Short Take: Collecting Data from a Vulnerable Population during the COVID-19 Pandemic

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Abstract
Conducting field research with a vulnerable population is difficult under the most auspicious conditions, and these difficulties only increase during a pandemic. Here, we describe the practical challenges and ethical considerations surrounding a recent data collection effort with a high-risk population during the COVID-19 pandemic. We detail our strategies related to research design, site selection, and ethical review.

Introduction
Conducting field research during a pandemic raises unique practical and ethical considerations for researchers (Will et al. 2020). Working around a highly communicable disease requires researchers to develop protocols that mitigate the risk of contagion for both research staff and participants (Dunlop et al. 2020; Gummer et al. 2020; Sastry et al. 2020; Silva and Mont’Alverne

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These problems are amplified in research with vulnerable populations (Kohler 2020; Scherpenzeel et al. 2020). People who use drugs (PWUD), for example, are at higher risk for health problems (Bell et al. 2001; Degenhardt et al. 2017; Dombrowski et al. 2016; Lineberry and Bostwick 2006) and may be particularly vulnerable to COVID-19 (Jenkins et al. 2020; Walters et al. 2020). PWUD and other vulnerable populations may be less willing to trust and participate in research studies, making data collection even more challenging (Costenbader et al. 2006; Dunlop et al. 2020).

We report on study protocols that were developed pre-COVID-19 for a pilot project, which we modified for safe implementation during the pandemic. Our modified data collection efforts resulted in a sample of 28 PWUD, in line with our pre-COVID-19 target sample size of 30 (see Online Appendix A for details about recruitment and the sample). Below, we describe the strategies employed to mitigate risks to all parties. We pay close attention to the balance between data quality and infection risk. We end by discussing remaining challenges and open questions for future research.

**Original Research Design and COVID-19 Modifications**

Our primary task was to modify the original study design to mitigate infection risk. Our original research design was developed to examine the role of drug use in daily interactions, activities, and the well-being of PWUD. The study included both in-person and digital components spanning four weeks. Participants arrived at the site, completed an electronic intake survey, and received a smartphone device (Capon 2016; Roth et al. 2017; Tyler and Schmitz 2017). Using an app on the device, participants answered daily questions about drug use and social interactions and returned weekly to receive compensation for their responses (see Online Appendix B). After four weeks, participants returned to complete an outtake survey, a semi-structured exit interview, and to collect final compensation. The intake, outtake, and weekly compensation appointments were to be held in-person in a private interview room at the university.

COVID-19 spreads most easily in poorly ventilated, indoor locations (Stadnytskyi et al. 2020). Our original study design relied on a high frequency of in-person interactions within a single indoor space. We considered several modification options to balance data quality, participant engagement, field staff resources, and COVID-19 risk. Ultimately, we made three significant changes to our protocols: We moved our site outdoors, shortened the duration of the study, and shifted many interactions to a virtual format.

**Research Site Relocation**

Our first change was moving our data collection site from an indoor space to an outdoor site. This move opened up complicated questions about control over
physical space, and a researcher must be prepared to negotiate with different institutional bodies to acquire the rights to a research site. Moving outside also raised concerns about participant privacy, protocol logistics, and feasibility.

Any study in a public outdoor setting faces the challenge of maintaining participant privacy, a primary concern when studying PWUD. We did not want to “out” any of our participants, nor did we want to expose them to other unforeseen risks (e.g., interactions with police) (Chang et al. 2020; Jenkins et al. 2020). Given these concerns, we chose an isolated study location. We purchased a four-sided canvas tent, where participants could complete the intake/outtake surveys. We also provided participants with headphones to use for all extended interactions that we conducted virtually.

Moving outdoors created other logistical difficulties. Our protocol required transportation of study materials to and from the site and daily set up and tear down of the tent. These requirements added at least an hour to the day. As a result, we were left with less time for in-person visits and had to schedule appointments strategically to maximize efficiency and minimize labor.

Weather and seasonal change were other challenges entailed in relocation. The pandemic delayed our ability to begin data collection, pushing our data collection to mid-Fall, 2020. This put strong constraints on how long enrollment could continue, as potentially inclement weather in the coming months posed a threat to study completion.

