



HHS Public Access

Author manuscript

AIDS Educ Prev. Author manuscript; available in PMC 2018 January 15.

Published in final edited form as:

AIDS Educ Prev. 2017 June ; 29(3): 205–217. doi:10.1521/aeap.2017.29.3.205.

Facilitators and Barriers to Participation in PrEP HIV Prevention Trials Involving Transgender Male and Female Adolescents and Emerging Adults

Celia B. Fisher, Ph.D.,

Fordham University Center for Ethics Education

Adam L. Fried, Ph.D.,

Fordham University Center for Ethics Education

Margaret Desmond, B.A.,

Fordham University Center for Ethics Education

Kathryn Macapagal, Ph.D., and

Northwestern University, Feinberg School of Medicine

Brian Mustanski, Ph.D

Northwestern University, Feinberg School of Medicine

Abstract

Despite the disproportionate burden of HIV facing transgender youth, they continue to be under-represented in studies designed to provide an empirical basis for pre-exposure prophylaxis (PrEP) programs that can meet the unique needs of this population. This study examined facilitators and barriers to participation in a PrEP adherence study. Ninety transgender male (TM) and 60 transgender female (TF) 14 – 21 year olds attracted to cisgender male sexual partners completed an online survey to examine (a) gender identity, age and family disclosure; (b) sexual experience, HIV/STI testing history and perceptions of HIV risk; (c) prior health services and (d) perceived PrEP research risks and benefits (e) and the relationship of these factors to the likelihood of study participation. Approximately 50% were likely to participate in the PrEP study. Participation facilitators included prior sexual and health service experiences (i.e. number of sexual partners, STI testing history, comfort discussing sexual orientation and HIV protection with health providers) and study access to PrEP and health services (i.e. daily HIV protection, not having to rely on a partner for protection, regular health check ups). Participation barriers included lack of concern about HIV, potential medication side effects, the logistics of quarterly meetings, remembering to take PrEP daily and reluctance to discuss gender identity with study staff. Requiring guardian consent was a participation barrier for youth under 18. Results suggest that successful recruitment and retention of transgender youth in PrEP prevention studies warrant protocols designed to address youth's underestimation of HIV risk, concerns regarding medical risk and study logistics, and their need for gender and sexual orientation affirming health services.

Transgender youth (TGY) have been identified as a key population at particularly high risk for HIV (Institute of Medicine, 2011; Pettifor et al., 2015). Available data suggest that in the U.S. HIV prevalence rates for transgender female (TF) and transgender male (TM) adolescents and emerging adults who have sex with cisgender men range between 5%-22% (Brennan et al, 2012; Feldman et al., 2014; Harbarta et al, 2015; Herbst, Jacobs, Finlayson, McKleroy, Neumann, & Crepaz., 2008; Reisner et al 2015; Wilson et al., 2015). Despite the disproportionate burden of HIV facing transgender youth, they continue to be under-represented in HIV research, including studies on adherence to preexposure prophylaxis (PrEP) (Andrasik, Yoon, Mooney, Broder, Bolton, Votto et al., 2014; Galindo et al., 2012; Reisner et al., 2016; Singh, 2016). For example, TF persons are often grouped with and under-represented in studies of cisgender men who have sex with men (Bowers et al., 2012; Escudero et al., 2014) and TM youth have been excluded from PrEP research on the erroneous assumption that their sexual relationships are nearly exclusively with cisgender women, despite an emerging literature on HIV risk among TM who have sex with men (Bauer et al, 2013; Reisner et al., 2015; Scheim et al., 2016; Wansom et al., 2016).

The urgent need for effective HIV prevention tools for at-risk transgender youth has prompted increased research focus by the Adolescent Medical Trials Network for HIV/AIDS Interventions (Andrasik et al., 2015; NIH, 2015; Siskind et al, 2016;). These initiatives recognize that effective HIV prevention programs should be based on research tailored to transgender youth's unique life contexts rather than simply adding them to pre-existing groups (Andrasik, 2015; Fisher & Mustanski, 2014; Grant et al., 2016; Pettifor et al., 2015; Sevelius et al., 2014; Singh, 2016; Smalley et al., 2016; Taylor). Despite documentation of TGY's unique medical needs, experiences with healthcare discrimination, concerns about drug-interactions with hormone therapy, and societal and family rejection (Anderson et al., 2016; Bauer et al., 2013; Bockting et al., 2013; Macapagal, Bhatia & Greene, 2016; Reisner et al., 2016; Sevelius et al., 2016; Taylor, Bimbi, Joseph, Margolis, & Parsons, 2011) little is known about barriers or facilitators for their participation in PrEP prevention trials. The aim of this study was to examine transgender youth's attitudes toward the benefits and risks of participation in PrEP HIV prevention studies within the context of their sexual and health care experiences and family acceptance.

