Such differences

in experience with technology may lead to underappreciation of the challenges likely encountered by participants in the study and may threaten the validity of the desired data describing feasibility and acceptance of the intervention. Among relevant burdens is the cost associated with owning and operating mobile devices over time. While investigators often provide the necessary devices to participants during the course of a research study, failure to acknowledge the financial burden associated with using the technology outside of the research setting may threaten the sustainability and, ultimately, the real-world impact of mHealth interventions. Similar ethical challenges are often faced when conducting research in low-resource settings in the developing world, where socioeconomic disparities between research teams and participants tend to be pronounced.

3.2. Fair Participant Selection. Benchmarks of fair participant selection include several requirements [11]. The selection of research populations must be justified in terms of the scientific validity and social value of the research (i.e., eventual generalizable knowledge leading to improvements to health or health care for the intended beneficiary population). Inclusion and exclusion criteria for individual participants must be similarly justified. If the inclusion of vulnerable populations and individuals is necessary on grounds of scientific validity and social value, additional protective safeguards must be in place.

In our case example, the selection of the research population, IDUs who are living with HIV, appears readily justifiable. Given that the development of interventions to support persons living with HIV/AIDS and substance abuse may justifiably require including IDUs in biomedical research, it is important to consider vulnerability. Participating populations and individuals may be vulnerable due to the stigmatization of HIV/AIDS or economic deprivation and may often be exposed to elevated risk of incarceration from engagement in criminalized behaviors. These vulnerabilities make it imperative, in general, to include relevant safeguards for the protection of research participants living with HIV/AIDS and substance abuse, as detailed below in the discussion of risks. In addition, research on mHealth interventions in particular might exacerbate preexisting vulnerabilities. In recruiting participants, it is inappropriate for investigators to target intentionally and specifically those who, due to low income or unstable housing, may not have access to newer devices and other modes of mobile technology and may thereby be unduly influenced by the incentive of access to technology in a way that more affluent groups or individuals would not be.

A further ethical issue specific to mHealth arises regarding the inclusion and exclusion of individual participants. A *de facto* inclusion criterion for participation in mHealth research involving interactive data collection, even if it is not formally specified in the research protocol, is some degree of fluency in the use of mobile digital technology: for example, being able to send an SMS or being familiar with smartphone operations. Some older or less educated prospective participants—indeed, perhaps those most in need of supplemental patient support—are thereby excluded.

Strategies to overcome such barriers to participation may be warranted, perhaps in the form of short “trainings” to impart the necessary skills to perform basic technical functions. Again, in many low-resource settings, both in developing countries and among underprivileged populations within developed countries, it is possible to overcome such technical barriers through the use of pictorial menus or simple icon-driven interactions; for instance, text-based queries can be replaced by recorded voice messages. These, of course, come with additional costs to the researcher but may prevent unnecessary exclusion of the least-advantaged members of the target population.

3.3. Favorable Risk-Benefit Ratio. The principle of favorable risk-benefit ratio requires that risks to individual research participants be delineated, justified, and minimized [10]. Research with persons living with HIV/AIDS and substance abuse, while sometimes offering individual participants the prospect of direct benefit (such as through clinically relevant test results and referral to needed clinical followup), at the same time requires special care in delineating and minimizing research-related risks such as invasion of privacy or breach of confidentiality, since both HIV/AIDS and substance abuse carry some social stigma and substance abuse may involve criminalized behaviors. We focus here on the ways in which mHealth research, specifically, might exacerbate preexisting risks or introduce new risks for persons living with HIV/AIDS and substance abuse.

3.3.1. Physical, Social, Behavioral, and Psychological Risks. Investigators should think through the following concerns, ensuring that they take into account the life circumstances of the groups, communities, or populations from which they seek to enroll research participants. The provision of a high-value mobile mHealth device might expose participants to physical targeting for theft if the technology is far beyond what is “normal” among their peers; or it might enable high-risk behavior through exchange (or resale) of the device for money or drugs; or it might induce psychological stress due to perceived responsibilities of ownership or safeguarding. Researchers can address these sorts of concerns by developing studies that utilize the participants’ own phones or devices or by emphasizing technologies currently accessible to their peer group. The market value of the devices used in mHealth research can be minimized by restricting nonstudy features and by incorporating technology that allows the remote inactivation of the device as a deterrent from diverting or attempting to resell the device. Another behavioral concern is that some participants might perceive mHealth systems as a substitute for standard care (as when algorithm-based “personal feedback” is mistaken for live monitoring). A related risk is the creation of a false belief on the part of participants that mobile monitoring in itself offers additional protection for high-risk behaviors. A recent study in Uganda by Jamison and colleagues found the unexpected result that providing mobile-phone-based information about sexual health actually increased levels of promiscuity among users—another possible unintentional consequence of access

to information that changes behaviors in ways unforeseen by the investigators [12]. Researchers could try to address this type of concern through a combination of counseling (both during the informed consent process and as the study progresses) and safety monitoring based upon ongoing data collection.

Studies using biosensors need to guard against social risks of further marginalization and psychological risks due to the perception of looking “different” by allowing for appropriate concealment of sensors. Advances in sensor miniaturization allow for complex biosensors to be concealed in unobtrusive formats as benign as a large “Band-Aid.” Wireless technologies such as Bluetooth (TM) allow for data to be transmitted between sensors and mobile phones without obvious wires or leads, while advances in battery life and low-power circuit designs permit extended device use without requiring participants to frequently recharge their mHealth devices.

3.3.2. Risks to Privacy and Confidentiality. Given that mobile digital data exchange is a defining attribute of mHealth, risks to privacy and confidentiality are highly salient in mHealth research. While both privacy and confidentiality must be protected, adequate protection of both requires noting the distinction between the two: “Privacy can be defined in terms of having control over the extent, timing, and circumstances of sharing oneself (physically, behaviorally, or intellectually) with others. Confidentiality pertains to the treatment of information that an individual has disclosed in a relationship of trust and with the expectation that it will not be divulged to others in ways that are inconsistent with the understanding of the original disclosure without permission” [13].

Ecologic momentary assessment (EMA), as described above, is potentially invasive to privacy, as it can continuously or intermittently record and transmit detailed information about where a person is and, to some extent, what they are doing. Physiologic EMA poses risks of inadvertent insight into a participant’s behavior (e.g., through activity patterns or respiratory signatures), revealing information beyond the profiles that are scientifically justified and being sought through data collection. Such potential violations of privacy accompanying EMA pose distinct problems related to informed consent, as privacy might turn out to be violated in ways that were not anticipated *ex ante* by either investigators or participants. Workarounds to minimize intrusiveness include the use of frequent electronic permission prompts or reminders that monitoring is on or off, and the possibility of setting limits to the hours during which data will be collected (e.g., 9 a.m. to 9 p.m.) so as to avoid infringement on “personal” time.

The fate of text (SMS) messages is inherently uncontrolled as messages can be read by persons other than the intended recipient of the information; moreover, messages can be forwarded and can remain resident on unsecured devices for the lifetime of the technology. Text messages containing reminders to take medications, for example, could result in unintended disclosure of the presence of a medical condition even without specifying any details of the type of treatment.

The onus is on researchers to protect identifiable data and to ensure that participant confidentiality is maintained. In some instances where sophisticated systems for data storage, encryption, and authentication are not available, code words or euphemistic coded messages have been used in order to guard against the inadvertent disclosure of private information to third-party bystanders. Some institutions, beyond complying with legal requirements such as the United States Health Insurance Portability and Accountability Act (HIPAA), have implemented policies that limit electronic communication to patients for clinical care. While it may be possible to bypass such restrictions in the context of research, they may impede implementation and scale-up of beneficial interventions into clinical settings. Consultation with local institutions that provide care to the target population when developing an mHealth research protocol is therefore important to ensure that the intervention appropriately addresses the needs and limitations of all relevant stakeholders.

Regarding the confidentiality of research data, it is of special note that the very behaviors and risk factors that place substance users at high risk of treatment failure are also ones that expose them to legal risk. Accordingly, the protection of confidentiality in mHealth research studies that collect data on these behaviors and risk factors requires extra care above and beyond standard measures, including consideration of obtaining a Certificate of Confidentiality, a legal tool available in the United States [14], or a similar legal safeguard if available in other countries. For mHealth generally, data security issues are a major source of regulatory concern, from transmission of data to local storage of data, and “ownership” of what is otherwise considered confidential patient data. In late June of 2013, the Thomson Reuters Foundation, in collaboration with the mHealth Alliance and other partners, released a report entitled “Patient privacy in a mobile world,” reviewing the state of mHealth security guidelines and directives globally [15]. In addition, the International Organization for Standardization (ISO) has issued health information management guidelines that provide recommendations on appropriate safeguards of patient data, relevant to mHealth research and implementations [16, 17].

4. Conclusion

The advent of mHealth technologies has extended, in ways previously unimaginable, our ability as researchers to study, track, and understand high-risk behaviors within the individual and geospatial contexts in which they occur. This unprecedented availability of granular, real-time data may produce novel strategies that improve patient outcomes and increase self-efficacy. However, the rapid rate of adoption of these methods and technologies requires careful consideration of the ethical issues associated with their use. Existing standards and best practices may need to be supplemented with new guidelines to ensure that patients and vulnerable populations are appropriately protected. The pace of technological innovation sometimes exceeds that of ethical standards and guidance. We hope that this discussion will serve as a springboard for continued conversation to minimize this

gap moving forward, providing mHealth researchers and implementers a starting point and a framework to examine and mitigate potential risks associated with their work on an important frontier of public health innovation.

Conflict of Interests

The authors declare that there is no conflict of interests regarding the publication of this paper.

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Research Article

Smartphone Delivery of Mobile HIV Risk Reduction Education

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We sought to develop and deploy a video-based smartphone-delivered mobile HIV Risk Reduction (mHIVRR) intervention to individuals in an addiction treatment clinic. We developed 3 video modules that consisted of a 10-minute HIVRR video, 11 acceptability questions, and 3 knowledge questions and deployed them as a secondary study within a larger study of ecological momentary and geographical momentary assessments. All 24 individuals who remained in the main study long enough completed the mHIVRR secondary study. All 3 videos met our a priori criteria for acceptability “as is” in the population: they achieved median scores of ≤ 2.5 on a 5-point Likert scale; $\leq 20\%$ of the individuals gave them the most negative rating on the scale; a majority of the individuals stated that they would not prefer other formats over video-based smartphone-delivered one (all $P < 0.05$). Additionally, all of our video modules met our a priori criteria for feasibility: $\leq 20\%$ of data were missing due to participant noncompliance and $\leq 20\%$ were missing due to technical failure. We concluded that video-based mHIVRR education delivered via smartphone is acceptable, feasible and may increase HIV/STD risk reduction knowledge. Future studies, with pre-intervention assessments of knowledge and random assignment, are needed to confirm these findings.

1. Introduction

The use of mobile and desktop computer technologies in HIV healthcare and prevention delivery has been on the rise using a variety of technology platforms, including desktop computers [1–4], web-based systems [5–8], social networking sites, interactive voice response [9], personal digital assistants (PDAs)/smartphones, and short message service (SMS)/text messaging [10–13]. The range of indications for these electronic interventions is even broader than the range of technologies used; electronic interventions have been explored for HIV prevention [2], self-efficacy enhancement [14], antiretroviral therapy adherence [7], social support, appropriate care referrals [1], and internet health literacy [15].

The interest in electronic technology in healthcare delivery derives in large part from its potential to increase access to care in a cost-effective manner, especially for people who are underserved due to poverty, rural residence, unforgiving schedules, or other barriers to regular office visits. There is growing evidence that mobile health technologies can be

effectively utilized in resource-limited settings in both the developed and developing world. For example, Muessig et al. [16] found that for young black men who have sex with men (MSM) in North Carolina, mobile technologies were widely used as an acceptable means of HIV intervention. Winstead-Derlega et al. found that it was feasible and acceptable to use mobile media to deliver peer health messages to HIV-positive adults in rural Virginia [17]. In a randomized study in Kenya, Lester et al. found that patients who received a mobile phone SMS intervention had significantly improved adherence to antiretroviral therapy (ART) compared with those who received standard of care [18]. Additional benefits of electronic intervention include the potential for the immediate delivery of care in the participant's natural environment with reduced needs for space, staff, and training.

Evidence is mounting for the effectiveness of electronic delivery of health information relevant to HIV risk reduction. A 2012 meta-analysis of 15 randomized controlled trials showed that compared to minimal intervention, interactive computer-based interventions had significant effects on

sexual health knowledge, safer sex self-efficacy, safer sex intentions, and sexual behavior [14]. Improved dissemination of HIV prevention education related to intravenous drug use and sexually transmitted disease has been demonstrated for computer-based [16] and video-based [17] programs. Some studies even suggest that privacy during the electronic delivery of the HIV education is preferred [16], though the addition of an interactive group session can enhance the benefits of the videos [19]. Person et al. surveyed over 300 individuals with HIV, latent TB, or who were being screened for HIV, TB, or syphilis and found that cell phones and text messaging were prevalent and receptiveness to text messaging for healthcare-related communication was high [20].

The widening use of smartphones promises to enhance the disseminability of mobile health education videos. Jones et al. [21–23] tested the use of smartphones for the delivery of HIV prevention messages to women in a randomized clinical trial, comparing 12 weekly videos of the educational soap opera *Love, Sex, and Choices* to 12 weekly HIV prevention messages. Baseline and post-intervention interviews at 3 and 6 months were completed by an audio computer-assisted self-interview (ACASI). At baseline, 99% of the participants reported having unprotected vaginal sex and 44% reported having unprotected anal sex with high-risk partners. Both intervention groups reported a significantly reduced risk post-intervention ($P < 0.001$); the magnitude of reduction did not statistically significantly differ by group; $P = 0.23$. However, after adjusting for baseline sexual activity, women receiving the video intervention had roughly a 20% greater reduction in risk behavior. The authors concluded that both smartphone interventions were viable for HIV prevention [21–23].

Our goal was to develop and deploy via smartphone an interactive mobile HIV Risk Reduction (mHIVRR) education intervention and determine via smartphone-delivered assessments whether it reduces HIV/STD-related risk via increased HIV/STD knowledge. For our intervention, we selected *Safe in the City*, an STD/HIV prevention video geared for patients in an STD clinic waiting room that was shown to decrease STDs in a controlled clinical trial [24]. *Safe in the City* is distributed in user-friendly kits as a part of the Diffusion of Effective Behavioral Interventions (DEBI) project of the Centers for Disease Control and Prevention (CDC). We evaluated the feasibility and acceptability of *Safe in the City* modified for “on demand” delivery on a handheld device in opioid-dependent patients in methadone maintenance therapy. Our mHIVRR modules consisted of 3 components: (1) the videos themselves, (2) questions about their acceptability to the user, and (3) questions about their perceived effectiveness for the user.

2. Materials and Methods

2.1. Study Participants. This study was conducted as part of a larger 46-week natural history study of personal and environmental stress and drug use, the goal of which is to develop field-deployable measures of environmental influences (stressors, drug exposure, etc.) that could ultimately be used in studies of gene-environment interactions.

Participants in the main study were opioid-dependent poly-drug users recruited by newspaper and word of mouth. They received opioid agonist treatment (OAT) with either methadone or buprenorphine, based on their preference, and weekly individual counseling. Inclusion criteria included age between 18 and 75, physical dependence on opioids, and residence in or near Baltimore. Study exclusion included history of any DSM-IV psychotic disorder, bipolar disorder, or current Major Depressive Disorder; current dependence on alcohol or sedative hypnotics; cognitive impairment severe enough to preclude informed consent or valid self-report; and medical illness or medications that affect the hypothalamic-pituitary-adrenal (HPA) axis. As part of the main study, participants provided thrice weekly urine for toxicology and were issued a smartphone and GPS to track drug use, stress, and geographical location (a measure of environmental risk) for 16 of the first 18 weeks of the main study. They were allowed one smartphone replacement for a lost, stolen, or damaged unit. If a second unit was lost, damaged, or stolen, the participant was withdrawn from the main study and transferred to OAT in the community. At the end of the main study, participants were given the option to either keep the smartphone or return it and receive \$100.

For recruitment into the present mHIVRR secondary study, participants in the main study were asked in person by investigators to participate once they reached week 7 of the main study. Participation in the main study was not affected by their decision to participate or not in the mHIVRR secondary study. This study was approved by the Institutional Review Board of the NIDA Intramural Research Program, included a Certificate of Confidentiality, and each participant gave written informed consent.

After giving written informed consent for the mHIVRR study, participants were given a 5-minute demonstration on how to initiate a module and answer questions. Participants were asked to view a video and answer the subsequent questions at least once during the week but could watch it as many times as they chose. Participants met weekly with investigators, at which time new modules were downloaded onto the smartphone and the data uploaded from the smartphone. Uploaded data included logs of the number of times video viewings were attempted and completed, the percentage of the video viewed each time, and the responses to the questionnaires. Each time a new module was downloaded onto the phone, the prior week's module remained available for repeated viewing. Participants completed questionnaires on the smartphone after each viewing of $\geq 75\%$ of an HIVRR video component. If less than 75% of the video was viewed, no questions appeared. Participants were compensated \$20 if they watched a module and answered all the questions at least once. Total compensation for completing all 3 video modules at least once was \$60.

2.2. Video Component. *Safe in the City* is a 23-minute STD/HIV prevention video geared for patients in an STD clinic waiting room. The video contains key prevention messages aimed at increasing knowledge and perception of STD/HIV risk, promoting positive attitudes towards condom use, building self-efficacy and skills to facilitate safer sex, and

the acquisition, negotiation, and use of condoms. There are three interwoven vignettes that model negotiating safer sexual behaviors among young couples of diverse racial/ethnic backgrounds and sexual orientations. Animated segments demonstrate proper condom use and the variety of condoms available. We divided the 3 vignettes into 3 separate videos, each about 8–10 minutes including credits and formatted them for use on a smartphone running the Windows Mobile 6 operating system.

2.3. Acceptability Questions and Feasibility Assessment. The same 11 acceptability questions appeared on the smartphone after each viewing of $\geq 75\%$ of the video component in all 3 modules. The acceptability questions were divided into 3 main categories: functional acceptability, educational acceptability, and comparative acceptability (Table 1). The functional acceptability questions assessed the ease of loading and playing the mHIVRR videos on the smartphone. The educational acceptability questions assessed the perceived educational value of the videos. The comparative acceptability questions assessed whether participants would have preferred to have the intervention delivered through a different medium.

To assess the acceptability of the mHIVRR modules, we collected data on four main elements. For questions 1 through 7, element 1: the median rating on a 5-point Likert scale, with acceptability defined as ≤ 2.5 , and element 2: the percentage of participants rating anything as 5 (“very hard,” “not at all effective,” “not at all applicable,” and “very boring”) with acceptability defined as $\leq 20\%$. For question 8, element 3: the percentage of participants giving a rating of 5 (“much too long”) and/or 1 (“nowhere near long enough”), with acceptability defined as $\leq 20\%$. For questions 9–11, element 4: the percentage responding “no,” with acceptability being a majority. To assess feasibility, we collected data on two additional elements: (1) data missing due to noncompliance, with feasibility being defined as $\leq 20\%$; and (2) data missing due to technical failure, with feasibility being defined as $\leq 20\%$.

2.4. Knowledge/Effectiveness Questions. While effectiveness assessment was not the main focus of this nonrandomized study, we did want to get a sense of whether participants were actually learning or reinforcing HIVRR knowledge. Three unique knowledge questions directly related to the video component followed each appearance of the acceptability questions (Table 2). We considered the mHIVRR intervention effective if at least 80% of the participants score $> 65\%$ “correct” on most modules.

2.5. Other Study Activities

2.5.1. Ecological Momentary Assessment (EMA). Using the same smartphones utilized in the mHIVRR project, participants initiated entries (1) each time that they used a drug and (2) each time that they felt overwhelmed, anxious, or stressed more than usual. Participants also made 3 random

signal-triggered recordings per day and one brief “end of day” recording.

2.5.2. Urine Toxicology. Participants provided urine samples three times per week. Samples were tested for amphetamines, barbiturates, benzodiazepines, THC, cocaine, methadone, codeine/morphine, and PCP.

