

ORIGINAL ARTICLE

## Potential Risks of Ecological Momentary Assessment Among Persons Who Inject Drugs

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### ABSTRACT

**Background:** Ecological momentary assessment (EMA)—which often involves brief surveys delivered via mobile technology—has transformed our understanding of the individual and contextual micro-processes associated with legal and illicit drug use. However, little empirical research has focused on participant's perspective on the probability and magnitude of potential risks in EMA studies. **Objectives:** To garner participant perspectives on potential risks common to EMA studies of illicit drug use. **Methods:** We interviewed 38 persons who inject drugs living in San Diego (CA) and Philadelphia (PA), United States. They completed simulations of an EMA tool and then underwent a semi-structured interview that systematically explored domains of risk considered within the proposed revisions to the Federal Policy for the Protection of Human Subjects or the "Common Rule." Interviews were transcribed verbatim and coded systematically to explore psychological, physical, social, legal, and informational risks from participation. **Results:** Participants perceived most risks to be minimal. Some indicated that repetitive questioning about mood or drug use could cause psychological (i.e., anxiety) or behavioral risks (i.e., drug use relapse). Ironically, the questions that were viewed as risky were considered motivational to engage in healthy behaviors. The most cited risks were legal and social risks stemming from participant concerns about data collection and security. **Importance:** Improving our understanding of these issues is an essential first step to protect human participants in future EMA research. We provide a brief set of recommendations that can aid in the design and ethics review of the future EMA protocol with substance using populations.

### KEYWORDS

mHealth; ethics; risks; persons who inject drugs; polydrug use

### Background

Polydrug use and its study is a significant public health issue, especially because it is highly associated with overdose, the single largest cause of accidental death in the United States (Warner, Chen, Makuc, Anderson, & Miniño, 2011). Deaths from drug overdose have tripled since 1990, and approximately 75% of such deaths involved more than one drug (US Department of Health and Human Services (USDHHS), 1999; Warner et al., 2011). In spite of its prevalence and importance to public health, polydrug use remains a poorly understood practice. Among persons who inject drugs (PWID), considerable heterogeneity exists with regard to individual, social, and structural factors impacting decisions about polydrug use, the timing and combination of drugs used, and the immediate outcomes of such drug use (Betts et al., 2015; Coffin et al., 2003; Kuramoto, Bohnert, & Latkin, 2011; Lankenau & Clatts, 2005; Monga et al., 2007). However,

this information comes primarily from ethnographic literature, which is limited by small sample size, and epidemiological literature, which is limited by its reliance on participant recall and questions that elicit general patterns of behavior (e.g., Likert scales).

Mobile health ("mHealth") approaches, including ecological momentary assessment (EMA), may offer a solution to the methodological challenges of studying polydrug use. Within addictions research, EMA has been used to describe individual, social, and environmental micro-contextual processes that influence drug use. Most EMA studies have focused on triggers to relapse, such as craving or changes in mood for both legal (tobacco) and illegal substances (Serre, Fatseas, Swendsen, & Auriacombe, 2015; Shiffman, 2009). To conduct this research, contextual information about events of interest, such as drug use, and their putative triggers, is measured via personalized mobile devices such as cell phones, physiological sensors,

or global positioning devices. Events are measured frequently (two to five times per day) to capture frequency and distribution of drug use, variation in the thoughts, feelings, and places associated with drug use, and to avoid the pitfalls of participant recall (Shiffman, 2009).

The collection of a large volume of individualized and highly specific data is a methodological strength of EMA. However, the frequency with which participants are assessed, the sensitive nature of drug abuse, and the use of mobile technology raises a number of important questions regarding the protection of participants in EMA studies.

