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Study protocol

Recruitment of heterosexual couples in public health research: a study protocol

James M McMahon*[1], Stephanie Tortu[2], Leilani Torres[1], Enrique R Pouget[1] and Rahul Hamid[1]

Address: [1]National Development and Research Institutes, New York, USA and [2]Tulane University School of Public Health and Tropical Medicine, New Orleans, USA

Email: James M McMahon* - mcmahon@ndri.org; Stephanie Tortu - stortu@tulane.edu; Leilani Torres - torres@ndri.org; Enrique R Pouget - pouget@ndri.org; Rahul Hamid - hamid@ndri.org

* Corresponding author

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Abstract

Background: Public health research involving social or kin groups (such as sexual partners or family members), rather than samples of unrelated individuals, has become more widespread in response to social ecological approaches to disease treatment and prevention. This approach requires the development of innovative sampling, recruitment and screening methodologies tailored to the study of related individuals.

Methods: In this paper, we describe a set of sampling, recruitment and screening protocols developed to enlist urban, drug-using, heterosexual couples into a public health research study. This population is especially hard to reach because they are engaged in illegal and/or stigmatized behaviors. The protocols were designed to integrate adaptive sampling, street- and referral-based recruitment, and screening procedures to verify study eligibility and relationship status.

Discussion: Recruitment of heterosexual couples through one partner, preferably the female, can be an effective enlistment technique. Verification of relationship status is an important component of dyadic research. Comparison of parallel questionnaires administered to each member of a dyad can aid in the assessment of relationship status. However, multiple independent sources of information should be used to verify relationship status when available. Adaptive sampling techniques were effective in reaching drug-using heterosexual couples in an urban setting, and the application of these methods to other groups of related individuals in clinical and public health research may prove to be useful. However, care must be taken to consider potential sources of sampling bias when interpreting and generalizing study results.

Background

The importance of human relationships and social interactions in the spread of infectious diseases and promotion of public health has long been recognized. However, only recently have traditional individualistic-cognitive approaches to disease prevention and treatment given way to more social ecological approaches. Groups of related individuals, such as families, sexual partners, co-habitants, co-workers, and other such groups, are increasingly becoming the loci of research, rather than samples of unrelated individuals [1]. These developments have created the need for new and innovative recruitment and

screening methods aimed at groups of interconnected research participants.

In this paper we describe a set of procedures developed for the sampling, recruitment and screening of heterosexual couples into an HIV and hepatitis surveillance and prevention program in East Harlem, New York City. Although the target population consisted of drug-using urban women and their primary heterosexual partners, the procedures described here can be adapted for use with other dyadic populations (e.g., homosexual partners, non-drug-users) and study objectives (e.g., psychotherapy, clinical trials).

Study Protocol: Women Drug Users, their Male Partners, and HIV Risk (East Harlem, NYC)

Study Overview and Objectives

Research by our team has shown that crack, cocaine or heroin-using women from East Harlem are at particularly high risk of acquiring HIV infection from their primary sex partners [2–4]. A cross-sectional study entitled "Women Drug Users, Their Male Partners, and HIV Risk" (S. Tortu, P.I.) was funded by the National Institute on Drug Abuse (NIDA) to (a) conduct HIV and hepatitis B and C counseling and testing, (b) quantify the prevalence of these pathogens among women drug users and their primary heterosexual partners, (c) collect survey data on the sex- and drug-related HIV risk behaviors engaged in by these couples, and (d) determine the individual- and dyadic-level predictors of HIV/AIDS disease risk in order to inform subsequent prevention programs. The study enrolled 353 couples recruited from East Harlem, NYC, between February 2001 and July 2003. Sampling methods, eligibility and screening criteria are discussed below. All study participants reviewed and signed informed consent forms. Urinalysis was conducted to confirm recent drug use. Female and male partners were simultaneously administered structured interviews in separate, private offices by gender-matched interviewers. All participants were offered the opportunity to test for HIV and hepatitis B and C. Pre- and post-test counseling was conducted using standard protocols as outlined by the Centers for Disease Control and Prevention (CDC).