Method

Participants

The sample for this study was drawn from a national online survey on transgender youth's experiences and attitudes toward health services and participation in HIV prevention research in Spring 2016. Participants were recruited through Facebook advertising posts and e-mails to over 120 LGBT youth organizations across 45 states. Advertisements and e-mails included affirming pictures of transgender youth and provided a brief study description and link to an eligibility questionnaire. Inclusion criteria for this study included identification as transgender, 14 – 21 years old, living in the U.S., self-reported HIV negative serostatus and sexual attraction or experience with cisgender mento represent those most likely to be recruited for and in need of future PrEP prevention services.

Study variables

Items were developed from previous measures (Fenway Health 2010; Fisher, Arbeit, Dumont, Macapagal & Mustanski, 2016; Siskind, Andrasik, Karuna, Broder, Collins et al 2016) and refined from focus groups and interviews with transgender youth, an expert advisory board, and online piloting. This resulted in the inclusion of both checklist and transgender and sexual orientation affirming open-ended questions (e.g. “What is your preferred pronoun? What term best describes your gender identity? What words would you use to describe your sexual orientation?”) Our preliminary procedures also led to the inclusion of gender and sexual orientation sensitive educational information about HIV acquisition and prevention information (e.g., “ Simply being transgender does not automatically put you at risk. HIV can affect anyone who is sexually active, particularly when people have sexual contact without protection” “To date there are no known harmful effects of PrEP associated with hormone treatments” (Anderson et al., 2016). In addition to basic demographic items, yes-no, Likert-type, and multiple-choice questions assessed family disclosure and acceptance of gender and sexual orientation identities, sexual history, HIV testing history and attitudes, and receipt of transitioning and transgender and sexual orientation-affirming health services (see Tables 1 and 2 for item details).

Following demographic items, the survey described different components of a PrEP adherence prevention study sequentially to guard against information overload and to help enhance focus on specific aspects of the study. We began with a general description of the purpose of a 12-month study to test whether daily text messages (versus no text messages) could increase sexually active transgender youth's adherence to taking a PrEP pill everyday to protect against HIV acquisition. The study would require HIV testing and HIV prevention counseling with study staff at the beginning and every 3 months and newly diagnosed youth would be referred to a doctor for treatment. This description was followed by questions focused on youth's attitudes toward the HIV testing components of the trial. Next, the importance of taking PrEP daily and the need for condoms as additional protection was described along with the potential short-term (e.g., nausea, diarrhea, or stomach aches) and rare (i.e., minor decrease in bone density and kidney health) medication side effects. This was followed by questions on perceived health benefits of PrEP and sexual health counseling and perceived medical risks and adherence and logistical challenges, and the likelihood that the respondent would get an HIV test as part of a PrEP study versus on their own. A question on whether a requirement for written guardian permission to be accepted into the study would effect participation choice was included for under-age youth 14 – 17 years. Item details are provided in Table 3.

Data collection

Participants meeting inclusion criteria were provided with a unique code number and invited to text the number and their email address to a secure site created specifically for this study. Staff monitored the contact information to minimize threats to external validity caused by use of free web-based phone numbers and phone bots and sent eligible individuals a link to a page of detailed informed consent information and the survey. Ineligible youth were re-directed to the project's Facebook page (www.facebook.com/lgbtrelay), which continues to be updated daily with sexual and gender minority youth-specific news items and resources.

The survey website included firewall protections with data encryption and the investigators received a Certificate of Confidentiality from the Department of Health and Human Services. Participants could end their participation at any time and select to not answer specific questions. Upon completion respondents were directed to a separate webpage to receive a \$20 Amazon.com gift certificate. The study was approved by the institutional review board of each university.

Data analytic plan

We first computed relevant frequencies, means and standard deviations, and proportions for all survey responses. Chi square and multivariate analyses of variance were performed to compare responses across gender identity and age (below and above 18 years). When appropriate 5-point Likert-type items responses were dichotomized to apply Chi Square analyses to potential differences in proportion of responses by gender identity. Correlations were performed to assess the relationship of demographic, family disclosure and acceptance, sexual history, HIV testing history and attitudes, health care history, and attitudes toward health benefits and risks of experimental procedures to the likelihood of participating in a PrEP adherence trial. A multivariable regression was performed to examine independent effects.

Results

Characteristics of sample

The sample included 90 TM and 60TF 14 – 21 year olds, 45.3% under age 18. Table 1 displays demographic information by gender identity. The average age of transgender self-identification was 13.1 (range = 2.5 – 20 years). The majority was non-Hispanic white in high school or college, living with family, and working part-time or unemployed. Youth endorsed multiple sexual orientation identities with TM more likely to endorse “gay” ($X^2_{1} = 4.38, p < .05$) and “queer” ($X^2_{1} = 11.00, p < .001$) and TF more likely to endorse “heterosexual” ($X^2_{1} = 3.86, p < .05$). Most had disclosed gender and sexual orientation to at least one caregiver who was somewhat to very supportive.