2.5.3. Questionnaires and Interviews. The questionnaires and interviews from the main study that were included in this secondary study analysis were the Addiction Severity Index (ASI) [25] and the HIV Risk-Taking Behavior Scale (HRBS) [26]. The ASI was interviewer-administered and completed at baseline prior to entry into the main study. The HRBS, which assesses behaviors associated with an increased risk of HIV infection and includes subscales for drug-related risk (6 questions) and sex-related risk (5 questions), was completed via computer prior to participation in the mHIVRR secondary study. We made two modifications to the HRBS: we added a sixth question to the sex-related risk section inquiring about condom use during anal sex, resulting in two subscales, each with 6 questions, and we changed the timeframe from the last month to the last 2 weeks to match the frequency of questionnaire administration.

2.6. Data Analysis. We compared median scores for all functional acceptability and educational acceptability questions using the Wilcoxon rank sum test, a nonparametric alternative to the paired *t*-test, appropriate for ordinal variables. We utilized Fisher’s exact test to analyze the comparative acceptability and knowledge/effectiveness questions. We also undertook exploratory analyses for indications that acceptability varied by OAT (methadone versus buprenorphine), sex, or other demographic and drug use variables utilizing the Fisher’s exact test and *t*-tests.

Although the study was designed to assess feasibility and acceptability, we also explored the intervention’s possible role in behavior change by comparing the percentage of urines positive for heroin and/or cocaine in the 12 urine time points (approximately 1 month) pre-mHIVRR intervention to the 12 urine time points (approximately 1 month) post-mHIVRR intervention utilizing paired *t*-tests and Wilcoxon signed rank tests. We assessed EMA reporting of route of administration of heroin and/or cocaine during these same time frames utilizing the same tests. Analyses were done with Stata 10 (StataCorp LP, 1996–2013).

3. Results

The demographic and drug use characteristics of our sample are shown in Table 3. All participants approached to participate in this secondary study agreed to participate. Our sample included 26 participants, 24 (92%) of whom completed all 3 mHIVRR modules. Two participants did not complete the mHIVRR study because, while participating in it, they were discharged from the main study as per protocol for missing more than 3 consecutive clinic days without contacting the clinic. At entry into the mHIVRR secondary

TABLE 1: Acceptability questions across all 3 videos (n (%)).

Functional acceptability		Methadone (MTD), $n = 11$	Buprenorphine (BUP), $n = 13$	Total	P value
(1) How easy was it to <i>play</i> this module? Median (IQR) 1 (1,1)	1—very easy	53 (64%)	64 (89%)	117 (75%)	$P < 0.005$
	2	16 (19%)	7 (10%)	23 (15%)	
	3	7 (8%)	1 (1%)	8 (5%)	
	4	4 (5%)	0 (0%)	4 (3%)	
	5—very hard	3 (4%)	0 (0%)	3 (2%)	
(2) How easy was it to <i>see and hear</i> this module? Median (IQR) 1 (1,2)	1—very easy	52 (63%)	52 (72%)	104 (67%)	$P = 0.172$
	2	19 (23%)	14 (20%)	33 (21%)	
	3	7 (8%)	4 (6%)	11 (7%)	
	4	3 (4%)	1 (1%)	4 (3%)	
	5—very hard	2 (2%)	1 (1%)	3 (2%)	
(3) How easy was it to <i>understand</i> this module? Median (IQR) 1 (1,1)	1—very easy	56 (68%)	61 (85%)	117 (75%)	$P = 0.007$
	2	18 (22%)	11 (15%)	29 (19%)	
	3	6 (7%)	0 (0%)	6 (4%)	
	4	1 (1%)	0 (0%)	1 (1%)	
	5—very hard	2 (2%)	0 (0%)	2 (1%)	
Educational acceptability		Methadone (MTD)	Buprenorphine (BUP)	Total	P -value
(4) How effective was this module in teaching you <i>something new</i> about HIV/AIDS? Median (IQR) 1 (1,2)	1—very effective	48 (58%)	60 (83%)	108 (70%)	$P < 0.005$
	2	16 (19%)	6 (8%)	22 (14%)	
	3	13 (16%)	2 (3%)	15 (10%)	
	4	4 (5%)	2 (3%)	6 (4%)	
	5—not at all effective	2 (2%)	2 (3%)	4 (2%)	
(5) How effective was this module in <i>reminding you</i> of things you knew about HIV/AIDS but had not been thinking about? Median (IQR) 1 (1,2)	1—very effective	54 (65%)	60 (83%)	114 (74%)	$P = 0.021$
	2	24 (29%)	7 (10%)	31 (20%)	
	3	4 (5%)	2 (3%)	6 (4%)	
	4	1 (1%)	1 (1%)	2 (1%)	
	5—not at all effective	0 (0%)	2 (3%)	2 (1%)	
(6) How much did this module <i>apply to situations in your life</i> ? Median (IQR) 2 (1,4)	1—very applicable	19 (23%)	31 (43%)	50 (32%)	$P = 0.722$
	2	30 (36%)	5 (7%)	35 (23%)	
	3	15 (18%)	7 (10%)	22 (14%)	
	4	11 (13%)	7 (10%)	18 (12%)	
	5—not at all applicable	8 (10%)	22 (30%)	30 (19%)	
(7) How <i>entertaining</i> was this module? Median (IQR) 2 (1,3)	1—very entertaining	26 (31%)	50 (70%)	76 (49%)	$P < 0.005$
	2	17 (20%)	11 (15%)	28 (18%)	
	3	28 (34%)	6 (8%)	34 (22%)	
	4	12 (15%)	2 (3%)	14 (9%)	
	5—very boring	0 (0%)	3 (4%)	3 (1%)	

TABLE 1: Continued.

Functional acceptability		Methadone (MTD), <i>n</i> = 11	Buprenorphine (BUP), <i>n</i> = 13	Total	<i>P</i> value
(8) How appropriate was the <i>length</i> of the module?	1—nowhere near long enough	2 (2%)	5 (7%)	7 (4%)	<i>P</i> = 0.408
	2—not quite long enough	15 (18%)	0 (0%)	15 (10%)	
	3—just about right	58 (70%)	65 (90%)	123 (80%)	
	4—a little too long	6 (7%)	2 (3%)	8 (5%)	
	5—much too long	2 (2%)	0 (0%)	2 (1%)	
Comparative acceptability		Methadone (MTD)	Buprenorphine (BUP)	Total	<i>P</i> -value
(9) Would it be better if the information was in a <i>booklet</i> instead of on the smartphone?	No	76 (92%)	62 (86%)	138 (89%)	<i>P</i> = 0.312
	Yes	7 (8%)	10 (14%)	17 (11%)	
(10) Would it be better if the information was on a full-size <i>computer</i> instead of on the smartphone?	No	60 (72%)	50 (69%)	110 (71%)	<i>P</i> = 0.725
	Yes	23 (28%)	22 (31%)	45 (29%)	
(11) Would it be better if the information was <i>text</i> instead of video?	No	71 (86%)	70 (97%)	141 (91%)	<i>P</i> = 0.012
	Yes	12 (14%)	2 (3%)	14 (9%)	

Questions 1–8 were analyzed using the Wilcoxon rank sum test for ordinal variables, and Questions 9–11 were analyzed using Fisher's exact test for dichotomous variables and small sample sizes.

TABLE 2: Knowledge/effectiveness questions and scores.

Module question no.	Question	Correct responses <i>n</i> (%)
1-1	Do you always have symptoms with a sexually transmitted disease (STD)?	45 (88%)
1-2	Do condoms come in different sizes, shapes, styles, colors, and flavors?	49 (96%)
1-3	Do you need to squeeze the tip of the condom when placing it on?	43 (84%)
	Total (%) correct for module 1	137 (88%)
2-1	Do you need to use a <i>new</i> condom every time you have sex from start to finish?	55 (100%)
2-2	Are body lotions, oils, or Vaseline good products to use with latex condoms?	51 (93%)
2-3	Should you remove a condom when the penis is still erect?	46 (84%)
	Total (%) correct for module 2	152 (92%)
3-1	Can having too much to drink or being high increase your risk for STDs and HIV?	43 (88%)
3-2	Can you tell if someone has an STD or HIV just by looking at them?	47 (96%)
3-3	Do condoms protect you against STDS, HIV, and pregnancy?	48 (98%)
	Total (%) correct for module 3	138 (94%)
	Total (%) correct for all 3 modules	92%

study, among participants receiving methadone the average dose was 88 ± 23 mg (mean \pm SD) and among participants receiving buprenorphine the average dose was 17 ± 4 mg (mean \pm SD).

We assessed HIV risk with the HRBS prior to entrance into the main study. The total risk score was 4.9 ± 4.6 (mean \pm SD); there was no difference based on OAT type (methadone versus buprenorphine) ($t = 0.100$, $df = 16$, and $P = 0.922$). The drug-related risk score was 0 (0,1) (median (IQR)) and the sex-related risk subscale score was 2.5 (0,6) (median

(IQR)); neither differed by OAT type ($z = 1.679$, $P = 0.093$ and $z = -1.069$, $P = 0.285$, resp.).

3.1. Functional and Educational Acceptability. Acceptability questions 1–3 addressed functionality in regards to being able to play, see/hear, and understand the video modules. Questions 4–7 assessed the perceived educational value of the video modules. Median ratings for questions 1–7 across all videos for all participants were less than or equal to 2.5.

TABLE 3: Demographic and drug use characteristics at baseline ($n = 24$).

	Methadone (MTD) $n = 11$	Buprenorphine (BUP) $n = 13$	<i>P</i> -value
Male (n (%))	9 (81%)	11 (85%)	n.s.
African American (n (%))	8 (73%)	7 (54%)	n.s.
Age (mean \pm SD)	43.5 \pm 8.7	40.5 \pm 6.8	n.s.
Education in years (median (IQR))	12 (12,12)	12 (11, 12)	n.s.
Married (n (%))	0 (0%)	3 (30%)	n.s.
Days paid for work in last 30 (mean \pm SD)	3.6 \pm 8.4	9.2 \pm 8.9	n.s.
Usual full-time employment (n (%))	4 (44%)	3 (30%)	n.s.
Days cocaine use in last 30 (median (IQR))	0 (0, 15)	0.5 (0, 4)	n.s.
Days heroin use in last 30 (mean \pm SD)	19.6 \pm 10.4	13.5 \pm 10.4	n.s.
Days other opiate use in last 30 (mean \pm SD)	4.1 \pm 6.0	17.7 \pm 11.6	<0.005
Days alcohol use in last 30 (median (IQR))	0 (0, 0)	1 (0, 3)	n.s.
Days alcohol intox last 30 (median (IQR))	0 (0, 0)	0.5 (0, 3)	n.s.
Years cocaine use (median (IQR))	10 (1,20)	1 (0, 7)	n.s.
Years heroin use (mean \pm SD)	17.9 \pm 12.0	12.3 \pm 9.3	n.s.
Years other opiate use (median (IQR))	0 (0,2)	1 (0,7)	n.s.
Years alcohol use (median (IQR))	4 (0,4)	1 (0,13)	n.s.

Categorical variables (gender, ethnicity, marital status, and employment status) were analyzed using Fisher's exact test. Continuous variables were analyzed using student *t*-tests (normally distributed) and Wilcoxon rank sum tests (nonnormally distributed).

There were differences by OAT with the methadone group providing significantly higher (but still less than or equal to a median score of 2.5) ratings on questions 1 (play), 3 (understand), 4 (learn something new), 5 (remind me of something I knew), and 7 (entertaining) (Table 1).

In addition to exploring median ratings of functional and educational acceptability, we looked at the percent of participants rating each question a 5 which was the most negative response category on the 5-point Likert scale. A percent rating of 5 for questions 1–7 was $\leq 20\%$ and consistent with acceptability as we defined a priori for all of the questions across all 3 videos. When broken down by OAT, only question 6 (applicability) in the buprenorphine group received a percent rating of $>20\%$ (31%) (Table 1).

Question 8 addressed the perceived appropriateness of the length of the video modules. All percent ratings for extreme responses (1 or 5 on the Likert scale) for question 8 were $\leq 20\%$ and in keeping with our definition of acceptability. A percent rating of 1 (“nowhere near long enough”) for question 8 occurred in 4.5% of the responses and 5 (“much too long”) occurred at a rate of 1.3% (Table 1).

3.2. Comparative Acceptability. Responses to questions showed that no other medium of delivery was hypothetically preferred over the smartphones. The booklet-based format was not preferred in 87.3% to 91.8% of participant viewings across all 3 videos. The computer-based format was not preferred in 63.3% to 76.4% of participant viewings across all 3 videos. The text-based format was not preferred in 89.1% to 93.9% of participant viewings across all 3 videos. The only difference by OAT was more methadone compared to buprenorphine participants preferred a text-based format

($P = 0.012$) but none of these alternate format preferences achieved a majority which is consistent with our a priori definition of acceptability (Table 1).

3.3. Feasibility. There were no data missing due to participant noncompliance; all 24 participants viewed $\geq 75\%$ and completed all acceptability and knowledge questions for all 3 videos. There were also no data missing due to technical failure.

3.4. Knowledge/Effectiveness. We met our a priori criterion for module effectiveness (at least 80% of participants scoring $>65\%$ “correct” on most modules). Across all 3 videos, all 3 knowledge questions, and all participants, 92% of responses were correct (Table 2).

3.5. Urine Toxicology and EMA. We compared urine results in the 1 month (12 urines) prior to the 4-week mHIVRR intervention to urine results in the 1 month (12 urines) after the intervention period. We found no change in the percent of heroin-positive or the percent of cocaine-positive urines.

For the same time periods, we compared EMA reports of drug use to determine whether routes of administration of heroin and/or cocaine changed pre- and post-intervention. We found no change in the real-time self-reported route of administration.

4. Discussion

This project was in keeping with the suggestion, in a 2012 Cochrane Review, that investigators conduct further

research into mobile phone messaging interventions for self-management of long-term illnesses [27]. We noted a high completion rate of 92% for all 3 mHIVRR modules, we met all our a priori criteria for acceptability, and we encountered no technical issues, showing that the use of smartphones to deliver HIV-risk education is both feasible and acceptable in our polydrug-using population.

Overall, our sample was representative of treatment seekers in Baltimore [28, 29]. Their drug use histories were also similar to those seen in previously published studies and did not differ by OAT medication (with the exception of “other opiate” use in last 30 days, which was higher in the buprenorphine-treated group than in the methadone-treated group).

At baseline, our sample had low overall levels of drug-related risk, sex-related risk, and total risk (previous studies have demonstrated that IDUs’ reports of both demographic and HIV risk behavior can be reliable) [30]. That finding is consistent with those of the national Drug Abuse Treatment Outcome Studies (DATOS), which found that treatment programs in cities with higher prevalence rates of HIV/AIDS such as Baltimore admitted clients with lower baseline levels of risk behavior than other cities [31]. In 2011, Chaudhry et al. [32] reported that among 303 buprenorphine-maintained individuals across nine US sites, 24% had had sex without a condom and almost 9% had shared needles in the previous 90 days. In their sample, as in our sample, risk factors for unprotected sex included having a regular partner. Addressing transmission risk behaviors is an important secondary HIV prevention strategy, and, based on our data and those of others, there is still a need for education surrounding needle cleaning and condom use.

Our participants’ responses to questions on functional and educational acceptability met our a priori criteria for “acceptable as is.” For all 3 videos, there were differences by OAT, with the methadone group having higher (but still ≤ 2.5) median ratings than the buprenorphine group. Given that demographic and drug use characteristics were similar across the two groups, it is unclear why the methadone group rated the videos more negatively.

Across all 3 videos, the percentage of participants rating a 5 (most negative response) was $\leq 20\%$ and consistent with acceptability as we defined it a priori. However, when we broke down the results by OAT and by question, we found that for question 6 (how much did this module apply to situations in your life?), 31% of buprenorphine-maintained participants stated it was “not at all applicable to my life.” The higher negative rating for this question may have been a result of participants’ taking the question to refer to whether they had same-sex partners, rather than thinking more broadly about the video’s messages regarding condom use and STD testing. Additionally, while participants were assured that the information we gathered was for research purposes only, there may have been a concern regarding the perceived stigma related to same-sex partners or adultery, causing participants to falsify their response to this question. Negative ratings were more frequent in the buprenorphine group in all 3 videos, but there were no significant differences between groups in median ratings or percentages.

Video module length was rated “just right” by the majority of participants, both for each individual video and for all three videos combined. Several of the videos were watched more than once, further supporting the questionnaire responses on the videos’ appropriate length and high functional and educational acceptability.

None of the alternative formats presented in the comparative acceptability questions were preferred over the smartphone-delivered video-based format. These comparisons were hypothetical, however, since the participants were not exposed to the booklet or computer-delivered format during the study. Again, the fact that multiple participants viewed the videos more than the required one time also supports the comparative acceptability of the modules.

Based on the low rates of data missing due to noncompliance and technical failure, we determined that the mHIVRR intervention was feasible. The high compliance rate we achieved in this mHIVRR study may be partly attributed to the fact that participants were participating in a larger EMA study and had already been using the smartphones for at least 7 weeks. We assessed the technical issues by participant interviews at the weekly meetings for data upload and video download. There were viewing initiations that did not reach the 75% completion mark, and by design no acceptability and knowledge questions appeared. These incomplete initiations were expected, as we had provided no way to pause and restart the video, given the sensitive nature of the video topics, in case the smartphone was left unattended or picked up by another individual. According to participant report, the incomplete initiations resulted from social interruptions, not technical difficulties. All smartphones were password-protected to reduce the risk of confidentiality breach; no individuals misplaced their log-in or password information. There were also no issues with recharging the devices, and no smartphones were lost or damaged.

While not a main focus of the study, we found that the overall knowledge and effectiveness scores across all participants and all 3 videos greatly exceeded our a priori criteria. It is possible that HIVRR knowledge was high at baseline in this population. Unfortunately, we did not conduct pretests of our participants’ knowledge in this pilot study.

To get a sense of behavior change possibly resulting from the mHIVRR intervention, we compared urine results for 1 month before and 1 month after the intervention period. We found no change in percent heroin-positive and percent cocaine-positive urines. The lack of impact may have been due to the short duration of the intervention and the fact that baseline drug use in our participants was already low at the start of the trial.

During the same pre- and post-intervention time periods, we compared EMA event-contingent entries initiated during drug craving or use events to determine if route of administration of heroin and/or cocaine changed pre- and post-intervention. We found no change in real-time self-reported route of administration. Again, this may be related to the short intervention length and low rates at baseline of HIV risk behaviors.

Limitations of the study include the lack of pre-intervention knowledge assessment and lack of random assignment to an intervention and a control group. Although we were unable to comment on relative knowledge gain as a result of the intervention due to the lack of pre-intervention knowledge assessment, we did find high rates of absolute HIVRR knowledge post-intervention. Our future studies will include randomization into control and intervention groups, additional video modules, longer intervention lengths, and pre-intervention knowledge assessment.

This project was unique because in addition to delivering the HIVRR video education via smartphone, we also conducted all acceptability and knowledge assessments on the smartphone in the participant's natural environment. Previous studies describing HIVRR video-based smartphone interventions conducted assessments by ACASI [21, 22] or by smartphone in a laboratory setting with a researcher present [33]. Another advantage of this study was that the video modules were loaded onto the smartphones and did not rely on streaming, which minimized the possibility of technical issues with syncing, reception, and network coverage [21]. Additionally, this obviated the need for an expensive data plan. To our knowledge, only one previous study utilized smartphone-delivered video-based HIVRR education delivery, but this study used computer-based ACASI acceptability assessments and streamed videos [21]. A third advantage of this study was that the video module initiation was done by the participant at a time he/she deemed convenient and private and was not prompted. Other studies have used email to prompt video initiation and have had difficulties with unreceived or accidentally deleted messages [21]. Therefore, although 24/7 viewing of the videos was possible (and encouraged) in those studies, viewing was only possible if the participant actually received the email and had no issues with video streaming, which was not always the case. In our study, participant-initiated viewing avoided the reliance on email and also allowed participants to view the video module several times during the week of release and thereafter, which maximized HIVRR knowledge acquisition. A final strength of our study was the 100% equipment recovery rate, which was likely related to providing compensation for device return and the fact that our participants were participating in a larger EMA and GMA study that required continued smartphone use. While the equipment recovery rate of 100% occurred in the small mHIVRR study sample, we also have a smartphone recovery rate of 90% in the larger parent study of over 130 individuals to date, which indicates that even in larger samples, there was minimal equipment loss.

5. Conclusions

Video-based mHIVRR education delivered via smartphone is acceptable, feasible and may increase HIV/STD risk-reduction knowledge. Future studies, with pre-intervention assessments of knowledge and random assignment, are needed to confirm these findings.

