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ORIGINAL PAPER

Testing the Feasibility of Using Ecological Momentary Assessment to Collect Real-Time Behavior and Mood to Predict Technology-Measured HIV Medication Adherence

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Abstract
Identifying distinct patterns of behavior and mood in natural environments that interrupt medication adherence among individuals with HIV will be useful in informing intervention development. This pilot study assessed the initial efficacy of using ecologic momentary assessment to define patterns of alcohol use, mood, and medication adherence. Participants reported intraday alcohol use and mood using app-enabled smartphones and MEMSCap pill bottles to measure medication adherence. There were 34 enrolled participants, 29 of whom completed the 28-day study. Participants drank a mean of 7.75 days of the study period. The positive and negative affect scores ranged from 10 to 50, with a mean of 25.7 and 11.4 for each, respectively. The average medication adherence for the sample was 94.1%. These findings suggest these types of data collection methods are increasingly acceptable in measuring real-time mood and behavior, which may better inform interventions addressed at increasing HIV adherence practices.

Keywords HIV/AIDS · Alcohol · Ecological momentary assessment · MEMSCap · Electronic medication monitoring · Medication adherence

Resumen
Identificación de patrones distintos de comportamiento y estado de ánimo en los ambientes naturales que interrumpen el cumplimiento con la medicación entre los individuos con VIH será útil para informar el desarrollo de la intervención. Este estudio piloto evaluó la eficacia inicial de utilizar evaluación ecológica momentánea (EMA) para definir patrones de adherencia de uso de alcohol, estado de ánimo y medicación. Los participantes informaron uso de alcohol intradía y estado de ánimo usando MEMSCap píldora botellas y teléfonos inteligentes basados en la aplicación se utilizaron para medir el cumplimiento con la medicación. Hubo 34 participantes inscritos, 29 de los cuales completaron el estudio de 28 días. Los participantes tomaban un promedio de 7,75 días del período de estudio. Las puntuaciones de afecto positivo y negativo variaron de 10 a 50, con una media de 25,7 y de 11,4 para cada uno, respectivamente. El cumplimiento con la medicación media para la muestra fue de 94,1%. Estos resultados sugieren que estos tipos de métodos de recolección de datos son cada vez más aceptables en la medición en tiempo real estado de ánimo y comportamiento, y que puede informar mejor a las intervenciones dirigidas a aumentar prácticas de adherencia VIH.

Introduction

Approximately 1.1 million people are living with HIV infection (PLWH) in the U.S. and are experiencing less morbidity and mortality than ever before [1]. Advances in biomedical prevention and care among PLWH have demonstrated how viral suppression can be used to eliminate new HIV infections [2, 3]. While HIV medication requires approximately 75% adherence to successfully reduce the risk of virologic and immunologic failure and transmission [2, 3], only 31%

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of PLWH in the U.S. currently have achieved HIV viral suppression [1]. Barriers to medication adherence include psychiatric disorders as well as substance use disorders, social determinants of health including housing, income, and education [4–6]. Some intervention efforts that have implemented comprehensive care services, alcohol reduction, and mental health care provision have shown to improve care engagement and medication adherence [7, 8].