### ***Salient ethical issues in EMA research with persons who inject drugs***

#### ***Respect for persons and informed voluntary consent***

Respect for both persons and informed and voluntary consent is a relevant concern across disciplines. Unique consideration is given to “individuals with diminished autonomy” with special attention paid to “the degree that they are capable, given the opportunity to choose what shall or shall not happen to them” (Belmont Report, 1979). Significant research has focused on whether or not monetary incentives have undue influence on self-determination and whether, in the face of payment for participation, economically marginalized persons living with addictions are able to give consent without undue influence (Emanuel, 2005; Oransky, Fisher, Mahadevana, & Singer, 2009; Slomka, McCurdy, Ratliff, Timpson, & Williams, 2007). This issue is particularly salient in EMA studies, given their often generous compensation for high levels of participation. Participation is incentivized through a combination of payment per assessment completed (US\$0.75–4 per assessment; Hensel, Fortenberry, Harezlak, & Craig, 2012; Johnson, Barrault, Nadeau, & Swendsen, 2009), personal use of the study-provided mobile device (e.g., personal computer, cell phone, etc.), and/or the ability to retain the device upon successful study completion (Epstein et al., 2009). Such compensation may be appropriate, given the level of participant engagement in EMA studies. However, it also raises questions related to “respect for persons” if potential participants feel unable to refuse to participate or withdraw from the research.

#### ***Psychological, social, and legal risks***

Psychological impact is another category of risk that is particularly salient in EMA studies. These risks are also common in other types of research, but are heightened in EMA because participants may be asked to recall highly stigmatized behavior frequently throughout each

day of enrollment. The intensity of these assessments has the potential to induce stress or exacerbate psychiatric symptoms or negative self-perception (National Research Council, 2014). Similarly, participants may face social risks through the repeated disclosure of stigmatized behavior or when cues to initiate data entry occur when participants have limited time or privacy to respond. In addition, participants could be targeted for theft from carrying mobile devices or experience violence as a consequence of a robbery attempt. While some may consider this an indirect risk of participation, it is worth noting that physical risks may be more salient in EMA studies than in other types of behavioral research. Finally, informational risk or the “potential for harm from disclosure of information about an identified individual” is certainly heightened in EMA studies because of near-constant sharing of electronic data (National Research Council, 2014). Like Labrique and colleagues, we believe that it is worth differentiating informational risks to privacy and confidentiality in EMA studies (Labrique, Kirk, Westergaard, & Merritt, 2013). Privacy may be threatened by the nature of EMA protocol, namely, whether or not the participant has input in the timing and duration of assessments. Informational risks to confidentiality stem from the transmission and storage of confidential participant data (Labrique et al., 2013). In the EMA studies of drug use, these risks are even greater, given participants are sharing information about illegal behavior.

To date, little empirical research has focused on the probability and magnitude of potential risks in EMA studies (Labrique et al., 2013). In this paper, we describe ethical issues, specifically potential risks that arise in the EMA studies on substance abuse with persons who inject drugs. Our goals are to describe and contextualize important ethical considerations, and provide recommendations for the development and review of EMA protocols to adequately protect human subjects without unduly hampering behavioral research.

## **Methods**

### ***Settings***

We were interested in whether perceptions of risk would be similar across drug users based on their drug of choice and by the intensity of drug use. Thus, we conducted this study in two cities with contrasting drug markets: one predominated by methamphetamine and Mexican black tar heroin (in San Diego, CA); the other predominated by cocaine and South American powder heroin (in Philadelphia, PA; Drug Enforcement Agency, 2013). Data were collected sequentially from February to April 2015.

## Participants

Inclusion criteria were (1) age  $\geq 18$  years; (2) reported injecting illicit drugs at least once in the past month; (3) reported weekly polydrug use; and (4) ability to provide informed consent. For this study, polydrug use was defined as a sequential or simultaneous use of more than two drugs at least weekly, including heroin, methamphetamine, cocaine, benzodiazepines, or marijuana. In San Diego, participants were recruited from STAHR-II, a prospective and mixed-methods observational cohort study (Robertson et al., 2014) between May 2014 and July 2014. In Philadelphia, participants were recruited from a not-for-profit agency providing a variety of harm reduction services, including syringe exchange and overdose prevention services, drug treatment, and primary medical care. Recruitment took place between February 2015 and April 2015.