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Clinical Study

Preliminary Evidence for Feasibility, Use, and Acceptability of Individualized Texting for Adherence Building for Antiretroviral Adherence and Substance Use Assessment among HIV-Infected Methamphetamine Users

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The feasibility, use, and acceptability of text messages to track methamphetamine use and promote antiretroviral treatment (ART) adherence among HIV-infected methamphetamine users was examined. From an ongoing randomized controlled trial, 30-day text response rates of participants assigned to the intervention (individualized texting for adherence building (iTAB), $n = 20$) were compared to those in the active comparison condition ($n = 9$). Both groups received daily texts assessing methamphetamine use, and the iTAB group additionally received personalized daily ART adherence reminder texts. Response rate for methamphetamine use texts was 72.9% with methamphetamine use endorsed 14.7% of the time. Text-derived methamphetamine use data was correlated with data from a structured substance use interview covering the same time period ($P < 0.05$). The iTAB group responded to 69.0% of adherence reminder texts; among those responses, 81.8% endorsed taking ART medication. Standardized feedback questionnaire responses indicated little difficulty with the texts, satisfaction with the study, and beliefs that future text-based interventions would be helpful. Moreover, most participants believed the intervention reduced methamphetamine use and improved adherence. Qualitative feedback regarding the intervention was positive. Future studies will refine and improve iTAB for optimal acceptability and efficacy. This trial is registered with ClinicalTrials.gov NCT01317277.

1. Introduction

Mobile health (mHealth) interventions aiming to enhance health behaviors have recently proliferated [1]. mHealth strategies are designed to be integrated into the everyday lives of patients in order to minimize barriers to intervention implementation and facilitate use and generalizability [2].

Both the mobility and popularity of cell phones make it possible to remotely deliver services to assist people with behavior modification and disease self-management [3], thereby improving health outcomes. Short-message service (SMS; i.e., text messaging), in particular, represents a low-cost route to promoting health behaviors, such as treatment adherence, due to the ubiquitous nature of this technology

on mobile devices. Furthermore, SMS technology supports interactivity (e.g., two-way communication) and can be personalized at the individual level [4, 5].

Thoughtful mHealth interventions grounded in behavior change theory may therefore be particularly advantageous in advancing aspects of health care (e.g., delivery and assessment). Despite relatively few high-quality randomized controlled trials (RCTs) supporting mHealth tools, several interventions to improve adherence to antiretroviral therapy (ART) among persons infected with human immunodeficiency virus (HIV) have yielded positive results [1]. ART is currently the standard of care for persons infected with HIV, and effective adherence to ART is the key to deriving therapeutic benefit [6, 7]. SMS-based interventions have begun to show efficacy in promoting ART adherence in RCTs but are currently in the early stages of development and refinement [8–10]. mHealth interventions have potential to decrease barriers to traditional ART adherence interventions, particularly in difficult-to-track groups because they ameliorate obstacles such as transportation, insurance, and physical limitations [11]. Substance users are one such high-risk subgroup of persons living with HIV who have been documented to be especially nonadherent to ART [12, 13]. Taken together, HIV+ substance users may represent both a critical and feasible target of public health significance for such mHealth adherence interventions.

In addition to ART adherence, substance use behaviors may also be a potential target for assessment or modification via mHealth interventions. Notably, a recent survey involving patients in substance abuse treatment documented that the vast majority of patients reported having access to mobile phones (91%) and to text messaging (79%) [14]. Challenges remain in accurately assessing risk of relapse among substance users, and mHealth technologies may be able to assist by obtaining “real time” data, such as self-reported mood and engagement in substance use. This “real time” data could potentially enable earlier relapse intervention and/or keep individuals continuously engaged in treatment. The deployment of mHealth for substance use disorder treatments is a developing area of research, and early work in this field is promising (see [15] for a review). To our knowledge, investigations using mHealth to promote ART adherence have not yet included or targeted persons with active substance use [16]. The use of mHealth technologies may therefore be efficacious in simultaneously monitoring and assessing medication adherence and substance use among persons with HIV infection and co-occurring substance use problems.

In the context of HIV infection, methamphetamine use may be a particularly relevant substance of abuse given the high comorbidity rate between these two conditions [17]. In fact, methamphetamine users are more likely to be HIV infected than opioid users in the western United States [18], which is primarily facilitated by the link between methamphetamine use and risky sexual behaviors [19]. Importantly, recent methamphetamine use is particularly predictive of poor ART adherence (e.g., [13, 20–22]). Given that suboptimal ART adherence can lead to virologic rebound, development of medication-resistant strains of HIV, and more rapid

progression to AIDS and death [23–25], sustained treatment and ART adherence is critical.

Based on the growing evidence supporting mHealth assessment and intervention, the ubiquity of SMS technology, and the critical need to improve ART adherence among persons with methamphetamine use and HIV infection, the overarching goal of the parent study was to develop and evaluate an SMS intervention to improve ART medication adherence among persons with methamphetamine use and HIV infection. While the RCT of the developed intervention (individualized texting for adherence building (iTAB)) is ongoing, the goals of this present study were to use preliminary data to (1) examine response rates to text messages regarding methamphetamine use and medication adherence, (2) determine whether our assessment of methamphetamine use gathered via SMS is consistent with self-report information of substance use gathered in a clinical interview (i.e., construct validity for methamphetamine use assessment via SMS), and (3) summarize preliminary participant feedback of the ongoing intervention. The rationale for reporting these preliminary data is driven by recent publications suggesting a more rapid approach to publishing behavioral intervention data, especially as it relates to the rapid dissemination of the content of mHealth interventions (e.g., [26–28]). The information presented herein may be informative for the development of other mHealth interventions to improve health outcomes in difficult-to-treat individuals.

2. Method

2.1. Participants. This report represents results from the first 29 HIV-infected active methamphetamine-dependent individuals (i.e., use within 30 days of baseline) enrolled in an ongoing pilot RCT designed to improve or maintain ART medication adherence. Target enrollment for this ongoing study is 50 individuals in the active condition (iTAB) and 25 individuals in the active comparison condition. The unbalanced design was chosen to maximize the ability to investigate the data from within the iTAB group. Of the 29 individuals presented here, 20 were assigned to the iTAB arm and 9 were assigned to the control arm. As this study was still ongoing, data were not available for all subjects for all outcomes. Analyses of SMS and substance use data included 21 participants (13 iTAB, 8 control); analyses of feedback questionnaires included 26 participants (17 iTAB, 9 control); and analyses of qualitative feedback interviews included 19 participants (12 iTAB, 7 control). The UCSD Human Research Protection Program approved the current study. Participants provided written informed consent to participate.

Inclusion criteria were the capacity to provide informed consent, age 18 years or older at enrollment, documentation of HIV infection, self-reported methamphetamine use within the last 30 days, DSM-IV-TR diagnosis of methamphetamine abuse or dependence via the Composite International Diagnostic Interview [29], and an active prescription for an antiretroviral medication. Participants also had to be willing to respond to text messages and utilize electronic medication tracking devices (i.e., medication event monitoring system

as previously described [30]) for the identified antiretroviral medication over the study period. Participants needed to show capability of responding to text messages at baseline by direct observation. Exclusion criteria were minimal in order to enhance generalizability and recruitment feasibility in that many of these individuals had several co-occurring conditions (e.g., psychiatric disorders, hepatitis C virus). Of note, plasma HIV viral load detectability was not an inclusionary criterion for the present study. Given that (1) methamphetamine use is a well-established risk factor for antiretroviral nonadherence, (2) self-reported antiretroviral adherence tends to overestimate actual adherence, (3) viral load detectability is dynamic, and costly to gather at a screening visit, and (4) recruitment of actively using methamphetamine HIV+ persons is difficult, we chose to enroll persons with both detectable and undetectable HIV viral loads.

Participants received monetary incentives for both the initial (\$50) and follow-up assessments (\$60). Participants were encouraged to use their own cell phones and were reimbursed for any additional costs incurred by participating in the study over their regular cell phone use. A mobile phone, not a smartphone, with a comprehensive texting plan was loaned to those participants who did not own a cell phone or were unable to receive text messages on their current phone (ten of 29 participants were provided a cell phone for use on the study).

2.2. Focus Groups and Intervention Development. The intervention was developed by means of a user-centered approach. Two focus groups, each with ten persons with methamphetamine abuse or dependence and HIV infection (not enrolled in the current study), were conducted to assess the feasibility of a text message intervention to improve adherence among this population, as well as to aid the development of SMS content for the intervention. In brief, focus group participants were recruited from large ongoing research studies of HIV infection and substance use. The focus groups generated broad barriers and facilitators for adherence and preferences for personalized reminder text messages to promote adherence using an mHealth intervention. Findings from these focus groups are described in a separate manuscript [31]. As a result of these focus groups, 40 reminder text messages that fall into eight reminder themes were developed for use in the intervention. We piloted the intervention with five individuals (data not included in the current study) after the initial development and made further minor modifications accordingly.

2.3. Pilot Randomized Controlled Trial. These interim results represent randomized participants with the outcomes of interest (i.e., this was not an intent-to-treat analysis). Both the iTAB ($n = 20$) and control groups ($n = 9$) received the following intervention components.

2.3.1. Medication Adherence Education. The medication adherence education included multiple components of previously successful medication interventions and pub-

lished barriers to successful medication adherence among substance users [12, 13, 32, 33]. The adherence education presented the importance of attention to medication maintenance, health benefits of adherence to ART medication, adverse medication and methamphetamine use effects, problems of adherence for methamphetamine users, and practical medication adherence strategies. The medication adherence psychoeducation was delivered via PowerPoint, lasted approximately 30 minutes, and provided time for the participants to ask questions and speak about their own experiences adhering to medications.

2.3.2. Creation Process of Personalized Reminder and Reinforcement Text Messages. During the medication adherence presentation, all participants were informed about the use of reminder strategies (e.g., creating a “note to self” to put in a visible place or writing a reminder on a calendar) to facilitate their antiretroviral adherence. Participants assigned to iTAB then selected, modified, and/or created ten personalized reminder text messages working from a list of 40 predetermined text message reminders. Participants in the control group also selected ten messages from the same list that were printed on one sheet of plain white paper for them to take home and use as they desired. For example, a participant might write the messages on sticky notes around his or her home or set reminders on their own phones as discussed in the psychoeducational portion of the study. The control group did not receive daily ART reminder text messages during the intervention.

In addition to the personalized reminder text messages, participants in the iTAB group also selected ten reinforcement text messages working from a list of 20 predetermined choices (e.g., “Great job, every dose helps” and “Keep up the good work.”). Participants also had the option of writing their own reinforcement text messages and/or modifying the existing messages. The reinforcement text messages were sent to reinforce events where the participant reported taking his or her medication.

2.3.3. Text Messages to Evaluate Daily Methamphetamine Use. Both groups received a daily text message asking if they had used methamphetamine in the last 24 hours. To protect the participants from any potential legal or personal ramifications associated with disclosure of methamphetamine use, the word “methamphetamine,” or variants thereof, were not included in the text messages. Instead, as a proxy for a direct question about methamphetamine use, at the baseline visit, participants were instructed to respond to a daily 9 a.m. message inquiring: “Have you done anything in the past 24 hours? (Y) yes (N) no.” It was further emphasized that answering either “yes” or “no” to this question would not impact individuals’ participation in the adherence study.

2.4. iTAB Specific Intervention Components. In addition to selecting individualized reminder and reinforcement text messages, participants in the iTAB group provided his/her preferred name and a description of their tracked medication (e.g., “the white pill”) to be used in the messages. Participants

were guided to use a description of the medication rather than the name of the medication itself in order to avoid a potentially stigmatizing medication name appearing in the content of the text message. The participant and examiner identified appropriate time(s) for the reminder text message (i.e., once daily or twice daily, depending on the instructions for the ART regimen). An example reminder message might read, "John, it's med time! Pls take ur big blue pill now. Pls reply (A) took (D) didn't (G) snooze." A reinforcement message might read, "Great job! Ur current adherence: 75%. Adhr when u take ur next dose: 80% (4/5 doses)."

Additionally, the automated system sent out a "noncompliance" message to the participant after three consecutive days of missed messages, and an alert was sent to the study coordinator. The study coordinator had real-time access to participant response logs to identify problems and contact participants who were having difficulties responding to the system (i.e., two days after "noncompliance" message if still no response).

2.5. Intervention Feedback. At the final visit, participants were given a standardized feedback questionnaire using Likert-type response options. Questions addressed ease of understanding/problems with reminder text messages, overall satisfaction with the study, self-perceived efficacy as it relates to participation in the study, and likelihood of using the system in the future. Questions with response options are listed in Table 2. To bolster the feedback questionnaire data, participants completed a semistructured feedback interview regarding their involvement in the study. Specifically, participants were asked to describe their experience in participating in the study and to comment on the text messages.

2.6. Other Assessments

2.6.1. 30-Day Substance Use Interview. At followup, subjects were administered a detailed substance use interview, recording both frequency and quantity of methamphetamine use. To allow for direct comparison to text message responses regarding methamphetamine use, only methamphetamine use during the 30-day study period was analyzed. Similarly, only the last 30 days of text message data were considered for subjects whose visit interval covered a period longer than 30 days.

2.7. Statistical Analyses. Comparison of positive versus negative responses to the SMS methamphetamine use messages (i.e., use versus nonuse) was examined using a matched-pairs *t*-test. Additionally, analyses examining associations between SMS methamphetamine use responses and self-reported substance use obtained by the 30-day Substance Use Interview were determined using nonparametric Spearman's rho correlations. The standardized feedback questionnaire data were summarized as response proportions for various Likert-type scales. Pearson chi-squared tests were conducted to compare responses on the standardized feedback questionnaire. Quantitative statistical analyses were performed using JMP 9.0.2 Statistical Software.

Transcripts of the semistructured feedback interview were analyzed in the following manner. The content of each interview was audio taped and subsequently transcribed by a single study investigator (Shereen Georges). The transcripts were then independently coded, based on emergent themes, by two investigators (Jessica L. Montoya & Shereen Georges). Segments of the transcript could be assigned more than one code. Disagreements in description or assignment of codes were resolved by consensus among investigators and led to the refinement of codes. The final coding structure of the transcripts was reviewed to determine the level of agreement in the codes applied. Data analysis was performed using QSR International's NVivo9 qualitative data analysis software.

3. Results

3.1. Demographics and Sample Characteristics. Participants in the present study were, on average, middle-aged non-Caucasian males with approximately one year of college education. In terms of HIV disease, approximately two-thirds had undetectable viral loads. Details of the sample are provided in Table 1. There were no significant differences between the groups for any of the variables shown. Participants were monitored for an average of 29.9 days (range: 29-30).

3.2. iTAB Condition: ART Reminder Text Messages. Among persons assigned to the iTAB condition, the overall mean response rate to medication reminder text messages was 69.0%. Participants rarely responded that they did not take ART medications (3.6%). Figure 1(a) shows the response pattern to the adherence reminder text messages.

Using a matched pairs analysis among the iTAB group, participants were significantly more likely to respond that they had been adherent than to indicate nonadherence ("took" responses: $M = 19.08$, $SD = 9.3$ versus "didn't take" responses: $M = 1.23$, $SD = 2.1$; t ($df = 12$) = -6.52 , $P < 0.001$).

Among the received responses to adherence messages, we examined the proportion of responses indicating that the individual took his/her medications (81.8%), did not take his/her medication (5.3%), or sent a snooze response indicating that they would like to receive a reminder in an hour (12.9%). That is, the denominator used in these calculations represents the number of received participant responses of any type (i.e., "took," "did not," or "snooze"), but does not include instances where the participant failed to respond to the adherence text message.

3.3. Text Message Assessment of Methamphetamine Use. The overall mean response rate to the methamphetamine use text messages was 72.9% ($M = 21.3$ responses per participant), while the overall mean nonresponse rate was 27.0% ($M = 7.9$ nonresponses per participant).

Examining response patterns among participants in both groups, we observed that participants were more likely to indicate that they were not using methamphetamine via the SMS messages than to indicate that they were using

TABLE 1: Descriptive characteristics of the study groups ($N = 29$).

	iTAB ($n = 20$)	Control ($n = 9$)
Demographics		
Age; mean (SD)	46.8 (8.3)	52.4 (6.6)
Education; mean (SD)	13.2 (2.7)	14.3 (2.7)
Male; % (#)	90.0% (18)	100.0% (9)
Caucasian; % (#)	55.0% (11)	33.3% (3)
HIV disease characteristics		
CD4 count; median [IQR] ^a	586.5 [140.5, 974.8]	606.5 [198.3, 1053.8]
Nadir CD4 count; median [IQR] ^b	148 [14.8, 493.8]	235 [153, 362.5]
HIV RNA plasma; median [IQR] ^c	1.6 [1.6, 1.9]	1.6 [1.6, 3.2]
RNA plasma detectable % (#) ^d	26.3% (5)	37.5% (3)
AIDS % (#) ^e	50.0% (2)	50.0% (2)
Time since first positive test; mean (SD) ^f	125.5 (101.0)	201.1 (104.9)
Meth use characteristics		
Age of first use; mean (SD) ^g	30.0 (12.0)	29.2 (14.6)
Total days used; mean (SD)	1634.8 (2190.8)	1516.2 (1551.5)
Total quantity used; mean (SD) ^h	1058.7 (1663.4)	1593.4 (2396.4)

Key: ^a $n = 8$, ^bNadir CD4 count is self-reported, $n = 16$; ^cin log copies/mL, $n = 27$; ^d<50 cp/mL, $n = 27$; ^eAIDS status based on the 1993 CDC classification scheme, $n = 8$; ^ftime since first positive test is calculated in months, $n = 8$; ^g $n = 25$, ^htotal quantity is in grams. Note: no significant differences were observed for any of the reported variables.

methamphetamine (“no”: 18.2 days, 62.2% versus “yes”: 3.1 days, 10.7%; $t = 10.3$ ($df = 20$), $P < 0.001$). An overall pie chart showing response rates for the SMS methamphetamine question, including instances where the participant did not respond, is shown in Figure 1(b).

Similar to the approach used above for the adherence messages and in order to control for instances where participants failed to respond to SMS message of methamphetamine use, relative values of methamphetamine use and abstinence were calculated by dividing the number of SMS messages indicating use or nonuse by the number of total responses by the participant (versus across the total study period). Using this method, participants indicated adjusted methamphetamine use 14.7% of the time and non-use 85.3% of the time across the study period.

3.4. Comparison of 30-Day Substance Use Interview and Daily Methamphetamine Text Message Data. Using data derived from the examiner administered semistructured interview reviewing methamphetamine use over the 30-day study period (and thus directly overlapping with the time period of SMS methamphetamine use reporting), participants reported actively using methamphetamine 27.3% of the time ($M = 8.2$ days). The number of SMS messages endorsing methamphetamine use was significantly correlated with the number of self-reported days of active methamphetamine use over the study period on the substance use interview ($\rho = 0.65$, $P = 0.001$). Importantly, the number of SMS messages denying methamphetamine use was not associated with days of methamphetamine use on the substance use interview ($\rho = -0.17$, $P = 0.46$), indicating divergent validity supporting SMS assessment of methamphetamine use. Non-response to

SMS messages was not associated with number of days of methamphetamine use as reported during the interview ($\rho = -0.14$, $P = 0.54$).

3.5. iTAB Standardized Questionnaire Feedback. There were no statistically significant group differences on the standardized feedback questionnaire ($P > 0.05$; see Table 2). In terms of feedback on the text messages, participants across both groups reported no difficulties with understanding the text messages (94% iTAB versus 89% control). Additionally, the majority of participants indicated that they experienced no interference with their daily activities by receiving daily text messages (76% iTAB versus 100% control). Similarly, results indicated high overall satisfaction with participation in this study (65% iTAB versus 44% control reported being “extremely satisfied”). In terms of self-perceived efficacy, iTAB participants reported that the daily methamphetamine text message (i.e., “Have you done anything in the past 24 hours?”) may have influenced their use behaviors: 35% reported they used “a lot less,” 35% reported they used “a little less,” and 24% reported using “about the same.” Control participants, on the other hand, reported using methamphetamine “about the same” 44% of the time, while 22% of controls reported using “a lot less” and 33% reported using “a little less.” Responses related to intervention influences on changes in ART medication adherence were as follows: “about the same” (29% iTAB versus 33% control), “a little better” (24% iTAB versus 56% control), and “much better” (35% iTAB versus 0% control). Overall, most participants indicated that they would participate in similar studies in the future (71% iTAB versus 78% control) and that a text messaging

TABLE 2: Participant intervention feedback as provided on a standardized questionnaire: text message ease of understanding/problems, satisfaction, self-perceived efficacy, and future direction.

