Challenges in Recruiting People Who Use Drugs for HIV-Related Biomedical Research: Perspectives from the Field

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Abstract

Recruitment of people who use drugs (PWUD) for HIV-related research has been undertaken since early in the epidemic. In early studies, recruitment was often performed by outreach workers with familiarity with the target population, who distributed risk reduction materials, and administered the surveys being conducted on drug use and risk behaviors. The evolution of effective treatments for HIV has provided opportunities for PWUD to participate in biobehavioral studies testing the efficacy of medical treatment advances and exploring the underlying biomedical basis for prevention and treatment efforts. Recruitment for these studies has led to new challenges for outreach workers and institutions conducting this research. PWUD, particularly those from race/ethnic minority populations, have had lower rates of engagement in HIV care and have been underrepresented in HIV/AIDS medical studies. To address these health disparities, enhanced efforts are needed to increase their participation in biomedical studies. This article examines the challenges identified by experienced outreach workers in recruiting PWUD for HIV-related biomedical studies, including individual (participant)-, institutional-, and recruiter-level challenges, and provides recommendations for addressing them.

Introduction

SINCE EARLY IN THE HIV EPIDEMIC in the United States, in the mid-1980s, outreach workers have been hired to recruit people who use drugs (PWUD), including those who inject drugs, to participate in studies related to HIV infection. Recruitment was generally conducted in community-based locations where PWUD would be found, including drug use areas, needle exchange programs, and near drug treatment programs.

In some research projects, outreach workers also served as interviewers. Survey instruments focused on obtaining greater understanding of injection-related risk behaviors to inform interventions and policy. The NIDA-funded NADR projects, beginning in 1987, were a large-scale example of this, hiring outreach workers to recruit people who inject drugs (PWID) (and their sex partners) for interviews and, in many cases, HIV testing in 41 projects operating in over 60 communities throughout the United States.¹ In many instances, these

workers also distributed risk reduction tools (e.g., needle cleaning equipment and condoms), discussed risk reduction strategies, and referred clients to health/social services (e.g., needle exchange programs or housing services).^{2,3}

Staff who recruited PWUD for research studies required special skills, which included familiarity with the drug users, their neighborhoods, and locations where PWUD could be found. They were often of similar race/ethnic backgrounds, and some were themselves current or former drug users, or HIV-infected.³ As part of the recruitment and consent process, they informed potential participants about the content areas of the survey, the conditions under which HIV testing was to occur (e.g., confidential or anonymous), and the incentives provided (usually a modest payment for time spent in interviews or interventions). These outreach-based interventions were generally assessed as very successful in reaching the target populations and engaging them in risk reduction interventions and resulted in reduced HIV risks.⁴ These early studies (before

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1995) were conducted before effective combination antiretroviral treatment (i.e., cART) was widely available for HIV treatment.

The evolution of effective treatments for HIV infection has led to the need for other types of studies, for example, how best to engage and retain people in HIV clinical trials and in HIV care.⁵⁻⁷ These efforts are especially needed for drug users who have lower rates of engagement along the HIV continuum of care, including lower retention in care.⁸ In addition, as other biomedical advances relevant for PWUD have developed, including PrEP and PEP (pre- and postexposure prophylaxis) and treatment for HCV, there has been an increased need for studies that recruit PWUD to further our knowledge of these treatments and to help ensure equity in their delivery. This is particularly important given that many PWUD are racial/ethnic minorities, and although race/ethnic minorities are overrepresented in HIV/AIDS cases, they are underrepresented in HIV/AIDS medical studies.^{7,9} Recruitment for biomedical studies has created new challenges for recruiters and for institutions conducting these studies, and guidance to enhance recruitment strategies is needed.

In this article, we describe the challenges encountered by experienced outreach workers in recruiting (and retaining) PWUD, primarily racial/ethnic minorities, and PWID for biomedical studies. Recommendations to address these barriers are provided for (a) ensuring that study participants are fully informed about the studies they are entering; (b) preparing institutions that may not have recruited PWUD in previous studies to enhance capabilities for this work, and (c) training the outreach workers who will be needed to effectively recruit participants.

Examples of Studies

Five of the authors of this article (P.B., A.B., E.S., M.C., and P.G.) have recruited PWUD to be participants for biomedical studies related to HIV and HCV. Following is a brief description of the biomedical component of recent studies for which they have conducted recruitment. It should be noted that all studies included initial screening of potential participants, which may have involved taking blood and urine samples, and collection of sociodemographic and risk behavior information.

