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Conducting Clinically-Based Intimate Partner Violence Research: Safety Protocol Recommendations

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Abstract

Background—Maintaining safety is of utmost importance during research involving participants who have experienced intimate partner violence (IPV). Limited guidance on safety protocols to protect participants is available, particularly information related to technology-based approaches to informed consent, data collection, and contacting participants during the course of a study.

Purpose—The purpose of the paper is to provide details on the safety protocol developed and utilized with women receiving care at an urban HIV clinic, and who were taking part in an observational study of IPV, mental health symptoms, and substance abuse and their relationship to HIV treatment adherence. The protocol presents the technological strategies to promote safety and allow autonomy in participant decision-making throughout the research process, including Voice over Internet Protocol telephone numbers, and tablet-based eligibility screening and data collection. Protocols for management of participants at risk for suicide and/or intimate partner homicide included automated high-risk messaging to participants and research staff and facilitated disclosure of risk to clinical staff based on participant preferences are discussed.

Discussion—Use of technology and partnership with clinic staff helped to provide an environment where research regarding IPV could be conducted without undue burden or risk to participants. Utilizing tablet-based survey administration provided multiple practical and safety benefits for participants. The majority of women who screened into high-risk categories for suicide or intimate partner homicide did not choose to have their results shared with their healthcare providers, indicating the importance of allowing participants control over information sharing whenever possible.

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Keywords

data collection methods; intimate partner violence; research ethics; research participant safety

Parker and Ulrich (1990) published the first guidance on safety protocols for intimate partner violence (IPV) research. This initial work focused on methods to safely contact women experiencing IPV for recruitment and follow-up during research studies and identified maintaining participant confidentiality as a key factor to address when developing study procedures. Investigators have continued to add to the safety protocols to promote safe and ethical conduct with IPV survivors (Btoush & Campbell, 2009; Ellsberg & Heise, 2005; Sullivan & Cain, 2004). Safety protocols often focus on contacting and interacting with women, confidentiality, mandatory reporting laws for IPV disclosures, and Certificates of Confidentiality (Btoush & Campbell, 2009; Parker & Ulrich, 1990; Sullivan & Cain, 2004). Safety and ethical discussions often revolve around women's autonomy in decision-making regarding not only their participation in research, but also how information will be shared as a result of voluntary or mandatory IPV reporting policies or laws (Btoush & Campbell, 2009; Fontes, 2004; Sullivan & Cain, 2004).

A major limitation of existing protocols is the lack of attention to the increased use of technology in IPV research. Although Department of Health and Human Services regulations such as the Health Insurance Portability and Accountability Act Privacy Rule (Standards for Privacy of Individually Identifiable Health Information, 2016) and regulations regarding the conduct of research with human subjects (Protection of Human Subjects, 2016) have standardized and mandated data handling practice (e.g., password protection and encryption) across clinical and research institutions, limited guidance is provided on safety when using hardware, software, and Internet and wireless technology with IPV research (Bloom et al., 2014; Garabedian, Ross-Degnan, & Wharam, 2015; Gilbert et al., 2016; Glass et al., 2015; Hegarty et al., 2015; Marcano Belisario et al., 2015). A second notable gap is the lack of guidance regarding determining and responding to research participant reports of risk for suicide and/or homicide during study activities and their preferences sharing this information to providers or receiving referrals to available services.

Purpose

We present the protocols used to maintain research participant safety and autonomy during a study of IPV and health outcomes among HIV-positive women seeking care in an urban HIV clinic (Anderson et al., 2017). The study examined past year prevalence of IPV, mental health symptoms, and substance abuse and their relationship to HIV treatment adherence.

Setting the Stage for Safety: Preparation and Training

Clinic Partnership

Safety for study participants begins with establishing a collaborative relationship with clinical leadership and staff to examine and discuss existing protocols, clinic workflow, and prioritize safety and confidentiality in clinic-based recruitment, consent, and data collection.

The partnership informed the protocols in several areas, including options for privacy and referral of participants to their healthcare providers that are discussed in subsequent sections.

Tablet-Based Data Collection

Tablet-based data collection has both practical and safety benefits. For example, the clinic is busy and few areas for private interviews; therefore, the tablets provide an opportunity for women to individually and confidentially complete the eligibility screening, consent, survey measures, and risk follow up in the waiting area. Guards against women participating more than once were integrated into the eligibility screening, specifically names and birth dates were automatically compared to the study database to identify duplicate entries. Immediate scoring and postsurvey messaging to research staff provided information on participant risk for homicide or suicide reported in study measures.

Tablet-based data collection included benefits such as direct entry of data by the participant, the ability to prompt participants regarding unanswered questions, and automatically captured length of time to complete the survey instruments. Direct data entry by participants minimized risk of data entry errors and prompts regarding incomplete fields helps to minimize missing data (Barentsz et al., 2014; Weber, Yarandi, Rowe, & Weber, 2005). Due to the sensitive nature of some questions, we did not use this technology to require responses except those needed for eligibility screening, participant identification, and risk protocols. Similar methods and technologies have been used by the authors in multiple studies and settings, and no significant technological challenges presented themselves during this study.

