
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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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 among persons older than 50 years (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 the challenges that arose during the recruitment and data collection stages of a study on health and sexual practices of older heterosexual men using drugs prescribed for treating erectile dysfunction (ED), and the strategies that were used to meet these challenges. Lessons learned from this study will be discussed, as will be implications for HIV/STD researchers and clinicians.

Background

Research has suggested that use of oral phosphodiesterase-5 (PDE-5) inhibitor drugs (i.e.,

sildenafil [Viagra], vardenafil [Levitra], or 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 multidisciplinary conference, funded by the National Institute of Mental Health, was held to evaluate scientific research and evidence related to ED drugs and sexual risk behavior. Conclusions drawn from the conference 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.

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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 for heterosexual men older than age 50 who were prescribed oral PDE-5 inhibitor medications for treatment of ED. The aim of the study was to explore whether older heterosexual men using prescribed ED drugs were knowledgeable about risk for transmission and acquisition of HIV or other STDs and whether they were using appropriate safer sex practices. The target population was sexually active English-speaking or bilingual heterosexual men older than 50 years who had been prescribed an oral PDE-5 inhibitor drug (i.e., sildenafil, vardenafil, or 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 who are 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 determine the factors associated with safer sex practices among sexually active heterosexual men older than age 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. Although 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 Older Than 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 disconcerting at first. Midway through the 2-year recruitment phase of the study, recruitment phone logs revealed that although 100 men had called or had been contacted regarding the study, only half of them met the eligibility criteria, and only half of that group had agreed to participate.

Recruitment issues were discussed at ongoing study team meetings. The study team originally comprised only females, which 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

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