Question	iTAB (n = 17)	Control (n = 9)
<i>Text message ease of understanding/problems</i>		
I had difficulties understanding the text messages		
Not at all	16 (94%)	8 (89%)
A little bit	0 (0%)	1 (11%)
Moderately	1 (6%)	0 (0%)
Quite a bit	0 (0%)	0 (0%)
Very much	0 (0%)	0 (0%)
Receiving text messages interfered with my daily activities		
Not at all	13 (76%)	9 (100%)
A little bit	1 (6%)	0 (0%)
Moderately	2 (12%)	0 (0%)
Quite a bit	0 (0%)	0 (0%)
Very much	1 (6%)	0 (0%)
<i>Satisfaction</i>		
How would you rate your overall satisfaction of participating in this study?		
Extremely unsatisfied	0 (0%)	1 (11%)
Somewhat unsatisfied	0 (0%)	0 (0%)
Neither unsatisfied nor satisfied	1 (6%)	2 (22%)
Somewhat satisfied	5 (29%)	2 (22%)
Extremely satisfied	11 (65%)	4 (44%)
<i>Self-perceived efficacy</i>		
Do you feel that the daily text message, "Have you done anything in the past 24 hours?" made you use methamphetamine		
A lot less	6 (35%)	2 (22%)
A little less	6 (35%)	3 (33%)
About the same	4 (24%)	4 (44%)
A little more	0 (0%)	0 (0%)
A lot more	1 (6%)	0 (0%)
The intervention made my overall ART medication adherence		
Much worse	0 (0%)	1 (11%)
A little worse	2 (12%)	0 (0%)
About the same	5 (29%)	3 (33%)
A little better	4 (24%)	5 (56%)
Much better	6 (35%)	0 (0%)
<i>Future direction</i>		
I would participate in similar studies in the future		
Not at all	0 (0%)	1 (11%)
A little bit	1 (6%)	0 (0%)
Moderately	3 (18%)	0 (0%)
Quite a bit	1 (6%)	1 (11%)
Very much	12 (71%)	7 (78%)
A text messaging intervention could be helpful to me in the future		
Not at all	1 (6%)	1 (11%)
A little bit	1 (6%)	0 (0%)
Moderately	3 (18%)	3 (33%)
Quite a bit	2 (12%)	1 (11%)
Very much	10 (59%)	4 (44%)

Note: no significant differences were observed for any of the reported variables.

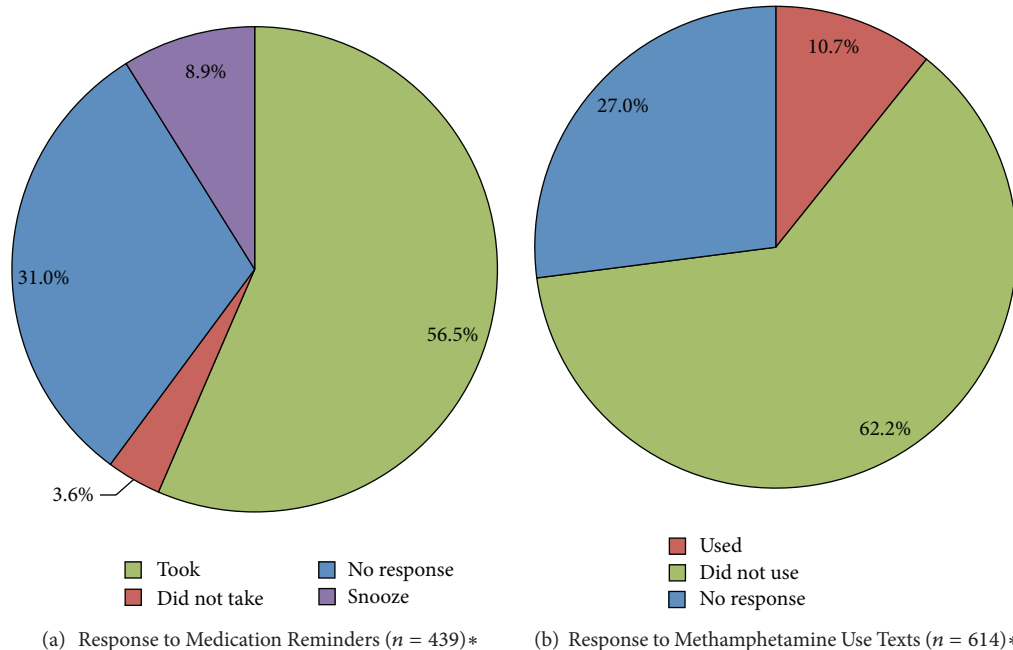


FIGURE 1: Response patterns for (a) medication adherence reminder text messages and (b) methamphetamine-use text messages. Note: * Sample size represents number of messages sent to participants not the number of participants on study.

intervention could be “very much” helpful to them in the future (59% iTAB versus 44% control).

3.6. Qualitative Feedback of Intervention. Analysis of the semistructured feedback interviews demonstrated high degree of concordance between raters of nine identified themes of 171 coded statements (mean $\kappa = 93.3$, SD = 0.21). When prompted to describe their participation experience, 17 persons indicated experiences that were coded as “positive.” The following participant quotation provides an example of a positive experience response.

“It [the study] was interesting. The reminders were helpful as far as reminding me to take my meds [...] The text asking if I’ve done anything in the past 24 hours was helpful because it actually made me ask myself on a daily basis if I did anything.” (iTAB 1)

Another participant expressed enthusiasm about the study, as it related to the daily text messages and the supportive nature of the text message content.

“I loved the day-to-day messages that I got. It was reassuring and comforting, and it was just nice knowing someone was out there looking after me.” (iTAB 2)

Not all respondents, however, indicated positive experiences. Such responses were coded as “negative” experiences in the analyses. Two respondents reported not liking certain aspects of the study. For example, one participant indicated a negative experience as it related to the questions about methamphetamine use and how it made him feel about taking medications.

“The study had a suggestive impact on my behavior which was that, rather than just to monitor my behavior, I experienced much more recreational drug use than I would have participated in had I not been in the study. I used drugs much more frequently and much more than I have ever used drugs; and to a more severe degree [...] It sort of, overall, made me resent taking the medications which I haven’t felt that before. I’ve been taking HIV meds for the last 2 years.” (iTAB 3)

In summary, the majority of participants’ interview feedback content was coded as indicating a “positive” experience, while a minority experienced “negative” consequences from participation in the study.

When asked during the feedback interview what they thought about the text messages they received during the study, the participants offered varied free responses. The following seven themes about the text messages were coded from the participants’ responses: likeable, helpful, easy, annoying, improved with time, tiring with time, and unlikeable. Many participants (i.e., one control and ten iTAB participants) expressed liking the texts in general. For example, one participant stated

“I like them [the text messages]. I like how they were all different.” (iTAB 4)

Three participants reported that they found the text messages helpful. For example, one participant stated the following.

"[The text was] very nice; it was very good. Good reminder. It helped me stay on track." (iTAB 5)

One control participant indicated that he found using the text messaging system to be easy.

"I feel like it was easy. Once I developed the position of all the keys, I was able to do it in my sleep almost." (Control 1)

One control participant described feeling annoyed at times by the text messages.

"Sometimes they were annoying." (Control 2)

One participant who indicated initial difficulty with the system indicated that the text messages improved with time.

"First bad, but then [the text messages] got better. I think I just made it harder on myself [...] The first few days were overwhelming, but after you explained it to me, it was fine." (Control 3)

In contrast, one iTAB participant reported finding the texts to be initially good but then tiring with time.

"Good, it got a little tiring towards the end." (iTAB 2)

In summary, participants indicated varied, although mostly positive, thoughts in regard to the text messages.

4. Discussion

The present study shows preliminary evidence of feasibility and acceptability of an SMS intervention to gather data on methamphetamine use and to provide adherence reminders among persons with HIV infection and recent methamphetamine use. The significant positive correlation between SMS and interview-based methamphetamine use reports provides preliminary support for the construct validity of methamphetamine use assessment via SMS. Participants also responded to the adherence reminder message system approximately two-thirds of the time, reported very few difficulties in understanding the messages, and provided positive feedback regarding the intervention. Thus, an SMS messaging system targeting both substance use evaluation and medication adherence improvement appears feasible to implement in this difficult-to-treat group.

Accurately capturing details of substance use has traditionally posed a challenging problem for substance use researchers and providers [34]. There have been recent advances using portable technology for real-time monitoring of drug cravings and use (e.g., [35]). Our preliminary evidence is consistent with these previous publications. Using calculations from the days when participants responded to SMS messages, individuals reported methamphetamine use on approximately 14.7% of days (as compared to 27.3% using a retrospective interview approach). The slightly lower rate of methamphetamine use as obtained via SMS may be attributed to (1) the potential that, on the days that participants failed to respond, they may have been using methamphetamine, (2) a

hesitancy from some individuals to report methamphetamine use via SMS, (3) the difficulty of recalling information over longer periods of time for the interview, which was conducted at the final study visit, (4) the use of a nondirect question about methamphetamine use to secure participant privacy, and/or (5) a combination of these factors. It is important to note that the SMS assessment of methamphetamine use was embedded in a study focused on medication adherence and therefore was not the exclusive focus of the study. Moreover, it is possible that receiving text message inquiries about methamphetamine use during the study may have influenced retrospective self-reporting of substance use behavior at the study follow-up visit.

On the structured feedback questionnaire, 70% of persons reported that they believed that the daily methamphetamine use text message made them use a little to a lot less methamphetamine. Qualitative feedback gathered from a semistructured interview supported the idea that, in general, participants viewed the methamphetamine text messages favorably because they helped maintain the goal of abstinence. For example, during the interview one participant described how the methamphetamine text message kept abstinence at the forefront of his mind. Thus, self-monitoring methamphetamine use via text messages may be a useful and an easy way for participants to monitor and/or gain insight to the frequency of their methamphetamine use. This may be particularly important for a group of individuals that are known to have attention and memory deficits [36].

In acknowledgment of the potential detrimental effects of inquiring about methamphetamine use on a daily basis, we observed one participant who believed that the daily messages regarding methamphetamine use may have served as a trigger for subsequent and continued use. On the standardized feedback questionnaire, this same participant endorsed that the daily methamphetamine use text made him use "a lot more." Additionally, this participant described feeling resentment regarding the need to take medications as a result of his participation in the study, even though he had been on an ART regimen for the prior two years. Although the majority of participants indicated satisfaction with the various study components, a text message specifically inquiring about substance use may not be appropriate for all current substance users. Further research is needed to determine the individual factors that influence positive and negative experiences of a daily assessment of substance use behaviors.

Participants enrolled in the iTAB condition demonstrated similar engagement with the adherence text messages as was illustrated with the methamphetamine messages (i.e., iTAB participants responded to 69.0% of the adherence reminder text messages). One interesting response pattern is that participants rarely chose the "didn't [take]" response to the adherence reminder texts. This response pattern may reflect the possibility that the participants were, in fact, largely ART adherent and simply forgot, or did not have time, to respond to the text message promptly. Alternatively, the results may indicate that participants opted not to respond rather than admit nonadherence. Given that there is rich data in why individuals fail to take medications, subsequent

interventions and feedback questions should focus on why participants rarely choose the option of reporting missed doses; future studies could then incorporate this information in development of novel approaches to better ascertain those data (e.g., softer language or reinforcers, such as “did not get to it today,” “you’ll get it next time!” versus simply “did not take”). The current iTAB system is designed such that a “didn’t [take]” response triggers a follow-up text regarding reasons for the missed dose. Participants may have wanted to avoid this additional text. Responses to the feedback questionnaire item, “Receiving text messages interfered with my daily activities,” provides some indication that fewer messages may have been more optimal. Specifically, none of the control participants indicated that the daily messages interfered with daily activities whereas 24% of the iTAB participants endorsed some interference with daily activities. Of note, iTAB participants received more text messages than the control participants thereby adding to the overall burden of participation for iTAB participants and possibly negatively impacting responding rates. In addition, there is some indication in mHealth HIV adherence research suggesting that fewer text messages may be optimal for adherence and participant engagement and satisfaction [37]. Future research is needed to tackle the trade-off between providing fewer text messages (to improve participant acceptability) and providing a sufficiently intense intervention to be effective (improve adherence). Moreover, the research literature has not yet explored the possibility of allowing participants the ability to control the frequency of messages. Detailed examinations of the content of adherence messages, ranging from simple messages not specifically addressing adherence (e.g., “How are you?”) to more complex messages intended to be motivating and targeted at health promotion (e.g., “People care about you...”, “Not taking your meds could make you resistant...”) are also warranted. Finally, determining whether there are specific HIV-infected subpopulations for which a given type of messaging may or may not work is also worthy of investigation.

Although there were not significant differences between the iTAB and control groups on the standardized feedback questionnaire, participants generally reported a positive experience. Explicitly, the feedback from participants showed that 94% of iTAB individuals were at least somewhat satisfied with the intervention as compared to 66% of control participants, 35% of individuals in the iTAB group reported that the intervention made their medication adherence “much better” as compared to 0% of individuals in the control group endorsing this response, indicating some specificity of the ART text messages to adherence behaviors. Perhaps more interesting is the fact that 56% of the control group felt that the text messages about methamphetamine use made adherence at least “a little better.” Therefore, participants in the control condition may have generalized their engagement with substance use assessment text messages (i.e., methamphetamine use) to other health behaviors beyond the content of the messages (i.e., adherence). Thus, reminder messages, perhaps regardless of content, in the context of a stated goal to improve medication adherence may be useful. The process of receiving messages on a daily basis may, therefore, instill

a sense of health behavior accountability in participants. Additionally, data from the open-ended feedback interview suggests the possibility that participants felt supported by the intervention. This finding is consistent with previous work in which social support has been identified as an important factor for positive adherence outcomes [33]. Participants also clearly indicated that they would be willing to participate in future studies, with approximately three-quarters of individuals endorsing that they would “very much” like to participate in future studies of this type. Participants additionally indicated that a text messaging intervention such as the study described here would be “very much” helpful (59%) to them in the future. These data suggest that interventions such as the one described here may be scalable and that uptake may be feasible in future studies.

There are several limitations to the current study that should be mentioned. This was a small sample of convenience taken from an ongoing RCT. As a result, the data are more descriptive than is typically reported, and we do not yet have objective outcome data on whether the intervention changed the target behavior of adherence or non-target behaviors such as substance use. With that said, participants were generally responsive and positive about the intervention. We cannot rule out that any perceived benefits of the study simply represented subject-expectancy effects (e.g., the participant feels compelled to say she or he liked the intervention). An additional limitation of reporting data from an ongoing RCT was that data were not available for all subjects for all outcomes. Recent research advocates the use of imputation-based strategies to handle “nonignorable” missing data [38], which future analyses may employ. As previously noted, a measure of ART adherence was not used as inclusionary/exclusionary criteria. Thus, although the study was designed to improve ART adherence among active methamphetamine users, it is possible that the study features are only capable of maintaining, worsening, or having no effect on adherence for already adherent participants. Finally, we are not able to examine predictors of non-adherence at the present time because outcome data are still pending. Nonetheless, the information provided, specifically as it relates to the feasibility and validity of the SMS methamphetamine use, is novel.

Future directions for mHealth interventions are numerous. Specifically, future mHealth interventions could target the reduction of substance use behaviors by replicating components of traditional substance use interventions in supportive text messaging. Alternatively, interventions could build on existing social networks by texting a friend or family member when substance use is reported, take advantage of geolocation tools by sending messages about areas that may serve as triggers for substance use, and/or provide resource information such time and location of the next Narcotics Anonymous meeting. There are challenges with the larger implementation of these interventions as well, such as who would fund or support the messaging systems in the clinic setting. For optimal delivery, systems would need to be integrated into existing large-scale electronic health systems.

5. Conclusions

In summary, the results of this preliminary analysis of an ongoing RCT to improve medication adherence and assess methamphetamine use show that SMS messaging is feasible, acceptable, and perceived to be helpful. Importantly, we provide initial support that endorsement of methamphetamine use via text messaging was externally valid in comparison to retrospective reports. Results regarding the ability of the iTAB intervention to lead to tangible changes in adherence behavior are pending the completion of this trial. mHealth interventions offer opportunities for reaching challenging and marginalized populations and may be a useful and low-cost approach to improving the health of people with co-occurring HIV infection and methamphetamine abuse or dependence.

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Research Article

Acceptability of Mobile Phone Technology for Medication Adherence Interventions among HIV-Positive Patients at an Urban Clinic

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Mobile phone technology is increasingly used to overcome traditional barriers limiting access to care. The goal of this study was to evaluate access and willingness to use smart and mobile phone technology for promoting adherence among people attending an urban HIV clinic. One hundred consecutive HIV-positive patients attending an urban HIV outpatient clinic were surveyed. The questionnaire evaluated access to and utilization of mobile phones and willingness to use them to enhance adherence to HIV medication. The survey also included the CASE adherence index as a measure of adherence. The average age was 46.4 (SD = 9.2). The majority of participants were males (63%), black (93%), and Hispanic (11.4%) and reported earning less than \$10,000 per year (67.3%). Most identified themselves as being current smokers (57%). The vast majority reported currently taking HAART (83.5%). Approximately half of the participants reported some difficulty with adherence (CASE < 10). Ninety-six percent reported owning a mobile phone. Among owners of mobile phones 47.4% reported currently owning more than one device. Over a quarter reported owning a smartphone. About 60% used their phones for texting and 1/3 used their phone to search the Internet. Nearly 70% reported that they would use a mobile device to help with HIV adherence. Those who reported being very likely or likely to use a mobile device to improve adherence were significantly more likely to use their phone daily ($P = 0.03$) and use their phone for text messages ($P = 0.002$). The vast majority of patients in an urban HIV clinic own mobile phones and would use them to enhance adherence interventions to HIV medication.

1. Introduction

Optimal adherence to HAART strongly predicts HIV viral suppression [1] and is linked to improved survival [2]. Low adherence to HAART in the United States is common with approximately only 50%–70% of prescribed doses taken [3, 4]. One meta-analysis found that those who participated in HAART-related adherence-enhancing interventions were significantly more likely to achieve 95% adherence and viral load suppression compared to the control condition [5]. A recent systematic review analyzed findings from 31 projects assessing use of SMS (short message service) technology, most for patients with HIV/AIDS in developing countries [6]; the findings pointed towards SMS as a promising and mostly well-accepted intervention strategy for use in healthcare.

The utilization of technology-based health applications for disease prevention and management has been progressively explored and expanded upon [7–11]. Promising results have been found for a number of conditions (e.g., diabetes mellitus, asthma, nicotine use, and obesity) with use of mobile phone technology [12, 13] as well as more specifically with text messaging [14, 15]. This extends to people living with HIV (PLWH), and the utilization of technology in improving education, adherence, and biological markers (CD4 count and viral load) has shown promising results [16–18]. As mobile technology access has become increasingly widespread, this seems to be an ideal tool to reach a large segment of PLWH in a cost-effective manner [19]. Thus far, technologies employed with this population have included computer-based programs [20, 21], mobile devices (both for phone counseling sessions [22–24] as well as text messaging)

[16–18, 25, 26], and paging devices [27]. These have been used as educational resources and as reminders for taking HAART, in an effort to improve disease control.

As mobile technology evolves, many people are updating their devices to smartphones, which offer a greater number of features and may allow for more creative and interactive interventions for improving adherence in PLWH. Ability and willingness to utilize this technology are key factors in ensuring the success of planned intervention strategies. This study aimed to evaluate access and willingness to use smart and mobile phone technology for promoting adherence among people attending an urban HIV clinic. To our knowledge, this is the first study to specifically address potential incorporation of smartphones in treatment paradigms.

2. Materials and Methods

2.1. Study Design and Sample. This single site study sought to evaluate access and willingness to use smart and mobile phone technology for promoting adherence among people attending an urban HIV clinic. Eligibility for the study included having a diagnosis of HIV and attending the clinic on the day of recruitment. Potential participants were recruited in May 2012. One hundred consecutive adult (18 years of age and older) HIV-positive patients attending an urban HIV outpatient clinic were surveyed. All eligible participants on the day of recruitment were given the opportunity to participate in the study. None declined. Everyone enrolled in the study completed the survey. The study was reviewed by the University of Maryland Baltimore's Institutional Review Board and given an exempt status. Participants were paid \$10 for completing the study survey.