Demographic characteristics and family disclosure and acceptance did not differ significantly across gender identities or age nor were they significantly associated with the likelihood that youth would participate in the PrEP adherence study. Despite the fact that a majority of the 68 14-17 year olds who were under the age of legal consent had disclosed their gender and sexual orientation identities to at least one guardian (76.5% and 73.5% respectively), 48.5% ($N = 33$) reported they would probably or definitely not participate in the PrEP study if guardian permission was required. Rather, the extent to which the primary parent was accepting of youth's gender and sexual orientation significantly predicted whether they would agree to participate under a guardian permission requirement ($r = .26, p = .03$ and $r = .43, p < .001$, respectively).

Sexual History, HIV Testing and Attitudes, and Health Services

As illustrated in Table 2, the mean number of lifetime sexual partners, sexual partners within the past 12 months, and cisgender male partners did not significantly differ by gender

identity. Older (>18 years) reported more lifetime and 12 month sexual partners ($M = 6.34$, $SD = 6.34$; $M = 2.96$, $SD = 3.17$) than younger youth ($M = 2.68$, $SD = 2.05$, $M = 1.96$, $SD = 1.47$, respectively; $F_{1,148} = 20.55$, $p < .001$, $F_{1,148} = 5.83$, $p < .05$). Most older (74.4%, $N = 61$) and 50% of younger ($N = 34$) youth reported at least one lifetime cisgender male sexual partner ($X^2_{1} = 9.52$, $p < .01$). Approximately half of youth thought HIV infection was unlikely and the majority did not worry about HIV acquisition. Having a cisgender male sexual partner did not affect these attitudes. Of the 111 youth who reported sex with cisgender males, 82% thought they were extremely or somewhat unlikely to become infected, although 41% had been tested and 36% reported they worried about HIV.

In terms of health services, approximately half the youth had discussed their transgender and sexual orientation identities with a physician. While, few had received puberty blocking therapy TF individuals were more likely than TM to have this treatment ($X^2_{1} = 21.26$, $p < .001$). Almost half (43.9%, $N = 36$) of TGY ages 18 – 21 had received hormone replacement therapy compared to 17.6% ($N = 12$) of younger teens ($X^2_{1} = 11.77$, $p < .001$). TF persons reported greater comfort discussing HIV prevention with their regular doctor than TM ($X^2_{1} = 7.41$, $p < .006$).

Relationship of sexual experience, HIV/STI testing and attitudes, and health services to participation choice

Approximately half the respondents indicated they would definitely or probably participate in a PrEP adherence study. The Pearson correlation coefficients provided in Table 2 indicate that the likelihood of participating in a PrEP adherence study significantly increased with the number of sexual partners, prior HIV/STI testing, whether they had been prescribed HRT, and how comfortable youth felt asking their regular pediatrician or family doctor about HIV prevention. The likelihood of participation significantly decreased the less youth thought they could be infected with or worried about HIV infection. Those variables significantly correlating with participation choice were entered in the first step of a multiple regression. The analysis yielded an adjusted $R^2 = .245$, $F_{10,139} = 5.82$, $p < .001$. STI testing, worrying about HIV, and comfort asking doctors about HIV prevention yielded significant *Beta* scores indicating independent influences when other factors were held constant ($\beta = .32$, $.25$, $.15$ respectively, $p < .002$).

Study Factors Facilitating PrEP Research Participation

As the percentages in Table 3 illustrate, approximately half the respondents endorsed daily protection against HIV, free access to PrEP, learning how to protect themselves against HIV and not having to rely on a partner for protection as reasons to participate in a PrEP study. Approximately 40% endorsed statements reflecting the study benefits of a trusting and more frequent relationship with the investigative team. There were no significant effects of age, gender, or parental disclosure on these responses with 2 exceptions: (1) youth who had not disclosed their sexual orientation to guardians were significantly more likely to endorse getting PrEP medication for free as a study benefit ($X^2_{1} = 5.90$, $p < .015$) and (2) the higher percentage of TM individuals who endorsed not having to rely on partner protection closely approached significance ($X^2_{1} = 3.65$, $p = .056$). All of these variables were positively and significantly correlated with study participation choice and were entered in the second step

of the multiple regression yielding an adjusted $R^2 = .409$, $F_{9,131} = 5.26$, $p < .001$. *Beta* scores indicated the value of having HIV protection on a daily basis exerted an independent influence when other factors were held constant ($\beta = .31$, $p < .001$).