Study Setting and Location

Located in the northeast corner of Manhattan, East Harlem has a population of over 117,000 within an area of about 1.4 square miles. East Harlem residents are primarily Hispanic (52%; mostly Puerto Rican and Mexican), Black non-hispanic (36%), and White non-hispanic (7%). This diversity accounts for the vibrant social and cultural character of East Harlem neighborhoods, several of which have undergone substantial revitalization in recent years. Nonetheless, East Harlem is burdened by many social problems including poor education, high unemployment, poverty, homelessness, crime, and substance abuse. Among those 25 years of age or older only 56% have completed high school. About 37% of residents receive some form of public assistance, and among those in the work force 17% are unemployed. Median annual household income for East Harlem residents is just above $21,000, with nearly 40% living below the poverty level [5]. Along with Central Harlem, East Harlem has the highest per capita crime rate in Manhattan, with nearly one crime victim per 100 residents per year [6]. Drug abuse/dependence is the third leading cause of hospitalization in East Harlem, with a rate of 724 per 100,000 residents aged 18 to 64, more than double the city-wide rate [7]. Compounding these social problems, East Harlem residents also suffer disproportionately from many debilitating health-related illnesses. The infant mortality rate in East Harlem is one of the highest in New York City with 9.7 deaths per 1000 births [7]. The incidence of AIDS, chronic hepatitis, *Chlamydia*, gonorrhea, syphilis, tuberculosis, asthma, cryptosporidiosis, and salmonellosis are in most cases double the city-wide average [7]. The prevalence of AIDS in East Harlem is the second highest overall (4,768 per 100,000 persons) in New York City, and the highest among women [8]. Hepatitis B and C infections are hyperendemic among East Harlem drug-users, with rates as high as 70%-80% in some groups of injection drug users [9].

Target Population

Our target population consisted of crack, cocaine or heroin-using adult women and their primary heterosexual partners from East Harlem. Table 1 presents sociodemographic and disease risk data derived from the study sample. Social indicators such as lack of education, low income, homelessness, and poor health status, are even more pronounced in the target group than among those in the general population of East Harlem. The prevalence of HIV and hepatitis B and C in this group, for example, are among the highest of any heterosexual group in New York City.

Gendered Context of Drug-using Couples and Sample Recruitment

In recruiting drug-using couples from East Harlem special attention was given to the gendered context of interpersonal dynamics, communication, and conflict. Social research involving low-income minority women has demonstrated a gender-based male-favored imbalance in decision-making, economic dependence and disempowerment in the context of women's sexual relationships [10]. High rates of domestic violence and abuse against women in these populations further reflect this gender-based imbalance of power [11]. It was therefore critical to include recruitment and screening strategies in our study that ensured the protection of women

Table 1: Sociodemographic and risk characteristics of study sample (n = 353 couples).

	Females	Males
Age (mean, sd.; years)	39.8 (7.5)	41.3 (8.0)
Race/ethnicity (%)		
Hispanic	44.2	44.5
Black (non-Hispanic)	37.7	42.8
White (non-Hispanic)	14.5	12.2
Other	3.7	0.6
Education: high school diploma or equivalent (%)	46.5	60.6
Enrolled in Medicaid (%)	86.4	72.2
Employment status (%)		
Employed full-time	1.1	10.8
Underemployed (<30 hrs/wk)	5.4	9.1
Unemployed	57.2	53.0
Unable to work (disabled)	27.2	25.2
Out of the work force (e.g., retired, student, other)	9.1	2.0
Income (average monthly; %)		
<$ 100	7.1	20.7
$ 100–$ 299	49.3	47.3
$ 300–$ 499	28.3	18.7
>= $ 500	15.3	13.3
Marital status (%)		
Single	4.8	5.7
Married	20.4	19.6
Common-law married	68.3	72.5
Divorced, separated, widowed, other	6.5	2.3
Resident pattern (%)		
Permanent residence	54.1	49.0
Transient (living temporarily with friend, family, hotel)	30.6	34.3
Homeless (living in street, car, shelter)	15.3	16.7
Ever convicted of a criminal offense (%)	86.1	93.2
Spent time in jail, prison or holding-cell in last 30 days (%)	5.1	10.8
Number of children (biological, adopted, or stepchildren; %)		
None	15.0	17.6
1–2	40.5	40.5
3–5	36.3	32.3
> 5	8.2	9.6
Drug use history (%)		
Ever injected drugs?	64.9	64.6
Ever smoked crack?	89.2	81.0
Ever snorted cocaine?	96.0	96.3
Ever snorted heroin?	88.7	87.3
Ever snorted speedball (cocaine/heroin mixed)?	46.7	44.5
Ever smoked marijuana?	96.3	98.6
Ever consumed alcohol?	97.5	96.6
Ever smoked cigarettes?	98.0	95.8
Current drug use (used in last 30 days; %)		
Injected drugs?	37.4	36.3
Smoked crack?	55.5	45.9
Snorted cocaine? [1]	23.1	24.4
Snorted heroin? [2]	50.3	43.8
Snorted speedball (cocaine/heroin mixed)? [3]	4.9	4.6
Smoked marijuana? [2]	35.6	38.5
Consumed alcohol? [2]	56.5	57.7

Table 1: Sociodemographic and risk characteristics of study sample (n = 353 couples). *(Continued)*

Smoked cigarettes?	96.6	89.8
Currently in drug treatment? (%)	70.3	57.8
Had unprotected vaginal sex with partner in past 30 days? [4] (%)	81.0	79.6
Had unprotected anal sex with partner in past 30 days? [4] (%)	16.4	24.4
Exchanged sex for drugs or money in past 30 days? [5] (%)	14.7	5.7
Ever tested positive for HIV/AIDS? [4] (%)	19.3	17.3
Ever tested positive for hepatitis B? [4] (%)	12.2	11.9
Ever tested positive for hepatitis C? [2] (%)	30.1	31.0

[1], N = 703 due to missing data; [2], N = 704; [3], N = 702; [4], N = 705; [5], for females exchange indicates providing sex for money or drugs, for males exchange indicates providing money or drugs for sex. Note. Percentages may not add up to 100 due to rounding.

participants against potential partner conflict and violence. For example, we recruited couples solely through the female partner so that abusive relationships and potentially harmful situations could be screened-out and avoided in advance of male participation. Other precautions implemented to ensure women's safety are discussion in more detail below.

