Published in final edited form as:

J Assoc Nurses AIDS Care. 2011 ; 22(4): 320–329. doi:10.1016/j.jana.2010.10.009.

Lessons From the Viagra Study: Methodological Challenges in Recruitment of Older and Minority Heterosexual Men for Research on Sexual Practices and Risk Behaviors

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Abstract

Although all sexually active persons may be at potential risk for HIV and other sexually transmitted diseases (STDs), there is a common misperception that older heterosexual adults are not at risk (Smith & Christakis, 2009). HIV is a continuing concern in persons ages 50 and older (Goodroad, 2003; Savasta, 2004). Therefore, research with this population is warranted. However, little literature addresses the recruitment of middle aged and older heterosexual men, particularly minority men, into research studies on sexual behaviors and practices. The purpose of this article is to discuss challenges that arose during the recruitment and data collection stages of a study on health and sexual practices of older heterosexual men using prescribed erectile dysfunction (ED) drugs, and the strategies that were used to meet these challenges. Lessons learned from this study will be discussed, as well as implications for HIV/STD researchers and clinicians.

Keywords

HIV risk; Latino; machismo; older heterosexual men; sexual practices; study recruitment; Viagra

Background

Research has suggested that use of oral phosphodiesterase 5 (PDE-5) inhibitor drugs (i.e., sildenafil [Viagra®], vardenafil [Levitra®], tadalafil [Cialis®]) may be associated with increased risk for HIV infection among men who have sex with men (MSM) and drug using men (Fisher et al., 2006; Mimiaga et al., 2008; Sanchez & Gallagher, 2006; Schwarcz et al., 2007; Spindler et al., 2007). In September 2005, a National Institute of Mental Health-funded, multidisciplinary conference was held to evaluate scientific research and evidence related to erectile dysfunction (ED) drugs and sexual risk behavior. Conference conclusions

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Disclosure

The authors report no real or perceived vested interests that relate to this article (including relationships with pharmaceutical companies, biomedical device manufacturers, grantors, or other entities whose products or services are related to topics covered in this manuscript) that could be construed as a conflict of interest.

were that “In the absence of recreational drug use, particularly methamphetamines, the role of PDE-5 inhibitors as an independent predictor of high-risk sexual activity remains uncertain” (Rosen et al., 2006, p. 965). However, the conference ended with a call for further research in this area to address identified gaps in knowledge for PDE-5 use by certain groups, such as heterosexual populations.

Between 2006 and 2009, a study, Safer Sex Practices of Over-50 Heterosexual Viagra Users (“the Viagra study”), was conducted in South Florida to identify and describe health promotion behaviors and safer sex practices of heterosexual men ages 50 and older who were prescribed oral PDE-5 inhibitor medications for treatment of ED. The aim of the study was to explore whether or not older heterosexual men using prescribed ED drugs were knowledgeable about risk for transmission and acquisition of HIV or other STDs and whether or not they were using appropriate safer sex practices. The target population was sexually active English-speaking or bilingual heterosexual men over the age of 50 who had been prescribed an oral PDE-5 inhibitor drug (i.e., sildenafil, vardenafil, tadalafil) by health care providers for the treatment of ED for a period of 3 months or longer. Eligible men could be single, married, divorced, or widowed but needed to have been sexually active within the previous year.

This study was significant for nursing and HIV care because it provided new knowledge in an important area for HIV prevention that has not been previously studied. From a public policy and prevention perspective, it is important to know whether men prescribed oral PDE-5 inhibitor medications for ED treatment are practicing unsafe sex, which might lead to an increase in transmission of HIV. It is also important to know factors associated with safer sex practices among sexually active heterosexual men over the age of 50. Initial findings from this study have been reported elsewhere (Jones et al., 2009). However, lessons learned during the recruitment and data collection stages of the study are also valuable to inform programs about HIV prevention for older heterosexual adults, from research, clinical, and educational perspectives.