Study Factors As Barriers to PrEP Research Participation

As illustrated in the percentages provided in Table 3 about half the youth were extremely or somewhat worried about the possibility of negative medical side effects of PrEP and 23% did not want to add another medication to their health regime. Over 30% endorsed study logistical concerns about getting to quarterly appointments and remembering to take the pills daily. A smaller percentage did not want to talk to researchers about their gender identity. These responses were not affected by gender identity or age. All these variables were negatively and significantly correlated with study participation choice and were entered in the third step of the multiple regression yielding an adjusted $R^2 = .544$, $F_{6,125} = 7.47$, $p < .008$. *Beta* scores indicated concerns over mild side effects, difficulty getting to appointments, and discussing gender identity with research staff exerted independent negative influences on participation when other factors were held constant ($\beta = -.208$, $-.203$, $-.136$, respectively, $p < .03$).

Discussion

HIV prevalence rates among transgender adolescents and emerging adults highlight the urgent need for effective and targeted HIV prevention strategies based on population focused and gender affirmative research (Pettifor et al., 2015). Identifying facilitators and barriers to participation specific to this population is critical to meeting the goal of reducing sexual health disparities among transgender youth. To our knowledge this is the first study to elicit perceptions of both male and female transgender youth ages 14 – 21 on risks and benefits of participation in PrEP adherence studies and we hope it informs the inclusion of young transgender participants in future studies.

Our findings point to a number of avenues for future HIV research and prevention designs and protocols. First, although likelihood of PrEP study participation was associated with number of sexual partners and a history of HIV/STI testing, under-estimation of HIV risk among transgender female and male youth with cisgender male sexual partners emerged as a significant barrier to participation. Our data thus suggest recruitment for HIV prevention trials would benefit from enhanced HIV risk literacy and that funding for research focused on improving transgender inclusive school-based and media driven HIV education programs may be an important step toward reducing sexual health disparities and achieving equitable participation of this population in HIV prevention trials.

Second, transgender male and female youth in our study perceived free access to PrEP, daily protection against HIV, protection independent of partner cooperation, and transgender affirmative counseling as study benefits and half indicated they were more likely to get an HIV test as part of a PrEP study than on their own. Barriers to PrEP study participation uncovered in our data were also health related (e.g., concern about PrEP side effects, adding another medication to their regimen) as well as logistical (e.g. taking medications everyday and getting to appointments). It should be noted that youth who had received HRT were

more likely to endorse study participation, suggesting that PrEP medication concerns may not be directly tied to transitioning treatments. Taken together these data suggest that PrEP adherence studies tailored to the needs of gender minority youth may not only be important for establishing appropriate evidence-based services but also serve as a critical gateway for HIV testing, prevention services and counseling, and when appropriate, HIV treatment referrals for this underserved population. The reported barriers to participation also support recommendations that HIV prevention trials should be integrated into transgender inclusive and affirmative HIV prevention and treatment services (Bockting et al., 2005; Galindo, Walker, Hazelton, Lane, Steward et al., 2012; Jadwin-Cakmak et al., 2015; Reisner et al., 2016).

The multiple sexual orientation identities endorsed by individual respondents and among participants including the prominence of “pansexual” as a self-descriptor highlights the need for research designs that incorporate understanding of how the intersecting stigmas and marginalization of gender identity and sexual orientation add to the unique syndemic of HIV risk among TGY (Poteat, German & Kerigan, 2013). These findings also suggest that efforts to include transgender affirming language in HIV epidemiologic and prevention protocol development consider the inclusion of self-report options that reflect the intersecting and dynamic nature of gender identity and sexual minority orientation. In addition, our finding that approximately 30% of TM identified themselves as “gay” or “bisexual”, adds to the growing body of literature countering traditional assumptions that TM prefer relationships with cisgender women and underscores the need to ensure that TM who have cisgender male sexual attractions and partners are included in HIV prevention research and services (Bockting et al., 2005; Reisner et al., 2010; Singh, 2016).

Our study has several strengths and limitations. First, our online data collection and recruitment methods yielded a national sample of transgender youth, however the anonymous nature of the study does not allow for absolute certainty that inclusion criteria were met and limited participation to those with Internet or mobile phone access and who frequent sexual and gender minority social media sites (Miner et al., 2012). Second, despite efforts to recruit from Facebook sites featuring racial/ethnic minority transgender media figures, our sample was predominantly non-Hispanic white. Racial and ethnic minority TGY deserve additional attention to illuminate their distinct health care needs within the context of not only social stigma and health disparities associated with the intersectionality of gender and sexual minority status, but those historically associated with institutional and structural racism (Macapagal, Bhatia, & Greene, 2016; Reisner, Mimiaga, Bland, Driscoll, Cranston & Mayer, 2012; Smalley et al., 2016). Third, the majority of participants were out to some people and at least one guardian about their gender and sexual orientation identities with most parents at least somewhat accepting. Thus our study may not have captured the views of youth from impoverished, family abandoned, or homeless situations who may be engaged in sex work or other sexual behaviors that would increase HIV infection concern and risk (Harawa & Bingham, 2011; Hotton, Garofalo, Khuns, & Johnson, 2013). However, the data revealed associations between disclosure and familial acceptance and study attitudes that were unexpected. Neither transgender nor sexual orientation disclosure or acceptance was associated with attitudes toward PrEP research with two exceptions: Those who were out to more people about their sexual orientation were more likely to agree to study

participation. This may suggest that young transgender individuals perceive HIV testing and preventive care as more closely aligned with sexual orientation stigma than with social attitudes toward gender identity differences.