Methods

Research Site and Setting

Study enrollment, assessment, and HIV/hepatitis B and C counseling and testing were conducted at our research site in East Harlem. This facility has been in operation since 1992, and is used exclusively for research by the National Development and Research Institutes (NDRI). The center consists of a reception/waiting area, a small pantry (refreshments, such as coffee, are available to respondents in the waiting area), a group room that can accommodate up to 15 people, sound-proofed offices equipped with networked computers, a private medical room for phlebotomy and biological testing, and washroom facilities. The site has the look and feel of a community health clinic. Located in central East Harlem, the center is easily accessible by foot, car, bus, or subway.

Sampling Procedures

The target population for the study consisted of crack-, cocaine- or heroin-using adult women from East Harlem and their primary heterosexual partners. Street-based sampling was employed to circumvent the limited generalizability inherent in convenience samples obtained from institutional settings, such as clinics and drug treatment centers [12]. Couples were recruited through the female partner. This approach was consistent with our focus on women's health and disease risk, and further afforded women the opportunity to privately decline participation if they perceived any potential threat or conflict stemming from their partner's involvement.

Use of conventional probability sampling was not feasible given our target population of hard-to-reach drug users [13]. An adaptive sampling strategy was developed which included the following elements: (1) use of systematic sampling [14] for initial street recruitment of women drug users based on street-by-street "sweeps" that included canvassing all sectors of East Harlem, (2) targeted sampling [15] in which ethnographic mapping was used to identify geographic areas for concentrated recruitment [14], and (3) respondent-driven sampling [16] in which female participants were asked to refer other females into the study.

In the initial stage of sampling, pairs of experienced outreach workers systematically canvassed the streets of East Harlem and approached women who appeared to be at least 18 years of age. Women were initially approached by a female outreach worker displaying an ID tag and carrying a clip-board. The female outreach worker followed a script in which she briefly introduced herself and conveyed selected information about the study. Women who expressed an interest in participating in the study were administered the study eligibility questionnaire.

Data collected from the street-by-street canvassing were used to develop a sampling frame of locations in which concentrations of the target population occurred and to characterize the sample on important variables [13]. Targeted sampling was then employed to focus recruitment efforts in specified locations of East Harlem, which were sampled systematically for the duration of the project. Areas in which female drug users tended to convene frequently changed over the period of recruitment (due to police activity, for example). It was therefore necessary to regularly update our geographic mapping information based on ethnographic data and observations of outreach workers.

To supplement our street-based targeted sampling method, and reach couples who were less likely to be found on the street, we applied respondent-driven sampling techniques, in which female participants referred their peers into the study. Previous research has demonstrated that data obtained using respondent-driven techniques yield representative samples of drug-users [16,17].

Sampling Bias

Data from a true probability sample of East Harlem drug users is not currently available, and it was therefore not possible to assess the representativeness of our sample. Several limitations to our sampling strategy may have introduced bias. For example, the level of monetary incentive offered to study participants may have skewed the sample in favor of couples whose incomes are low–drug-using women and men whose earnings are sufficient to meet their needs may be underrepresented. In addition, excluding couples from the study due to women's concerns about partner threats or conflicts may have biased the sample in favor of relationships less prone to conflict or violence. Couples who are illegal residents or those who have day-time employment (and were therefore less likely to be on the street during recruitment hours) may also be underrepresented in the sample.

Street-based Recruitment and Screening Procedures

Street recruitment and screening procedures are summarized in the form of a sampling profile presented in Figure 1. Recruitment was initiated by pairs of experienced outreach workers (identified by ID tags) who approached women on the streets of East Harlem with a scripted introduction. The script read as follows: "Hi, my name is _____ and this is my partner _____. We work for a public health project in East Harlem, and we're looking for people to participate in a paid health study. Would you be interested in learning more about it?" Women who expressed an interest were given further information about the objectives of the study, study location, expected time commitment, and monetary compensation. Women who consented were then screened for study eligibility (see eligibility section below).

Eligible women were asked if they and their primary male partner were available to travel to the research site to participant in the study. Women who were not immediately available were asked to recruit their primary partner into the study, and were given a numbered information card containing a brief description of the study and a toll-free number to call to make an appointment. Matching ID numbers were recorded on the information cards and eligibility screening forms. Women were told that they had to call personally to make an appointment (no calls were accepted from male partners) and to give their assigned ID number when calling. Eligible women and their primary partners who were immediately available to participate in the study were screened to verify their status as a couple (see Street-based CVS Protocol section). Couple verification screening (CVS) procedures are described in detail below. Couples who passed the CVS were escorted to our research site, enrolled into the study, and administered the study protocol.