A review of the literature was conducted to discern issues related to challenges in studies of sexual risk behaviors. In an article on general methodological challenges in research on sexual risk behaviors, Schroder, Carey, and Vanable (2003) discussed issues in the assessment of sexual behavior related to item content, scaling, data analysis, self-reporting errors, and data accuracy. While other articles revealed numerous issues related to recruitment of special populations (Dinitto et al., 2008; Pérez-Jiménez, Seal, & Serrano-García, 2009; Warren-Findlow, Prohaska, & Freedman, 2003; Williams, Zenilman, Nanda, & Mark, 2008), no reports specifically addressed issues related to recruitment and data collection in the study of sexual risk behaviors of heterosexual and minority older men.

The purposes of this methodology brief are to (a) describe the unexpected challenges that arose during the recruitment and data collection stages of the “Viagra study,” and (b) discuss strategies that arose from study team discussions and were used to overcome these challenges. Methodological issues to be addressed included (a) recruitment of older heterosexual Hispanic men; (b) gender of recruiters and interviewers for minority male participants; (c) recruitment settings: community strategies versus provider-office recruitment; (d) instrument length, language, and appropriateness; (e) choice of incentives for different populations; (f) privacy issues with participants; and (g) privacy issues with use of personal versus pay-per-use cellular phones for conducting interviews.

Recruitment of Heterosexual Men Over Age 50

After approval was obtained from the Institutional Review Board for the Protection of Human Subjects at the investigators’ university, recruitment for the Viagra study was

initiated. The desired sample was 100 men. Initially, recruitment of heterosexual men was a major challenge for the study. Although the researchers had conducted successful recruitment of women and MSM for other studies, the response rate for heterosexual men for the Viagra study was at first disconcerting. Midway through the 2-year recruitment phase of the study, recruitment phone logs revealed that while 100 men had called or had been contacted regarding the study, only half met eligibility criteria, and only half of that group had agreed to participate.

Recruitment issues were discussed at ongoing study team meetings. The study team had originally been composed of all females and included two female graduate students who were responsible for study recruitment and for conducting the telephone interviews. To increase the number of data collectors for the study, undergraduate and graduate nursing students enrolled in research courses were invited to join the study and/or attend study team meetings. Several of the students were male and Hispanic.

To understand why recruitment was problematic, the students were asked to address this issue “from the male perspective.” The students reported that, from their personal and professional experiences, heterosexual men did not like to talk about sex and particularly did not like to discuss taking sildenafil (“Real men don’t NEED Viagra!”). This concept was a particular concern to older Hispanic men, who comprised a majority of the target population in South Florida. As one student commented, taking sildenafil was not in keeping with the Hispanic image of *machismo*. Machismo is a term used to denote attitudes and characteristics associated with Hispanic masculinity and manliness including the need to be “strong, reliable, virile ... and be knowledgeable regarding sexual matters” (Sobral, 2006, p. 348). Machismo has both positive and negative connotations (Falicov, 2010). Positive aspects include the expectation that men behave valiantly to protect the honor and welfare of their families. However, machismo may also infer “men’s active subjugation of women and performance of high-risk activities to prove their masculinity” (Galanti, 2003, p. 183).

From a cultural perspective, the need for sildenafil or other ED drugs could possibly imply that a male had “lost his power as a man.” Therefore, older Hispanic heterosexual men might have been reluctant to acknowledge that they needed to use ED drugs for sexual activity, which could negatively have affected recruitment efforts. As a solution to this problem, a Hispanic male nurse practitioner student recommended promoting the study as the “FIU [Florida International University] Men’s Study” instead of the “Viagra Study.” The research team concurred that adapting the promotional name of the study to a more generic focus on men’s health, rather than sexual problems, might be less threatening to participants. Messages on the research office telephone and recruitment flyers were updated to reflect the new title. Changing the name of the study and adding Hispanic men to the team, combined with other strategies to be discussed, resulted in a rise in the number of inquiries and a 70.9% increase in completed interviews over the remaining year.

Gender of Recruiters and Interviewers

Exploring the male perspective led to consideration of the gender of recruiters and interviewers for participants. As one student noted during study team discussions, “Men may talk to other men about sex, but they will not talk about their sex life with women if they are not having sex with them.” Another student reported that older Hispanic men would be extremely uncomfortable talking about sex with female interviewers because this was not part of the cultural norm. The logs of female recruiters and interviewers further highlighted the gender discordance problem. One student wrote, “He told me, ‘I don’t want to answer your questions, but will you go out on a date?’”