GALT studies

These studies were undertaken to determine the effect of injection drug use on immune activation in blood and tissue for HIV-infected and -uninfected PWID. Data collection included a blood draw and performance of a flexible sigmoidoscopy with biopsy to assess levels of select markers of immune activation in blood and tissue (A.B., P.B., E.S.).

ACT 2

The ACT2 Program was a peer-driven intervention to increase screening for and participation in AIDS clinical trials (ACTs) among adult African Americans/blacks and Hispanics/Latinos and women living with HIV/AIDS. While most participants were not PWID, many were current users of substances (A.B.).

Hepatitis C treatment study

This project sought to clarify the contribution of chronic hepatitis C infection in immune activation in current and

former PWID. HCV-genotype 1 chronically monoinfected participants were recruited into a 24-week study and received a 12-week course of HCV therapy with fixed dose combination Ledipasvir/Sofosbuvir (HARVONI) (P.B.).

iPEPcare study

This pilot project assessed the viability of PEP as a means of preventing infection with HIV in high-risk populations by expanding pharmacy services to include the provision of nonoccupational HIV PEP and risk reduction information to PWID, who buy syringes at pharmacies, and PWID peers. Recruitment included pharmacists, PWID, and PWID peers (friends who they inject with or not), and when indicated, PEP was provided (M.C., P.J.).

Recruiting PWUD for Medical Research Studies, Challenges, and Recommendations

A semistructured interview was administered (by the first author) to a convenience sample of five recruiters (including himself). Information was obtained on demographics and years of experience in conducting recruitment, and open-ended questions probed for barriers to recruitment and retention for biomedical studies and recommendations for addressing them. All recruiters were highly experienced, with an average of 9 years (ranging from 5 to 15 years) in conducting recruitment of PWUD for research studies. All interviewees recruited for one or more of the studies were described in the prior section. Data were reviewed and discussed by the first and second authors (P.B. and S.D.) to identify themes and issues that were repeated across interviewees, who subsequently reviewed a draft of the identified challenges.

General characteristics of successful recruiters

All recruiters agreed that regardless of the study content, several personal characteristics were necessary to be successful in engaging racial/ethnic minorities or PWUD to participate in the research. These included familiarity with the population to be recruited and how to engage with them; ability to navigate the different neighborhoods where potential participants can be found; and persistence, self-motivation, and ability to relate to the population. Furthermore, empathy and compassion were also helpful to be an effective recruiter. These were similar to those characteristics of successful recruiters identified earlier in the epidemic³ and help to engage participants in a discussion about the study that is built on a relationship and a sense of trust.

There was also agreement that new challenges emerged in recruiting participants for studies with biomedical components. These challenges have been organized as follows: (a) individual-level challenges, that is, challenges for the potential participants, (b) institutional-level challenges, and (c) recruiter-level challenges.

Individual-level challenges

Technical language. Medical research as described in a research proposal or an informed consent form often uses language that may not be accessible to everyone, especially since many of the current and former PWUD in New York City have not attained a level of education beyond high school graduation or GED. A recruiter needs to be able to communicate what a study is about while translating the medical

language to the potential participant so that he/she can understand what will happen if they take part in the study and the possible benefits and risks of the study.

For example, as part of the GALT studies, a flexible sigmoidoscopy was performed. This is a procedure used to see and take tissue samples from inside the sigmoid colon and rectum. The procedure is similar to a colonoscopy, but while trying to explain this using medical terminology, most potential participants did not understand what was being described. To overcome this barrier, recruiters had to explain it to potential participants in a way that was more understandable for them. Participants were told that the procedure involved “putting a tube in your butt” to check the immune system and take samples. This proved to be very effective and time saving. Once participants heard this description, they knew immediately if they wanted to hear more information or not. Those who were interested in participating were given an appointment at the research location, where a detailed informed consent was administered.

Recommendation. To overcome the technical language barriers while doing recruitment for studies involving medical procedures, a recruiter needs to be able to explain the research and its components clearly and understandably to potential participants. The recruiter must also be comfortable with describing the study and be able to answer questions. Before a recruiter goes into the field, he/she needs to learn all the steps involved in the study and consult with the medical staff about the technical language, the meaning of it, and how to communicate this clearly to others. It is also important for the recruiter to be able to consult quickly (by phone/text) with the medical staff in case any new question arises while in the field. In addition, having a physician available to answer any questions readily may further validate the study in the eyes of potential participants or the staff at places where recruitment is undertaken.