There is a need to better understand factors that interrupt medication adherence practices. Namely, there is limited examination of when and how these factors change daily; repetitive behaviors such as alcohol use, physical activity, sleep, sexual behavior, medication adherence, and psychological distress symptoms are likely to be influenced by different social and physical environments [8]. Surveys that measure these symptoms and behaviors over a recalled specified period of time fail to capture the complexity of use patterns, which vary along multiple dimensions and are affected by situation, mood, timing, and physical and social context [4–6, 9, 10]. The ubiquity of mobile technology supports ecological momentary assessment (EMA) and ambulatory assessment (AA) of real-time behaviors and their predictors in ways that are likely more efficient and accurate [4–6, 11]. Daily diary reports fall short of thorough exploration of mood fluctuation and alcohol and other drug use reporting, as recall may be challenging each day, rather than EMA-based data collection throughout the day [12, 13]. While daily diaries offer a more accurate approach to examining daily fluctuations in mood and behavior, EMA can utilize mobile technology to provide real-time assessment of intraday behaviors and predictors in natural environments. This is a promising method to address these concerns more accurately and as they are experienced [12, 13]. Prior studies using EMA have improved our understanding of tobacco cessation, substance use, pain management, and clinical treatment [4, 5, 14–18]. More recent HIV-related studies have tested how EMA can better predict drug use, mood, and behavior among populations at risk for and with HIV [19, 20]. Some of these studies have examined how mood is related to behavior using smartphone-delivered EMA; specifically, patterns of detrimental alcohol use were related to methamphetamine use, and these measures were more accurate than retrospective recall [19, 20]. Further, EMA measures identified higher pain symptomatology among older PLWH who were more socially isolated, as they were assessed over a one-week period [21]. These previous studies provided the necessary foundation for this study and highlighted the need to measure behavior and mood in real-time and in natural environments. While EMA has been used to measure mood and alcohol use concurrently, previously there have not been studies including technology-measured medication adherence throughout an extended study period.

Intervention development has been stunted in ways due to the reliance on retrospective reports of behavior and their predictors. These gaps in understanding social and physical context is particularly important among PLWH where daily medication adherence is expected and may be interrupted due to unknown barriers, as previously identified [21]. Our study was specifically designed to examine intra-day variation in alcohol use, mood, and daily antiretroviral therapy (ART) adherence using technology. Therefore, this study was conducted to test the feasibility and acceptability of using technology to collect these types of intraday data among a sample of engaged in care individuals living with HIV, in order to better understand acceptability of these data collection methods and crucial aspects of detailed behavior and how they relate to daily ART adherence.

Methods

Participant Recruitment

Recruitment of potential participants occurred during regular clinic visits from the Washington University Infectious Disease Clinic (WU ID Clinic) in St. Louis, Missouri between March 2015 and May 2016. The Washington University ID Clinic is the largest HIV care provider in the region, serving nearly 2200 patients per year. Inclusion criteria were: current WU ID Clinic patient, previous diagnosis of HIV infection, $\geq$21 years of age, endorsed using alcohol within previous 30 days, lived in the St. Louis Metropolitan region, among those who were employed during day time hours, and receiving ART for at least 6 months with no plan to change over the next 6 months. Electronic medical records were reviewed to determine eligibility for participation. Patients were ineligible if they were unable to give informed consent, had active psychosis or uncontrolled mental illness, or were incarcerated.

Measures

Baseline interviews included measures of sociodemographic characteristics, current gold standard measures of alcohol use and substance use disorders, sexual behaviors, and psychological distress symptoms using valid and reliable instruments [22–25]. The baseline interview lasted up to 1.5 hours.

Real-time data collection occurred through an application (app) that was developed to measure mood and alcohol use, which was loaded onto a study-specific Android smartphone. The smartphone was provided to the individuals for

the duration of their participation. Lastly, participants were given a MEMSCap™ (Medication Event Monitoring System, MEMSCap Inc., Durham, NC, USA) pill bottle.

Intraday Measures via EMA App

The app collected data and transmitted through a secure, encrypted server.

Measures

The frequency and quantity measures of alcohol use were used [26]. The measures were "Did you have an alcoholic beverage? What type of alcohol did you have? How many drinks did you have? (Participants were informed that a drink size was 12-ounce beer, 1-ounce shot of liquor alone or in a drink, and 4-ounces of wine). The Positive And Negative Affect Schedule-Short Form (PANAS-SF) was used to measure intraday mood [27]. PANAS-SF yields a positive and negative affect score, each ranging from 10-50. This measure included 20 symptoms of positive and negative mood, such as "Please indicate the extent you feel this way right now: Distressed, Excited, Interested, Upset, etc." with a Likert-type response options ranged from very slightly/not at all to extremely.

