PERSONS WHO INJECT DRUGS’ PERSPECTIVES ON THE RISKS AND BENEFITS OF PARTICIPATION IN A MOBILE HEALTH STUDY OF POLYDRUG USE

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HEAL
HEALTH EQUITY ADVANCEMENT LAB
Outline

Building a research line in empirical ethics centering on how vulnerable populations anticipate risks and benefits associated with drug research and the specific challenges of emerging technology in drug research:

1. **RETI Fellowship Study**: Persons who inject drugs’ perspectives on the risks and benefits of participation in a mobile health study of polydrug use

2. **Current Study**: Feasibility of wearable biosensors to characterize the physiologic context of opioid use and outcomes
Persons who inject drugs’ perspectives on the risks and benefits of participation in a mobile health study of polydrug use
Acknowledgements

Participants

Collaborators

- Dr. Janie Simmons
- Dr. Richard Garfein
- Dr. Richard Armenta
- Marisa Felsher, DrPH(c)
- Megan Reed, DrPH(c)

Funding

- NIDA R25 DA031608 (Fisher)
- NIDA T32 DA023356 (Strathdee)
- NIDA 1R01 DA031074 (Garfein)
Mobile Health (mHealth) Research

• mHealth research leverages the capabilities of mobile devices to monitor behavior and deliver health care

• The harms and benefits of using mHealth approaches have yet to be systematically assessed

• Best-practice guidelines are not yet available; such guidelines are particularly salient for research with vulnerable populations
Potential Risks in mHealth

- Theft of devices
- Stigmatization
- Participant burden
  - Behavioral assessments 2-5 times per day\(^1\)
  - Either pre-specified or random times\(^1,2\)
- Fairly generous compensation structures\(^2-5\)
- Collection of high-volume of data on illegal behavior
Potential Benefits in mHealth

- Research has documented unanticipated benefits of participation in diary and interview studies

  → Increased self-awareness, empowerment, and ability to manage emotional reactions

  → May effect cognitive processes

  → Participants may begin to assess predictors, consequences and correlates of their behaviors
Study purpose

To explore participant perspectives on the potential risks and benefits associated with participation in a hypothetical mHealth study of polydrug use
Methods: Scenario

- Participants were informed they would have the opportunity to help researchers design a longitudinal study of polydrug use.

- Polydrug use types
  1. Simultaneous
  2. Sequential

- Polydrug use is associated with negative health outcomes including drug overdose.
Methods: Recruitment

- Participants were:
  1) ≥ 18 years of age
  2) Reported injecting illicit drugs in the past month
  3) Reported weekly polydrug use

- Recruitment occurred in San Diego, CA (N=18) and Philadelphia, PA (N=20)

- Participant demographics were similar in both cities
  - Mean age 44.5 years, 64% male, 56% white, 56% homeless
Methods: Data Collection & Analysis

• Completed simulations of a cell phone diary
• Interviewed about experiences

“How do you think completing diaries might impact your life?”

“Can you think of any bad [good] things that could happen as a result of answering the questions over time?”

• Qualitative analysis of interview texts for ethical themes
Findings: Potential Benefits

• All participants reported potential indirect benefits associated with participation

• Many felt repeated behavioral assessments would be a positive influence by encouraging reflection and increasing self-awareness

• Utilization of expertise and potential to help others

• Use of phone (and payment for participation) as economic benefit
Participant Perspectives on Benefits

Reflexivity

“It would make me reflect on my day-to-day activities…make it more clear as you’re answering the questions where you should be putting in effort to make a change. It’s like putting a mirror in front of you.”

(Steve, 43, San Diego)
Participant Perspectives on Benefits

**Being recognized as an expert**

“[If] you take heed to what I talk about…I’ll feel like, alright, I did something…I’ll feel good about myself…It makes me want to do other things to make me feel good about myself.”

(Rana, 34, San Diego)
Participant Perspectives on Benefits

Altruism

“If what we’re doing…is going to stop someone from getting on…or help someone get off heroin, let’s do it. I wouldn’t wish this on anyone.”