Site-based Recruitment and Screening Procedures

Figure 2 graphically depicts the site-based (phone-in) sampling protocol. As noted, women who passed the street eligibility screening but who were not immediately available to participate in the study were asked to recruit their primary male partner and call a toll-free number to make an appointment for couple screening and enrollment. Women who called to make an appointment were asked for the ID number on their information card, and their street eligibility form was retrieved and verified. An appointment date and time was then scheduled, and women were given directions to the research site. Women were told that the appointment was for further screening to determine eligibility for the study. If eligible, they would be asked to provide informed consent to participate in the study, which would last approximately two-to-three hours.

As part of the respondent-driven referral procedure, phone inquiries by participant-referred women were also accepted. In such cases, women were screened for eligibility over the phone, then asked to recruit their male partner and make an appointment for further screening and study enrollment.

Eligibility Screening

Due to our focus on women's disease risk and prevention, couple's eligibility was based almost exclusively on characteristics of the female. Women's eligibility criteria included: (a) 18 years of age or older, (b) use of crack, cocaine or heroin (injected or noninjected) in the previous 30 days, (c) had current primary heterosexual partner (defined as husband, common-law husband, or steady boyfriend of at least one year), (d) had sex with primary partner at least once in previous 30 days, (e) perceived no partner-related conflicts, threats, or other problems that might stem from involvement in the study, and (f) able to recruit male partner into the study. Male partners had to be at least 18 years of age to qualify. Since some of the eligibility criteria involved a time limit (e.g., the use of specified drugs in the prior 30 days), eligibility screening was always administered on the day of study enrollment, regardless of whether such screening had been conducted previously.

Although study eligibility was determined solely on the basis of female responses to eligibility criteria, males were administered a "spurious" eligibility screening, which contained items similar to those of the female eligibility questionnaire. This practice helped diffuse any "blame" associated with a couple's failure to meet the research criteria.