A self-initiated mood dysregulation event was measured by "How much did your mood change, from not at all to extremely" and "Are you in a better, worse, or the same mood as before?". Their response options included "spent time with a friend", "received bad/good news", and "had a drink". Participants were never prompted to respond to this survey, if they did not initiate this significant change in mood survey. Thus, it was a self-assessed measure of mood change, not one that would have otherwise been identified. It was only included as a method to capture specific mood events that participants experienced and wanted to report outside the context of reporting mood during the other surveys.

Additionally, there were morning reports, 3 intraday randomly-timed surveys, and event-specific surveys. Each morning, participants received an alert to complete their morning report. This survey included measures of frequency and quantity of alcohol use, to capture any missing data from the previous night, and current mood using PANAS-SF [25]. The morning report was only collected 8am-12 pm. If participants awoke after 12 pm, they were not asked to complete the morning report that day. The randomly-timed surveys were conducted between 12 pm and 8 pm, participants responded to questions about their alcohol consumption to capture any missed episodes and mood at the moment.

Initial drinking and drinking follow-up surveys were the event-specific surveys implemented to capture each time alcohol was consumed, collecting data about type of alcohol, amount based on size of drink, as well as current mood. The participants were alerted every 30 min to follow up if they had consumed additional drinks. This process was conducted until participants reported not drinking 3 times in a row (1.5 hours after they completed their drinking event).

Medication Adherence

Medication adherence was measured using a MEMSCap, which records each date and time of when the pill bottle is opened. This method of monitoring medication adherence is well-established [28–30]. Participants were given the pill bottle at the baseline interview, and the bottle was collected at day 28. Three of the participants had medication that was prescribed to be taken twice daily and the rest of the sample had medication that was to be taken once per day. Overall medication adherence was calculated as the number of doses reported through MEMSCap divided by the number of expected doses during the study period.

Clinical biomarkers were abstracted from electronic medical records during routine medical visits that occurred during their recruitment visit. The HIV management parameters collected were CD4 T-cell count, nadir CD4 T-cell count, and HIV RNA viral load. Viral suppression was considered to be HIV RNA viral load <200 copies/mL, and being virally undetectable was considered to be <20 copies/mL. Three biomarkers of alcohol use were also assessed at the start of the study: aspartate aminotransferase (AST), alanine aminotransferase (ALT), and mean corpuscular volume (MCV). Normal range for AST is 10–40 units/L (for males); 9–32 units/L (for females); normal range for ALT: 7–55 units/L; and normal range for MCV: 80–96 fL.

Participants were remunerated $40 for their baseline and follow-up interviews, respectively. Additionally, each week participants returned to the clinic to check in they received a graduated incentive with EMA compliance, $10, $15, $20, and $25. EMA compliance was measured by weekly summaries of each participant's completion of the morning reports and randomly-timed surveys.

Statistical Analysis

Descriptive analyses were conducted from these disparate sources of data collection. Baseline data described the sociodemographic characteristics of the sample. EMA completion data were summarized as feasibility to conduct EMA data. Medically abstracted data were described and MEMSCap data were reported to describe medication adherence patterns throughout the study period. Normality of distribution of the continuous variables was evaluated using the Kolmogorov–Smirnov test. Spearman correlations and Kruskall–Wallis tests were used to assess

relationships between demographic characteristics and survey non-response.

The follow up interview used a Timeline Follow Back (TLFB) measure of alcohol use for 7 days, and thus, reliability assessments to be conducted to assess real-time alcohol use versus recalled alcohol use within the previous 7 days. These analyses were conducted for overlapping periods of time for each participant. Alcohol use reporting (number of drinks) was tested for its reliability using intraclass correlations (ICCs) for continuous variables and Kappa scores for dichotomous variables (types of alcohol consumed). Kruskall-Wallis tests were used to assess differences in number of reports of alcohol use across weeks of the study period.