Data on disclosure and acceptance also raises important caveats for investigators and institutional review boards (IRBs) who may erroneously assume that simply being “out” to parents indicates guardian permission for HIV research is acceptable to transgender youth. Despite the fact that a majority of 14 – 17 year olds reported disclosure and at least some family acceptance, approximately half reported they would be unlikely to participate if guardian permission was required. Fear of being stigmatized, punished, or in some cases, victimized by their families if guardian permission results in disclosure of their sexual orientation or gender identity has been identified as a barrier to participation among lesbian, gay and bisexual youth (D'Amico & Julien, 2012; DiClemente, Sales, & Borek, 2010; Fisher et al., 2016; Gilbert et al., 2015; Macapagal, Coventry, Arbeit, Fisher, & Mustanski, 2016; Mustanski, 2011; Mustanski et al., in press).

The present study thus joins others in highlighting how well-intentioned IRBs that do not apply federal regulations permitting the waiver of guardian permission for sexual health research may contribute to the persistence of health disparities and undermine sexual and transgender minority youth's right to evidence-based interventions essential to their health and wellbeing (Fisher et al., 2016; Fisher et al., 2013; Fisher & Mustanski, 2014; Mustanski & Fisher, 2016). To remedy this situation, investigators can partner with their IRBs in developing materials that enhance youth's ability to give informed and voluntary consent through age appropriate informational materials (Fisher et al., 2016; Ott et al., 2013) and materials that provide transgender appropriate and informative information about levels of risk for HIV given one's gender identity, sexual orientation and risk practices to enable youth to accurately estimate their own risks for infection. Additional strategies for increasing transgender youth access to HIV prevention studies include providing informational materials to parents to facilitate healthy communications and reduce barriers to PrEP initiation, ensuring staff are trained to provide gender affirming support throughout the research process, and providing peer health navigators that can help transgender youth make informed participation decisions and overcome logistical barriers to regularly scheduled HIV testing and counseling when guardian permission is not a reasonable protection for their rights and welfare.

Youth who reported open discussions with their regular physicians about their sexual orientation and HIV prevention were more likely to endorse study participation. In addition, it was somewhat alarming that less than 5% had discussed PrEP with their regular physician. These findings suggest that engendering trust among transgender adolescents and emerging adults for participation in HIV prevention trials may require efforts to address prior histories of gender and sexual orientation discrimination and lack of person affirming care by health care professionals. These findings also call for additional investigation into links between healthcare experiences and research mistrust among transgender persons and exploration of how current and future HIV epidemiologic and prevention research may be applied to much needed medical training tailored to the sexual health care needs of transgender youth.

Acknowledgments

This research was supported by a grant from the National Institute on Minority Health and Health Disparities (# R01MD009561, Celia B. Fisher & Brian Mustanski, PIs). We wish to thank Dr. Miriam Arbeit and Melissa Dumont for their assistance during the piloting phase of this project and the staff and clients at Harlem United and the Adolescent AIDS Program at the Children's Hospital at Montefiore for their contributions.

This research was supported by a grant from the National Institute on Minority Health and Health Disparities (# R01MD009561, Celia B. Fisher & Brian Mustanski, PIs).