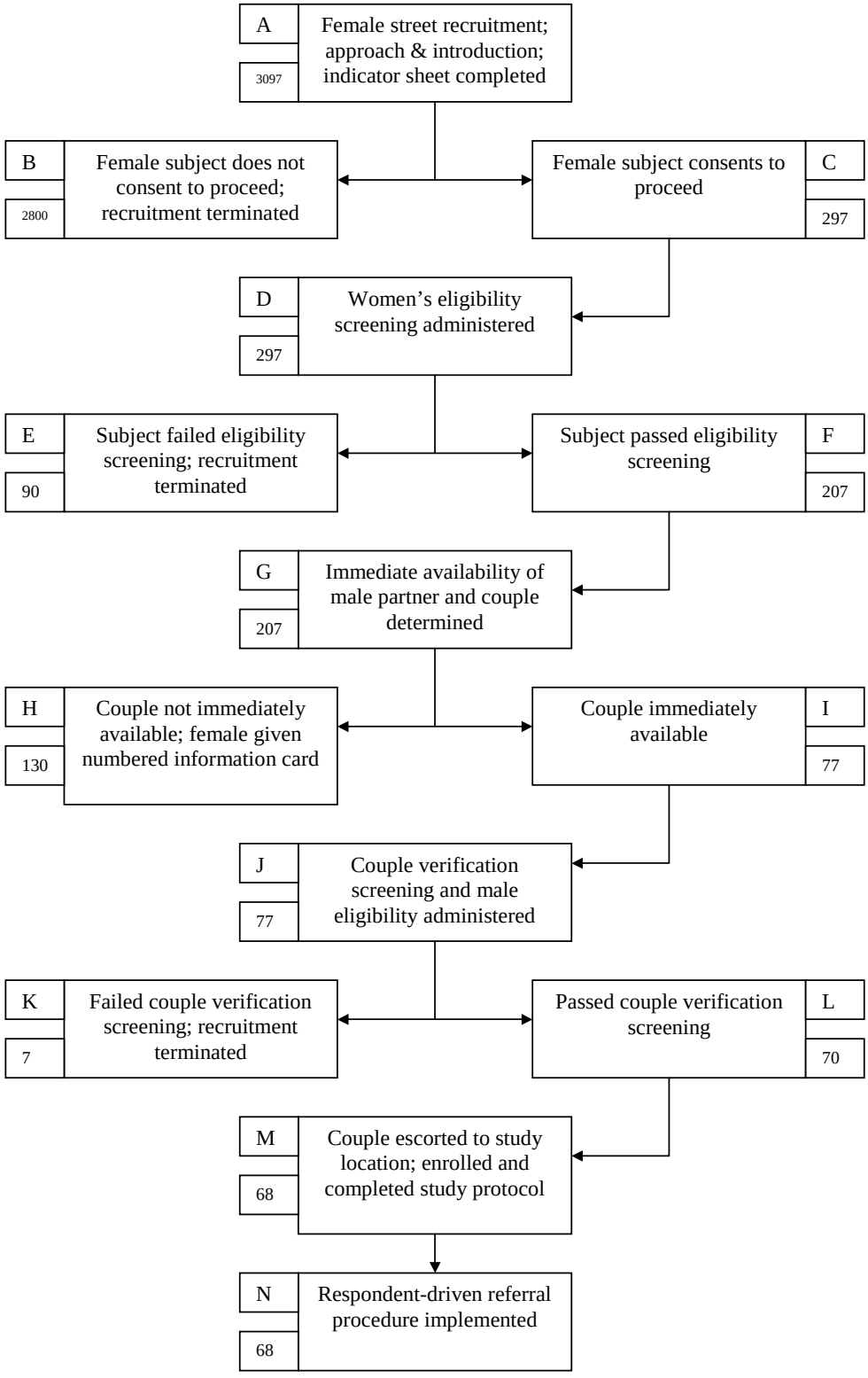

Figure 1
Street recruitment and sampling profile.

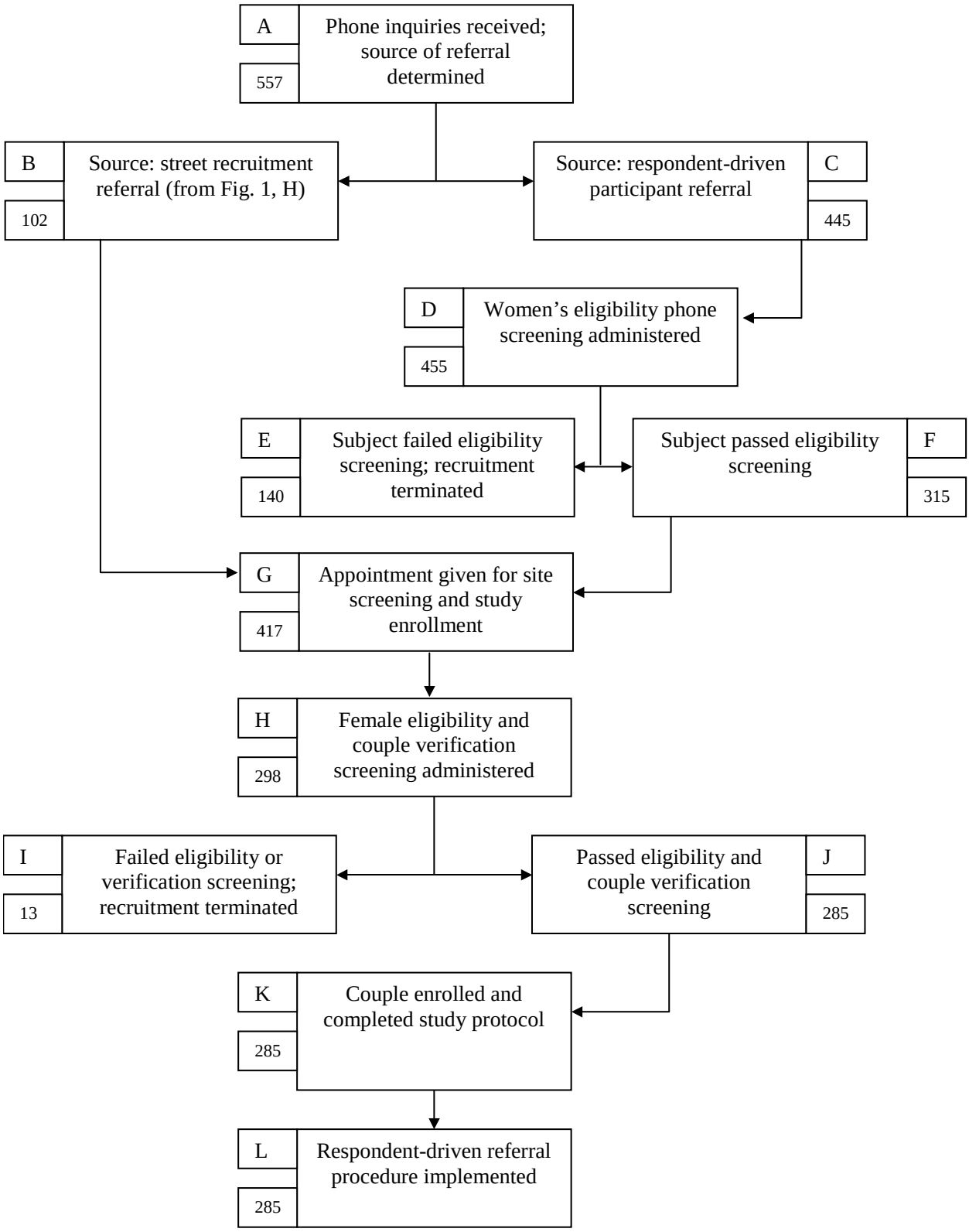

Figure 2
Phone appointment and referral sampling profile.