The issue of gender concordance between participants and interviewers/researchers has been discussed in the literature (Chun, Tavarez, Dann, & Anastario, 2010; Fenton, Johnson, McManus, & Erens, 2001). More specifically, gender issues have been noted in research on HIV prevention with Latinos. For example, in a study of HIV prevention for heterosexual Latino couples, Pérez-Jiménez et al. (2009) found that the gender of education facilitators was important. One service provider elaborated:

I believe that one important thing is that facilitators be men because [men] are not going to listen to women. "A woman is not going to teach me anything." So, it is better that they are men. That they speak one-to-one, peer-to-peer, and also they can talk about men's things with another man's woman, or with an unknown woman, they do not dare discuss. (p. 15)

As noted, at the start of the study the recruiters and interviewers were all female. Realizing that this may have been an impediment to recruitment, a choice was made to actively involve male nursing students as study recruiters and interviewers. Use of male recruiters and data collectors, combined with the other strategies that will be discussed, were essential components for increasing the sample size from 25 to 86 men by the end of the study.

Recruitment Settings: Community Versus Provider Offices

Another methodological issue was related to settings for recruitment. At the start of the study, recruitment strategies were focused on advertising the study in community settings. Flyers were created and displayed in areas where sexually active older heterosexual men were thought to congregate. These settings included parks, clubs, bars, and retail stores such as Bass Pro Shops® and Home Depots®. This type of recruitment strategy had been successfully used for a variety of HIV and safer-sex studies with other target populations (Baigis, Francis, & Hoffman, 2003; Cabral et al., 2003; Hatfield et al., 2010).

The study flyer included a telephone number for interested participants to call and inquire about the study. However, the problem that arose was that persons outside of the target population began calling about the study. Many non-heterosexual men and men younger than 50 called to inquire about the amount of incentive that was being offered for study participation. Women even called to ask if they could be in the study and how much they would receive for study participation. These calls consumed a great deal of study recruiters' time and energy yet yielded few eligible study participants. Male friends and family members of the researchers were then asked to help with recruitment by posting flyers in "male-only" areas such as locker rooms of private golf clubs and men's bathrooms in sports bars. To the researchers' surprise, the men stated that they were very uncomfortable about doing so and with being associated with the Viagra study.

Serendipity solved the problem. One student who began working on the study also happened to be working for a urology practice that was conducting a variety of research studies on male urology problems, including the use of ED drugs. After a discussion about the study, the chief urologist allowed the student to recruit participants from the clinic's urology patients. Another student was associated with a group of surgeons who specialized in surgery for cancer of the rectum. Many of their male clients were placed on ED drugs after surgery. This student discussed the study with the surgeons, who were very interested in the study topic. The surgeons began mentioning the study to eligible clients and referring them to the student for further information. Since these clients were already being prescribed ED drugs, were introduced to the study by the health care provider who had prescribed the drugs, and were referred to the study by someone associated with the provider practice, the men were open to and interested in the study. Therefore, the provider-office-based

recruitment strategy was a more effective means for recruiting for this study than the use of community-based recruitment.

Instrumentation

A further study challenge was the instruments that had been selected for use in the study. To address comments received from study reviewers, the original proposal had been revised to include an expansion of study instruments. The final funded proposal included an extensive battery of study instruments for which reliability and validity estimates had previously been reported in the research literature on older adults and on HIV prevention. The study instruments included a demographic data questionnaire; the 8-item Older Men's Health Program and Screening Inventory (OMHPSI; Loeb, 2003); the 27-item Safe Sex Behavior Questionnaire (SSBQ; DiIorio, Parsons, Lehr, Adame & Carlone, 1992); the 18-item Brief HIV Knowledge Questionnaire (HIV-KQ-18; Carey & Schroder, 2002); 48 items from subscales of the Condom Attitude Scale (CAS; Sacco, Levine, Reed, & Thompson, 1991); an adapted version of the Centers for Disease Control and Prevention's (CDC) Sexual Behavior Questionnaire (SBQ; Lentine et al., 2000), and a TimeLine Follow Back (TLFB) interview on sexual history and alcohol and drug use (Carey, Carey, Maisto, Gordon, & Weinhardt, 2001).