## EMA measures

Ecological momentary assessment entries queried a variety of contextual determinants that were thought to play a key role in polydrug use. Using closed-ended survey questions, each entry began with an assessment of participant mood and drug use via a three-path system. Participants were sent to *Path A* when they indicated drug use occurred. Participants entered the substances they used from alcohol, marijuana, cocaine (powder and crack), stimulants, methamphetamine, inhalants, benzodiazepines, synthetic drugs (like spice or K2), heroin, prescription opioids, methadone as well as buprenorphine (suboxone/subutex). They were then asked to describe the route of administration for each drug (i.e., snort, swallow, smoke, or inject), the amount of each substance consumed (i.e., number of bags of heroin, number of prescription pills, number of beers, shots, or 8 oz. glasses of wine), and the street value of the drug consumed. If injection drug use occurred, they were asked additional contextual information about their last injection event, including the nature of their relationship to their injection partner (i.e., stranger, regular date, trick or john, drug dealer, friend, boyfriend/girlfriend, fiancé/spouse); whether they were not consuming drug(s) alone; where drug use occurred (i.e., at my home, at someone else's home, at a hotel/motel, in an abandoned building, in a car, in a park or other public space, in a bar, or at work); whether HIV risk behaviors occurred (i.e., syringe/injection equipment sharing; distributing drugs from one syringe to another); and the rationale for sharing (i.e., "I know the HIV serostatus of the person I shared with"). *Path B*, completed during periods of drug abstinence, included questions on daily activities

(i.e., spending time with friends or family, providing childcare, doing household chores, handling US\$10 or more, etc.); drug craving (described as a strong desire or urge to use and assessed for each drug listed in Path A with 11-point rating scale where 10 represents the highest possible intensity); income-generating activities (i.e., working on a job, recycling, sex work, borrowing money, stealing money, panhandling, and dealing drugs), and reasons for non-use (i.e., being tired of getting high, trying to stay clean, not having money to buy drugs, being with friends or family who do not use, fear of arrest, inability to reach a drug dealer, incarceration, etc). *Path C* assessed sexual activity when indicated and included which sexual behaviors occurred (i.e., kissing, anal, oral, and/or vaginal sex) and condom use. We captured a unique partner identifier for each sexual event. Regardless of the path (A or B), diary entries were designed to take approximately the same amount of time, and both paths routed participants through Path C (sexual activity).

## EMA simulation

In order to ensure that participants were routed through all potential paths, they completed two EMAs: one for path A/B and another for path B/C. Each simulation was designed to last approximately 15 min. Simulations were completed on a cell phone in a private space at either the study (San Diego) or syringe exchange program (Philadelphia) office. Prior to beginning the simulation, research staff explained the study's purpose, including an overview of EMA. Second, participants were shown the specific data security measures being employed by the study, including both cell phone and password-protected EMA portal. Third, participants were informed that data were entered through an encrypted Internet connection and would be stored on a secure server. Participants were also informed that no information would be retained on the phone to help protect their privacy. Fourth, participants were also instructed how to enter data on the phone. Fifth, they were instructed to initiate data entry and asked to "think aloud" or voice any concerns or questions regarding the assessment as they entered their data (De Jong & Schellens, 2003; McDonald & Edwards, 2014). This "think aloud" procedure is often used in consumer-driven product development and usability testing.

## Interviews

After the simulations, participants were interviewed about their experience and potential risks associated with participation. For example, we asked, "How do you think being in an EMA study might impact your life?" This was

followed with probes relating to potential risks. For example, “Can you think of any bad things that could possibly happen as a result of answering the questions repeatedly over time?” and “If you began to carry a cell phone like the one you just used, what would people think (do) if they noticed?” In addition, we assessed “Thinking back to how you felt when you were answering those questions, were you more or less comfortable than you would be answering questions your medical doctor or counselor would ask you?” Participants were compensated US\$30 for participating in the 60–90 min interview (and socio-demographic and behavioral survey when applicable). All interviews were digitally recorded and transcribed verbatim. Research activities were approved by the Institutional Review Boards (IRBs) at the University of California San Diego, Drexel University, and the harm reduction agency in Philadelphia.