2.2. Assessment Instruments. The study questionnaire evaluated access to and utilization of mobile phones and willingness to use them to enhance adherence to HIV medication. The present study was given an exempt status by the Institutional Review Board (IRB). All patient data was de-identified, and confidentiality was thus preserved. All study procedures occurred behind a locked, closed door.

The questionnaire included the following sections.

Demographic Questionnaire. Standardized questions were used to gather demographic information including age, gender, race, education, job description, employment history, and smoking status.

Ownership, Access, and Willingness to Use Mobile or Smartphone Devices. Questions were created de novo or adapted from that questions that were developed by the Pew Research Center, Pew Internet and American Life Project, to evaluate use of mobile and smartphone devices. Questions regarding ownership (including number of phones, types of phones, and service plan utilized); access (e.g., internet); utilization (including utilization of text messaging, phone calling, software applications, and social network sites), and willingness to use mobile devices to access and enhance medical care were employed.

The Pew questionnaire assessed the following categories of cell phone use: (1) take a picture; (2) send or receive text messages; (3) access the internet; (4) send or receive email; (5) record Video; (6) download applications; (7) look for health or medical information online; and (8) check bank account balance or do any online banking. These categories were stratified in the Pew questionnaire according to the following demographic data: gender, age, race/ethnicity, annual household income, and education level. The Results section will outline the modifications to the questionnaire that were utilized in the present study.

Center for Adherence Support Evaluation (CASE) Adherence Index [28]. The CASE index is a 3-item adherence questionnaire. The three self-reported measures of adherence are as follows: A1—frequency of “difficulty taking HIV medications on time” (no more than two hours before or two hours after the time the patient's doctor instructed to take the medication); A2—“average number of days per week at least one dose of HIV medications was missed”; and A3—“last time missed at least one dose of HIV medications.” With regards to scoring, A1 contributes a possible range of one to four points, while A2 and A3 each contributes one to six points. A score of greater than 10 is associated with good adherence. A score of 10 or less is associated with poor adherence. For those who reported missing a dose of HAART medication on the CASE adherence index were asked questions about the reasons for which they missed taking medications from the AACTG Adherence Instrument [29]. The AACTG Adherence Instrument includes 11 reasons a person may not have taken HIV medication. Questions are rated on a 4-point likert scale (never, rarely, sometimes, and often).

2.3. Analysis. Univariate distributions included percentages for dichotomous variables and means for normally distributed continuous variables. Comparison of means was made using two-sided *t*-tests, while comparison of percentages was made using the chi-square of Fischers exact method. Data was analyzed using SAS. All reported *P* values are two-sided.

3. Results

3.1. Participant Characteristics. The average age was 46.4 years (SD = 9.2). The majority of participants were males (62.6%), black (93.0%), and Hispanic (11.4% (*n* = 9)) and reported earning less than \$10,000 per year (67.3%). Most identified themselves as being current smokers (57%). The vast majority reported currently taking HAART (83.5%) (see Table 1).

3.2. Ownership and Utilization of Mobile Phones. Ninety-six percent (*n* = 100) reported owning a mobile phone. Among owners of mobile phones 47.4% reported currently owning more than one device, 75% reported using it for one year or more, and 81% report using it 5–7 days a week. Forty-two percent reported having a phone plan without

TABLE 1: Demographic characteristics of study sample.

Demographic characteristic	
Age (mean \pm SD)	46.4 \pm 9.2
Gender ($n = 99$)	
Male	62.6%
Race ($n = 99$)	
Black	93.0%
White	4.0%
Other	3.0%
Ethnicity ($n = 79$)	
Hispanic	11.4%
Education ($n = 99$)	
<High school	36.3%
High school/GED	37.4%
>High school	26.3%
Income (\$/year) ($n = 99$)	
<10,000	67.3%
10,000–30,000	23.5%
>30,000	9.2%
Taking HAART ($n = 99$)	83.5%
Current smoker ($n = 98$)	57%

TABLE 2: Reasons given for using their cell phone.

Reasons ($n = 96$)	%
Call out or receive phone calls	92
Camera or video camera	64
Send or receive text messages	59
Clock	49
Calendar/scheduling	48
Alarms	47
Calculator	41
Access the Internet	34
Listen to music	32
Send or receive email	29

a contract and the vast majority report never having to discontinue service because they could not afford it (66%). Nearly all reported using their cell phone to make telephone calls (92%). Fifty-nine percent used their phones for texting. Those who report using text messaging were significantly more likely to be younger (42.1 years \pm 9.8 versus 51.2 years \pm 7.3) compared to those who did not report texting. No other demographic factor was significant in bivariate analysis. Thirty-four percent used their phone to search the Internet. Nearly half used their phone to set alarms (47%); schedule events using a calendar (48%); and use the clock (49%) (see Table 2).

Over a quarter (28.7%) reported owning a smartphone. Those who reported owning a smartphone were significantly more likely to be younger (39.8 years \pm 8.6 versus 47.3 \pm 11.6, $t = 3.20$, $P = 0.002$) and more likely to have incomes greater than \$10,000 per year compared to those with higher incomes

(76.9% versus 40.7%, $P = 0.03$). No other demographic factor was significant in bivariate analysis.

3.3. Adherence to HAART. Among those reporting taking HAART, approximately half (51% ($n = 42$)) had poor adherence as evaluated by the Center for Adherence Support Evaluation (CASE) adherence index (i.e., CASE < 10). Bivariate analysis did not demonstrate any significant differences in demographic characteristics comparing those with poor adherence (i.e., CASE < 10) to those with good adherence (i.e., CASE > 10). Among those reporting ever missing a dose of HIV medication ($n = 25$) the most frequent reasons included (1) simply forgetting (52% reported “sometimes”); (2) sleeping through the dosage (52% reported “sometimes”); (3) being away from home (39% reported “sometimes” and 9% reported “often”); and (4) having a change in daily routine (40% reported “sometimes” and 4% reported “often”) (see Table 3).

All participants were asked how likely they would be to use a cell phone that could remind them every day when to take HIV medication. The vast majority reported (69%) that they were “likely” or “very likely” to use it. Those who said they were “very likely” or “likely” to use a cell phone to remind them to take medication were significantly more likely to report ever using their phone to receive or send text messages (68.3% versus 33.3%, $\chi^2 = 9.97$, $P < 0.002$); more likely to use the phone 7 days a week (71.9% versus 48.1%, fisher exact test, $P < 0.03$); and use their phone to set alarms (53.9% versus 29.7%, $\chi^2 = 3.47$, $P < 0.04$).

4. Discussion

The vast majority of patients in an urban HIV clinic own mobile phones and would use them to enhance adherence interventions to HIV medication. In particular we found that nearly all (96%) of the participants surveyed owned a mobile phone and nearly half (47.4%) reported currently owning more than one device. Sending or receiving text messaging was the most common additional feature that was used on the mobile devices. Although 58% reported sending or receiving a text message, this was somewhat less than the 80% of cell phone owners who are reported nationally to use their cell phone to send or receive a text message [30]. Potential reasons for this discrepancy is that the population studied is on average of an older age and thus may be more used to using landline phones. In addition, the overall education level of the population is low, and this may impact comfort level with regards to typing messages.

Nearly 70% reported that they would use a mobile device to help with HIV adherence. Those who reported being very likely or likely to use a mobile device to improve adherence were significantly more likely to use their phone daily ($P = 0.03$) and use their phone for text messages ($P = 0.002$). Text messaging has been shown to help with multiple aspects of care in a number of medical conditions (including HIV), with demonstrable improvement in medication adherence and biological markers [18, 31]. A number of studies have addressed how best to employ this instrument in optimizing compliance [26, 32, 33]. Promising results using text

TABLE 3: Response to the AACTG Adherence Instrument among participants who reported ever missing a dose of HIV medication (expressed in percentages).

List of reasons (<i>n</i> = 25)	Never	Rarely	Sometimes	Often
Simply forgot	8	40	52	0
Fell asleep/slept through dosage	16	32	52	0
Away from home (<i>n</i> = 23)	30	22	39	9
Had a change in daily routine	36	20	40	4
Fell ill or sick	42	23	31	4
Felt depressed/overwhelmed	52	12	28	8
Did not want others to notice me taking pills	68	8	12	12
Had too many pills to take	68	8	24	0
Wanted to avoid side effects	64	16	20	0
Had problems taking meds at specific time	48	32	20	0
Felt drug was toxic or harmful	76	12	12	0

messaging have been found in several studies [16–18, 25, 26, 33]. One of the seminal studies in this area was a multisite randomized controlled trial (RCT) utilizing mobile device technology to improve adherence to highly active antiretroviral therapy (HAART)—the WelTel Kenya study [33]—in which a single SMS was sent to the participants at the beginning of the week asking, “How are you?” compared to a control group receiving standard care. In terms of adherence, 62% of the intervention groups participants had greater than 95% compliance, compared to 50% compliance in the control group. The intervention group also reported greater viral suppression at 12 months. Another RCT in Kenya reported a statistically significant improvement in HAART adherence at 48 weeks in the group receiving weekly SMS reminders, as compared to the control group [26]. Interestingly, the latter study did not find a significant increase in adherence in the group receiving daily messages.

Individual patient characteristics need to be recognized in order to maximize intervention responses, particularly with regards to patterns of cell phone use. Individuals are more or less comfortable with certain aspects of their cell phones, and this degree of comfort will influence how likely they are to participate in proposed interventions. Sidney et al. conducted a study in which 139 adult HIV patients who were on regular antiretroviral therapy received a weekly interactive call as well as a neutral pictorial SMS [34]. The participants were requested to report what their adherence had been like the previous day; in the case of failure to respond, additional calls to the individual patients were made. In their study, only 11% of patients preferred only receiving an SMS, while 87% indicated a preference for the phone call reminder.

It should be noted that participants seemed to have a greater knowledge of the phone-related functions as compared with the SMS (e.g., calendar, alarm, and listening to music). This correlates with the findings in our study and makes logical sense; participants who expressed being more likely to use mobile phone reminders were those who use a greater number of functions on their phones, and use them on a more regular basis. How interactive an intervention is may also be a key component, as the individual may variably

feel more or less involved in their own care, depending on the investment the intervention team makes in ensuring they are reading the messages, as opposed to being just a passive recipient of an impersonal reminder. In an RCT performed at a teaching hospital in Boston, 23 HIV-positive participants were randomized to either receive a mobile phone message with content selected by the patient from a list of options (e.g., weather report, news, and Bible verses) or to receive a beeper [17]. Participants using the mobile device were encouraged to respond to the reminder (devices would continue to beep until this occurred), whereas the pager would only beep once, irrespective of the participant’s response. When using mixed measures of adherence, there was a statistically significant difference between the two groups at both three ($P = 0.0129$) and six weeks ($P = 0.002$), favoring the mobile phone group. Results may have been favored by the fact that there were constant reminders until a response was obtained in the intervention groups; this is important due to possible user fatigue over time—there was a decrease in participants’ responses to text messages between weeks three and six of the study. To exemplify further, in the study by Simoni et al., there was no improvement at any point of the intervention in terms of antiretroviral adherence when utilizing a two-way pager system (though there was improvement in biological markers of illness) [27]. One of the potential strategies to assist individuals who do not utilize text messaging would be to offer training in the use of a self-contained mobile application.

Randomized controlled trials (RCTs) which intervened sending individuals text messages on a weekly basis reported significant improvement in adherence [18, 26]. In the study by da Costa et al. with Brazilian women with HIV/AIDS [25], there was a nonsignificant improvement in medication compliance in the group receiving SMS multiple times during the week, and over 63% of participants reported that the intervention helped them to take their medications more regularly. Intermittently sending reminders (as opposed to everyday) has been utilized as a way of keeping patients from underestimating the importance of the messages, as well as focusing on days which have been shown to be more strongly associated with noncompliance (e.g., weekends) [25, 35].

User fatigue and trivializing of frequent messaging may be hampering factors in maintaining compliance.

In our study, approximately a quarter reported owning a smartphone, which was considerably less than the national smartphone ownership of 52% reported by the Pew Internet and American Life Project [30]. This difference may be due to the cost associated with owning a smartphone, the additional cost of the data-plan, and possibility of a less robust market penetration of these devices at the time of the study. However, with the increased penetration of smartphone ownership only growing, there is a greater opportunity to harness the utility and multiple applications associated with smartphones.

One limitation to studies of this nature is the potential difficulty in generalizing some of the findings. This has been highlighted by other authors in the past [31], emphasizing the small sample sizes of some of the studies and the limited population being studied [36, 37], although there have been robust findings in at least one study with greater power [26]. One particular concern is patient confidentiality, as their personal cell phone may not always be on their person, and access by other people to reminders on the mobile device may be a sensitive issue [25]. This is especially salient given the nature of the illness and the potentially revealing messages that may be sent to patients. On the other hand, some authors have found that the vast majority of patients do not feel that their privacy is being intruded upon [34]. Either way, there are many options which can be utilized to better protect patient privacy (a concern which has been raised before) [38]. Another limitation of the study is that we did not collect information on the total number of missed appointments an individual had up until the start of the study. This information may have improved our understanding of adherence behaviors. Finally, we did not collect information regarding HIV risk factors or biological markers (i.e., viral load or CD4 count) of disease.

5. Conclusions

Future directions include incorporation of ever-evolving technology as it becomes increasingly accessible to the general population. PLWH have shown they are open to employ these strategies in the management of their illness [34]. Development of interactive, economically viable options for PLWH has been shown to be a very promising field, which could benefit a significant portion of the HIV/AIDS population. The vast majority of patients in an urban HIV clinic own mobile phones and would use them to enhance adherence interventions to HIV medication. In addition, our study indicates that smartphone use is becoming a reality for this population, which could open new avenues for technology-based interventions, though continued data collection through well-organized RCTs is needed.

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Clinical Study

Information and Communication Technology to Link Criminal Justice Reentrants to HIV Care in the Community

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The United States has the world's highest prison population, and an estimated one in seven HIV-positive persons in the USA passes through a correctional facility annually. Given this, it is critical to develop innovative and effective approaches to support HIV treatment and retention in care among HIV-positive individuals involved in the criminal justice (CJ) system. Information and communication technologies (ICTs), including mobile health (mHealth) interventions, may offer one component of a successful strategy for linkage/retention in care. We describe CARE+ Corrections, a randomized controlled trial (RCT) study now underway in Washington, that will evaluate the combined effect of computerized motivational interview counseling and postrelease short message service (SMS) text message reminders to increase antiretroviral therapy (ART) adherence and linkage and retention in care among HIV-infected persons involved in the criminal justice system. In this report, we describe the development of this ICT/mHealth intervention, outline the study procedures used to evaluate this intervention, and summarize the implications for the mHealth knowledge base.

1. Introduction

The criminal justice system in the USA comprised prisons, jails, and community supervision programs including probation and parole and incarcerates more persons than any other nation in the world which disproportionately affects persons of color, the economically disadvantaged, and those who suffer from mental illness [1, 2]. In 2011, there were close to 7 million persons within the CJ system, among which 1.5 million were in prison, 4.5 million were on probation or parole, and close to 750,000 were held in local jails [3]. Prisons typically incarcerate sentenced individuals for periods of one year or greater, whereas jails incarcerate the majority of persons for short periods of time (days, weeks) before releasing them back to the community. A significant proportion of arrests are related to drug and alcohol use [4], with more than 50% of inmates meeting the DSM-IV criteria for drug dependence or abuse [5]. Due to drug laws and

punitive sentencing, the criminal justice system is a nexus for large numbers of substance using individuals, many of whom are living with or are at risk for HIV [6].

It has been estimated that one in seven HIV-infected persons in the USA passes through correctional facilities in a given year [7], and for these persons, release into the community has been shown to be detrimental to antiretroviral therapy (ART) adherence and maintenance of HIV care [8–10]. New and innovative methods including tools for real-time communication need to be developed to ensure ART adherence and linkage to care for HIV-infected being released from criminal justice facilities. To address these needs, we have developed information-and-communication-technology- (ICT-) based tools to facilitate the delivery of education and counseling regarding the importance of ART and care adherence during the community reentry period. If these tools are found to improve adherence to ART, enhance linkage to community care, and be cost effective, they have

the advantage of being able to be readily disseminated throughout the criminal justice system.

The Washington, DC Department of Corrections (DOC) Central Detention Facility (CDF) has conducted routine opt-out HIV testing since 2006. The HIV prevalence among the Washington, DC DOC population has been estimated to be between 5-6% and among those completing HIV testing upon entrance, close to 1% test positive and among those, 60% represent new HIV diagnoses [11]. These data strongly support the need to apply the Seek, Test, Treat, and Retain strategy [12] to control the HIV epidemic within the DC correctional facilities as part of a broader community strategy to identify persons with HIV, start antiretroviral treatment, and support linkage to and retention in care leading to improved health outcomes and reduced viral load/secondary HIV transmission. To do this effectively, however, new strategies for incarcerated populations are needed [13]. Our study, “CARE+ Corrections”, will assess a combined ICT and mHealth intervention to support HIV linkage to, and retention in, HIV care after jail release in Washington, DC, a city with one of the highest HIV prevalence rates in the USA.

2. Materials and Methods

We took a user-centered design [14] approach to adapt two well-developed ICT tools to create the CARE+ Corrections intervention. These tools included the CARE computerized counseling platform (Resources Online, Seattle, WA) and CommCare (Dimagi, Boston MA), an SMS text messaging platform. CARE is a computer-based counseling platform offering HIV risk assessment, tailored counseling, and health promotion planning in versions designed to facilitate rapid HIV testing (Test CARE) and to support ART adherence and secondary HIV prevention (CARE+). The platform uses Microsoft .NET framework with a MySQL backend; a web-based version is now available. The platform was developed using street intercept surveys to review paper prototypes [15], followed by pilot testing and then RCTs. The platform uses narrated self-interviewing to ascertain behavioral risk, assess self-efficacy/motivation, and provide tailored feedback on specific risk behaviors. Prior to developing a health promotion plan around sexual risks or medications, users watch skill-building videos appropriate to their stage of readiness for behavior change. The CARE tool now exists in several forms with different counseling content (rapid HIV testing and primary HIV risk reduction for persons with unknown HIV status and ART adherence and secondary risk reduction for persons already known to be HIV-infected), and it has been adapted for use in several languages (English, Spanish, Kiswahili) and has been used in multiple settings including HIV clinics, community-based organizations, hospitals/emergency departments, and mobile HIV testing services [16–18]. The CommCare SMS platform developed by Dimagi was originally used for data collection by community health workers [19]. In order to make it accessible to all populations, content in the CARE+ tool and the SMS texting intervention is at the 5th grade reading level.

To inform the development of the CARE+ corrections intervention, we conducted formative research with individuals released from either jail or prison (also called “returning citizens”) in the District of Columbia and Rhode Island to determine perceptions of using technology-based tools designed to facilitate linkage to community-based care and viral suppression for HIV-positive jail detainees on ART being released to the community. A complete description of this formative research is reported separately [20], but briefly, 24 qualitative interviews were conducted in Rhode Island ($n = 12$) and Washington DC ($n = 12$) among HIV positive persons with a history of recent incarceration. Participants were asked about their perceptions of the acceptability, usability, and ideas for best practices regarding ICT/mHealth tools including (1) the computer-based counseling intervention; (2) cell phone technology; and (3) text messaging. The returning citizens in this qualitative study reported positive experiences when testing an older version of the CARE+ computerized counseling platform and provided favorable feedback regarding the use of technology-based tools to facilitate linkage to HIV care in the community and adherence to HIV medications. Participants with little to no experience using a computer reported feeling comfortable using the tool and felt that the tool would provide more confidentiality than a live counselor. In addition, participants identified additional content that would be relevant for the criminal justice population, including substance use and housing support.

To develop the SMS text message component of the intervention, we reviewed published and unpublished mHealth resources to develop a library of relevant text messages ([21], W. Curioso personal communication). We then worked with the CommCare team to modify the platform so it could be used to deliver text messages from different subject categories at times and frequencies determined by the participant. In addition, we added flexibility so that participants could alternatively create personalized messages in each subject category.

