#### **ERECTILE FUNCTION**

# Off-Label Use of Phosphodiesterase Type 5 Inhibitor Erectile Dysfunction Medication to Enhance Sex Among Gay and Bisexual Men in Australia: Results From the FLUX Study



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#### **ABSTRACT**

**Background:** Gay and bisexual men (GBM) use oral erectile dysfunction medications (EDMs) often with little evidence of medical indication necessitating their use.

Aim: To investigate the prevalence, contexts, and motivations for oral EDM use and its relation to sexual risk behavior.

**Methods:** A total of 2,250 Australian GBM completed an online survey of licit and illicit drug use and their associated behaviors. Multivariate logistic regression analysis identified factors associated with use of EDMs in the previous 6 months and, for those who had used EDMs, factors associated with use on a weekly basis.

Outcomes: Any EDM use and at least weekly use in the previous 6 months.

Results: The median age of the sample was 33.0 years (range = 16–81). Two thirds (67.7%) reported no lifetime history of EDM use. Approximately 1 in 10 participants (11.1%) had last used an EDM more than 6 months previously. In the previous 6 months, 11.5% reported using EDMs less than monthly, 5.3% reported using EDMs approximately monthly, and 4.5% reported using EDMs at least weekly. Of men who had used EDMs in the previous 6 months, common reasons cited for its use were to maintain an erection for longer (73.3%), to make it easier to "get hard" (67.3%), and difficulty in attaining or maintain an erection (53.5%). Use of EDMs in the previous 6 months was associated with illicit drug use and higher rates of sexual risk behavior. Weekly users were more likely to have severe anxiety than less frequent users.

Clinical Translation: The use of EDMs in the context of intensive sex partying, with the associated potential for increased risk of HIV transmission and illicit drug use, indicates a need to consider the use of EDMs among GBM in HIV prevention and minimizing harm.

**Strengths and Limitations:** This large-scale study of drug use among GBMs includes comprehensive detailed data on their history of use and rationales for use. Our online methodology potentially decreases social desirability bias in reporting illegal or stigmatized behaviors. This volunteer online convenience sample might not be representative of all GBMs in Australia.

Conclusion: GBMs who used an oral EDM in the previous 6 months often used it for recreational purposes, but many of those who used it on a weekly basis also might have used it for therapeutic reasons. GBMs often use EDMs to enhance their sexual experiences often in the context of intensive sex partying (which can include risky sexual behavior). Hammoud MA, Jin F, Lea T, et al. Off-Label Use of Phosphodiesterase Type 5 Inhibitor Erectile Dysfunction Medication to Enhance Sex Among Gay and Bisexual Men in Australia: Results From the FLUX Study. J Sex Med 2017;14:774–784.

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**Key Words:** Viagra; Cialis; Levitra; Oral Erectile Dysfunction Medication; Off-Label Use; Gay and Bisexual Men; Intensive Sex Partying; HIV Risk Behaviors and Transmission; Phosphodiesterase Type 5 Inhibitor

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## INTRODUCTION

Gay and bisexual men (GBMs) use erectile dysfunction medications (EDMs) such as Viagra (sildenafil citrate; Pfizer, Mission, KS, USA), Cialis (tadalafil; Eli Lilly and Company, Indianapolis, IN, USA), and Levitra (vardenafil HCl; GSK, Brentford, UK) often with little evidence of medical indication that might necessitate their use. 1-5 EDMs were developed to treat medically diagnosed erectile dysfunction, which currently affects more than 150 million men worldwide. EDMs currently remain the first-line treatment for erectile dysfunction because of their efficacy and safety.<sup>8</sup> Nevertheless, EDMs also have been used recreationally particularly among GBM. 4,5,9 Off-label use of EDMs is sometimes used to counter the effects of other illicit recreational drugs<sup>10</sup> and/or to enhance sexual experiences among GBM. EDM use, particularly combined with illicit drug use (such as amyl nitrite,  $\gamma$ -hydroxybutyrate, and crystal methamphetamine) have been implicated in the transmission of sexually transmissible infections, including HIV, because of higher levels of sexual risk behaviors. 2,11-15