Results

This prospective study was conducted with 34 participants who completed baseline surveys and 29 (85%) follow-up surveys. One of those participants did not have valid EMA data and was excluded from the final analytic sample.

The majority of the sample was African American (73.5%), male (76.5%), and reported an annual income of less than $10,000 (55.9%). Just over half (58.8%) had attained education beyond high school. Half of the participants reported being either employed full- or part- time. One respondent (2.9%) considered themself to be homeless. Table 1 shares sample characteristics.

The morning report was initiated 964 times and completed 666 times (69%). The initial drinking survey was initiated 165 times and completed 151 times (92%). The drinking follow-up was initiated 1383 times and completed 915 times (66%). The three random daily surveys were initiated a total of 2273 times and completed 1295 times (57%). The relationships between missed survey responses and race, gender, age, income, educational attainment, employment, and marital status were all assessed. All relationships were non-significant ($p < 0.05$), providing an indication that non-response was not associated with any demographic characteristics in the study sample. Further, there was no identified relationship between baseline depression symptoms nor substance use. Substance use, outside of marijuana use, was only reported among 1 participant. There was no hypothesized relationship between baseline marijuana use and missing alcohol use reports.

Real-time alcohol use pattern information was available for 27 individuals. Over the study period, participants reported an average of 7.75 (SD: 5.58) days on which they drank, with a minimum of 1 day and a maximum of 22 days. Individual drinking episodes were identified by the completion of an initial drink report or a random survey indicating that the individual had consumed alcohol since the last survey they answered. The average number of drinking episodes reported per person was 8.11 (SD 5.74), with a minimum of 1 and a maximum of 22 drinking episodes over the study period. This yielded a total of 227 drinking episodes across the 27 participants; this was indicated either by initial drinking event or during random surveys where drinking episodes were captured. On average, a drinking episode lasted 112.30 (SD 131.17) minutes, with a range of 30 to 678 min. The mean number of drinks participants consumed per episode was 4.84 (SD 5.11) with a median of 3.0. Total number of drinks per episode ranged from 1 to 27. Across all episodes, the average number of drinks per hour was 3.44 (SD 2.49) with a median of 2.69 and a range of 0.09 drinks to 16 drinks per hour.

The mean number of alcohol episodes during each week of the study period was as follows: 3.25 episodes (95% CI 2.38, 4.12) during week 1; 2.29 episodes (95% CI 1.61, 2.97) during week 2; 1.71 episodes (95% CI 0.97, 2.45) during week 3; and 1.46 episodes (95% CI 0.76, 2.16) during week 4. There was a significant association between episodes and week number (Kruskal–Wallis $p = 0.004$). Nonetheless, the confidence intervals for the means show that the only significant difference is between weeks 1 and 4, as these are the two confidence intervals that do not overlap. All other week-to-week comparisons are non-significant, as indicated by the overlapping confidence intervals. Regardless, when examining the effect sizes of the number of drinks reported per week and comparing the differences throughout the study period, we noted that there was a trend in the reduction of drinking episodes reported. It is unknown whether there were actual reductions in alcohol consumption or reports of alcohol use.

The comparison of reliability for alcohol use reporting between using real-time data collection and the 7-day recall (using TLFB) had low concordance. The number of drinks reported on the previous day had lowest concordance when comparing yesterday using EMA versus TLFB (ICC = 0.3891), but was higher in the following timeframes: the day before yesterday (ICC = 0.7455) and the previous 7 days (ICC = 0.6341). Furthermore, reports of type of alcohol (wine, beer, liquor alone or in a drink) that was consumed during alcohol episodes were compared with the TLFB reports for the previous 7 days as well ($\kappa = 0.172$, 0.632, and 0.483, respectively). Although there was low concordance in comparing the number of drinks reported using these disparate methods, a paired t-test indicated that these differences were not statistically significant.