Training

Required human subjects research training with study team members was enhanced by the principal investigator (PI), a nurse with IPV clinical and research expertise to ensure familiarity with IPV and safety. The PI conducted one-on-one or small group discussions with research team members as well as provided preceptorship in the clinic setting. Training included information on survey administration with participants who had difficulty with reading or use of the tablet, assessing and responding to participants who wished to speak about suicide or homicide risk, and an introduction to the clinic staff and workflow.

Protocols to Address Participant Safety Concerns

Recruitment and Contact Information

The study used a generic university email address and a study Voice over Internet Protocol (VoIP) phone number to communicate with participants. The VoIP allowed for privacy regarding study purpose if persons other than the participant (e.g., friends, family members, or partners with access to the participant's phone) made contact with the study. The safe contact protocol allowed investigators to call or text participants from a phone that did not appear on caller ID as either a blocked or hospital phone number. This prevented unintentional disclosure of the nature of the study (as being related to HIV and/or IPV), while minimizing unanswered and unreturned calls from blocked numbers. Regardless of the physical telephone of the research team member, incoming calls had the VoIP number; therefore, team members could answer the phone by saying "women's health study" instead

the clinic or names of the investigators, which could be easily identified as being someone who specializes in HIV or IPV. Use of a VoIP number also allowed calls to be forwarded to any phone (cell or landline) in order to answer or return calls quickly.

Upon participant completion of study measures, a trained research assistant (RA) logged into the database to verify if the participant had consented to follow-up contact. The RA then completed an electronic form with contact information provided by the participant. The electronic form included prompts on safe communication with participants (e.g., safe time to call or text, and how to safely leave voice messages).

Informed Consent

The protocol was approved by the Johns Hopkins Medical Institutions Institutional Review Board (IRB). In accordance with the IRB approval, the trained RA collected verbal consent. The approved verbal consent script was provided to participants on the tablets, and was reviewed by the participant and RA together. After the RA answered any questions raised by the participant, the participant was asked to indicate consent by checking the mark on the tablet. Those who declined to take part were able to select “no” and were directed to a thank you message. No additional information was collected regarding women who declined to participate.

Mandatory reporting laws and policies vary greatly among institutions and jurisdictions. Despite variation, all locations generally have a requirement for professionals to report known or suspected child abuse, elder/vulnerable adult abuse, and imminent risk of harm to self or others (Appelbaum & Rosenbaum, 1989; Child Welfare Information Gateway, 2016; Department of Justice, 2017; Steinberg, Pynoos, Goenjian, Sossanabadi, & Sherr, 1999). It is important for research team members to be familiar with reporting requirements and assuring that reporting is completed when necessary. Participants must be made aware of the research team responsibilities during the consent process, and know that disclosures could trigger a mandatory report and how the report would be handled (Btoush & Campbell, 2009; Sullivan & Cain, 2004). No mandatory reports were triggered during this study.

Suicide and Homicide Risk Screening and Disclosure

The study included a protocol to identify risk of suicide and/or intimate partner homicide, which are both consequences associated IPV and HIV. Risk for intimate partner homicide was assessed with the Danger Assessment (DA) (Campbell, 2004; Campbell, Webster, & Glass, 2009), a lethality assessment tool designed and validated for clinical and research use to identify women at risk of being killed by their current or former intimate partners. The tool is available freely for clinical and research use (Campbell, 2004). Standardized scoring for the DA ranges from -3 to 37, and there are four defined danger risk categories: Variable, Increased, Severe, and Extreme (Campbell et al., 2009). Risk messaging was triggered for women scoring in the Severe and Extreme Danger categories (DA scores > 13). Women with a DA score of > 13 received an additional screen at the end of the survey that provided local and national IPV-related resources, as well as a request on how to safely receive (e-mail, print out) the resource list and if they wanted the DA score and risk information shared with their provider at the clinic (Table 1).

If a participant indicated “yes,” they were asked to provide a safe contact method for the provider (e.g., phone number, e-mail address). Women were also assured that answering “yes” to this question would indicate their consent to share *only* their DA score information, not their answers to other items. Established relationships with the clinic and consent of the participant allowed the team to access the electronic medical record to send the DA score and information on referrals to support the provider in a discussion with the participant on IPV, health, and safety.

Assessment of suicide risk included three questions in the survey measures. Responding *yes* to two of three questions triggered the participant to receive a message about concern for safety. Two questions were part of the Center for Epidemiologic Studies Depression Scale (CES-D) (Radloff, 1977), how many days in the past two weeks that they endorsed the following statements, “I wished I were dead” and “I wanted to hurt myself.” Participants who answered “Nearly every day for two weeks” or “5 to 7 days” to either question were considered at suicide risk. The third question came from the DA and asked if the participant had ever threatened or attempted suicide (Campbell, 2004; Campbell et al., 2009).