References

- Adolescent Medicine Trials Network (ATN) for HIV/AIDS Interventions Website. Retrieved January 31, 2017, from <https://www.atnonline.org/public/default.asp>
- Anderson PL, Reirden D, Castillo-Mancilla J. Pharmacologic considerations for pre-exposure prophylaxis in transgender women. *Journal of Acquired Immune Deficiency Syndromes*. 2016; 72(Suppl 3):S230–S234. [PubMed: 27429188]
- Andrasik MP, Yoon R, Mooney J, Broder G, Bolton M, et al. Exploring barriers and facilitators to participation of male-to-female transgender persons in preventive HIV vaccine clinical trials. *Prevention Science*. 2014; 15(3):268–276. [PubMed: 23446435]
- Bauer GR, Redman N, Bradley K, Scheim AI. Sexual health of trans men who are gay, bisexual, or who have sex with men: Results from Ontario, Canada. *The International Journal of Transgenderism*. 2013; 14(2):66–74. [PubMed: 24971043]
- Bockting WO, Miner MH, Swinburne Romine RE, Hamilton A, Coleman E. Stigma, mental health, and resilience in an online sample of the US transgender population. *American Journal of Public Health*. 2013; 103(5):943–951. [PubMed: 23488522]
- Bockting WO, Robinson BE, Forberg J, Scheltema K. Evaluation of a sexual health approach to reducing HIV/STD risk in the transgender community. *AIDS Care*. 2005; 17(3):289–303. [PubMed: 15832877]
- Bowers JR, Branson CM, Fletcher JB, Reback CJ. Predictors of HIV sexual risk behavior among men who have sex with men, men who have sex with men and women, and transgender women. *International Journal of Sexual Health: Official Journal of the World Association for Sexual Health*. 2012; 24(4):290–302. [PubMed: 24660042]
- Brennan J, Kuhns LM, Johnson AK, Belzer M, Wilson EC. Adolescent Medicine Trials Network for HIV/AIDS Interventions. Syndemic theory and HIV-related risk among young transgender women: The role of multiple, co-occurring health problems and social marginalization. *American Journal of Public Health*. 2012; 102(9):1751–1757. [PubMed: 22873480]
- D'Amico E, Julien D. Disclosure of sexual orientation and gay, lesbian, and bisexual youths' adjustment: Associations with past and current parental acceptance and rejection. *Journal of GLBT Family Studies*. 2012; 8(3):215–242.
- DiClemente RJ, Sales JM, Borek N. Barriers to adolescents' participation in HIV biomedical prevention research. *Journal of Acquired Immune Deficiency Syndromes*. 2010; 54(Suppl1):S12–S17. [PubMed: 20571418]
- Escudero DJ, Kerr T, Operario D, Socías ME, Sued O, et al. Inclusion of trans women in pre-exposure prophylaxis (PrEP): A review. *AIDS Care*. 2015; 27(5):637–641. [PubMed: 25430940]
- Feldman J, Romine RS, Bockting WO. HIV risk behaviors in the U.S. transgender population: Prevalence and predictors in a large Internet sample. *Journal of Homosexuality*. 2014; 61(11):1558–1588. [PubMed: 25022491]
- Fenway Health. Glossary of gender and transgender terms. 2010. http://www.fenwayhealth.org/site/DocServer/Handout_7C_Glossary_of_Gender_and_Transgender_Terms__fi.pdf
- Fisher CB, Arbeit M, Dumont M, Macapagal, Mustanski B. Self-consent for HIV prevention research involving sexual and gender minority youth: Reducing barriers through evidence-based ethics. *Journal of Research on Human Research Ethics*. 2016; 11(1):3–14.

- Fisher CB, Brunnquell DJ, Hughes DL, Liben LS, Maholmes V, et al. Preserving and enhancing the responsible conduct of research involving children and youth: a response to proposed changes in federal regulations. *Social Policy Report*. 2013; 27(1):3–15.
- Fisher CB, Mustanski B. Reducing health disparities and enhancing the responsible conduct of research involving LGBT youth. *The Hastings Center Report*. 2014; 44:S28–S31.
- Galindo GR, Walker JJ, Hazelton P, et al. Community member perspectives from transgender women and men who have sex with men on pre-exposure prophylaxis as an HIV prevention strategy: Implications for implementation. *Implementation Science*. 2012; 7:116
- Gilbert AL, Knopf AS, Fortenberry JD, Hosek SG, Kapogiannis BG, et al. Adolescent self-consent for biomedical HIV prevention research. *The Journal of Adolescent Health*. 2015; 57(1):113–119. [PubMed: 26095412]
- Grant RM, Sevelius JM, Guanira JV, Aguilar JV, Chariyalertsak S, et al. Transgender women in clinical trials of pre-exposure prophylaxis. *Journal of Acquired Immune Deficiency Syndromes*. 2016; 72(Suppl 3):S226–S229. [PubMed: 27429187]
- Habarta N, Wang G, Mulatu MS, Larish N. HIV testing by transgender status at Centers for Disease Control and prevention–funded sites in the United States, Puerto Rico, and US Virgin Islands, 2009–2011. *Am J Public Health*. 2015; 105(9):1917–1925. [PubMed: 26180964]
- Harawa NT, Bingham TA. Exploring HIV prevention utilization among female sex workers and male-to-female transgenders. *AIDS Education and Prevention*. 2009; 21:356–371. [PubMed: 19670970]
- Herbst JH, Jacobs ED, Finlayson TJ, McKleroy VS, Neumann MS, et al. Estimating HIV prevalence and risk behaviors of transgender persons in the United States: a systematic review. *AIDS & Behavior*. 2008; 12(1):1–17. [PubMed: 17694429]
- Hotton AL, Garofalo R, Kuhns LM, Johnson AK. Substance use as a mediator of the relationship life stress and sexual risk among young transgender women. *AIDS Education and Prevention*. 2013; 25:62–71. [PubMed: 23387952]
- Institute of Medicine Committee on Lesbian, Gay, Bisexual, and Transgender Health Issues and Research Gaps and Opportunities. *The Health of Lesbian, Gay, Bisexual, and Transgender People: Building a Foundation for Better Understanding*. Washington, D.C.: The National Academies Press; 2011.
- Jadwin-Cakmak L, Radix A, Popoff E, et al. Transgender adolescents: care and support. *American Academy of HIV Medicine. HIV Specialist Magazine*. 2015; 7:12–17.
- Macapagal K, Bhatia R, Greene GJ. Differences in healthcare access, use, and experiences within a community sample of racially diverse lesbian, gay, Bisexual, transgender, and questioning emerging adults. *LGBT Health*. 2016; 3(6):434–442. [PubMed: 27726496]
- Macapagal K, Coventry R, Arbeit M, Fisher CB, Mustanski B. “I won't out myself just to do a survey”: Sexual and gender minority adolescent's perspectives on the risks and benefits of sex research. *Archives of Sexual Behavior*. 2016 Online July 28, 2016.
- Miner MH, Bockting WO, Romine RS, Raman S. Conducting Internet research with the transgender population: Reaching broad samples and collecting valid data. *Social Science Computer Review*. 2012; 30(2):202–211. [PubMed: 24031157]
- Mustanski B. Ethical and regulatory issues with conducting sexuality research with LGBT adolescents: A call to action for a scientifically informed approach. *Archives of Sexual Behavior*. 2011; 40(4): 673–686. [PubMed: 21528402]
- Mustanski B, Coventry R, Macapagal K, Arbeit M, Fisher CB. Parental permission for HIV testing, but not for sex? Sexual and gender minority adolescents' views on HIV research. *Perspectives on Sexual and Reproductive Health*. in press.
- Mustanski B, Fisher CB. HIV rates are increasing in gay/bisexual teens: IRB barriers to research must be resolved to bend the curve. *American Journal of Preventive Medicine*. 2016; 51(2):249–252. [PubMed: 27061893]
- National Institutes of Health. FY2016–2020 Strategic Plan to Advance Research on the Health and Well-being of Sexual and Gender Minorities. 2015. Retrieved January 31, 2017, <https://dpcpsi.nih.gov/sgmro/reports>