(Eddie, 65, Philadelphia)
Findings: Potential Risks of Participation

- **Physical** risks arise from carrying a study cell phone
- **Behavioral** and **psychological** risks stem from repeated disclosure of mood state or behavior
- **Legal** risks were those that might arise if law enforcement obtained any information about participants
- **Informational** risks arose from unintentional disclosure of drug use or other stigmatized information more broadly
"It’s hard to keep stuff of value when you’re using drugs, you know what I mean? 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… [Once,] I fell asleep and when I woke up, I didn’t have my money. I didn’t have this. I didn’t have that.”

(Carlos, 40, Philadelphia)
Participant Perspectives on Risks

Triggers & potential psychological risks

“If a participant is constantly being reminded that they’re in the bottom of the barrel and feeling depressed, constantly having to go over how they feel could make them more anxious and want to commit suicide or overdose.”

(Mike, 40, Philadelphia)
Participant Perspectives on Risks

**Mitigating harms**

“Say, ‘Listen, you’re gonna have to constantly monitor your mood. I want you to be aware that during the course of what’s going on in your life, if something bad was to occur that would make you have a bad mood or irritated, that you need to be aware you will be constantly reminded of it.”

(Mike, 40, Philadelphia)
Conclusion

• Engagement in mHealth might confer important benefits

• Risks described as unlikely, however, it remains important for researchers to implement reasonable safeguards

• As mHealth becomes more widely used, it will be important to conduct research on harms and benefits
  
  o Actual harms and benefits could be different than those reported here
CURRENT STUDY
FEASIBILITY OF WEARABLE BIOSENSORS TO CHARACTERIZE THE PHYSIOLOGIC CONTEXT OF OPIOID USE AND OUTCOMES

Embedded within: Piloting a naloxone intervention in an emergency response community (ERC) to reduce opioid overdoses in Philadelphia 1 R34 DA044758-01 (PIs: Lankenau and Schwartz)
Acknowledgements

• Co-investigators
  o Stephen Lankenau, PhD
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• Research assistants
  o Brogan Piecara, MPH
  o Allison Mitchell, MPH
  o Marisa Felsher, MPH

• Consultants
  o Devon Hensel, PhD (Indiana University Purdue University Indianapolis)
Give naloxone, save a life.
Aims
1) Identify barriers and facilitators of acceptance and use of a smartphone-based emergency response community (ERC) naloxone intervention
2) Pilot test the implementation of UnityPhilly in an ERC consisting of 55 non-medical opioid users and 55 community members
3) Synthesize knowledge acquired in Aims 1 and 2 to be used in a subsequent R01 study to conduct a large-scale, multi-site implementation trial

Design
Mixed methods, longitudinal:
12 monthly quantitative surveys, 1 waves of qualitative interviews (n=30)
How to Send an Opioid Overdose SOS (Android)

PRESS the SOS button

Let the counter reach 0

SOS active.
Looking for responders.
Help is on the way.
How to Respond to an Opioid Overdose SOS Alert
How to Respond to an Opioid Overdose SOS Alert
SensOD: Using Technology to Combat the Crises
Wearable biosensors hold promise for better characterizing the physiologic context of drug use and for preventing ODD.

These devices can be programmed to:

1) identify physiological signs of opioid overdose-induced respiratory depression
2) buzz and ring to alert a person who has overdosed
3) sound an alarm to alert bystanders of an emergency; and
4) automatically trigger a call to emergency medical services

Wearable biosensors have been used to improve outcomes for chronic conditions

However, they have yet to be applied to the study of opioid use and overdose
AIMS & METHODS

• Aim 1. Demonstrate the feasibility of a wearable biosensor to capture incidence and physiologic response to opioid use.

• High-volume (defined as >2 opioid events daily during preceding month) people who use opioids will be assigned a biosensor that measures functional oxygen saturation of arterial hemoglobin ($\text{SpO}_2$), pulse rate, and physical activity (accelerometer) for 5 days.

• Quantitative analyses will characterize incidence and physiologic responses to opioid, cocaine, and polydrug use.

Oxitone

Spire Health Tag
AIMS & METHODS

• **Aim 2.** Explore opioid use events to understand affective, cognitive, and environmental factors temporally related to each event.

• Participants will complete a semi-structured daily timeline follow-back interview every 24 hours for 5 days and self-report on the context of each event measured by the biosensor.

