**Mobile Health (mHealth) Risk Profiles to Predict HIV Treatment Outcomes among Drug Users**

1. **Introduction/Importance, Goals**

Despite the wide availability of antiretroviral therapy (ART), many HIV-infected Injection Drug Users (IDUs) remain unengaged in HIV care and have poor treatment outcomes. It is widely believed that the drug user’s environment and lifestyle contributes to the lack of engagement in HIV care and subsequent poor adherence to their HIV medications. To better predict who in this high-risk population will be successful on ART, more accurate methods for assessing the dynamics of drug use are necessary. This proposal utilizes data collected in real time, known as Ecologic Momentary Assessment (EMA) data, to capture the dynamic process that drug use represents. A complex interplay at multiple levels, drug use involves psychosocial stress and neighborhood level determinants that are subject to social desirability reporting when self-reported. Additionally, self-reported data collected at one time point does not reflect the long-term exposures or patterns of drug use over time. This analysis utilizes a novel mobile health (mHealth) longitudinal data collection method (EMA) carried out in real-time on injection drug users from the Exposure Assessment in Current Time (EXACT) study to assess situational and psychosocial triggers of drug use in real time. We hypothesize that by including sociodemographic, situational and behavioral factors in the characterization of drug use (as ‘drug use profiles’) predicting ART adherence among HIV infected IDUs will be more accurate than examining adherence behaviors alone. Accordingly, the specific aims of this proposal are:

AIM 1: **To develop clinic deployable ‘drug using profiles’ utilizing sociodemographic, behavioral and situational factors collected through Ecologic Momentary Assessment (EMA) among IDUs.**

Unique characterization of drug use at the individual level will enable providers a better understanding of a patient’s expectant success upon ART initiation given their drug-using environment in the EXACT study.

AIM 2: **To identify the sampling window that most accurately captures the ‘drug using profiles’**.

EXACT participants are followed for 30 days, however, it may be that drug use risk and its environment can be assessed in a shorter window of time. To operationalize the ‘drug using profiles’ an optimal window to assess drug risk using EMA methods is necessary, especially among high-risk drug users. With a smaller sampling window, user fatigue of the mobile device may be reduced and acceptance and reliability of reporting drug use may increase.

AIM 3: **Evaluate real-time profiles in predicting HIV care outcomes among out-of-care HIV positive injection drug users**

To examine the external validity of the ‘drug using profiles’ approximately 30 new out-of-care HIV infected drug users will be followed using EMA methods to determine their drug using profile over the sampling window determined in Aim 2. Once classified, time to viral load suppression will be examined.

Given this novel method of data collection and characterization, we are well positioned to show that EMA is a mHealth method effective at describing the socio-demographic, behavioral, and situational factors of drug use. This multilevel characterization will allow for more accurate predictions of ART adherence among HIV infected IDUs rather than examining adherence behaviors alone.

2. **Methods**

Traditional data collection methods of cohort studies require participants to attend study visits every 6 months and answer questionnaires/surveys concerning events in those past 6 months. At best, data is obtained twice a year if a participant is retained in the study. Ecologic momentary assessment (EMA) methods utilize smart phones to collect data concerning study participants over 30-60 consecutive days. Typically in ecologic momentary assessment studies momentary assessments are ascertained when the provider or investigator sends electronic prompts to participants for immediate response randomly throughout the day (known as the random prompt responses). Additionally, participants are required to self-cue and self-report through the mobile device when an event occurs (known as event contingent responses). The random prompts enables assessment of the base rates of exposure to possible relapse precipitants such as cues and stressors and provides a truly prospective approach to the question of what events preceded specific event episodes. The event-driven data provide near real time self-report of such episodes. This two-way communication is
how EMA allows for real-time data collection on any activity or mood hourly. Utilizing EMA methods of real-time data collection, sociodemographic, behavioral and situational factors can be more precisely measured.

The Exposure Assessment in Current Time (EXACT) study assesses exposure to drug use and psychosocial stress in real time through Ecological Momentary Assessment (EMA). Ninety-one (91) participants (recruited in 3 rounds of 30-31 participants) used smartphones to record drug use events as they occurred every day for 30 days. Additionally, participants reported recent or ongoing activities in response to randomly timed prompts throughout the day. Global Positioning System (GPS) devices also tracked their whereabouts. This study provided the data for aims 1 and 2.