- Ott MA, Alexander AB, Lally M, Steever JB, Zimet G. Preventive misconception an adolescents' knowledge of HIV vaccine trials. *J Med Ethics*. 2013; 39 <http://dx.doi.org/10.1136/medethics-2012-100821>.
- Pettifor A, Nguyen NL, Celum C, Cowan FM, Go V, et al. Tailored combination prevention packages and PrEP for young key populations. *Journal of the International AIDS Society*. 2015; 18(Suppl 1):19434. [PubMed: 25724507]
- Poteat T, German D, Kerrigan D. Managing uncertainty: a grounded theory of stigma in transgender health care encounters. *Social Science & Medicine*. 2013; 84:22–29. [PubMed: 23517700]
- Reisner S, Mimiaga M, Bland SE, Driscoll MA, Cranston K, Mayer KH. Pathways to embodiment of HIV risk: Black men who have sex with transgender partners, Boston, Massachusetts. *AIDS Education and Prevention*. 2012; 24:15–26. [PubMed: 22339142]
- Reisner SL, Perkovich B, Mimiaga MJ. A mixed methods study of the sexual health needs of New England Transmen who have sex with nontransgender Men. *AIDS Patient Care and STD*. 2010; 24(8):501–513.
- Reisner SL, Veters R, White JM, Cohen EL, deClerc M, et al. Laboratory-confirmed HIV and sexually transmitted infection seropositivity and risk behavior among sexually active transgender patients at an adolescent and young adult urban community health center. *AIDS Care*. 2015; 27(8):1031–1036. [PubMed: 25790139]
- Reisner SL, Radix A, Deutsch MB. Integrated and gender-affirming transgender clinical care and research. *Journal of Acquired Immune Deficiency Syndromes*. 2016; 72(Suppl 3):S235–S242.
- Schein AI, Santos GM, Arreola S, et al. Inequities in access to HIV prevention services for transgender men: results of a global survey of men who have sex with men. *Journal of the International AIDS Society*. 2016; 19(Suppl 2):1–7.
- Sevelius JM, Keatley J, Calma N. 'I am not a man': Trans-specific barriers and facilitators to PrEP acceptability among transgender women. *Global Public Health*. 2016; 11(7-8):1060–1075. [PubMed: 26963756]
- Sevelius JM, Saberi P, Johnson MO. Correlates of antiretroviral adherence and viral load among transgender women living with HIV. *AIDS Care*. 2014; 26(8):976–982. [PubMed: 24646419]
- Singh JA. Ethical issues to consider in the design of HIV prevention trials involving transgender people. *Journal of Acquired Immune Deficiency Syndromes*. 2016; 72(Suppl 3):S252–S255. [PubMed: 27429192]
- Siskind RL, Andrasik M, Karuna ST, Broder GB, Collins C, et al. Engaging transgender people in NIH-funded HIV/AIDS clinical trials research. *Journal of Acquired Immune Deficiency Syndromes*. 2016; 72(Suppl 3):S243–S247. [PubMed: 27429190]
- Smalley KB, Warren JC, Barefoot KN. Differences in health risk behaviors across understudied LGBT subgroups. *Health Psychology*. 2016; 35(2):103–114. [PubMed: 26375040]
- Taylor RD, Bimbi DS, Joseph HA, Margolis AD, Parsons JT. Girlfriends: Evaluation of an HIV-risk reduction intervention for adult transgender women. *AIDS Education and Prevention*. 2011; 23:469–478. [PubMed: 22010810]
- Wansom T, Guadamuz TE, Vasani S. Transgender populations and HIV: Unique risks, challenges and opportunities. *Journal of Virus Eradication*. 2016; 2(2):87–93. [PubMed: 27482441]
- Wilson EC, Chen YH, Arayasirikul S, et al. Differential HIV risk for racial/ethnic minority trans*female youth and socio-economic disparities in housing, residential stability and education. *American Journal of Public Health*. 2015; 105(Suppl):e41–e47. [PubMed: 25905826]