The informed consent process is an essential aspect of clinical research and, as intended, was critical in having participants fully understand all details of the research studies, including medical procedures. For example, in several of the studies, when a participant came to be consented, a recording of the consent form was played for the participant to listen to while they read it with the recruiter present. The recording was stopped at certain points during the consenting process to assess if the material was clear, and the participant was asked if they understood what they had read so far and to explain it to the recruiter. This helped assure that the participant understood what was going to happen if they consented to take part in the study and provided opportunities to address any concerns or questions they might have.

Transportation. Many participants struggle economically and cannot afford to get to and from research clinics or study sites. While this issue may apply to many types of studies, it may be particularly important for biomedical studies. Locations of sites performing some of these studies, for example, at medical facilities, are often outside of the participants' usual communities, raising new transportation challenges. Simply getting the potential participant's agreement to participate and scheduling a screening visit cannot assure that the appointment will be kept. Rainy or cold days can be especially discouraging for participants, and much effort in contacting and scheduling appointments can be lost.

Recommendation. Providing participants with monetary support for transportation before their appointment greatly improved the likelihood of keeping their scheduled appointment. In addition, having another contact with the recruiter the day before the appointment served as a reminder. For some participants, the recruiter may determine that even with this monetary support, the challenge of getting up early and traveling to an unfamiliar location may be too great to overcome. Being able to provide a pick-up and drop-off service for appointments would be ideal in this situation. If this option is not available, then funds should be available to arrange alternate transportation such as car service so that participants can make appointments, particularly in inclement weather.

Mistrust of medical research. Participants often express concerns about not wanting to be used as a guinea pig in research studies, and this can create significant barriers for recruitment. A recruiter needs to be able to address those misconceptions by providing the potential participants with accurate information and describing how the research study can be beneficial to them and their communities. This concern is not confined to individuals as even some of the program locations that provided access to the population (e.g., CBOs that served this population) did not allow recruitment on their sites due to the perception that institutions that do medical research just want to use their participants, or take advantage of them, with little benefit in return.

Recommendation. The repercussions of past unethical studies conducted with minorities (e.g., the Tuskegee Syphilis Study in the 1930s) continue to impact how many minorities feel about taking part in medical research studies. While some individuals who express concern about taking part in medical research might not know the specifics about why there is a general sense of distrust about medical research, nevertheless those feelings prevail and overcoming this mistrust can be particularly challenging. Several steps can be taken to address this perception.

Before initiating a study, providing information to local CBOs such as harm reduction centers in the recruitment community can be helpful in addressing the concerns about medical research. Information sessions for staff and potential participants at the recruitment sites can be used to explain how the research can be beneficial on multiple levels: for example, for the individual (because they can get needed treatment and get compensated for their participation), for the institution (because it connects their members to healthcare they may need), and for the community (how the research will be used to answer important public health questions). Potential risks and how they will be addressed should also be discussed. Participation at these meetings by the research investigators and medical staff involved in the project can be helpful in answering any questions and addressing misconceptions that may be raised. Testimony of individuals who have taken part in prior research can also be helpful and they can talk about their experience, including challenges and how their participation may have been helpful to them. These meetings can also serve to increase knowledge of the researchers about community programs and other resources.

Providing individuals with the opportunity to talk about their concerns has been found to increase engagement in HIV-related clinical trials.¹⁰ Ultimately, however, addressing

concerns about the unethical treatment of racial/ethnic minorities in the course of clinical research must be handled by project staff admitting that this unethical behavior has occurred in the past, but since then, many measures have been put in place to prevent a recurrence. The rights of research participants and the procedures to protect those rights (e.g., consent forms, Institutional Review Board review of all procedures) should be described.

Institutional-level challenges

Medical staff unfamiliar with participant population. Biomedical research studies may take place at clinics or locations with staff not used to dealing with PWUD. Some participants may be heavy drug users and, as a result, staff may find it difficult to interact with them as they would with other patients. Others may be homeless with no place to shower or do laundry and may experience the staff as stigmatizing or discriminating against them based on their physical appearance, level of personal hygiene, or life situation. As a result of negative experiences, these participants may not want to return for future appointments.