3. Study Design/Protocol

3.1. The CARE+ Corrections Intervention. The intervention consists of (1) a counseling session delivered on the CARE platform prior to jail release or soon after release in the community and (2) the SMS text messaging intervention delivered in the community after release. The computerized counseling session on the CARE platform will consist of a one-time, interactive session delivered on a standalone basis on a tablet computer with a touch screen. The session is audio-narrated and 30–40 minutes in length during which participants provide responses to questions about demographic characteristics, sexual risk behaviors and attitudes, substance use, mental health, and HIV treatment and adherence. Based on this assessment, the tool provides tailored feedback messages, displays skill-building videos (topics include barriers to postrelease adherence and linkage to care, partying and HIV, you and your HIV provider, talking about condoms, and tips for remembering your meds) for participants to view



FIGURE 1: Examples of CARE+ corrections counseling content.

to support the delivered feedback, and allows users to make a postrelease health promotion plan to support ART adherence and linkage to community care. Finally, a printout provides a referral list that is customized to meet their identified needs (Figure 1). The counseling session will be delivered 2–4 weeks prior to jail release to HIV-positive detainees recruited inside jail and immediately-after release among persons enrolled through community-based organizations serving this population in the DC area. The goal of the counseling session is to motivate the detainee to anticipate barriers and facilitators to their health care, including linkage to community HIV care and adherence to HIV medications after release.

The cell phone text messaging component of the intervention will be delivered in the community after release from jail. Participants will receive a study cell phone or use an existing personal cell phone for delivery of the text messages to support the participant's linkage plan. Text messages are divided into four distinct categories addressing specific issues related to linkage to care: (1) appointment reminders; (2) medication adherence, (3) HIV secondary prevention, and (4) barriers to care (Table 1). Participants will receive additional administrative text messages related to testing the SMS system and also reminding participants of monthly study calls and regular study visits. A set of prescribed messages will be available for the participant to choose from

TABLE 1: CARE+ corrections text message library domains and examples.

Domains	Examples
Library of 10 possible appointment reminder messages or create a customized message	<ul style="list-style-type: none"> (i) Hey how you feeling? Don't forget to give a call and make your appointment (ii) You're worth it—remember your clinic appointment (iii) Your providers are here to help you—go to your appointment (iv) Call your case manager—he/she can help you get to clinic (v) Don't forget your clinic appointment—it's important (vi) Your health comes first—go to your appointment (vii) Can't remember when your next appointment is? Call the clinic to find out. (viii) Your doctor wants you to come to your appointment (ix) Going to the clinic helps you stay healthy (x) CARE+ Corrections message (staff-inputted from the CARE+ session “plan step groups’ subject selected”) . . . Remember, this was your plan: {insert from CARE+ database} (xi) Participant-created message
Medication adherence reminder sent to participant on a selected schedule	<ul style="list-style-type: none"> (i) Meds keep your body strong and healthy (ii) Don't forget your skittles! (iii) The best way to stay healthy is to take your meds on time and the right way (iv) Adherence to meds means taking your dose at the right time (v) Your meds may not work anymore if you forget to take them (vi) You got to play to win. So don't forget your meds (vii) Call your case manager—he/she can help you find ways to remember to take your meds (viii) Give meaning to your life . . . Now! (ix) Hey, take your vitamins! (x) CARE+ Corrections message (staff-inputted from the CARE+ session “plan step groups’ subject selected”) . . . Remember, this was your plan: {insert from CARE+ database} (xi) Participant-created message
Prevention reminder sent to participant on a selected schedule	<ul style="list-style-type: none"> (i) Safe sex is important. Use a condom (ii) Don't forget to wrap it or don't give it up! (iii) Did you read “Get your Freak on for Dummies”—it says you must wear a rubber! (iv) Be smart. Use a condom (v) Protect yourself and your partner. Use a condom (vi) If you are using, you may forget your meds (vii) One day at a time. Just for today, don't use (viii) Stay strong. Stay clean (ix) Staying clean is most important. Call your case manager for help (x) CARE+ Corrections message (staff-inputted from the CARE+ session “plan step groups’ subject selected”) . . . Remember, this was your plan: {insert from CARE+ database} (xi) Participant-created message
A “barrier to care” reminder message is sent to participant between registration and first check-in appointment (and sent again if person is reincarcerated)	<ul style="list-style-type: none"> (i) Remember to get a case manager: call xxx-xxx-xxxx (ii) Call your case manager, they're here to help (iii) Hey! Stay linked to your clinic so you can get your meds and care (iv) Need a ride to your appointment? Call your case manager at xxx-xxx-xxxx (v) Can't get your prescriptions? Call your clinic or case manager (vi) Get help for your housing: call xxx-xxx-xxxx (vii) Call transportation services so you can get to your clinic visits: call xxx-xxx-xxxx (viii) Check on job and training programs today (ix) Get help getting your entitlement/insurance programs: call xxx-xxx-xxxx (x) CARE+ Corrections message (staff-inputted from the CARE+ session “plan step groups’ subject selected”) . . . Remember, this was your plan: {insert from CARE+ database} (xi) Participant-created message
Welcome message sent during the week after registration	Welcome to the CARE study! We appreciate your participation. Call our staff at xxx-xxx-xxxx if you have any questions
Monthly message reminding participants to schedule their monthly check-in with study staff	Don't forget your monthly check-in meeting. Please call xxx-xxx-xxxx to be sure it is scheduled

addressing each of these domains, but participants will also have the opportunity to develop customized messages that may help to encode the messaging to increase confidentiality or that may be more motivating to their needs. For example,

instead of the message, “do not forget your upcoming medical appointment. If you cannot make it, call the clinic at xxx-xxx-xxxx,” participants may choose to customize the message to read, “Do not forget your upcoming meeting at the

church. If you cannot make it, call the pastor.” For each content category, the participant will be able to choose from several different text-message frequency options (such as daily, every other day, three times weekly, and weekly). The content and frequency of text messages in each content category can subsequently be changed by the participant at the monthly check-in encounters with study staff according to their preference. To maintain confidentiality, text messages will not contain participant names, mention of HIV infection or HIV medications, or specific providers that only provide HIV care.

The effectiveness of the combined intervention with respect to improving linkage to community HIV care after release and maintaining viral suppression on ART after jail release is being evaluated in a randomized controlled trial among 320 HIV-positive persons in Washington, DC. One-half of the study participants will be randomized to the combined CARE+ Corrections intervention. To achieve a level of intervention equity among study participants, those in the control arm will also view an educational video related to the prevention of overdose following release. All study participants will also receive standard discharge planning services. We will follow all participants for 24 weeks after release for those recruited in the DOC or from the time of study entry for those recruited from the community during which we will conduct follow-up assessments at 12-week and 24-week appointments to determine if linkage to care and adherence to HIV medications were higher in the intervention arm. Monthly check-in phone calls and/or in-person meetings will be used to update locator information and to adjust the content and frequency of text messaging. The main outcome of the trial is the overall proportion of participants in each arm with suppressed HIV viral load; secondary outcomes include attendance at community-based HIV care appointments and self-reported ART adherence. The cost effectiveness of the intervention to support linkage and engagement in care also will be assessed. Using the outcomes as observed within the trial, these analyses will examine the costs per outcome measure from both the correctional system and the community or societal perspective. Because the proposed trial is limited in the duration of observation yet induced benefits or costs may extend beyond the time horizon of the study; we will project future implications of the observed trial outcomes on health and on costs using Markov or simulation models.

The study protocol was approved by the George Washington University IRB (primary), the Miriam Hospital IRB, and the Office of Human Subjects Research Protection (OHRP).

4. Conclusions

We will test whether our combined ICT intervention consisting of an interactive tablet-based counseling tool delivered in jail before release or immediately after release combined with an SMS text messaging intervention delivered in the community can support this highly vulnerable group of returning citizens who are living with HIV. These returning citizens often are struggling with active substance use

and facing challenges related to poverty, unemployment, and unstable housing all of which create barriers to being retained in continuous HIV care [22]. We hypothesize that this mHealth tool will enable preparatory self-planning and provide ongoing support during community reentry. If found effective and cost effective, we anticipate wide-spread dissemination to criminal justice systems and related community-based organizations that may help address the needs of this vulnerable population and reduce the burden of HIV transmission in the community.

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Research Article

Feasibility and Acceptability of a Real-Time Adherence Device among HIV-Positive IDU Patients in China

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We collected data on feasibility and acceptability of a real-time web-linked adherence monitoring container among HIV-positive injection drug users (IDU) in China. “Wisepill” uses wireless technology to track on-time medication dosing. Ten patients on antiretroviral therapy (ART) at the Guangxi CDC HIV clinic in Nanning, China, used Wisepill for one ART medication for one month. We monitored device use and adherence and explored acceptability of the device among patients. Mean adherence was 89.2% (SD 10.6%). Half of the subjects reported a positive overall experience with Wisepill. Seven said that it was inconvenient, supported by comments that it was large and conspicuous. Five worried about disclosure of HIV status due to the device; no disclosures were reported. Twelve signal lapses occurred (5.4% of prescribed doses), of which one was due to technical reasons, nine to behavioral reasons (both intentional and unintentional), and two to unclear reasons. Although the technical components must be monitored carefully, and acceptability to patients presents challenges which warrant further exploration, the Wisepill device has potential for adherence interventions that deliver rapid adherence-support behavioral feedback directly to patients, including IDU. The use of wireless technology appears uniquely promising for providing time-sensitive communication on patient behavior that can be harnessed to maximize the benefits of HIV treatment.

1. Introduction

Interventions to improve adherence to antiretroviral therapy (ART) are urgently needed among HIV-positive patients, particularly in developing countries, where most of the world's HIV-infected population lives. China has experienced a major HIV/AIDS epidemic since the 1990s, with an estimated 780,000 persons living with HIV in 2011 [1]. Free ART is

available nationwide and over 126,000 Chinese patients are now on treatment. However, few ART adherence studies have been conducted in China. As it is elsewhere in the world, ART adherence is suboptimal in China in large part because HIV/AIDS is highly stigmatized [2, 3].

Recently, wireless technology has emerged as a potential tool for monitoring medication adherence in real time [4–8]. This is noteworthy given the recognized association between

late dose-timing and loss of viral suppression [9]. One promising tool, the Wisepill personal medication container (Wisepill Technologies, Cape Town, South Africa), detects the exact date and time whenever the patient opens it to access medication. It then transmits a real-time signal by general packet radio service (GPRS) to a central server where the data are recorded securely and accessible to appropriate clinicians or researchers. Wisepill and other similar devices are currently being pilot tested in various countries for different uses, such as infection control and oral hygiene [10, 11]. Although these devices have the potential to support adherence monitoring and counseling, few studies have assessed feasibility and acceptability among ART patients, particularly in developing countries [12, 13].

In a previous intervention study (Adherence for Life (AFL)), which tested the use of electronic drug monitoring (EDM) data as an information and counseling tool among primarily injection drug using (IDU) ART patients in China's Yunnan province, we found that monthly EDM-informed counseling significantly improved mean ART adherence and CD4 counts [14]. These findings indicate that use of electronic data-collecting pill containers is feasible in China and offer proof of concept that providing Chinese patients and providers with adherence data can positively impact patients' adherence.

To lay the groundwork for a larger intervention study in China using wireless technology to monitor adherence and intervene in real time among injection drug users (IDU), we conducted an in-depth feasibility and acceptability study on the use of the device in a small cohort of IDU patients. This approach allowed us to glean important information about the potential for use of the device given the sociocultural circumstances of provision of ART in China, including the following: HIV is highly stigmatized; ART is relatively new, and policies on provision have changed in recent years; use of cellphone technology, while ubiquitous and familiar, is in rapid transition; and the clinician-patient relationship, particularly when the patient is an IDU, is extremely hierarchical.

2. Materials and Methods

2.1. Study Site and Population. The study was led by Boston University's Center for Global Health and Development (CGHD), with enrollment at the Guangxi Centers for Disease Control (CDC) antiretroviral therapy (ART) clinic in Nanning, China, a large clinic that currently treats over 1,400 patients, including 1,040 adults, 370 children, and a high proportion of IDU among the adult patients. We provided ten current or former IDU patients who were being treated with ART at the clinic with a Wisepill device for one or more of their ART medications. We then monitored their use of the device for one month without the subjects receiving any information about their adherence data. This allowed us to collect pilot data on (1) acceptability of use of the Wisepill device among a Chinese patient population and (2) feasibility of monitoring patient adherence using the device in China. We limited the sample size to ten subjects due to budget constraints and to permit a rapid assessment prior



FIGURE 1: The Wisepill device.

to initiating the larger study, but often formative feasibility studies of this type have used similar sample size [12, 15].

2.2. Data. The study involved the following sources of patient data: (1) a baseline sociodemographic and health history questionnaire; (2) a brief self-report of adherence and use of Wisepill from subjects after 1 month of use; (3) continuous adherence data from the Wisepill device; (4) continuous data on reasons for signal lapses; and (5) CD4 and VL test results from patients' medical charts.

2.3. Sociodemographic and Wisepill Experience Data. The baseline and monthly interviews were administered in Mandarin Chinese by trained clinic staff. In addition to sociodemographic information and health history, the baseline instrument also covered route and duration of HIV infection, history of depression, and alcohol/drug use. Besides self-reported adherence, the monthly form included quantitative and open-ended questions covering acceptability and usability of the Wisepill device (ease/convenience of use, difficulties using the device, device storage, and potential stigma/loss of confidentiality), as well as perceptions of a possible intervention that makes use of Wisepill.

2.4. Wisepill Medication Dispenser and Adherence Monitoring Device. The Wisepill device measures $30 \times 60 \times 130$ mm and holds up to 60 small pills in two inner compartments (see Figure 1). It is powered by one rechargeable 3.7 volt 1100 mAh lithium polymer battery and contains a Subscriber Identity Module (SIM) card. The device creates a date and time stamp each time it is opened and transfers this information by general packet radio service (GPRS) to a central server in South Africa. The data are then available to research, clinic, and program personnel via a secure, internet-based interface.

2.5. Adherence Data and Measures. Data on Wisepill openings were transmitted automatically and continuously over

the month, as described previously. Investigators downloaded the data from a password-protected account on the Wisepill website. From these data, we calculated mean adherence over the one-month period using the following formula: (number of doses taken \pm one hour of dose time)/(number of prescribed doses); the approach used in the AFL study based on the adherence measure that was most significantly associated with viral load [16]. We also analyzed the adherence data self-reported by subjects in the monthly form using a visual analog scale (VAS) that indicates the proportion of total doses patient took and compared this with the adherence data generated by the Wisepill device.

2.6. Signal Lapses. We investigated all Wisepill signal lapses by a phone call to the subject within 2-3 days to determine whether a lapse was due to technical failure (battery failure, forwarder malfunction) or had a behavioral cause (missed dose, intentional nonuse). This information was recorded in a “signal lapse” report that we created for each subject over the month of data collection. We then calculated separately the proportion of technical issues and behavioral reasons among all expected Wisepill signal lapses.

2.7. Clinical Data. CD4 and viral load test results were collected from subjects’ medical charts as background information on subjects; no additional blood draws were required for the study.

2.8. Data Analysis. For all quantitative data, we calculated descriptive statistics (means, ranges, standard deviations for continuous variables, and frequencies for categorical variables). Qualitative data from the open-ended questions were analyzed using a thematic approach. All quantitative analyses were conducted using SAS 9.1 (The SAS Institute, Cary, NC, USA).

The study was approved by the Institutional Review Boards at Boston University Medical Center and the Guangxi Provincial Center for Disease Control, Nanning, China. All subjects provided written informed consent prior to enrollment. Because it was not a clinical trial, registration with <http://ClinicalTrials.gov/> was not required.

3. Results

3.1. Participants. The ten subjects were current and former injection drug users, and most (7) reported that they had been infected via shared needles. The mean age of the sample was 32.7 years (SD = 5.3); seven of the ten were men, and six were married. On average, the subjects had been on ART 40.9 months (SD = 29.4) and had a mean baseline CD4 count of 383 cells/ μ L (SD = 170 cells/ μ L). Seven had a history of depression, and two were alcoholic. Four reported having hepatitis C, and two reported having had syphilis. Nine of the ten had an educational level of middle school or lower. Most subjects had a low monthly income, typical of IDU in China. While one did not know and one reported a monthly income of 1001–5000 Yuan (approximately \$ 159–794), eight

had a monthly income of 1000 Yuan (approximately \$ 156) or less.

3.2. Wisepill Data Transmission and Adherence Lapses. The total prescribed (expected) number of device openings was 614 for the month of study. Twelve lapses occurred over the month (33 total doses); thus 33/614 or 5.4% of prescribed doses were not recorded in real time. The mean duration of real-time lapses was 2.75 doses (range 1 dose–21 doses).

Of the lapses, one was due to technical reasons, nine to behavioral reasons, and two to unclear reason. The technical problem was a lack of airtime on the SIM card, but this resulted in 21 consecutive openings missed because the subject could not be contacted. After the SIM card was reactivated, these initially missed doses were eventually received by the server, so they could be included in the subject’s adherence calculation. If these 21 openings not recorded in real time are included, the proportion of openings not measured by the device was 2.0% (12/614). Of the nine behavioral lapses, seven were due to a subject forgetting to take a dose, and one was due to a subject forgetting to close the device after use. The final behavioral lapse was due to a patient purposely not using the box (reportedly taking a dose out early and actually taking the medicine later at work).

3.3. Adherence Levels. Using Wisepill data, adherence was 97.2% (SD = 3.5%) of prescribed doses taken and 89.2% (SD = 10.6%) using a measure that incorporates dose timing (detailed previously). Using a visual analogue scale at the monthly visit, self-reported adherence was 98.5% (SD = 3.2%).

3.4. Acceptability of Wisepill Device. In quantitative questions, half of the subjects reported a positive or very positive overall experience with Wisepill; the other five reported a “somewhat negative” overall experience. Seven were willing or very willing to participate in a larger intervention study. Eight found the device very easy to use. However, seven said that it was inconvenient or very inconvenient. Five were somewhat or very worried about disclosure of their HIV status due to the device; no disclosures were reported.

3.4.1. Ease and Convenience of Use. In the open-ended questions exploring acceptability and usability of the Wisepill device (ease/convenience of use, difficulties using the device, device storage, and potential stigma/loss of confidentiality), six patients reported a positive feeling about the device, of whom four said knowing that someone was monitoring their adherence helped them take their medications more regularly. As two subjects explained:

Knowing that someone is monitoring my medication spurs me to take my medication better. The pill box is just a normal drug container; there is nothing good or bad about it.

I like the pill box, because first of all, there is no special label on the pillbox (comparing with the medicine bottle, on the instruction label there is information

about HIV medicine), so no one will know what medicine I am taking; second, it records the time of medicine taking, which helps me take doses better.

Three reported a negative experience. One said the device was inconvenient to carry and therefore a burden, and one did not like the feeling of being watched (this one had both positive and negative feelings as he/she also said using the device was a helpful reminder).

3.4.2. Difficulties of Use Including Potential Stigma and Loss of Confidentiality. When asked about difficulties encountered using the Wisepill device, one subject reported having no problem with the device at all, while another had no major problem because he/she “always carried it in a bag.” However, eight indicated that the device was inconvenient or felt uncomfortable using it. Many found it too big; one patient thought it should be wider. Additional feedback included the following: two subjects did not like that it could only hold one drug; two worried that drugs would be damaged while carrying the device; two were concerned about others seeing it. These were typical statements:

It is too big to carry. I have a feeling of unease using the Wisepill in front of other people. I never take the pillbox outside.

The pillbox is too big. I have a big concern that using this pill box could disclose my HIV status.

3.4.3. Device Management and Storage Strategies. Subjects reported a variety of ways to manage their use of the device. One compensated for the inconvenience by always taking doses at home, another changed his/her dose time to avoid carrying the device to work, and one told friends that the drugs were a hepatitis medicine instead of HIV-related medications. Seven of the patients reported keeping their device at home exclusively; six seemed to keep it hidden, whether at home or outside. Patients were also asked what they did with the device when they traveled. Half reported never taking the device away from home; the other half reported having found ways to travel with the device. One of the former elaborated that

I have no job in the past one month. I always take my medicine at home. Even when I go to parties or meeting friends, I did not bring the pill box with me. That's why, sometimes when I returned home late, I also took my medications late.

3.4.4. Reminder Messages and Willingness to Participate in a Larger Study. When asked specifically about text messages, only four patients thought reminder messages would be helpful. Of the six who did not, one was a truck driver and could not read messages while driving, one did not read text messages at work, and one thought that text message reminders are not much more useful than an alarm.

When asked about possibly participating in a larger study using Wisepill with text message reminders, six said they would be willing to participate, of whom four said it would

help them take their ART medications on time. As two explained:

Yes, the reminder message could help. I usually read short messages. I hope the message could be as simple as possible, like a symbol would be good.

Yes, the reminder message could help. The SMS could just be “It's time to take your medication, do not forget”. I do not worry about other people (knowing) my health status through this message.