### **Qualitative analysis**

Qualitative analysis involved an iterative process of reviewing texts from the interviews. First, a priori “structured codes” corresponding to the domains in the interview guide were developed. Second, “emergent codes” that reflected unanticipated themes from the interviews were incorporated into the coding framework. Two members analyzed each transcript and all coding discrepancies were resolved by discussion until inter-rater reliability exceeded 75%. In the final phase of analysis, illustrative quotes (exemplars) were selected for each qualitative sub-theme.

### **Quantitative data and analysis**

In addition to the simulations and interviews, we collected survey data to describe the samples. In San Diego, we obtained data from the participants’ most recent STAHR-II quarterly follow-up interview. In San Diego, we collected demographic and behavioral information using a self-administered electronic survey. In both cities, survey items assessed socio-demographic characteristics, drug and alcohol use, syringe and injection equipment sharing, and cell phone use. The recall period for demographic and drug-related questions was 6 months, while in Philadelphia, the recall period for these questions was 3 months. Owing to a technical error in the survey software, baseline interviews with two participants in Philadelphia were not captured, so the table that described the samples (Table 1) uses  $N = 36$ . All responses of “refuse to answer” were recoded as missing for purposes of calculating percentage values. Statistical analyses were performed using SPSS, which includes calculating the proportion of participants who noted any risks or benefits (IBM Corp, 2013).

## **Results**

### **Sample description**

A total of 38 participants were enrolled, 18 in San Diego and 20 in Philadelphia. In spite of being recruited from opposite coasts of the United States, participant characteristics were relatively similar across the sites. Median age, gender, income, age at first injection, syringe sharing, and current cell phone ownership were not significantly different between participants in the two cities. Participants in San Diego reported higher educational attainment (72.2% vs. 22.2% had some college education;  $p < .01$ ), reported more frequent binge drinking (76.9% vs. 16.7% daily binge drinking;  $p < .01$ ), and were more likely to report owning a smart phone (78.6% compared with 11.1%;  $p < .001$ ). Drugs injected most often also varied by the city ( $p < .01$ ). In San Diego, the most frequently injected drug was methamphetamine (73.3%), while in Philadelphia the most frequently injected drug was heroin (82.4%). Less than 5% of PWID reported simultaneous polydrug combination as their most frequently injected drug. However, 22.2% of San Diego and 61.1% of Philadelphia participants reported simultaneous heroin/methamphetamine and heroin/cocaine (speedball) injection over the last 6 and 3 months, respectively. Additional comparisons are shown in Table 1.

### **Salient ethical issues in EMA research with persons who inject drugs**

Overall, participants perceived relatively few informational, legal, social, behavioral, psychological, or physical risks from participation. The majority of participants (95%) either indicated that answering the questions would not cause any harm or did not identify the questions as making them feel any more uncomfortable than if they were speaking with a doctor or counselor—a benchmark for minimal risk in social and behavioral research (National Research Council, 2014). This sentiment is exemplified by Rana, a 43-year-old male in San Diego, who stated: “I wasn’t uncomfortable answering the questions really. And ... since this is private ... you’re not even talking to someone face to face. It’s not ... the slightest bit uncomfortable.” There were no differences in the perceptions of risk based on the participants’ gender, frequency of drug use, or city of recruitment.