Intensive sex partying has been described as a combination of several factors associated with the risk of HIV infection. <sup>16</sup> These include being very sexually active; being closely involved in gay community social and sexual networks; engaging in group sex; engaging in condom-less anal intercourse (CLAI); and using party drugs. <sup>16</sup> EDM use for intensive sex partying has been associated with sexual risk behaviors, <sup>3,4</sup> such as increased numbers of sex partners<sup>2</sup> and CLAI. <sup>15</sup>

Sexual sensation seeking has been found to be a strong indicator of men at risk of HIV and of GBM who engage in sexual risk behaviors and of the association between drug use and risky sex.<sup>17</sup> It also has been associated with many indicators of intensive sex partying.<sup>16,18</sup>

Sexual practices among GBM are influenced by shared understandings of HIV risk and gay community norms, particularly those regarding "safe sex." Aspects of drug using behaviors among GBM, particularly in relation to minimizing harm, have similarly been found to reflect normative values within specific gay community subcultures (cf Southgate and Hopwood<sup>21</sup>). This also might be true of attitudes toward the off-label use of EDMs.

Anxiety and depression are associated with self-esteem, <sup>22,23</sup> social withdrawal, <sup>24</sup> and erectile dysfunction. <sup>25</sup> EDM use can override these factors by providing increased confidence and relieving sexual performance anxiety.

Despite its role in HIV risk behaviors and transmission, few studies have described the characteristics of GBM who use EDMs, the history and frequency of their use, and their motivations for using EDMs.<sup>2,4</sup> These studies show that EDM use tends to be associated more often with sexual pleasure than with erectile dysfunction and, hence, their strong association with HIV risk behaviors and transmission.

## **AIM**

In this study, we used baseline data from a cohort of Australian GBM to investigate the prevalence and contexts of, and motivations for, phosphodiesterase type 5 inhibitor EDM use and its relation to sexual risk behavior.

#### **METHODS**

#### **Procedures**

The Following Lives Undergoing Change (FLUX) Study is an online prospective observational study of Australian GBM. The methods are described in greater detail elsewhere. <sup>26</sup> The FLUX Study aimed to:

- Identify individual and contextual factors associated with initiation and cessation of drug use and changes over time in patterns of sexual and drug use behaviors among GBM.
- Describe the relation between social and community norms and drug use behaviors and beliefs among GBM.
- Describe the role of particular aspects of gay community sexual and social life, and participation in these, in relation to attitudes and beliefs about drug use and drug use behaviors.

We developed sophisticated and automated procedures specific to this study.  $^{26}$ 

In brief, participants were recruited from August 2014 through July 2015 through gay community websites and online media, Facebook, mobile phone applications, and gay sexual networking websites. Ethical approval was provided by the human research ethics committee of the University of New South Wales (Sydney, Australia).

# Measurements

The online baseline questionnaire included demographic items, questions on sexual identity, HIV testing history and self-reported serostatus, sexual behavior with men, and attitudes and beliefs about drug use. Men described their lifetime and recent (ie, previous 6 months) use of licit and illicit drugs and the frequency and methods of EDM use. They also were asked about the reasons for their use of EDMs, including whether they used it to "enhance sex." We also included our previously used measurement of social engagement with gay men<sup>27</sup> and the measurement of sexual sensation seeking. To address intensive sex partying, <sup>16</sup> we included questions about group sex and using drugs for sex or to enhance sex ("party and play" or "chemsex").

The Generalized Anxiety Disorder Assessment (GAD7),<sup>28</sup> a seven-item self-report questionnaire screening for generalized anxiety disorders, and the Patient Health Questionnaire,<sup>29</sup> a nine-item self-report questionnaire that screens for depression, were included.

# Participants and Sample

Men at least 16 years 6 months old who lived in Australia were eligible for participation if they identified as gay or bisexual or

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