Table 2: HIV, hepatitis B and C prevalence by gender and injector status. (n = 353 Couples).

	Females	Males
HIV (% positive)		
Total sample (N = 335 females, 341 males)	22.1	22.0
Ever injectors (N = 218 females, 221 males)	24.8	26.2
Current injectors (N = 128 females, 125 males)	16.4	24.8
Hepatitis B (% anti-HBV reactive)		
Total sample (N = 297 females, 301 males)	43.1	47.8
Ever injectors (N = 185 females, 191 males)	49.7	61.3
Current injectors (N = 108 females, 107 males)	46.3	60.8
Hepatitis C (% anti-HCV reactive)		
Total sample (N = 297 females, 302 males)	51.5	52.7
Ever injectors (N = 185 females, 191 males)	73.5	74.4
Current injectors (N = 108 females, 107 males)	75.0	73.8

Note. Total of 4 inconclusive results not included in *n* or calculation of prevalence.

Couple Verification Screening (CVS)

Since couples in our study were not required to be legally married, legal documentation such as a marriage license was not used to verify couple status. Therefore, in order to ensure that female and male dyads were indeed primary sexual partners (as defined in our study) we administered a couple verification screening (CVS) instrument prior to study enrollment. During CVS women and men were separated and asked a rotating series of six parallel questions (drawn from a pool of 21 questions) of an intimate or personal nature, such as "When did you and your partner last have sex?" Female and male responses to these questions were then compared for consistency. CVS assessments were used to aid in the determination of primary couple status. The complete list of CVS items is provided in Table 3.

It became evident during the piloting phase of the study that some CVS questions were more effective at verifying primary partnership status than others. For example, the question "When did you and your partner last have sex?" was a more reliable indicator of primary heterosexual status than the question "What is your partner's birthday?", which may also be known to a sibling or close friend. Moreover, several of the screening items allowed for partially or closely matching responses. A good example of this is number of partner tattoos (which is another good indicator of couple status). If a female respondent stated that her partner had 11 tattoos, whereas he reported having 12, should these responses be considered "inconsistent"? Given these measurement issues, we decided against implementing a hard-and-fast rule for passing CVS (e.g., a minimum of five out of six exactly matching responses).

Moreover, exclusive reliance on the CVS instrument would have discounted the experience, observations and knowledge of our outreach workers with regard to determining couple status. For example, outreach workers may have previously observed the couple engaging in behavior typical of an intimate relationship, or may otherwise have knowledge of their relationship status. Therefore, the CVS instrument was used as an important tool to aid outreach workers rather than as the sole indicator in resolving partnership status. Different protocols for CVS were administered depending upon whether screening was conducted on the street or at our research location. Each of these protocols is described below.

Street-based CVS Protocol

During street CVS, outreach workers paired with female and male respondents and walked them apart (beyond normal hearing distance) and administered the CVS questionnaires. While one of the outreach workers compared the female and male responses and made a determination regarding primary couple status, the other outreach worker engaged the couple in discussion. Couples who passed the street CVS were escorted to the research site for study enrollment. Those who did not pass were told that they were not eligible to participate in the study, but were not given a specific reason beyond "not conforming to our research criteria." Items on the questionnaire were periodically changed to avoid predictability and minimize respondent preparedness. In practice, only about 20% of couple verification screenings were administered on the street, with the other 80% administered at the research site.

Site-based CVS Protocol

On-site couple verification screening was conducted using a somewhat different protocol. Once at the research site, prospective couples who had not previously been administered the street-based CVS were escorted to separate, private offices and were administered CVS using a computer-assisted personal interview (CAPI) network program cre-

ated specifically for this study (available from the first author). In her office, the female interviewer entered the assigned couple ID number into the CVS-CAPI data input screen. The program then randomly selected six CVS items (from the pool of 21; see Table 3) which appeared on the female interviewer's computer screen in the form of a CAPI questionnaire. (By randomly rotating the CVS items for each couple, information obtained from previous participants could not be used to predict the questions.) On this data entry screen, the female interviewer recorded (a) the result of the women's eligibility screening, (b) responses to the six randomly selected CVS questions, and (c) comments pertaining to the interviewer's knowledge or observations regarding couple status. This information was electronically written to a password-protected network database.

In a separate office, the male interviewer completed the (spurious) men's eligibility questionnaire and entered the same couple ID number into his CVS-CAPI data input screen. The CVS-CAPI program returned the same six matching CVS items that had been administered to the female respondent. The male responses to the six CVS items were then entered into the on-screen form, and matched with the female responses retrieved from the network database. Without leaving his office, the male interviewer could thus view the results of the women's eligibility screening, compare female and male responses on the parallel CVS items, and read any comments pertaining to couple status written by the female interviewer. Based on this information and his own knowledge of the couple, the male interviewer rendered a determination of couple status and eligibility. If the female respondent failed the eligibility screening, or if it was determined that the female and male were not primary partners, the male interviewer informed the male respondent that he and his partner were not eligible for enrollment in the study. We believe this approach has been effective in diverting any blame for failing the eligibility or couple status screening away from the female respondent, thereby avoiding potentially antagonistic situations.