In spite of this overall perception of low risk, some indicated how certain risks might be of greater significance to PWID more vulnerable to theft and/or violence, such as homeless persons. Carlos, a 40-year-old male in Philadelphia, described how life circumstances may predispose PWID to theft:

**Table 1.** Demographic and drug use factors by study site.\*,†

	Total (N = 36)	San Diego, CA N = 18	Philadelphia, PA (N = 18)
Age (years) (median, IQR)	44.5 (39.75, 54.25)	49 (42.75, 54.25)	41 (37.5, 55.5)
Gender (male)	23 (63.9%)	10 (55.6%)	13 (72.2%)
Race			
White	20 (55.6%)	9 (50.0%)	11 (61.1%)
Black	7 (19.4%)	1 (5.6%)	6 (33.3%)
Others	9 (25.0%)	8 (44.4%)	1 (5.6%)
Hispanic ethnicity, yes (vs. no)	N = 35 5 (14.3%)	3 (16.7%)	N = 17 2 (11.8%)
Annual income <US\$10,000 (vs. >US\$10,001)	28 (77.8%)	15 (83.3%)	13 (72.2%)
Educational attainment			
<High school	12 (33.3%)	5 (27.8%)	7 (38.9%)
High school or equivalent	7 (19.4%)	—	7 (38.9%)
>High school	17 (47.2%)	13 (72.2%)	4 (22.2%)
Housing status homeless (vs. housed)	20 (55.6%)	9 (50%)	11 (61.1%)
Syringe exchange usage, used (vs. not used)	N = 35 29 (82.9%)	13 (72.2%)	N = 17 16 (88.9%)
Age first injected, years (median, IQR)	22 (16.0, 30.0)	23 (13.75–30)	21.5 (15.75–33.0)
Shared syringes (vs. not), last 3 months	N = 31 18 (58.0%)	N = 13 12 (92.3%)	6 (33.3%)
Drugs injected most often	N = 32	N = 15	N = 17
Heroin	15 (46.9%)	1 (6.7%)	14 (82.4%)
Methamphetamine	11 (34.4%)	11 (73.3%)	—
Methamphetamine and heroin	2 (6.3%)	2 (13.3%)	—
Heroin and cocaine (speedball)	3 (9.4%)	—	3 (17.6%)
Cocaine	1 (3.1%)	1 (3.1%)	—
Binge drinking**	N = 31	N = 13	
Daily	13 (41.9%)	10 (76.9%)	3 (16.7%)
Weekly	4 (12.9%)	1 (7.7%)	3 (16.7%)
Monthly	6 (19.4%)	2 (15.4%)	4 (22.2%)
Never	7 (22.6%)	—	7 (38.9%)
Marijuana			
Daily	9 (25.0%)	7 (38.9%)	2 (11.1%)
Weekly	6 (16.7%)	3 (16.7%)	3 (16.7%)
Monthly	8 (22.2%)	3 (16.7%)	5 (27.8%)
Never	12 (33.3%)	5 (27.8%)	7 (38.9%)
Cell phone use			
Current cellphone ownership, yes (vs. no)	24 (66.7%)	14 (77.8%)	10 (55.6%)
Current cellphone type, smartphone (vs. other)	N = 24 13 (54.2%)	N = 14 11 (78.6%)	N = 10 2 (11.1%)

Notes. \*The recall period for questions was 6 months in San Diego and 3 months in Philadelphia.

\*\*Binge drinking was defined as consuming five or more drinks in a single day.

†Variations in N for demographic and drug use factors is due to missing or incomplete data for the indicated variable.

It's hard to keep stuff of value when you're using drugs. Some people have it harder than me, when you're living with vandals you don't have no security. I know people that wouldn't sell their stuff and they get their stuff stolen just cause they nod out.

Importantly, no participant thought that carrying the phone would jeopardize their safety and only 8% identified theft as a possible risk even after substantial probing.

Behavioral and psychological risks were considered possible, but not probable risks from participating in an EMA study. Most reported that the effect of being repeatedly questioned about mood or drug use would be minimal. However, some PWID were considered to be more vulnerable to these risks. For example, Tom, a 40-year-old male in Philadelphia stated:

It depends on how a person's feeling. If they're constantly being reminded that they're in the bottom of the barrel, feeling depressed, and constantly having to go over how they feel, then that could make them more anxious of not wanting to feel that way by either committing suicide or overdosing because they're constantly reminded of it ...