When planning the study, based on the review of the literature, an estimate was made that telephone interviews would take approximately 40 minutes to complete. The male interviewers quickly alerted the researchers to the fact that the interviews were taking more than 1 hour and up to 2 hours to complete. During the interview, some participants would say that they were tired and ask the interviewer to call back to complete the interview at a later time. However, when the interviewers called back at the agreed-upon time, the participants were not always available. Multiple follow-up calls to these participants were needed to complete the study instruments. Instrument fatigue and response burden were seen as problems by both the researchers and the data collectors.

In addition, older bilingual Hispanic men had many questions about the terms used on the instruments related to sexual activity and practices. It became apparent that instruments commonly used in HIV prevention studies for high-risk sexual populations might not be easily understood in relation to language used by older heterosexual men. For example, the study team reported that participants often reacted negatively ("Why would you ask me such a question?") to two questions from the SSBQ (DiIorio et al., 1992): "I insist on examining my sexual partner for sores, cuts or abrasions in the genital area" and "I use rubber gloves for sexual foreplay when I have cuts or abrasions on my hands." Additionally, the participants were "shocked" and seemed offended by questions about injecting drug use, time spent in prison, anal sex with other men, and trading sex for money or drugs.

The strategy used to address the issues of the length, language, and appropriateness of study instruments was a re-review of the instruments. The review revealed that different instruments actually had many similar items. For example, questions on the TLFB were very similar to questions that were previously asked on the CDC's SBQ. Therefore, the TLFB was dropped, and the data collectors reported back that the telephone interviews were then completed in about an hour. However, the data collectors and the researchers agreed that this was still too long a duration for telephone interviews.

To address this issue, the decision was made to mail the participants several of the instruments, which could be self-administered and recorded on a check-off list. The men who agreed to participate would then return their completed instruments and check-off lists along with their signed Informed Consent. Once received, the study recruiter would then ask a study interviewer to call the participant and complete the telephone interview, which now

specifically focused on a sexual history interview. Use of this data collection strategy reduced the telephone interview to less than 30 minutes, which was perceived as an acceptable duration by both study participants and study interviewers.

Incentives

Another challenge that arose was the choice of incentives for different populations. At the onset of the study, a \$25 gift card for a local grocery store was used as an incentive. While some men were happy with this incentive, other men decided to decline to participate after hearing the nature of the incentive. It became apparent that participants needed to be able to choose an incentive that was appropriate for them.

The researchers decided to try using a \$25 Visa® or American Express® gift card as an incentive. When participants were offered a choice, more men opted for the prepaid card over the grocery store gift card. However, the use of prepaid cards, such as Visa® or American Express® gift cards, posed some challenges to the study budget. Besides the \$25 fee for purchasing the gift card, the cards all carried an additional fee of \$3.99 to activate the cards. The study budget had to be revised to accommodate the increased cost. Additionally, the cards had expiration dates, and some carried additional fees if not used within 6 months. Participants needed to be notified to use the card within 6 months of receipt to avoid incurring a usage fee.

Although this strategy did work, the additional activation cost of \$3.99 for each \$25 gift card could be a challenge to researchers with limited study budgets. However, a strategy for successful recruitment and participation of heterosexual men is to select incentives that meet the needs or desires of the diverse target population, realizing that different men may want different incentives. For example, as previously noted, more men wanted a prepaid gift card than a gift card for a local grocery store, and more men requested a Visa® gift card than an American Express® gift card.

Privacy and Telephones

The last two methodological issues encountered in the Viagra study were related to the use of telephones. One issue with telephones was privacy concerns when contacting the participants who had been referred by care providers. After referral, interviewers called potential participants to explain the study and obtain initial verbal consent for their participation in the study. The telephone numbers used had been given to and were on file with the providers. Often, these were numbers for cellular phones. When a study recruiter called a participant to explain the study, he could have been in any setting. Some men were at work and stated that they could not talk because coworkers were around. Other potential participants gave a variety of reasons for why they could not talk at the time. One man stated, "I can't talk right now. My wife is at home, and she doesn't know that I am using Viagra." Another man stated that his wife was at home and did not know that he was using prescribed Viagra because he only used it when he was with his girlfriend. The strategy that was used to overcome this problem was for the recruiter to quickly explain that the institution was conducting a study and that the person had been referred by his health care provider as being eligible for the study before requesting an appropriate time to call back to discuss the study.