To assess the reliability of the CVS procedure we performed a multidimensional outlier analysis (minimum volume ellipsoid estimation [18]) on the completed dataset in an attempt to identify dyads who gave highly divergent responses on multiple items during the structured interview, thus calling into question their status as long-term intimate couples. Based on this analysis, none of the 353 dyads in the final sample could be disqualified as primary intimate couples. It thus appears that the CVS procedure was successful as a 'relationship screening' tool.

Confidentiality Issues

Concerns regarding confidentiality of reports of illegal or sensitive behavior by research participants were addressed in several ways. Use of computer-assisted self-interview (CASI) allowed respondents to provide sensitive information privately and discretely. In addition, respondents were informed about procedures to ensure the confidentiality of the information they provided, including the issuance of a Certificate of Confidentiality by the U.S. Department of Health and Human Services, which can help to protect against the subpoena of research-related data.

In addition to problems associated with eliciting information involving sensitive or illegal behavior, a new set of concerns arises in the context of couples-based research. Although parallel female and male interviews were conducted in separate offices, some respondents may nonetheless have felt uneasy providing sensitive information that may have been kept hidden from their primary partner. For example, information regarding extra-spousal intercourse, important for assessing risk for sexually transmitted infections, may have raised confidentiality concerns among some study participants. To allay these concerns, confidentiality messages were reinforced throughout the survey and HIV/hepatitis counseling and testing phases of the study. Participants were made aware of the procedures to safeguard the privacy and confidentiality of the information they provided, not only from their partners, but from others as well.

The following procedures were implemented to ensure the confidentiality of information provided by study participants. Research data were collected using the NOVA/QDS computer interview system (NOVA Research). Data were compiled into an electronic database which contained no respondent identifier information (such as name, address, or SSN). Matching ID numbers were the only link between female and male data obtained from couples. Research data (stored in digital form only), informed consent forms, viral test results, and post-test counseling locator information were stored in separate double-locked cabinets in different locations and were accessible only to key personnel. For example, the HIV Counselor had access to test result data, but not research data; the data analyst had access to research data but not informed consent forms or post-test counseling data.

Study Enrollment

A detailed description of study enrollment and data collection procedures is beyond the scope of this paper. However, a brief description will help establish the research context within which recruitment and screening procedures were conducted. Couples who passed the eligibility and couple verification screening were asked to

provide informed consent to participate in the study. Consenting participants provided urine samples to screen for recent heroin, cocaine, marijuana, and amphetamine use. Research by our team has demonstrated that when urine testing is conducted prior to interview and respondents are aware that results are available before the interview, self-reports of recent drug-use are valid 94% of the time [19]. Female and male members of each couple were simultaneously administered structured parallel questionnaires by gender-matched interviewers in separate offices. Questionnaires were administered using a combination of computer assisted personal interview (CAPI) and, for sensitive topics dealing with sexual risk behavior and drug-use, computer-assisted self interview (CASI). Respondents were further asked to provide informed consent to undergo counseling and testing for HIV (saliva OraSure test) and hepatitis B and C (Abbott EIA 2.0/VITROS CIA antibody screening). Post-test counseling and referrals were also provided. Study participants were each paid $25 (USD) compensation for their time.

Recruitment and Screening Results

As shown in Figure 1, over 3,000 women were approached by our outreach workers on the streets of East Harlem between February 2001 and July 2003. Of these, about 10% (297) agreed to undergo eligibility screening. Seventy percent (207/297) of these women passed the initial street eligibility screening. Only 77 women were immediately available to participate in the study with their partner; the other 130 women were given numbered information cards. Of the 77 couples who were immediately available, 70 couples passed the street CVS. Of these, 68 couples were escorted back to the research site and completed the study (two couples changed their minds and did not immediately enroll).

As shown in Figure 2, a total of 557 phone inquiries were received by project staff over the period of active data collection. One-hundred-and-two calls came from the pool of 130 women who had passed the street eligibility screening and had been given a numbered information card (see Fig. 1H). The other 455 calls came from women who had been referred to the study by a previous participant. Phone eligibility screening of these women determined that 315 were eligible while the remaining 140 were ineligible. Therefore, a total of 417 women (102 street eligible and 315 referral eligible) were given appointments to undergo further screening with their male partner. From this pool of phone appointments, 298 couples attended eligibility and couple verification screening at our research site (the other 119 couples were 'no shows'). Of these 298 couples, 285 passed the site eligibility and couple verification screening and were enrolled into the study. The total study sample of 353 couples was thus derived from 68 street-recruited/street-available couples, 70 street-recruited/phone-appointment couples, and 215 respondent-referred couples.