Importantly, while some (39%) participants indicated that repetitive questioning about mood or drug use could cause psychological (i.e., anxiety) or behavioral risk (i.e., drug use relapse), all participants (100%) indicated that completing the EMAs would likely be a benefit. Ironically, the same questions that were viewed as risky were also considered to be potential catalysts for thinking reflexively about drug use, which could increase motivation and self-efficacy to engage in healthy behaviors. Rana, who described the study's potential to encourage reflexivity, stated: “[Answering the questions] would make me, force me, to reflect on my day to day activities ... it would ... make it more clear where you should be like putting in effort to make a change .... It's like putting a mirror in front of you.”

A more serious social risk concerned members of participants' social networks noticing a new phone and viewing it as evidence of involvement with law enforcement. Thomas, a 58-year-old male in San Diego, expressed this real concern: “... people are paranoid about people out there walking around with cell phones anyway calling

the cops ... when you're on the phone, other people get suspicious.”

In spite of being reassured of multiple forms of data protection (i.e., password-protected cell phones, encrypted web connections, and secure servers) in the simulated study, the most frequently voiced risk for an actual EMA study of longer duration was “loss of confidentiality and data security.” Participants, who expressed a general lack of trust, disdain for, or fear of the police and the justice system, were concerned that information they disclosed could be obtained by the police through either a breach in data security or from researchers complying with a request from law enforcement to share data. Additional concerns were voiced as to how personal cellphones infused with EMA software, such as the study splash screen, could inadvertently reveal sensitive information about a participant. Regarding the study splash screen, which would appear each time a participant logged on, Charles, a 43-year-old male in San Diego, stated: “HIV Prevention Research, that's too sensitive ... and that's all my family would need ... I found out in '91 [about my HIV diagnosis] and my family doesn't know ...” He noted that the information on the study splash screen, including identification of the funding source, should be considered protected and potentially sensitive information.

Finally, all participants stated that having access to a phone would be a benefit that would encourage them to participate in an EMA study if personal use of the device (i.e., texts, calls, Internet, and games) was permitted. We assessed possible levels of payment, including different levels of payment per response (US\$1–2 per EMA), lower levels of payment with a bonus for completing 100% of EMA (US\$1 per EMA plus a US\$3 bonus weekly or entry in a raffle), and keeping the device at the end of the study. No consensus emerged among participants regarding the appropriate amount of compensation. Interestingly, participants responded positively to customizing compensation. For example, when offered the option to keep a study phone or return it for US\$50 cash, Timothy, a 44-year-old male in San Diego, stated: “I'd probably keep the phone .... It just depends how low I am on money, but I might keep it anyway thinking, ‘well, if I don't want to keep it I could sell it for a little more or trade it for a little more.’”

## Discussion

This study is the first to explore active injection drug users' (who were also polydrug users) perceptions of risks associated with participation in an EMA study. We found that PWID, a putatively vulnerable population of potential research participants, judge the risks of mHealth research to be low, and furthermore felt confident about assessing

the risks of such research and making an informed choice regarding research participation. However, participants who endorse more high-risk behaviors or experience different vulnerabilities may view the risk from mHealth research differently. Thus, investigators should assess population-based risks and perception of risk from this type of research prior to initiating EMA studies. Simple formative research, including informal conversations or a few focus groups, will help investigators understand risks, inform their understanding of the populations' perspective on research protections, and help them tailor informed consents to help ensure that participation is voluntary. We discuss the implications of our findings across each of the domains of risk we investigated below.