Participants who responded positively to suicide risk were shown an additional screen at the end of the survey (distinct from the IPV homicide risk screen) that included language regarding suicide risk. This message asked for more information on suicide risk, whether they had a plan, and/or a specific method or time to kill themselves. The language for this message was adapted from previous Internet-based work with women in abusive relationships, and was originally developed in collaboration with experts in trauma, IPV, and mental health (Eden et al., 2015). Women were then asked to indicate how they preferred to seek help. The options for seeking help are show in Table 1. Women were also asked if they wanted their CES-D score and suicide risk screening information shared with their healthcare team.

In addition to survey items and triggered risk messaging at the completion of the tablet-based survey, we also included information in the written protocol addressing participants who indicated that they wanted to speak with a research team member about their suicide risks and resources. The protocol included steps for the research assistant to implement regarding assessing suicidality and use of community and hospital resources as immediate referrals for women who were at emergent risk (i.e., the National Suicide Hotline, 911, or in-house emergency service activation). As part of the clinic standard of care, clinic-based therapists and psychiatrists provided patients who had previously established mental healthcare at the clinic to schedule acute appointments within two business days for urgent but nonemergent issues. While no emergent risk concerns arose during this study, the research team did assist one participant in obtaining an acute psychiatry appointment.

Of the 239 women included in the final dataset, 30 (13% of total sample, 25% of those reporting past year violence) met criteria for being at high risk for intimate partner homicide. During the initial piloting of the survey, one additional woman did not complete the DA, but due to an issue with the survey skip patterns, did receive the risk message questions and resources. Results from participants’ responses to the risk protocol question are presented in Table 1. Of note, one of the primary study aims was to assess the prevalence of IPV in the

clinic, so nearly half ($n = 117$; 49%) of the sample did not report any type of past year IPV. Seventeen women (7% of the total sample) met study criteria for potential suicidality. Of these 17 women, 10 (59%) had also screened as high risk for intimate partner homicide. Only one participant requested to speak with a research assistant about her suicidal risk, while the other 16 reported other help seeking preferences (Table 1).

For both the intimate partner homicide and suicide protocols, the majority (74% and 59%, respectively) of women declined to have their information shared with their clinic care teams. Anecdotal accounts from some participants included that providers were already aware of the issues participants screened as high risk for (sometimes prompting them to ask for the information not to be shared again, sometimes prompting them to consent to sharing), while others related that they did not currently consider themselves at risk (i.e., not currently having suicidal thoughts, having recently left an abuser, or having an abuser who was in jail) and did not want to involve the healthcare teams in nonacute issues.

Discussion

Our experiences highlight the use of technology to implement rigorous safety protocols without creating undue burden to participants or clinical partners. The relatively low number of participants meeting our risk criteria can be used to help estimate resources needed when planning studies to examine IPV in clinical settings. Even with broad definitions of risk, we did not find a volume of response that overwhelmed the available resources. Integration with clinic staff was beneficial in navigating the research and safety processes, allowing for recruitment from a designated area within the clinic, as well as for direct provider referrals of participants when needed.

Importantly, the majority of participants who triggered risk protocols did not want the information shared with providers. While data regarding reasons these decisions were not part of data collection, RA notes and debriefing found that some participants had previously disclosed IPV to their providers and did not feel like telling them again, and others were not in crisis and did not want to talk to their providers. The research team provided referrals to community and clinic resources to prevent suicide and promote safety while acknowledging participants' ability to make decisions is essential to build trust so patient participants in need of services they will reach out or return to the clinic.

Conclusions

Research with IPV survivors is critical to develop the evidence to prevent and respond to the health and safety needs of IPV survivors. Responsible conduct of research with survivors requires investigators to understand the multiple and complex safety issues associated with recruitment, disclosure of IPV, retention, informed consent, assessing for suicide and homicide risk, and referrals to clinical and community settings. Technology has the potential to enhance safety in research, however, integration of technology must be done in partnership with participants and the clinical or community site.

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TABLE 1**Safety Protocol Response Summary**

Question/response	Respondents	<i>n</i>	(%)
IPV resources list request	31		
Email copy		2	(6.5)
Paper copy		13	(41.9)
No copy		16	(51.6)
Share DA risk with provider	31		
Yes		8	(25.8)
No		23	(74.2)
Suicide risk answer	17		
Have own provider, counselor, or supportive person I can call		8	(47.1)
Can call National Suicide Hotline ^a		1	(5.9)
I want a research assistant from the study to talk with me today		1	(5.9)
I'm OK right now, but if it becomes a problem for me, I'll ask for help		7	(41.2)
Share suicide risk with provider	17		
Yes		7	(41.2)
No		10	(58.8)

Note. DA = Danger Assessment; IPV= intimate partner violence.

^aPhone number is: 1-800-273-TALK (1-800-273-8255); confidential counselors are available over the phone.