Another aspect of this unfamiliarity is that certain medical procedures may be more difficult to conduct with PWUD. For example, in a study that required venous blood samples from active PWID, it was difficult for some nurses to draw blood from thrombosed veins. This led to the inability to complete the screening process and disappointment among these potential participants.

Recommendation. Lack of familiarity with the participant population can be addressed in several ways: before initiating a new study, a training can be held with all research project staff likely to come into contact with participants regarding the purposes and benefits of the study. As part of this procedure, medical staff should be encouraged to express their concerns and be provided with sensitivity training to understand the needs and challenges of the specific population.

Where possible, the special challenges that may be encountered in biomedical studies with PWID, for example, difficulty in drawing blood, can be anticipated and addressed. For example, a medical technician with prior experience and skills with PWID may be necessary. In addition, screening of participants in the field can include questions regarding the ability of their physicians to draw blood during recent medical visits. This will help ensure that potential participants can complete the study screening process and will reduce the potential that individuals who cannot complete screening will discourage others from participating.

Participant population and community unfamiliar with research organization. Medical institutions or organizations without prior experience recruiting PWUD may not be familiar with the community and the participants who are being sought. When a new study begins, this lack of familiarity may raise concerns related to the mistrust of medical research and raise beliefs that these institutions only want to take advantage of participants, use them when they need them for guinea pigs, and never return to the community thereafter.

Recommendation. As described under the earlier Mistrust of medical research section under Individual-level challenges

section, educational efforts in the community, where information about research studies and about community programs is shared, can help reduce stigma. Furthermore, institutions planning to develop portfolios of research may want to establish a community ambassador. This would be a person who can be a link between the institution and the community. Within this structure, contacts can be maintained with places serving current and former PWUD. Local community members can be invited in for talks open to the public, and tours of the institution can be provided so they can see where research participants will be going. This can create a bond between institutions and the community that will be helpful in reducing stigma and reducing a participant's hesitation in taking part in a study at an unfamiliar location, as well as making community programs more willing to refer participants to the study.

Another way to help with presence in the community is attention to the particular channels used to promote research studies. Flyers and newspaper advertisements for studies should be placed in locations that are accessed or read by the population, for example, current and former PWUD. Using media and language that reach the target populations would help increase knowledge about these institutions and their interests and may lead to more successful recruitment.

For recruitment at agencies/programs in the community, establishing a relationship with the gatekeepers in the agency will be helpful. While an initial visit or contact by the investigator may be helpful in gaining access, the relationship of the recruiter and the program manager or even receptionist may be the key to successful recruitment. Once these key individuals understand that the study can provide benefits to their clientele, this personal connection can not only lead to access to the population but also the development of an ally who can spread the word about the study and encourage participation.

Scheduling. Rigid institutional schedules that do not accommodate the needs of PWUD interfere with successful recruitment. Many PWUD take part in drug treatment programs such as methadone treatment programs and may have program requirements regarding days and times of program visits.

Recommendation. When possible, research studies may need to accommodate their schedules to ensure participation. This can be done by scheduling appointments convenient for participants or extending scheduling hours to evenings and weekends (this may not be possible if particular blood processing or procedures can only be undertaken during regular work hours).

Recruiter-level challenges

Getting accurate and detailed locator information. Locator information may serve two purposes: after making initial contact with participants interested in a study, follow-up may be needed to remind them of study appointments. For studies that require adherence to medication and retention, follow-up may be needed to support adherence and study retention. This is often challenging with PWUD as their lives may be unstable and some do not have a consistent phone number, are homeless, or are living in a shelter. In some cases, participants may be lost

to the study because they get arrested or end up in a detox clinic where they cannot be reached for several days. Obtaining information about reasons why contact is lost may be important for interpreting study findings.

Recommendation. Getting accurate locator information during the screening process goes beyond the usual questions about current address and phone number. Additional information helpful in finding PWUD includes details about places where the person hangs out, where would he/she go if there was nowhere to go, who should be called if study personnel cannot get in touch with them, identification of who should be contacted in the event of an emergency, and what is their drug treatment location and counselor information if appropriate. In addition, every time a participant comes back to any of his/her follow-up appointments or is encountered in the community, it is important to ask if there have been any changes regarding their locator information so that existing information can be updated.