The last challenge was related to privacy issues with use of personal or office telephones versus pay-per-use cellular phones for recruitment and conducting interviews. As previously noted, flyers were posted at various community settings (i.e., parks, clubs, bars, stores) to advertise the study. The flyers listed the principal investigator's (PI) name and office telephone number as the contact for the study. The PI began receiving a variety of

inappropriate telephone calls and messages. For example, in one message, left at 1:00 a.m., the caller asked the PI to call back because the man was having a problem with his erection. Other calls came in during the day, and male callers asked intimate questions that were an invasion of the PI's privacy (e.g., the PI's marital status, the PI's interest in sexual activity). Additionally, at that time, the study employed female recruiters. The female recruiters used their personal cell phones to contact potential participants who had left their numbers on the PI's office telephone. The female study recruiters experienced many of these same problems.

The researchers determined that incoming calls to personal cell phones had become a privacy and safety issue for study staff. The problem was referred back to the researchers' institution, and the PI asked if cell phones could be purchased exclusively for study use. Unfortunately, the PI was informed that, due to federal regulations and based on the results of a previous audit, the institution could not use federal funds to purchase cell phones for the study.

The problem was resolved when a student suggested using prepaid, disposable cell phones. The PI then bought several prepaid phones (TracFones®) from a local department store. The phones cost \$20, and prepaid phone cards were purchased with variable fees for different amounts of minutes. This strategy was an excellent method to protect the privacy of the study staff. Other researchers may want to consider and plan for the use of disposable prepaid phones when developing study proposals and budgets.

Discussion

A variety of strategies were used to adapt to the challenges that arose during the recruitment and data collection stage of the Viagra Study. Comments and insights from members of the research team were invaluable in devising strategies to meet these challenges. Often, recruiters and data collectors are brought on board after a proposal is written and funded. However, preliminary informal focus groups with members of the population from which these personnel will be drawn as well as members of the target population during proposal development may provide insight to minimize recruitment problems prior to initiation of the study. This strategy is similar to conducting focus groups, interviews with key informants, and needs assessment surveys prior to development of clinical programs and community-level health interventions (Gilmore & Campbell, 2005).

In appreciation of the sensitive nature of the topic of erectile drug use, the promotional name of the study was changed from "The Viagra Study" to "The FIU Men's Study" to shift participants' attention to general men's health issues rather than only sexual behavior. This strategy was similar to successful recruitment approaches used by researchers who studied HIV risks in women such as Fauchald's (2004) "Rural Women's Health Study" and Jacobs' (2006) "Mature Women's Study." It has also been successfully used in the clinical setting. For example, a clinical program using a mobile van for sexual health testing for men who have sex with men had successful recruitment for the program by advertising the van as "The Health Van" (O'Connor, Patsdaughter, Lessard, & Gaucher, 2005).

To address gender and cultural issues in recruitment, Hispanic male data collectors were added to the recruitment team. As noted by Scott-Sheldon, Kalichman, and Carey (2010), research on sexual behaviors should take the participant's gender and culture into account. From a clinical perspective, older Hispanic men may prefer receiving care from male providers who are of the same ethnic background and who understand the importance of machismo at both individual and social levels.

Recruitment settings were reconsidered, and telephone-based recruitment from providers' clients was used along with flyers posted in community settings. For this study, more participants who met study inclusion criteria were recruited from providers' practices, including urology and oncology. A recommendation from this study is that researchers should consider collaboration with clinicians when conducting sexual health studies with hard-to-reach male populations.