• Items and event-level quantitative analyses will be guided by Zinberg’s “Drug, Set, Setting” to explore variation in drug use/outcomes.

• Payment = $20/day for 60 min interview and $30 for returning device

![Figure 3. Visual Display of Physiologic Data from Oxitone, 24 hours](image-url)
AIMS & METHODS

- **Aim 3.** Describe the acceptability of wearable biosensors to monitor drug use and detect overdose events using qualitative methods.
- At exit, participants will complete a brief qualitative interview on the risks and benefits of device use informed by the updated common rule and guidelines for mHealth research.
Ethical considerations for SensOD?
Ethical considerations for SensOD?

• How do these relate to justice, beneficence and respect for persons?
Ethical considerations for SensOD?

• How do these relate to Guidance from the Belmont Report that suggests risks and benefits can occur across five domains: psychological, physical (i.e., health), legal, social, and economic?
Ethical considerations for SensOD?

• What is the work that needs to be done prior to implementation?

• What is the work that needs to be done during implementation?

• What is the work that needs to be understand the participation experience?
Understanding Perceived & Real Risks and Benefits

• Design and piloting
• Implementation and post hoc analyses
Thinking about risks & benefits in RETI studies
Discussion?

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QUALITATIVE RESEARCH METHODS

in Empirical Ethics Studies on Drug Use and HIV
Ethical considerations for RETI studies

• Strengths and weakness of qualitative methods to understand research ethics and participant experiences in HIV or drug use research (compared to quantitative methods)?
How do we shape research questions to understand participant experiences in HIV or drug use research?

- Trying to understand how past experiences influence participation?
- Trying to understand how participants anticipate risks/benefits in something that may be unknown?
- Trying to understand how participants actually experience research?
How does the question influence the method?

- **Qualitative Interviews vs Focus Groups**
  - Purpose
  - Strengths
  - Difficulties

- **Important to think about the objective of your study in order to decide which type of interview is most appropriate for your study**

- **Sample**
  - Purposive
  - Stratification
  - Saturation

- **Feasibility matters —time, resources, staff, access to population**

- **Each person yields an extraordinary amount of data**
Data collection logistics

Who is going to collect the data?
Where will it happen?
How will you recruit people?
Who will you recruit?
How long will it take?
How will you ensure confidentiality?
Creating the field guide: overview

• The field guide is the instrument you use to generate data to answer your RQ

• Merely a tool for data collection – your interviewer is crucial to getting good data!

• No written rules around the structure/layout of these guides

• Often a series of questions with sub-questions or probes written beneath them
How scripted should we be?
Spectrum of in depth interviews (FGD)

- what the data collection tool would look like for each type?
- any strengths/weaknesses of each type?
- Which makes most sense for your MRP and why?
Ethical considerations for RETI studies

• How can ethical principles inform structure of your interview or FGD guide?
  
  o Research questions relating to Belmont Report principles of justice, beneficence and respect for persons...
  
  o Research questions relating to guidance that suggests risks benefits can occur across five domains: psychological, physical (i.e., health), legal, social, and economic?
Creating your field guide: interview questions

- Interview questions are those you will ask participants to help you answer your research questions.

- When developing your interview questions, you need to think about:
  - The language of your questions
  - The breadth and depth of your questions
  - Respondent burden
  - Logical sequencing of questions
Sequencing questions on an interview guide

• There are no rules about how to sequence questions on a guide
  • Other than: Don’t start with the most sensitive questions

• The questions should flow logically

• You need to be sensitive to how many questions you can cover in an allotted time frame.
  • For a 45 minute interview, you should not have more than 5-7 main interview questions for your interview guides.

• Within in each question you may have a number of probes, but don’t go in with more interview questions.
Example RQ and guide on ADOLESCENT MOTHERHOOD in South Africa

RQ1. How does adolescent motherhood affect adolescent girls’ experiences in high school in South Africa?

IQ1. Can you tell me a little bit about your experiences in school before you fell pregnant? Probe: How did you feel about school? What were some of the things you liked/disliked about it?