Three subjects were not willing to participate in a subsequent larger study. All three did not think text messages would work; two said the box was too inconvenient. One was concerned about possible disclosure of status via messages, and one did not use text messages.

4. Discussion

This study has demonstrated that use of a real-time, SMS-enabled web-linked ART adherence monitoring system is technically feasible in an urban Chinese clinical setting among predominantly IDU HIV patients. Only a few minor technical difficulties were encountered and easily addressed; the issue of acceptability is more complex.

The technical lapses due to inadequate time on the SIM card bear some discussion. In terms of adherence measurement, these types of lapses do not represent a major concern; as long as there is adequate battery power in the device, the openings are recorded but are just not transmitted to the server until the airtime on the SIM card is replenished. In other words, the transfer of information is delayed, but the data needed for characterizing adherence rates are not affected. Because the system did not work perfectly for capture of data in real time, however, this presumably would have an impact on its effectiveness as a tool for promoting adherence, including triggered SMS reminders. Moreover, if an intervention was designed to send an SMS message when the server does not receive a signal within a set time window, then the server would send an SMS reminder to the participant regardless of the reason for the lapse. In such an intervention context, the subject with the lapse of 21 doses in the present study would have received 21 reminder messages even though she/he actually used the device correctly and took all of the doses on time. Readers in the USA should also note that in most other countries including China, a mobile phone that has run out of SIM card airtime can still receive text messages. The main risk here is that patients might become annoyed. In short, the logistical requirements of the device are real (airtime, out of range issues, and battery power) and can cause some problems. A technical lapse due to the airtime issue does not preclude us from measuring and understanding adherence behavior, but to take full advantage of the technical capacity of the device, researchers and clinicians must pay close attention to these logistical requirements.

The study raises greater concerns about the acceptability of the device to patients. Several subjects complained about the size and inconvenience of the device. To overcome these

concerns, consideration should be given to the design and appearance of the device. Some ideas might include devising a carrying case or bag to make the device less conspicuous or creating a cell phone case that would hold both the phone and the monitoring device. A smaller less conspicuous box, perhaps retaining the removable pill containers for easy refilling that Wisepill currently offers, might also be considered. In addition, although no disclosures were reported during the pilot, subjects did raise concerns about disclosure and stigma due to the device in both closed and open-ended questions. This is a potential problem with the device which deserves further attention [8]. That said, the extent to which even our small sample of patients devised a variety of ways of using the device is striking. Input from patients with experience with the device will be critical to thinking about how to make it easier and potentially less stigmatizing to use in daily life.

A limitation of the study is the small sample of ten individuals who used the device, with no accompanying intervention that might foster more positive feelings about the device. The full wireless capabilities of the device were not tested and could not be appreciated. It is possible that subjects' attitudes might change after having the experience of receiving SMS reminders, particularly if they could see their adherence increase or their health improve as a result.

The technical findings from the study are more persuasive, but the qualitative aspects are by definition limited and subjective. Therefore, we revised aspects of the subsequent larger randomized controlled trial currently underway in the same clinic, including our data collection instruments, to allow more extensive collection of qualitative data. This will allow us to obtain more conclusive data from the larger study, in which intervention subjects receive a tailored SMS reminder message if they are more than 30 minutes late taking a dose. Those who are suboptimal adherers (<95%) also review a printout of their adherence behavior over the previous month in counseling sessions. The design of this larger study will permit us to collect quantitative and qualitative data on acceptability over time for both intervention and control groups and thereby gain a deeper understanding of the evolution of acceptability of the device over time in this Chinese patient population.

5. Conclusions

Although the technical logistical requirements must be monitored carefully, and acceptability to patients is not perfect, the Wisepill device shows potential for adherence interventions that deliver rapid adherence-support behavioral feedback directly to patients, including IDU, as well as in clinical settings. The fact is that each current adherence monitoring device or technology has its advantages and disadvantages, as well as a certain measure of intrusion for patients. Wisepill involves a high degree of intrusion but also a high degree of accuracy as well as the unique benefit of real-time monitoring which allows for real-time interventions to improve adherence before the substantial negative impact of poor adherence can accumulate to cause substantial harm. Other adherence measures (self-report, pill count, pharmacy

refill, e.g.) may involve a lesser burden for patients, but they are less accurate and do not permit real-time interventions. Electronic drug monitoring reviewed at the time of clinic visit (such as the Medication Event Monitoring System (MEMS)) imposes a similar degree of intrusion on patients compared to Wisepill, but again, there is no opportunity to intervene in real time. Thus, while the Wisepill delivery system is not perfect, we believe that it holds substantial advantages over other currently available adherence monitoring options. Just as so many recent technological advances offer the possibility of client-centered approaches, the use of wireless technology appears uniquely promising for providing time-sensitive communication on patient behavior that can be harnessed to maximize the benefits of HIV treatment.

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Research Article

Engagement in HIV Medical Care and Technology Use among Stimulant-Using and Nonstimulant-Using Men who have Sex with Men

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Aims of this study were to assess the associations between stimulant use and attitudes toward and engagement in HIV medical care and to examine technology use among stimulant-using and nonstimulant-using men who have sex with men (MSM). HIV-positive MSM ($n = 276$; mean age = 42 years; 71% white, non-Hispanic; 43% with college degree) completed an online survey in 2009. Most men (69%) had not missed any scheduled HIV medical appointments in the past year, while 23% had missed at least one, and 9% had not attended any appointments. Stimulant use was significantly associated with not attending any HIV medical appointments in the unadjusted model (relative risk ratio (RRR) = 2.84, 95% CI [1.07, 7.58]), as well as in models adjusted for demographic (RRR = 3.16, 95% CI [1.13, 8.84]) and psychosocial (RRR = 3.44, 95% CI [1.17, 10.15]) factors (P s < 0.05). Fewer stimulant-using than non-stimulant-using men rated HIV medical care a high priority (57% versus 85%; $P < 0.01$). Few significant differences were found in online social networking or mobile phone use between stimulant-using and non-stimulant-using MSM, even when stratified by engagement in HIV care. Findings indicate that stimulant use is uniquely associated with nonengagement in HIV medical care in this sample, and that it may be possible to reach stimulant-using MSM using online social networking and mobile technologies.

1. Introduction

Studies show that engagement in HIV medical care is challenging for many persons with HIV infection [1, 2]. Just over three quarters (77%) of persons who are aware that they have HIV are estimated to be linked to HIV care in the USA; even fewer (51%) who are aware that they have HIV are estimated to be retained in HIV care [3]. Illicit drug use is a significant risk factor for poor engagement in HIV medical care [4]; however, the specific influence of stimulant use on retention in HIV care is not presently well understood, despite its pervasive use in one of the populations most

heavily burdened by HIV infection—men who have sex with men (MSM). Stimulants are a class of drugs known to produce a sense of euphoria and increase sexual arousal [5] and include methamphetamine, amphetamine, cocaine, and MDMA (“ecstasy”) [6]. In a study of demographic and psychosocial factors associated with stimulant use among 711 MSM living in San Francisco in 2002-2003, the prevalence of any stimulant use in the past 6 months was 23% [7]. In that study, the most commonly reported stimulant was methamphetamine (17% of the sample), followed by powder cocaine (10%), crack cocaine (2%), and amphetamine (1%). Younger age, HIV-positive status, depressed mood, and

sexual compulsivity were associated with any stimulant use in the past 6 months [7]. Studies of HIV-positive MSM in USA show that methamphetamine use ranges from approximately 10% to 32% [8–12]. Taken together, current evidence suggests that stimulant use is prevalent among HIV-infected MSM.

Stimulant use among people with HIV has been associated with more rapid disease progression, including faster progression to AIDS, development of AIDS defining illnesses, and hastened AIDS-related mortality [13]. Studies consistently show that stimulant use is associated with decreased odds of antiretroviral therapy (ART) utilization, poorer ART adherence, difficulties with ART persistence (i.e., duration of time continuously on ART), and elevated HIV viral load [13–20]. In the era of HIV treatment as prevention (TasP), innovative approaches are needed to promote engagement in HIV care among stimulant users in order to achieve sustained viral suppression and decrease the likelihood of onward HIV transmission to their uninfected sexual partners [21].

Few, if any, studies have examined the association between stimulant use and poor engagement in HIV medical care. In interviews with 20 HIV-infected MSM who reported that they seroconverted in the context of methamphetamine use, 60% of men reported that methamphetamine use compromised their self-care behaviors, including attending medical appointments [22]. The most common reasons reported by men were that methamphetamine use caused them to forget to engage in self-care behaviors and that it reduced their motivation to engage in these activities. Although more research needs to be conducted to assess attitudinal barriers to engagement in HIV care among stimulant users, at least one study of barriers to attending drug treatment among stimulant users living in the Southern USA showed that a relatively low proportion of participants perceived the need for treatment (19%). Engagement in substance abuse treatment has a number of similarities with engagement in HIV medical care, including the prioritization of health behaviors and the potential for disruption of one's regular routine.

Stimulant-using persons may be less likely to prioritize their HIV care because of the acute effects of substance use or withdrawal, mental health comorbidities, or chaotic life circumstances [23, 24]. An emerging innovation in providing critical behavioral intervention messages or components in natural environments to hard-to-reach patient populations is to use available mobile and social networking technologies. It is estimated that 67% of USA Internet-using adults use social networking sites, and 46% of USA adults own a smart phone [25, 26]. Technology-based interventions for people with HIV have proliferated in recent years, including the use of mobile phone counseling, text messaging and interactive computer-based programs [27]. A recent study showed beneficial impacts of text messages to reduce methamphetamine use and sexual risk behavior among methamphetamine-using MSM [28].

Despite the potential reach and impact of technology to promote retention in HIV care among persons where disorganization and challenges to prioritization of self-care may be particularly acute, little (if any) information is available about social networking site and mobile phone

use among stimulant-using persons with HIV. Technology-based intervention approaches to promote engagement in HIV care, and other aspects of self-care would offer unique efficiencies in reach and coverage to the extent that the targeted population actually use these technologies. The purpose of this study with HIV-positive MSM was to (1) assess the associations of stimulant use with attitudes toward HIV medical care; (2) examine whether recent stimulant use is associated with poorer HIV medical care engagement, and (3) compare social networking site and mobile phone use between stimulant-using and nonstimulant-using MSM.

2. Methods

2.1. Participant Recruitment. Participants responded to an online survey between July and November, 2009. Inclusion criteria to participate in the online survey were 18 years of age or older, English speaking, self-reported HIV-positive status, and United States residence. A total of 387 participants completed the online survey. For the purpose of this study, the following exclusion criteria were established: 58 were excluded for not being born biologically male, 16 were excluded for not self-identifying as gay or bisexual, 36 were excluded for being diagnosed with HIV within 1 year of answering the survey (as HIV medical appointment engagement was assessed for the past 12 months), and 1 was excluded for not providing sufficient data. Thus, the final dataset used for the purpose of this study included 276 HIV-positive MSM.

2.2. Study Procedures. Study procedures are described in greater detail elsewhere [29]. Briefly, participants were recruited in several ways: (1) 53.5% were recruited from banner advertisements on, or e-mail newsletters from, HIV-related websites; (2) 12.8% were recruited from targeted ads on Facebook; (3) 4.5% were recruited from an e-mail sent to men who had participated in a prior study by the research team and requested to be notified of future research opportunities; (4) 1.6% were recruited from an online search; 27.6% were recruited from fliers and postcards at AIDS Service Organizations (ASOs) with information that directed participants to the study website. Regardless of how participants were recruited, they must have had a valid e-mail address to access the screening questionnaire, and they must have completed the survey online. Multiple security measures were used to block repeated attempts to screen for eligibility, including cookies placed in browsers, e-mail address screening, and IP address screening. Participants who were deemed valid and completed the survey were reimbursed \$25 for their time.

2.3. Measures

2.3.1. Demographic Variables. Demographic characteristics examined for the purpose of this study included age (in years); education (less than 8th grade; 8th to 11th grade; high school graduate/GED; technical school; some college or associates degree; college bachelor degree; graduate or

professional degree); race (African American, white, Asian or Asian American; American Indian or Alaskan Native; or Native Hawaiian or other Pacific Islander); ethnicity (Hispanic/Latino); and years living with HIV. Participants were asked to self-report the result of their most recent CD4+ count with the question: “T-cell (also called CD4+) count usually ranges from 0 to 1600 cells/mm³. What was your most recent T-cell (CD4+) count?”

2.3.2. Psychosocial Variables. Psychosocial variables used in this study were depression, life chaos, and alcohol use. Depression was measured with the 10-item *Center for Epidemiologic Studies-Depression* Scale (CES-D) [30], a widely used measure of depression in research studies ($\alpha = 0.88$ for this sample of MSM). A cut-off score of 10 or higher was used to indicate significant depressive symptoms [30, 31].

The *Life Chaos* Scale is a 6-item measure of whether someone has a stable and predictable lifestyle and has been shown to be psychometrically adequate among HIV-positive persons in a prior study ($\alpha = 0.67$) [32]. Higher life chaos scores indicate greater stability in daily routine, the ability to plan and anticipate the future (including making appointments) and being on time. Cronbach's alpha for the Life Chaos Scale among this sample of MSM was 0.76.

The *Alcohol Use Disorders Identification Test* (AUDIT) [33] was administered to determine whether participants were at risk for hazardous alcohol consumption or alcohol dependency. Prior research showed that 92% of persons who were diagnosed with an alcohol use disorder were classified as having harmful or hazardous alcohol use scored 8 or more on the AUDIT (the cut-off score for harmful and hazardous alcohol use) [33]. For the purposes of analysis, men with an AUDIT score between 0 and 7 were categorized as having no alcohol problem, between 8 and 14 as having a possible hazardous drinking problem, and 15 or higher as having possible alcohol dependency [34].

2.3.3. Stimulant Use. Drug use was assessed by asking participants to indicate the number of times they had used any of the following 10 illicit substances in the past 30 days: codeine purchased on the street, powder cocaine, crack cocaine, amphetamines, methamphetamines, GHB, ketamine, ecstasy, heroin, or cocaine and heroin mixed together. Consistent with federal definitions of illicit stimulant drugs [6], cocaine, crack, amphetamines, methamphetamines, and ecstasy were grouped as stimulant drugs for the purpose of this study. Participants who reported any stimulant use in the past 30 days were compared to those who did not report any stimulant use in the past 30 days.

2.3.4. Engagement in HIV Medical Care. Engagement in HIV medical care was assessed using a series of items, with skip patterns depending on participants' responses. First, all participants were asked “in the last 12 months, about how many medical appointments for HIV/AIDS did you make (this means all appointments you made, whether or not you missed them)?” with response options that included the following: “I have never had this kind of appointment;” “I have had

this kind of appointment, but not in the last 12 months; to options from 1 to 12 appointments. Next, participants who reported scheduling 1 or more medical appointments for HIV/AIDS were asked “of the medical appointments you made for HIV/AIDS in the last 12 months, what percent of the time did you miss or cancel those appointments for any reason without rescheduling? (note: if your doctor or nurse cancelled the appointment, do not include it in your count),” with response options ranging from 0 to 100 percent. The proportion of HIV medical care appointments to those scheduled is a common measure of treatment engagement [35].

Attitudes toward engagement were assessed with two 5-point Likert-scale items. First, all participants were asked, “when thinking about all of the things you need to do and take care of in your life, how important is HIV/AIDS medical care to you?” with options from “not a priority at all” (1) to “the most important priority” (5). Second, men who attended one or more appointments for HIV in the past year were asked: “how confident are you that you can attend all of the medical appointments for HIV/AIDS that your doctor recommends in the upcoming year?” with response options ranging from 1 (very unconfident) to 5 (very confident).

2.3.5. Technology Use. To assess regular social networking website use, participants were asked to indicate which of the following websites or features they use at least once a week: *Bebo*, *The Body.com* connect bulletin boards, *Facebook*, *LinkedIn*, *MySpace*, *Poz.com* community section blogs or forums, *Xanga*, or “other” (with a write-in option). Participants were asked to report what kind of phone they had, with options including smart phone brands (defined as “a smart phone allows easy Internet browsing and may have other capabilities beyond voice calls and text messaging,” e.g., *iPhone*, *Blackberry*), a mobile phone without smart phone features, or no mobile phone.

2.4. Analysis. Analyses were conducted using Stata (version 12.1 for Mac) [36]. Demographic and psychosocial variables were collapsed into groups shown in Table 1. Group differences between stimulant-using and nonstimulant-using men assessed using *t*-tests (for continuous variables) or nonparametric tests (e.g., chi-square or Fisher's exact) where appropriate.

Measures of HIV medical care engagement vary considerably depending on the study [37], and new data show that annual monitoring of CD4+ T-lymphocyte may be warranted for clinically stable patients [38]. We assumed that participants must have reported scheduling and attending at least one scheduled appointment in the previous year to be considered minimally engaged. (It may be argued that scheduling and attending one HIV medical appointment in the past year is equivalent to not being engaged in HIV care. Seven men (or 3% of the sample) scheduled and attended only one HIV medical care appointment in the past year. The estimated effect of stimulant use on engagement was not altered if these 7 men were categorized as “Not in HIV Medical Care” (versus categorizing them in the “No

TABLE 1: Sociodemographic and psychosocial characteristics.

	Total (<i>n</i> = 276)	No stimulant use (<i>n</i> = 232)	Stimulant use (<i>n</i> = 44)	<i>P</i> value
	M ^a (SD) ^b	M (SD)	M (SD)	
Age (in years)	42.2 (9.9)	42.5 (9.9)	40.3 (9.6)	0.18 ^f
Years with HIV	9.8 (7.2)	9.6 (7.1)	11.0 (7.4)	0.25 ^f
CD4+ count ^c	596.5 (318.7) ^c	571.9 (324.2) ^d	556.4 (290.4) ^e	0.78 ^f
Life chaos	15.4 (4.9)	15.1 (4.7)	17.1 (5.8)	0.01 ^f
	Column % (<i>n</i>)	Column % (<i>n</i>)	Column % (<i>n</i>)	
Race				
White, non-Hispanic	70.6 (195)	72.0 (167)	63.6 (28)	0.44 ^g
Black	10.1 (28)	10.3 (24)	9.1 (4)	
Hispanic	15.2 (42)	13.8 (32)	22.7 (10)	
Other	4.0 (11)	3.9 (9)	4.6 (2)	
Education				
High school or less	11.2 (31)	11.2 (26)	11.4 (5)	0.34 ^h
Tech school or some college	46.0 (127)	47.8 (111)	36.4 (16)	
College degree	42.8 (118)	41.0 (95)	52.3 (23)	
Depressive symptoms ⁱ				
No	36.4 (99)	37.1 (85)	32.6 (14)	0.57 ^h
Yes	62.5 (173)	62.9 (144)	67.4 (29)	
Alcohol use ^j				
No alcohol problem	68.1 (188)	72.0 (167)	47.7 (21)	<0.01 ^h
Hazardous drinking	17.8 (49)	17.2 (40)	20.5 (9)	
Alcohol dependency	14.1 (39)	10.8 (25)	31.8 (14)	

^a Mean; ^b standard deviation; ^c 9 missing cases, median = 524; ^d 6 missing cases, median = 527; ^e 3 missing cases, median = 522; ^f *t*-test; ^g Fisher's exact test; ^h chi-square test; ⁱ using the 10-item CES-D scale [30]; ^j using the AUDIT [33].

Missed Appointments" group). Next, men were grouped into one of three engagement in HIV medical care categories: (1) participants in the "No Missed Appointments" group reported scheduling at least 1 medical appointment for HIV in the past year and not missing any of their scheduled appointments; (2) the "Missed Appointment(s)" groups were those who scheduled two or more appointments in the past year and reported missing between 1% and 99% of those appointments; or (3) the "Not in HIV Medical Care" group included men who either (a) had not scheduled any medical appointments for HIV in the past year or (b) reported missing all of their scheduled appointments for HIV in the past year.

Responses to items assessing attitudes toward HIV medical engagement were dichotomized by grouping the responses of the two most positive response options toward HIV medical care (e.g., "a high priority" and "the most important priority") together and grouping less positive attitudes (e.g., "not a priority at all," "a low priority," or "Not any more of a priority than other things in my life") together. Differences in attitudes toward HIV medical care between stimulant-using and nonstimulant -using men were assessed using chi-square statistic.