Addressing frustrations and other emotional challenges for the recruiter. There are many challenges that a recruiter is likely to find while recruiting PWUD for biomedical studies. These include dealing with those who want to take part in the research, but are ineligible, and the frustrations that come from participants failing to keep initial or follow-up appointments.

Ineligible potential participants. The mission of a recruiter is to find candidates who meet the eligibility criteria of the research being conducted. On many occasions, recruiters will find people interested in the services being provided (e.g., HIV treatment, Hepatitis C treatment), but who are not eligible to take part in the research for different reasons (e.g., outside of age range, language barrier, not a good match [for studies matching different study arms by certain characteristics]). Dealing with these situations can be stressful. For example, in a study involving the provision of free HCV treatment, a participant reached in the community was told that he was unable to take part in the research study because he was outside of the age range criteria. After being informed that he could not participate, he expressed disappointment, asking the recruiter why he was denying him the care that he needed. He also told the recruiter "You are killing me . . .," and "I think it's illegal for you to not provide me with the care I need when you have it available." He explained that he had tried to get the treatment several times, but that insurance denied his claim because of the high cost and that he was not sick enough (some insurance companies were reported to be denying the cost of Hepatitis C treatment unless there was significant liver damage).

Situations like this can become stressful for the recruiter who wants to help the person and who may sympathize with their situation, but who needs to follow the research requirements. In some cases, it may be possible for the recruiter (or other research staff) to refer individuals to other programs that can provide care, but that is not always possible. Another challenge may occur when a recruiter is asked by potential participants to bend the eligibility criteria so that they can participate. Finally, significant work in recruiting and even accompanying potential participants to the research site may seem wasted if the participant does not meet the medical eligibility criteria (e.g., may have an exclusionary medical

condition they were not aware of). In addition to this being frustrating for the recruiter, some potential participants found to be ineligible may express anger or be upset with the recruiter because they could not enter the study.

Failure to show for appointments. Many PWUD have challenges in day-to-day survival and it is not unusual for individuals recruited for studies to miss appointments and for the recruiter to not be able to reach them, despite reminders and commitments to appear. Phones may not work, addresses may be nonexistent, and attempts to find individuals at their usual locations or hangouts may be fruitless. Among the recruiters interviewed for this article, study reasons for loss included incarceration, entry into detox, moving to another state, and even death due to drug overdose.

Recommendation. The requirements of research projects may necessitate criteria that exclude some individuals who may want to participate. For the recruiter to handle this, training in the criteria and why they are important to the study is needed. In addition, the recruiter's ability to listen to the participant's concerns and even life story with empathy and compassion is likely to be helpful to both the recruiter and the ineligible participant. One recruiter, being pressed to bend the rules, noted that if they did, it might eventually be discovered and they might lose their job; the participant was understanding of this concern.

In addition to training of recruiters in how to address issues that may arise with ineligible participants, the difficulty and frustration experienced by the recruiter should also be appreciated. Even after extensive efforts in recruitment are made, for various reasons beyond the recruiter's control, the individual may not enter into or complete the study. There are several ways to provide support for managing these frustrations. Individual or group supervisory sessions can provide opportunities to discuss these events, and recruiters can problem solve and share their strategies. Acknowledgment and appreciation of the various challenges that may arise for various members of the research team, as part of general team-building activities, can be helpful in supporting the recruiters as well as other team members.

Discussion

There are several limitations to this article due to the small sample size and the convenience sampling of recruiters. Nonetheless, the consistency of reports obtained and the fact that the information was based on very extensive recruitment experiences add validity to the observations and recommendations. As new interventions and tools to reduce the impact of HIV are developed, so must recruitment efforts be modified to adapt to these changes. While the observations and recommendations in this article were developed in relation to HIV/HCV research among PWUD, many apply to other patient populations, especially those who have been historically underrepresented in medical research.

A recruiter is an essential part of any medical research study and is an important part of the team that he/she works with, often including administrative, social work, and medical staff and the institutions involved. All those parts must work together to create a successful research environment and successful study. Additionally, enhancing efforts to recruit from populations that have been underrepresented in

biomedical research can help address health disparities and bring benefits to the participants, to the research field, and the larger community. Challenges to the recruitment of under-represented PWUD and minorities for biomedical studies are likely to continue. Efforts to address these challenges require further development and successful approaches require wide-scale implementation.

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