The positive affect scores ranged from 10 to 50 with a mean of 25.7 and a median of 25. Negative affect scores also ranged from 10 to 50, which had a mean of 11.4 and a median of 10. There were a total of 117 mood dysregulation reports completed in the study period. These reports were self-initiated when participants wanted to report significant

Table 1 Sample characteristics (n = 34)

	Frequency	Percent
Race		
African-American/Black	25	73.5
Caucasian/White	8	23.5
Latino or Hispanic	1	2.9
Gender		
Male	26	76.5
Female	7	20.6
Transgender: Male to Female	1	2.9
Highest level of education attained		
GED	4	11.8
Some high school	2	5.9
High school diploma	7	20.6
Vocational tech diploma	1	2.9
Associate degree	2	5.9
Some college	12	35.3
Bachelor degree	3	8.8
Master degree	3	8.8
Annual income		
Less than $10,000	19	55.9
$10,000-$29,999	12	35.3
> $30,000	3	8.8
Marital status		
Married or Partnered	5	14.7
Divorced	5	14.7
Separated	1	2.9
Never married	23	67.6
Employment status		
Unemployed or laid off and looking for work	4	11.8
Unemployed or laid off and not looking for work	3	8.8
Working full-time, 35 h or more a week	9	26.5
Working part-time, less than 35 h a week	6	17.6
Student	2	5.9
Retired	1	2.9
Disabled, not able to work	8	23.5
In a work rehabilitation or training program	1	2.9
Current residence		
Your own house or apartment?	24	70.6
Someone else's house or apartment?	8	23.5
A shelter or welfare boarding home?	1	2.9
On the streets like in an abandoned building, vacant lot, or park?	1	2.9
Consider self homeless	1	2.9
	Mean	SD
Alcohol use biomarkers		
Aspartate aminotransferase (AST)	25.6	12.1
Alanine aminotransferase (ALT)	22.8	11.8
Mean corpuscular volume (MCV)	94.9	7.8

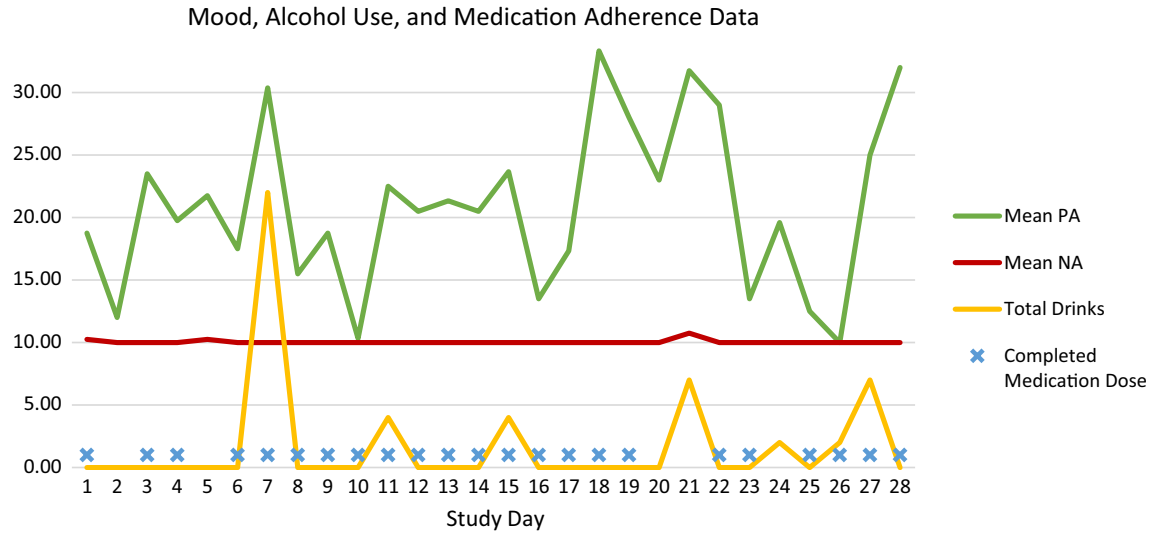
Table 1 (continued)