The effect of stimulant use in the past 30 days (two levels: yes versus no) on HIV medical care engagement (three

levels: No Missed Appointments, Missed Appointment(s), and Not in HIV Medical Care) was assessed using a series of three multinomial regression models with additional blocks of variables included for each successive model: (1) an unadjusted model; (2) a model including demographic variables that were at least marginally ($P < 0.10$) associated with treatment engagement in the bivariate analyses; and (3) a model including demographic and psychosocial variables that were at least marginally associated with treatment engagement in bivariate analyses. Stata provides an option to calculate the relative risk ratio (or RRR) from the multinomial log-odds coefficient. The RRR is interpreted as the change in the outcome relative to the referent group (the "No Missed Appointments" group) for each unit change in the predictor variable given that all other variables in the model are held constant [39]. The RRR often is interpreted similarly to an odds ratio, however, used when conducting multinomial logistic regression analyses.

Technology use variables were collapsed into those shown in Table 4 and assessed for the overall sample and by engagement in HIV medical care. Because Facebook was widely used, its use was assessed separately from other types of social networking sites. Group differences in any regular social networking site use, Facebook use, other (than

TABLE 2: Engagement in HIV care and attitudes toward HIV care among stimulant and nonstimulant-using men who have sex with men.

	Total Column % (<i>n</i>)	No stimulant use Column % (<i>n</i>)	Stimulant use Column % (<i>n</i>)	<i>P</i> value ^a
Attitudes toward engagement in medical care				
<i>How important is HIV/AIDS medical care to you?</i> ^b				
Low priority	19.6 (54)	15.1 (35)	43.2 (19)	<0.01
High priority	80.4 (222)	84.9 (197)	56.8 (25)	
<i>How confident are you that you can attend all of your medical appointments for HIV/AIDS?</i> ^c				
Low confidence	36.1 (91)	34.4 (74)	46.0 (17)	0.18
High confidence	63.9 (161)	65.6 (141)	54.0 (20)	
Engagement in HIV medical care ^b				
No missed appointments	68.8 (190)	71.6 (166)	54.6 (24)	0.05
Missed appointment(s)	22.5 (62)	21.1 (49)	29.6 (13)	
Not in HIV medical care	8.7 (24)	7.3 (17)	15.9 (7)	

^aChi-square tests; ^bincludes full sample ($n = 276$); ^cincludes only participants who attended 1 or more HIV care appointments in past year ($n = 252$).

Facebook) social networking site use, and mobile phone use were assessed with chi-square or Fisher's exact statistics.

3. Results

3.1. Participants. The men were on average 42 years of age and had been living with HIV for 10 years (Table 1). Most men identified as white (71%), highly educated (43% had a college degree), and experiencing significant depressive symptoms (63%).

3.2. Stimulant Use. Sixteen percent ($n = 44$) of men reported using one or more types of stimulant drugs in the past 30 days. Among men reporting stimulant use, the most common was methamphetamine (54.5%), followed by cocaine (38.6%), ecstasy (20.5%), crack (18.2%), and amphetamine (18.2%). As shown in Table 1, stimulant-using men reported significantly higher life chaos scores (mean = 17.1 versus 15.1, $P = .01$) and possible alcohol dependence problems (32% versus 14%, $P < .01$) compared to nonstimulant-using men. (When alcohol use is categorized as alcohol dependency (1) versus not (0), a significantly higher proportion of stimulant-using (32%) participants continues to report alcohol dependency than nonstimulant -using participants (11%), $\chi^2(1, N = 276) = 13.50, P < 0.001$).

3.3. Attitudes toward Engagement in HIV Care. Overall, most (80%) men reported that HIV medical care is a high priority (Table 2). Among men who had attended at least one HIV medical appointment in the past year, nearly two-thirds (64%) were confident that they could attend all of their HIV medical appointments in the upcoming year.

A smaller proportion of stimulant-using men than nonstimulant-using men rated HIV medical care as a high priority (57% versus 85%; $P < 0.01$). Although a lower percentage of stimulant-using men reported high confidence to attend all of their HIV medical appointments in the

upcoming year than nonstimulant-using men (54% versus 66%), this difference was not statistically different.

3.4. Association of Stimulant Use with HIV Treatment Engagement. Table 2 shows the proportion of men who reported no missed HIV medical care appointments, missing one or more appointments, or not attending any HIV medical care appointments in the past year. Over two-thirds (69%) of men did not miss any of their HIV medical care appointments, while 22% missed at least one, and 9% had not attended any of their appointments. The nonparametric analysis showed that stimulant-using men were more likely than nonstimulant-using men to miss one or more HIV appointments (30% versus 21%) and not attend any HIV appointments (16% versus 7%) in the past year ($P = 0.05$).

Table 3 shows the unadjusted and adjusted effects of current stimulant use on engagement in HIV medical care in the past year. Because age ($P = 0.01$), racial/ethnic minority ($P = 0.06$), education ($P < 0.01$), depression ($P = 0.04$), and life chaos ($P < 0.01$) were associated with HIV medical care engagement in the bivariate analyses at the $P < 0.10$ level, these factors were included in Models 2 and 3. In contrast, years living with HIV, alcohol use, and CD4+ count were not associated with engagement in HIV medical care in bivariate analyses ($P > 0.10$) and, therefore, were not retained in the models.

Stimulant users were significantly more likely to report not attending any HIV medical appointments in the past year than to report not missing any of their HIV medical appointments in the unadjusted model (Model 1: RRR = 2.84, 95%CI[1.07, 7.58]), as well as in models adjusted for demographic (Model 2: RRR = 3.16, 95%CI[1.13, 8.84]) and demographic and psychosocial (Model 3: RRR = 3.44, 95%CI[1.17, 10.15]) factors (P s < 0.05). In addition, nonwhite race/ethnicity was associated with not attending any HIV medical care appointments in Model 3. In contrast, stimulant use was not significantly associated with missing one or more HIV medical care appointments. However, higher levels of life chaos were significantly associated with missing

TABLE 3: Estimated effect of recent (past 30 days) stimulant use on engagement in HIV care in past year.

Ref. no missed appointments	Model 1 ^a RRR ^d (95% CI ^e), <i>P</i> value	Model 2 ^b RRR (95% CI), <i>P</i> value	Model 3 ^c RRR (95% CI), <i>P</i> value
Missed appointment(s)			
Stimulant use	1.84 (0.87, 3.87), <i>P</i> = 0.111	1.99 (0.91, 4.37), <i>P</i> = 0.085	1.73 (0.72, 4.16), <i>P</i> = 0.218
Age	— ^f	0.98 (0.94, 1.01), <i>P</i> = 0.121	0.97 (0.94, 1.01), <i>P</i> = 0.127
Nonwhite race/ethnicity	—	1.56 (0.82, 2.96), <i>P</i> = 0.173	1.68 (0.85, 3.32), <i>P</i> = 0.136
Education			
High school or less	—	Ref.	Ref.
Technical school/some college	—	0.45 (0.19, 1.08), <i>P</i> = 0.075	0.51 (0.20, 1.28), <i>P</i> = 0.152
College degree	—	0.20 (0.08, 0.52), <i>P</i> = 0.001	0.21 (0.08, 0.58), <i>P</i> = 0.003
Depression	—	—	1.04 (0.48, 2.27), <i>P</i> = 0.915
Life chaos	—	—	1.17 (1.09, 1.26), <i>P</i> = 0.000
Not in HIV medical care			
Stimulant use	2.84 (1.07, 7.58), <i>P</i> = 0.036	3.16 (1.13, 8.84), <i>P</i> = 0.028	3.44 (1.17, 10.15), <i>P</i> = 0.025
Age	—	0.97 (0.92, 1.01), <i>P</i> = 0.152	0.97 (0.92, 1.01), <i>P</i> = 0.162
Nonwhite race/ethnicity	—	2.33 (0.95, 5.70), <i>P</i> = 0.063	2.58 (1.04, 6.40), <i>P</i> = 0.041
Education			
High school or less	—	Ref.	Ref.
Technical/some college	—	0.64 (0.17, 2.31), <i>P</i> = 0.491	0.73 (0.20, 2.73), <i>P</i> = 0.642
College degree	—	0.22 (0.05, 0.94), <i>P</i> = 0.040	0.22 (0.05, 0.98), <i>P</i> = 0.047
Depression ^g	—	—	0.54 (0.19, 1.52), <i>P</i> = 0.242
Life chaos ^h	—	—	1.11 (0.99, 1.23), <i>P</i> = 0.065

Notes: ^aunadjusted model; ^bModel 1 plus demographic variables significantly associated with treatment engagement in the bivariate analyses; ^cModel 2 plus psychosocial variables significantly associated with treatment engagement in the bivariate analyses, 5 missing cases; ^drelative risk ratio; ^econfidence interval; ^fvariable not included in model; ^gusing the 10-item CES-D scale [30]; ^husing the life chaos scale [32].

one or more HIV-related medical appointments in the past year. Having a college degree was associated with a lower likelihood of not being in HIV medical care and missing one or more HIV-related appointments in the past year across all models.

3.5. Technology Use. Technology and mobile phone use for the overall sample of men and by level of HIV medical care engagement is shown in Table 4. Over three quarters (78%) of men reported using a social networking site at least once a week. *Facebook* was the most commonly reported social networking site, with 61% of men reporting its use (and 42%

among stimulant users). Just over one-half (54%) of men reported using one or more social networking sites other than *Facebook*, including *Poz.com* forums (31%, *n* = 85; stimulant users = 17%), *My Space* (20%, *n* = 55; stimulant users = 17%), *The Body.com* forums (12%, *n* = 33; stimulant users = 8%), *LinkedIn* (12%, *n* = 32; stimulant users = 17%), or a variety of other social networking websites (13%, *n* = 37; stimulant users = 17%). A significantly higher proportion of stimulant-using than nonstimulant-using men reported using social networking websites other than *Facebook* for the overall sample (71% versus 51%, *P* = 0.02) and among participants who had not missed any of their HIV medical appointments in the past year (75% versus 51%, *P* = 0.02).

TABLE 4: Technology use by stimulant use and engagement in HIV care.

	Total Column % (n)	No stimulant use Column % (n)	Stimulant use Column % (n)	P value
<i>Total (n = 276)</i>		<i>n = 232</i>	<i>n = 44</i>	
Any social network site use	77.5 (214)	76.7 (178)	81.8 (36)	0.46 ^b
Social network site used				
Facebook	60.9 (168)	62.1 (144)	55.6 (24)	0.35 ^b
Other	54.0 (149)	50.9 (118)	70.5 (31)	0.02 ^b
Mobile phone ^a				
No mobile phone	11.3 (31)	12.1 (28)	6.82 (3)	0.67 ^c
Mobile phone	42.6 (117)	42.0 (97)	45.5 (20)	
Smart phone	46.2 (127)	45.9 (106)	47.7 (21)	
<i>No missed appointments (n = 190)</i>		<i>n = 166</i>	<i>n = 24</i>	
Any social network site use	77.9 (148)	76.5 (127)	87.5 (21)	0.30 ^c
Social network site used				
Facebook	60.5 (115)	60.8 (101)	58.3 (14)	0.81 ^b
Other	53.7 (102)	50.6 (84)	75.0 (18)	0.03 ^b
Mobile phone ^a				
No mobile phone	8.5 (16)	9.1 (15)	4.2 (1)	0.80 ^c
Mobile phone	47.1 (89)	47.3 (78)	45.8 (11)	
Smart phone	44.4 (84)	43.6 (72)	50.0 (12)	
<i>Missed appointment(s) (n = 62)</i>		<i>n = 49</i>	<i>n = 13</i>	
Any social network site use	82.3 (51)	81.6 (40)	84.6 (11)	1.00 ^c
Social network site used				
Facebook	66.1 (41)	69.4 (34)	53.9 (7)	0.29 ^b
Other	61.3 (38)	57.1 (28)	76.9 (10)	0.34 ^c
Mobile phone				
No mobile phone	14.5 (9)	16.3 (8)	7.7 (1)	0.43 ^c
Mobile phone	37.1 (23)	32.7 (16)	53.9 (7)	
Smart phone	48.4 (30)	51.0 (25)	38.5 (5)	
<i>Not in HIV medical care (n = 24)</i>		<i>n = 17</i>	<i>n = 7</i>	
Any social network site use	62.5 (15)	64.7 (11)	57.1 (4)	1.00 ^c
Social network site used				
Facebook	50.0 (12)	52.9 (9)	42.9 (3)	1.00 ^c
Other	37.5 (9)	35.3 (6)	42.9 (3)	1.00 ^c
Mobile phone				
No mobile phone	25.0 (6)	29.4 (5)	14.3 (1)	0.85 ^c
Mobile phone	20.8 (5)	17.7 (3)	28.6 (2)	
Smart phone	54.2 (13)	52.9 (9)	57.1 (4)	

Notes: ^a1 missing case; ^bchi-square test; ^cFisher's exact test.

No other significant differences in social networking site use were found between stimulant users and nonstimulant users for the overall sample or within level of engagement in HIV medical care.

No significant differences were found between stimulant-using and nonstimulant-using men with respect to mobile phone use. Overall, 89% of men reported using a mobile phone. Among those who used a mobile phone, an approximately equivalent proportion used a mobile phone without smart phone features and a mobile phone with smart phone features (43% and 46%, resp.). Mobile phone use was similar among men who had missed one or more HIV medical

appointment in the past year or who had not attended any HIV medical appointments, with approximately half of each group reporting using a smart phone.

4. Discussion

The purpose of this study was to assess the association of stimulant use with engagement in HIV medical care and to compare technology use among stimulant-using MSM with varying degrees of HIV medical care engagement. Three findings are particularly noteworthy. First, stimulant use was

significantly associated with not being in HIV medical care in both the bivariate and multivariate analyses, although not associated with greater likelihood of missing HIV-related medical appointments. Second, a high proportion of stimulant-using MSM reported that HIV medical was a low priority and had low confidence in attending all of their appointments in the upcoming year. Third, social networking website, feature, and mobile phone use were similar among men in this sample regardless of whether or not they reported recent stimulant use. Each of these findings is discussed in greater detail in the following.

Studies demonstrate that a variety of factors are associated with nonengagement or suboptimal engagement in HIV medical care, including younger age, a history of mental health problems, and a history of drug use and injection drug use [40, 41]. There is growing evidence that stimulant use has a particularly deleterious effect on the health of people living with HIV, including more rapid HIV disease progression [13]. Sixteen percent of men in this sample reported stimulant use, which is generally within the range of stimulant use reported in other national samples of MSM [42], although lower compared to MSM residing on the west coast and in the south central USA [7, 42]. The results of the current study suggest that stimulant use may exert a disruptive effect on engagement in HIV medical care. Even when factors known to be associated with greater stimulant use among people with HIV (e.g., younger age [43]) are accounted for in the models, stimulant use appears to be uniquely associated with not attending any HIV medical care appointments in this sample of MSM. In addition, and consistent with prior studies [32, 44, 45], not having a college degree, racial and ethnic minority status, and greater life chaos may place people at risk for not engaging or missing HIV-related medical appointments. These results suggest that it may be critical to assess stimulant use at time of HIV diagnosis to determine who is at elevated risk for subsequent nonengagement and, therefore, may require additional supports.

Despite these findings, 54% of recent stimulant users report being engaged in their HIV medical care in this study. The findings of a qualitative study by Rajabiun and colleagues [46] provide some indication for what may distinguish persons with a substance use history who engage in their HIV medical care from those who do not. A high percentage of the 76 people with HIV (80%) interviewed in that study reported a lifetime history of substance use. However, those who were able to establish and maintain optimal engagement in HIV care reported greater coping and adaptive abilities than substance-using participants with suboptimal HIV medical care engagement. The results of the current study provide evidence that MSM who report current stimulant use are at elevated risk for not attending HIV medical care appointments and, in conjunction with the results from Rajabiun et al., suggest that such persons may benefit from additional coping skills and resources to engage or re-engage them in their HIV medical care. A relatively new approach may be to leverage peer navigators to assist patients at risk for default from HIV medical care [47, 48]. Facilitating and enhancing opportunities for stimulant-using persons to remain engaged in their medical care may be

critical to successfully addressing deficits in the treatment cascade for HIV-positive MSM.

Beliefs and attitudes toward the medical system and engagement in medical care are known predictors of treatment engagement. In a review of 16 studies that examined African American's beliefs toward HIV medical care engagement, experiences of racism, mistrust of the medical system, and patient-provider relationship were found to impact engagement [49]. A high proportion of stimulant-using MSM in the current study reported that HIV medical care was not a high priority and that they had little confidence that they would be able to attend all of their HIV medical care appointments in the upcoming year. Heightening the prioritization of, and confidence to engage in, a specified health behavior is well recognized in a number of health behavior theories [50], as these factors are associated with the likelihood of enacting the behavior [51]. Intervention activities that heighten the prioritization of HIV medical care and confidence to enact care engagement behaviors among stimulant-using MSM may be part of a larger intervention package to link and keep this difficult-to-reach population retained in HIV care. Models of engagement in care for persons living with chronic conditions, including HIV, that acknowledge the importance of medical care prioritization and confidence have been proposed [52]. The findings of this study confirm that there may be motivational and self-efficacy deficits among stimulant-using HIV-positive MSM that may be addressed to improve retention in HIV medical care.

A number of recent technology-delivered interventions to improve the health of people living with HIV have been examined to determine the degree to which they may be acceptable or beneficial [27]. However, with few exceptions [24], technology-based interventions have typically not addressed the needs of drug-using populations [23]. In part, the lack of research into the application of technology to deliver HIV-related intervention to drug-using populations may stem from the belief that such persons do not have access to online or mobile technologies that would be required for the successful widespread dissemination of these types of interventions. However, the results of this study support the use of such technologies, as there were few differences between the proportion of stimulant-using and nonstimulant-using MSM who frequently used social network websites, features, and mobile phones. In fact, a higher percentage of stimulant-using men reported weekly use of social networking websites and features that were not Facebook than men who did not report using stimulant drugs. The comparatively high percentage of stimulant-using men in this sample who regularly used social networking websites and features and had access to mobile phones supports ongoing efforts [24] to reach stimulant-using HIV-positive MSM using these technologies. However, it is noteworthy that online social networking use was lowest among stimulant-using MSM who were not in HIV medical care. Thus, as is the case generally with not-in-treatment groups, reaching them through online social networking websites may prove the most challenging. The degree to which online social networking and mobile phone technologies may be

used to reach and provide intervention to stimulant-using people with HIV should be explored further.

4.1. Study Limitations and Conclusions. This study has a number of limitations. First, this primarily online-recruited sample of MSM is not representative of all HIV-positive MSM or HIV-positive persons in USA. A noticeably higher percentage of respondents in this sample reported being engaged in HIV medical care compared to a nationally-representative sample of persons estimated to be retained in HIV care in the USA [3]. Discrepancies in HIV care retention findings between study samples and nationally-representative samples may be attributed to multiple factors, including inclusion criteria, sampling strategy, and varying definitions of retention in HIV medical care [53]. In addition, technology use rates may be inflated in the current sample of HIV-positive MSM given that most were recruited through online venues. Thus, the results of this study may not be generalized to other samples or populations. Second, this was a one-time cross-sectional survey that does not capture variations in stimulant and engagement in HIV medical care over time. Longitudinal data would be needed to more definitively determine the effect of stimulant use on HIV care engagement, although this was outside the scope of this study. Third, the survey was self-report, and participants actual drug use, technology use, and engagement in HIV medical care may differ from self-report due to a variety of recall and reporting biases. Thus, the results should be approached with caution and require additional confirmation from future studies. Fourth, best practices to measure and report engagement in HIV medical care have not been established [35, 53]. Although we measured engagement in HIV medical care using items described earlier and categorized men into three engagement groups, alternative measurement and categorization schemes may capture greater nuances in engagement in HIV medical care. A challenge to future research is to compare engagement and retention measures to each other and to clinical outcomes to determine a “gold standard” for measurement of these factors [53]. In addition, participants in this study may have had difficulty in estimating the percentage of missed HIV-related appointments in the prior 12 months. Finally, although a number of steps were taken to ensure that participants were valid and unique, we were not able to confirm that participants were unique respondents given that men completed the survey online.

5. Conclusions

Despite these limitations, this is the first study (that we are aware of) to examine the association between stimulant use and engagement in HIV medical care and to assess technology use by stimulant use and engagement in HIV care. The results provide important preliminary evidence that stimulant use negatively impacts HIV medical care engagement and that the use of a variety of emerging technologies may be a possible way to reach stimulant-using MSM. However, more research is needed to assess the acceptability of these

technologies for intervention purposes and—if acceptable—best practices for adaptation of effective interventions for dissemination using technology-based applications.

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