IQ2. Tell me about your experiences in school while you were pregnant. Probes: Was school different because of pregnancy? If yes, in what ways? How were you treated by teachers? How were you treated by other learners? How did the school – or specific people at the school - help you during your pregnancy, if at all? When did you stop going to school? Why?
• Ways to get people talking…
  • Stories
    • Think back to XXX.
    • Give prompts.
    • Ask people to tell you a story about XXX.

• What is your favorite ways to get people talking?
  • In an interview…
  • In a focus group…
TYPES OF Probes

• **Direct**: Used to follow up on topics that you know are of interest. Use probes to define terms that the interviewer may or may not be familiar with.

  - “What do you mean when you say_____?”

  - “So you said that __________ are major problems in your community. What other problems exist here? “
TYPES OF Probes

• **Indirect verbal probes:** Use active probes to summarize and confirm what an informant has said.
  - “I heard you say X about Y. Can you tell me more about Y”
  - “Anything else? “

• **Indirect non-verbal probes:** Use passive probes to gain information without interrupting the flow of the interview.
  - “uh huh”
  - (silence)
Anticipating probes ahead of time

What are the strengths of listing probes on an in-depth interview guide?

Any weaknesses?
• Importance of setting up your guide to get at a priori constructs of interest while leaving space to elicit the emergent

• Write a research question for your MRP study.
  • Write two interview or FGD discussion question that you think might help you begin to answer that research question.
EXAMPLE INTERVIEW GUIDES
<table>
<thead>
<tr>
<th>Theme</th>
<th>Domain</th>
<th>Prompt Question</th>
<th>Sample Follow-Up Probes</th>
</tr>
</thead>
</table>
| Beneficence | General assessment of harms & benefits | Think Back to the questions we have asked you over the past week. We asked a lot of detailed and sensitive information. We also collected data about how your body may have reacted to drug use.  
Tell me a little bit about your experience over the past week as a study participant.  
Sometimes bad things happen to people as a result of participating in a research study.  
- Again, because this technology is so new, we don’t know about the bad things that can happen to people participating in studies that use biosensors.  
- Did anything bad happen to you over the past 5 days that you specifically attribute to being in the study? | • How would you describe your experience to a friend who might also be interested in participating in the study?  
• Probe some of the bad things…” [triggering drug use, theft]  
• Elicit source of harm: meeting with RA, being tracked, payment, participant targeted for theft of device/phone uplink  
• What of all of the things we just discussed, most worries you? Why? |
<table>
<thead>
<tr>
<th>Physical &amp; psychological risks</th>
<th>How did having to wear the biosensor impact your day-to-day life?</th>
<th>How did knowing these data were continuously being collected impact you?</th>
</tr>
</thead>
<tbody>
<tr>
<td></td>
<td>How did wearing the device impact your use of drugs? Did you do anything differently when wearing the device, e.g., used more or less, different types of drugs, different times of day, or different people?</td>
<td>▪ How did wearing the device impact your use of drugs? Did you do anything differently when wearing the device, e.g., used more or less, different types of drugs, different times of day, or different people?</td>
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<td></td>
<td>What specific feelings did you have about wearing the device? Probe for anxiety, fear, surveillance-related anxiety, differentiate from anxiety related to being targeted for theft).</td>
<td>▪ What specific feelings did you have about wearing the device? Probe for anxiety, fear, surveillance-related anxiety, differentiate from anxiety related to being targeted for theft).</td>
</tr>
<tr>
<td></td>
<td>If you (or someone else) began to wear the biosensor on your wrist (Oxitone) like the one you just used, what would people think (do) if they noticed?</td>
<td>▪ If you (or someone else) began to wear the biosensor on your wrist (Oxitone) like the one you just used, what would people think (do) if they noticed?</td>
</tr>
</tbody>
</table>
| Legal risks | Drug use is technically an illegal behavior. How did knowing we were tracking your biological responses to engaging in an illegal behavior impact you? | ▪ How does this compare about your concerns day-to-day as a person who uses drugs?  
▪ Were you more or less concerned?  
▪ Probe for differences between people who use indoors/outdoors and alone/with others. |
| Technology | What concerns if any did you have about how we store your data? | ▪ What concerns if any do you have about who will see your data? |
| Psychological risks | How did doing the daily interview impact you? | ▪ Probe for intervention effects, probe for effects of compensation, probe for differences between people |