	Mean	SD	Median
HIV management			
CD4 Cell count	520.2	220.1	522.5
	Frequency	Percent	
HIV RNA < 20 copies/mL	23	67.6	
HIV RNA < 200 copies/mL	29	85.3	
ART Regimen			
Once per day	31		
Twice per day	3		

changes in mood, either positive or negative. Although not significant, individuals with mood dysregulation events had a lower positive affect score compared to those with no mood dysregulation events (24.5 vs 25.7, $p = 0.43$). Yet, individuals with mood dysregulation events had a significantly higher negative affect score compared to those with no mood dysregulation events (12.8 vs 11.3, $p < 0.01$). While not significant, individuals with mood dysregulation reports were more likely to have an increased number of drinks per alcohol episode (7.5 vs 7.0, $p = 0.80$) and an increased number of alcohol episodes (13 vs 12, $p = 0.74$).

The CD4 T-cell counts ranged from 44 to 960 cells/mm^3 and a mean of 515 (± 221) cells/mm^3. The nadir CD4 T-cell counts ranged from 0 to 531 cells/mm^3 with a median of 129 (IQR 14.5, 331) cells/mm^3. The HIV RNA viral load ranged from 20 to 20632 copies/mL and the majority of the sample (n = 28, 82.4%) had suppressed HIV RNA viral loads (< 200 copies/mL). The AST ranged from 13 to 61 U/l with a median of 21.5 (IQR 17, 30.5) U/l, ALT ranged from 6 to 56 U/l with a median of 19 (IQR 14, 28.5) U/l, and MCV ranged from 85.4 to 119.2 U/l with a median of 94.2 (IQR 88.7, 98.6) U/l. Table 1 includes these descriptions.

Medication adherence was good in this sample, as expected with the high rates of viral suppression. Most participants were prescribed a once-a-day regimen (n = 25), while three participants had twice-a- day regimens. The overall average medication adherence for the entire sample was 94.1% throughout the 28 days. Among participants with a once-a-day regimen, average medication adherence was 93.9%; 17 participants (68.0%) missed at least one dose in the study period. Among participants on once-a-day regimens, one participant missed more than half of their doses (adherence rate = 43.3%) and another participant missed one-third of their doses (adherence rate = 66.7%). The total number of missed doses among participants with once-a-day regimens ranged from 0 to



[1]: Mean PA: Mean Positive Affect, Mean NA: Mean Negative Affect

Fig. 1 Sample data from one study participant

17. Average medication adherence among those with a twice-a-day regimen was slightly higher (95.5%) than among those with a once-a-day regimen. All three of these participants missed at least one dose during the study period, though the total number of missed doses was low, ranging from 1 to 3. Figure 1 depicts an example of all the data described for one participant.

Discussion

This study was conducted to assess the feasibility of collecting EMA data to measure alcohol consumption and mood patterns among a sample of individuals with HIV, while managing their medication adherence. Overall, the use of EMA via mobile technology was found to be feasible with 85% completion of the study and moderate completion rates of each survey type. The results suggest that these methods of data collection are acceptable among this population. EMA has the potential to provide great insights and intervention opportunities that are sorely needed in the natural environment in which people with HIV live, work, and play.