**Reduction of Study Duration**

The second modification was to the duration of our study. We decided to collect daily ecological momentary assessment (EMA) (Shiffman 2009; Shiffman et al. 2008) data on smartphones for two weeks instead of four weeks to minimize in-person interactions between staff and participants. The reduction in the EMA collection period eliminated the need for weekly compensation appointments, reducing the total in-person interactions from five to two per participant. This decision also minimized the time we were required to be outdoors (see Online Appendix B). The clear cost to reducing the study period was that the volume of smartphone data collected was cut in half, but we saw this as a reasonable trade-off to reduce transmission risk.

**Modifying Interactions with Participants**

The last modification involved shifts in in-person interactions between us and participants. We made two important changes. First, all in-person interactions during the intake and outtake processes were modified to adhere to institutional and city-wide restrictions (Bach et al. 2020). Research staff self-evaluated daily and were tested regularly for COVID-19 during the study period. We asked participants if they were feeling well and observed them for obvious signs of
illness. We also adhered closely to masking recommendations. We only re-
moved our masks when we were outdoors, to eat or drink (Lerner et al. 2020).
Participants were also required to wear masks at all times, and we offered
masks to participants who arrived without them. When possible, we main-
tained the recommended six feet of distance between us and participants. After
each appointment, we disinfected all shared surfaces and discarded any study
items (like pens) that the participant had left behind.

Our second change transitioned as many in-person interactions as possible
to a virtual format. We shifted the longer parts of the intake and outtake
appointments online, conducted by a team member via Zoom. Similarly, we
used a study phone to keep participants engaged throughout the study period,
rather than encourage in-person drops-ins at the tent (Baruch and Holtom
2008). The study phone was manned by a single team member who spent
many hours “off the clock” answering phone calls and text messages from
participants. We did not lose any of our participants throughout the study
period, suggesting this was a successful practice.

Conclusions and Other Ethical Considerations

This brief article discussed a study of PWUD conducted during the COVID-19
pandemic. We made three main changes to our study to minimize COVID-19
risk: We relocated our site to an outdoor location, we shortened the study period,
and we digitized as many interactions as possible. Our experience suggests that
data can be successfully collected in-person during a pandemic, but there are
unavoidable risks, stresses, and trade-offs.

In our case, the ethical question of whether the study could be carried out
with sufficient safety was negotiated at the institutional level and interper-
sonally within our research team. Our institution required us to demonstrate
strict adherence to the university’s official COVID-19 mitigation policy and
our department required an even more stringent demonstration of precau-
tionary measures (see Online Appendices C and D). Moving forward was a
difficult decision because the least risky decision would have been to postpone
the study indefinitely. We would not have moved forward if the entire team did
not feel comfortable with the modified safety protocols.

Ultimately, no team members tested positive for COVID-19 during the
study period. Additionally, no participants experienced symptoms or left
the study due to COVID-19 complications. We consider our protocols
successful, as we minimized risk for participants and staff and collected
meaningful data. Future studies working with high-risk populations could
employ a more nuanced strategy to reflect variable vulnerabilities of their
participants. The risk of contracting COVID-19 increases dramatically with
age and co-morbidities (Clark et al. 2020). A researcher could employ the
strict protocols described in this study to protect the most vulnerable
participants. Alternatively, vaccinated participants could interact with staff in a more traditional fashion, using protocols that resemble pre-COVID-19 studies.

Conducting a study with participants during a pandemic is inherently risky. Before carrying out any studies, prospective researchers must be prepared to answer several uncomfortable questions. What if the protocols fail and a researcher or participant falls ill? If a researcher is sick and has to quarantine until he or she has obtained test results, will there be enough researchers to continue? If a researcher tests positive for COVID-19, will the study be terminated? These are not the kinds of scenarios a researcher wants to anticipate, but they represent the right frame of mind when collecting data on a vulnerable population during a pandemic.

Declaration of Conflicting Interests

The author(s) declared the following potential conflicts of interest with respect to the research, authorship, and/or publication of this article: The content is solely the responsibility of the authors and does not necessarily represent the official views of the National Institutes of Health or the University of Nebraska-Lincoln.

Funding

The author(s) received no financial support for the research, authorship, and/or publication of this article. This work was supported by the National Institute of General Medical Sciences of the National Institutes of Health (P20GM130461) and the Rural Drug Addiction Research (RDAR) COBRE at the University of Nebraska-Lincoln.

Supplemental Material

Supplemental material for this article is available online.

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