**AIM 1:** Semi-parametric growth mixture models (GMM) will be used to ascertain heterogeneous patterns of drug use in the EXACT study from the reported drug using events per day over 30 days. Socio-demographic, behavioral, and situational characteristics from the random prompt questionnaires will be examined as time-varying covariates to determine correlates of the drug risk profiles. These models will identify membership and patterns of drug use defined by distinctive longitudinal behavioral patterns of the covariates. Understanding these drug using profiles is necessary for better comprehension of the triggers of drug use and relapse as well as for developing effective treatment plans for those with HIV who plan on starting and adhering to their ART regimens.

**AIM 2:** The EXACT study followed participants for 30 days. For aim 2, socio-demographic, behavioral and situational characteristics utilized in Aim 1, will be examined over different sampling windows of 5, 7 and 10 days. Performance characteristics such as Kappa and c-statistics will assess how these related indicators map onto the derived latent profiles as “validating indicators”. The ultimate goal of aim 2 is to make the drug using profiles clinically useful and practical for clinicians when assessing drug use risk among their drug using patients. If however there is no smaller time frame that produces the same drug using risk profile as the 30-day window, the 30-day window will be used.

**AIM 3:** To examine the validity of the ‘drug using profiles’ a new population of 30 out-of-care HIV infected drug users will be recruited from the Johns Hopkins Moore Clinic and the AIDS Linked to the Intravenous Experience (ALIVE) study. In the EXACT study, approximately 135 participants were screened to achieve a sample size of 91. Therefore we anticipate screening approximately 45-48 individuals to achieve a sample size of 30.

Participants will be followed using EMA methods to identify their drug using profiles, and once classified, time to viral load suppression examined. The outcome for this aim is time from study start to viral load (VL) suppression comparing “high risk” drug using profiles to persons categorized as lower risk. We will validate the drug-using risk profiles determined in Aims 1 and 2 to predict HIV care outcomes, the most important of which is viral load suppression. Time to viral suppression represents the ability to engage in care, initiate and adhere to ART and suppress the virus.

**3. Significance**

Poor adherence to ART regimens for HIV infected IDUs is a common reason for poor HIV outcomes. Utilizing ecologic momentary assessment methods we hope to accurately describe, characterize and depict the lifestyle of injection drug users to include individual, behavioral and situational factors to better represent what it means to be an active drug user with a “chaotic” lifestyle. As illicit drug use represents a dynamic process resulting from a complex interplay of factors occurring at multiple levels, accurate exposure-ascertainment methods are clinically useful for identifying the pathways leading to drug use.

This project will also evaluate the feasibility of an interactive mobile health (mHealth) method for describing the drug using experience and subsequent medication adherence for HIV-infected injection drug users in natural settings. Few settings have sufficient resources to offer adaptive, individualized HIV care to all substance abusers that need it. Smart phones will assess patient level data: drug cravings, psychosocial stress and adherence to HIV treatments in real time, a novel approach to examining the drug-using environment. If effective, this analysis would provide a sustainable model for more accurately characterizing drug use with widely available technological tools that would allow for improvements in HIV treatment outcomes for substance abusing individuals.
4. Budget

Materials and Supplies

i. Cellular Phones: $3,600 ($120 per phone, 30 phones)

ii. Data plan and text messaging: $2,400 ($80 per phone, 30 phones)

Estimated Cost: $6,000

Other projected funding: The Department of Epidemiology Doctoral Thesis Fund ($5,000)

Total Projected Expenses: $1,000

Budget Justification: Materials and Supplies

Cellular Phones: EMA data collection requires that each participant carry a cellular phone to complete data collection. Participants will be provided Android smart phones (phones will be reused between participants) to complete surveys sent by study staff to record their real-time drug use.

Data plan and text messaging: The data plan will help run the eMocha platform that is necessary for the delivery of the random prompt surveys to the participants (as well as give participants the ability to report events of real-time drug use). Text messaging will be used for study staff to be in contact with participants if necessary.