Prior research has indicated that subject burden is relatively low, as EMA studies have been successfully performed in homeless populations, injection drug users, and patients with significant mental illness [4, 6, 11, 31]. These types of data collection methods were found to be feasible in this population, as was identified with similar populations [19, 21, 32]. The study lost 3 participants to follow up, including the smartphones and pill bottles during the study period, 1 participant did not report any drinking episodes throughout the study period, 1 participant had no data secured, and 1 participant dropped out of the study after 1 week. Additionally, with a large survey burden using mobile phones, we expected that alcohol use reports would decrease throughout the study period. However, the results identified a gradual decrease in alcohol reporting, suggesting future studies should incorporate either shorter study periods or using longitudinal burst designs. Interestingly, we are unable to identify whether there were fewer reports of alcohol consumption or actual less alcohol use as a function of the Hawthorne effect [33].

This study identified methods to improve data collection in order to better pinpoint intervention opportunities. The TLFB method for 7-day recall of alcohol use has been primarily used in survey settings to identify detrimental alcohol use patterns [18, 22, 34]. Our data demonstrate that EMA-based alcohol use data does not correlate strongly with TLFB results. This study highlighted that these retrospective reports appear to be limited in reliability. Given the real time nature of EMA data collection, these findings suggest that this data collection method is more reliable than recall methods and prioritizing these research methods will likely improve informed intervention development.

This study highlights that mood and behavior may be reliably reported within each day. These results suggest that improving the understanding of predictors of poor mood and behavior has the potential to better care for populations with HIV who experience interruptions to their HIV care. These interruptions often are only documented in clinic settings when HIV management is challenging, as measured by unsuppressed HIV viral loads. Often times identifying challenges to adherence may be significantly delayed, placing the patient and their sexual partners at risk of poor health outcomes and transmitting HIV infection. Real-time data monitoring using EMA, MEMSCap, and the overall use of technology to augment in-person clinical care presents the opportunity to assist HIV management in a manner that has been impossible thus far in clinic settings. Real-time data collection in natural environments allows the continuous measurement of patterns that may precede missed medication doses and loss to clinical follow up. Clinical and research practices should be focused on identifying patient populations at most risk rather than waiting to document interruptions in care practices or risk losing patients in need of follow-up in the clinic setting. Improved monitoring of populations and the development of targeted interventions when risk patterns emerge, should better address care for PLWH with greatest need has significant implications for the larger HIV epidemic.

Implementation of ecological momentary interventions (EMI) has a great opportunity to change health outcomes and the overall provision of preventative care. This study highlights the opportunity to monitor in order to address behaviors and moods in real-time in order to reduce delay of comprehensive care during clinic appointments. PLWH could benefit from a geofencing intervention where alerts could be triggered in order to prevent heavy drinking episodes when individuals are close to a risk environment such as a bar, where they had delayed dosing in their medication previously [35]. Additionally, noting patterns of negative mood in natural environments may provide a trigger to a mental health clinician or individuals within a person's social network to reach out to the patient who may be in need of intervention. These opportunities can provide intervention rather than waiting for when appointments are sought or kept, which addresses how life patterns fluctuate in their natural environment. We can help populations with HIV address their daily challenges and thus, are likely to reduce transmission risk, in turn, get closer to zero new infections.

This study was limited in scope due to its pilot and feasibility assessments. The sample was considerably limited in size and eligibility requirements included those participants

who had been stably medicated for HIV infection. Other populations are likely to have different challenges in how they adhere to medication and clinic care. Future opportunities include testing these methods with younger populations at risk for HIV infection or early in their HIV management.

Future studies must identify how to make daily routine data collection standard of care and develop a method to utilize those data to assist the public health and medicine in managing chronic diseases. By utilizing individual data that are collected in real-time and in natural environments, intervention development would be more likely to be effective in addressing detrimental mood and behavior patterns. Understanding behaviors and their determinants in their natural environments is now more widely possible as technology becomes more ubiquitous.

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Compliance with Ethical Standards

Conflict of Interest None of the authors have a conflict of interest.

Ethical Approval All procedures performed in studies involving human participants were in accordance with the ethical standards of the institutional and/or national research committee and with the 1964 Helsinki declaration and its later amendments or comparable ethical standards.

Informed Consent Informed consent was obtained from all individual participants included in the study.

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