Discussion

To our knowledge, this is the first study to successfully recruit urban street-based drug-using couples and verify their relationship status. Street-based sampling was employed to avoid problems associated with limited external validity characteristic of most convenience samples. Our adaptive sampling procedures demonstrated that couples can be successfully recruited by targeting one member (in our case, the female) of each couple. This approach has been employed in research involving other types of social networks (for example, recruitment of families and children through one parent [20]). While this type of sampling and recruitment strategy has obvious advantages over attempting to recruit both partners at the same time, careful consideration of relationship and gender dynamics is warranted. For example, recruitment through the male partner may have led to pressure on the female member to unwillingly participate. In our study, we recruited through the female partner partly because our research objectives focused on women's health and partly because women were most likely to experience adverse affects due to participation with male partners. It must be recognized that recruitment through individual group members may result in role-related selectivity and unintended sample bias, which must be taken into consideration when interpreting study results. Enlisting drug-using couples through the female partner may have biased the sample in favor of relationships less prone to conflict, and this will need to be taken into account during data analysis and interpretation.

Our study demonstrated that an adaptive sampling design can be successfully applied to recruit hard-to-reach drug-using couples into a public health research project. The observation that the majority of our study participants (about 60%; see Figures 1 &2) emanated from respondent referrals is consistent with previous studies using similar adaptive sampling designs, and should not contribute greatly to sample bias [16].

Verification of relationship status is an important aspect of research involving groups of related individuals. Verification methods should be based on how relationships are defined and operationalized in the study. In some cases simple self-report will suffice, while in other cases documentation may be required. In the current study, we introduced the use of a couple verification screening (CVS) instrument to aid in the determination of partnership status. This method proved invaluable in preventing female and male dyads who were not primary sexual partners from entering the study (about 6% of those screened). Similar screening techniques could be developed to verify

Table 3: List of couple verification screening (CVS) items.

Description	Gender specific wording	Item
Couple last had sex	F/M	When did you and your partner last have sex?
Couple last did drugs	F/M	When did you and your partner last do drugs together?
Who slept closer to the door	F/M	The last time you and your partner sleep in the same bed together, who slept closer to the door?
Female birth date	F	Please tell me your birthday.
	M	What is your main partner's birthday?
Male birth date	F	What is your main partner's birthday?
	M	Please tell me your birthday.
Female born what city?	F	Where were you born? (city-country)
	M	Where was your main partner born? (city-country)
Male born what city?	F	Where was your main partner born? (city-country)
	M	Where were you born? (city-country)
Female father's name	F	What is your father's first name?
	M	What is your partner's father's first name?
Male father's name	F	What is your partner's father's first name?
	M	What is your father's first name?
Female mother's name	F	What is your mother's first name?
	M	What is your partner's mother's first name?
Male mother's name	F	What is your partner's mother's first name?
	M	What is your mother's first name?
Female report number of male tattoos	F	How many permanent tattoos, if any, does your partner have on his body?
	M	How many permanent tattoos, if any, do you have on your body?
Male report number of female tattoos	F	How many permanent tattoos, if any, do you have on your body?
	M	How many permanent tattoos, if any, does your partner have on her body?
Female favorite meal	F	What is your favorite dish (meal)?
	M	What is your partner's favorite dish (meal)?
Male favorite meal	F	What is your partner's favorite dish (meal)?
	M	What is your favorite dish (meal)?
Female age	F	How old are you?
	M	How old is your partner?
Male age	F	How old is your partner?
	M	How old are you?
Female youngest sibling name	F	What is the name of your youngest brother or sister?
	M	What is the name of your partner's youngest brother or sister?
Male youngest sibling name	F	What is the name of your partner's youngest brother or sister?
	M	What is the name of your youngest brother or sister?
Female number of siblings	F	How many brothers and sisters do you have?
	M	How many brothers and sisters does your partner have?
Male number of siblings	F	How many brothers and sisters does your partner have?
	M	How many brothers and sisters do you have?

other types of relationships in clinical and therapeutic research. Multiple sources of information regarding relationship status, such as personal knowledge of recruiters and interviewers, should also be considered.

Given the essential role of human relationships in the spread of disease, relationship factors must be taken into account in disease treatment and prevention research. There is a growing need for the development of methodologies consistent with research involving dyads or larger groups of related subjects. An integrated set of procedures for sampling, recruiting and screening hard-to-reach couples into a public health surveillance and disease prevention study was presented. These procedures can be adapted for use with other hidden populations (e.g., illegal immigrants, commercial sex workers, homosexual partners) and study objectives (e.g., therapeutic, pharmaceutical, clinical trials).

Competing interests

None declared.

Authors' contributions

ST is the Principal Investigator of the study described in this article. ST, JM, LT and RH developed the original study protocols. JM wrote the first draft of the manuscript,

and all authors contributed to subsequent revisions. JM and EP conducted data analyses and table preparation.

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