The length, nature, language, and duration of instruments used for the study were also reevaluated. Duplicate, unclear, or offensive items were eliminated; participants were allowed to return completed surveys by mail; and telephone interviews were shortened to focus only on participants' sexual health histories. This strategy was consistent with recommendations made by Scott-Sheldon et al. (2010) regarding selection of data collection measures and the use of measures with terms that were clear and familiar to participants. The authors also discussed considerations to determine the most appropriate and acceptable method of data collection (e.g., interviews in the clinical setting vs. self-administered questionnaires for research studies). These recommendations should also be considered when conducting sexual health histories in clinical settings. Providers may need to devise or adapt sexual risk behavior questions into an appropriate language or format that puts older clients at ease and sets the climate for an interactive discussion of sexual practices and risk behaviors (Jones, 2001).

The type of incentive offered was expanded to give options for incentives. As noted by Patsdaugher, Christensen, Kelley, Masters, and Ndiwane (2001):

Participant incentives should also be carefully chosen with specific groups in mind. It is not necessary to choose expensive gifts as rewards but rather to find out what is of interest or meaningful to each particular group. Researchers must be creative in their selection of what is culturally appropriate as well as sensitive to what the participants see as an acceptable payback for their time and energy. (p. 126)

The use of appropriate incentives is also important in attracting participants to community education and prevention programs. For example, at a recent HIV Expo that was jointly sponsored by the Association of Nurses in AIDS Care and the International Association of Physicians in AIDS Care, more than 200 community participants came to the educational and HIV/STD testing event. Many participants reported that they were drawn to the event by the offer of a free bus pass for attendance.

Lastly, in relation to privacy issues, a scripted recruitment interview was used for telephone calls to potential participants, and prepaid disposable cell phones were provided for recruiters and data collectors. Although privacy concerns of participants have been addressed in the research literature (Scott-Sheldon et al., 2010), less attention has been paid to personal protection and privacy safeguards for data collectors and researchers. In the Viagra Study, privacy was a concern between male participants and female research team members; however, similar concerns may arise with same sex pairings. Similar to encounters and interviews in clinical settings, interactions between study recruits and participants and research team members need to be maintained on a professional level. Just as participants are informed in human subject materials that they do not need to answer questions that make them feel uncomfortable, study recruiters and data collectors should also be provided information on what to do when and if exchanges become personal or uncomfortable in nature in the context of studies on sexual behaviors.

Conclusion

Several valuable lessons were learned from the Viagra Study. Midway through the study, only 25 participants had been enrolled; after the implementation of revised recruitment strategies, the final study sample size was 86 men. Although the target population of 100 men was not reached, the sample size was more than adequate to address the research questions and for statistical analysis of the data.

From a research perspective, certain populations, such as heterosexual older men and particularly minority men, may be harder than others to access when discussing personal information such as ED drug use and safer sex practices. Additionally, culture, gender, and age-specific factors may also impede recruitment and participation of heterosexual men in studies of safer sex practices. There is a need to develop safer-sex questionnaires and instruments that use terminology or statements that are perceived as acceptable or appropriate by older adults.

The lessons learned from our research are also relevant to clinical and community settings. Many of the strategies used in the Viagra study are applicable in planning and delivering community-based HIV education and prevention interventions for middle-aged and older men. From a clinical perspective, providers should be cognizant that older men using prescribed ED drugs may unknowingly be at risk for HIV infection and other STDs. While HIV/STD risk assessment should be a component of a comprehensive health history on every client, reluctance to discuss sexual matters may deter older heterosexual and minority men from adequately or honestly revealing behaviors and practices that put them at risk. Providers in clinical settings may need to devise or adapt sexual risk behavior questions into appropriate language or format, with consideration of age, gender, and cultural issues. These strategies may help to facilitate an informed and interactive provider-client discussion of sexual practices and risk behaviors.

Acknowledgments

The study was funded by grant # S06GM08205, National Institute of General Medical Sciences, National Institutes of Health, Minority Biomedical Research Support (MBRS) Support of Competitive Research (SCORE) Program.

At the time of the study, Vicente M. Martinez Cardenas was a graduate nursing student at Florida International University. The authors wish to acknowledge the contributions of other nurses who were students at the time and who served as study recruiters and interviewers or gave input to the study including Xochil Echeona, Roberto Evora, Mercedes Garcia, Claudia Hodgson, Carmen McNichol, Carlos Pardo, J. Craig Phillips, Armando Riera, Javier Rios, Luis Sanchez, Vanessa Santiago, and Zimbrek Zvonimir.

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