### *Psychological, social, and legal risks*

Using the Common Rule as our guide, we queried participants about risks common in EMA research. Across settings, participants were not personally concerned about psychological and physical risks. However, participants indicated that more vulnerable PWID, such as those with psychiatric co-morbidities or those who are homeless, could have increased susceptibility to these risks. The most referenced risk was informational and centered on breaches in data security or the intentional sharing of data with law enforcement. This finding is not surprising and has been reported in other studies investigating participant perspectives on ethical concerns of sensitive research (Beskow, Check, & Ammarell, 2014). Participants in this study were concerned that any data shared with police could lead to arrest or incarceration. While the privacy protections put in place were enough to assuage these concerns for the simulated study, additional research is needed to understand whether participants understand these protections. Beyond fear of arrest, participants indicated social consequences of study participation if peers perceived they were collaborating with the police. For some this could lead to minor interpersonal skirmishes while for others the consequences could be graver, including threats of or violence.

### *Respect for persons and informed voluntary consent*

While the generally low perceived risks of mHealth research are encouraging, it remains important for researchers to implement reasonable safeguards concerning such risks. To this end, participants provided numerous suggestions that they believed would protect PWID participating in an EMA study. These suggestions included a detailed informed consent process outlining data security and phone protection measures; describing the domains being included in EMA and

highlighting areas that could trigger psychological distress or unwanted behaviors (i.e., relapse); flexible windows for data entry to ensure the participants' ability to find a private or secluded space; provision of device with low street value; and limiting the amount of sensitive information about the study available publically (i.e., on study website or the phone's splash screen).

Although not the focus of the present article, participants also reported that EMA studies might offer unique benefits to research participants. They reported that recalling their feelings and actions could serve as a catalyst for positive change by increasing motivation or self-efficacy to make positive changes. Regarding this point, the literature on reactivity in EMA studies is mixed. While some scholars have reported that the magnitude of reactivity to EMA is small (Heron & Smyth, 2013; Hufford, Shields, Shiffman, Paty, & Balabanis, 2002; Rowan et al., 2007), others conducting longitudinal research have indicated therapeutic effects. Gunn, Roth, Center, and Wiehe (2016) reported that participation in a 4-week EMA and interview study had unanticipated positive impacts on female sex workers' anxiety, depression, and self-esteem. Similarly, Stopka, Springer, Khoshnood, Shaw, and Singer (2004) reported that several PWID either expressed a desire to quit using drugs or enrolled in drug treatment shortly after completing a pencil-and-paper diary study of HIV risk. While further research is needed to confirm whether or not these effects can be attributed to participation in EMA studies, we believe these potential benefits should be included as part of the informed consent process.

### **Limitations and the future studies**

While this study constitutes an important preliminary step in empirically characterizing the risks of EMA research, our findings should be interpreted with important limitations in mind. First, this study enrolled a small number of individuals reporting very heavy drug use, and their viewpoints on research risk might not be representative of all PWID. In addition, we assessed for risks associated with the collection of electronic EMA data (via an encrypted web connection) on smart phones. Studies using other methods (i.e., SMS texts, GPS devices, other sensors) pose distinct threats to data security, which may impact participants' perceptions of risks, and thus our results may not be generalizable to all EMA studies. Rather than results based on an actual EMA study, this study examined risks from a hypothetical perspective by asking participants about the kinds of risks that might be encountered. We did not have an opportunity to examine different levels or types of compensation that might

impact participation. Others have found that higher payments and cash payments can improve retention and participant satisfaction (Festinger, Marlowe, Dugosh, Croft, & Arabia, 2008). Future studies should examine the ethical and pragmatic issues relating to compensation in EMA studies of longer duration as those may be different than those highlighted here.

### **Conclusions**

Ecological momentary assessment has advanced research on drug use and a host of other public health issues by improving reliability and precision in data collection. However, this approach also raises questions regarding ethical concerns such as privacy, stigma, the burden of research participation, and the triggering of unwanted feelings or self-destructive behaviors. In this small ethics study, a bicoastal sample of PWID found few risks associated with participation in a hypothetical EMA study, and furthermore expressed confidence regarding their capacity to understand, weigh, and make an informed choice about participation. Findings identify and clarify possible ethical issues in mHealth research and offer practical guidance to researchers and IRBs.

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### **Declaration of interest**

The authors report no conflicts of interest. The authors alone are responsible for the content and writing of the article.

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