Table 1
Demographic information, age of transgender identity, parental disclosure and acceptance of gender and sexual identities for transgender male (TM) and transgender female (TF) youth and emerging adults

	TM N = 90	TF N = 60	Total N = 150
Race/Ethnicity			
African American/Black	4 (4.4%)	4 (6.7%)	8 (5.3%)
American Indian/Alaska Native	6 (6.7%)	3 (5.0%)	9 (6.0%)
Asian	3 (3.3%)	3 (5.0%)	6 (4.0%)
Hispanic/Latino/a	10 (11.1%)	7 (11.7%)	17 (11.3%)
Non-Hispanic White	81 (90.0%)	52 (86.7%)	133 (88.7%)
Pacific Islander	1 (1.1%)	0 (0.0%)	1 (0.7%)
Other	9 (10.0%)	2 (3.3%)	11 (7.3%)
Age			
14 – 17 years	41 (45.6%)	27 (45.0%)	68 (45.3%)
18 – 21 years	49 (54.5%)	33 (55.0%)	82 (54.7%)
Grade			
7 - 12	44 (48.9%)	33 (55.0%)	77 (51.3%)
College	26 (28.9%)	17 (28.3%)	43 (28.7%)
Not in school	20 (22.2%)	10 (16.7%)	30 (20.0%)
Living situation			
Living alone	7 (7.8%)	6 (10.0%)	13 (8.7%)
Living with parents/family	62 (68.9%)	45 (75.0%)	107 (71.3%)
Living with others	19 (11.1%)	8 (13.3%)	27 (18.0%)
No permanent address	2 (2.2%)	1 (1.7%)	3 (2.0%)
Employment			
Full-Time	6 (6.7%)	3 (5.0%)	9 (6.0%)
Part-Time	30 (33.3%)	29 (48.3%)	59 (39.3%)
Unemployed	54 (60.0%)	28 (46.7%)	82 (54.7%)
Age first identified as transgender	13.6 SD3.47	12.3 SD4.20	13.1SD3.82
Disclosure Gender Identity			
Primary Caregiver	75 (83.3%)	45 (75.0%)	120 (80.0%)
Secondary Caregiver	51 (56.6%)	20 (33.3%)	71 (47.3%)
Very – Somewhat Accepting Gender Identity			
Primary Caregiver (N= 120)	56 (62.2%)	37 (61.6%)	93 (62.0%)
Secondary Caregiver (N= 72)	32 (35.5%)	15 (25.0%)	47 (31.3%)
Sexual Orientation			
Identify as Pansexual	56 (62.2%)	33 (55.0%)	89 (59.3%)
Identify as Gay	25 (27.8%)	8 (13.3%)	33 (22.0%)*
Identify as Bisexual	30 (33.3%)	20 (33.3%)	50 (33.3%)
Identify as Lesbian	3 (3.3%)	5 (8.3%)	8 (5.3%)

	TM N = 90	TF N = 60	Total N = 150
Identify as Heterosexual	4 (4.4%)	8 (13.3%)	12 (8.0%) *
Identify as Asexual	16 (17.8%)	4 (6.7%)	20 (13.3%)
Identify as Queer	47 (52.2%)	15 (25.0%)	62 (41.3%) ***
Identify as Unsure/Questioning	9 (10.0%)	9 (15.0%)	18 (12.0%)
Disclosure Sexual Orientation Identity			
Primary Caregiver	67 (74.4%)	45 (75.0%)	112 (74.7%)
Secondary Caregiver	47 (52%)	25 (42%)	72 (48%)
Very – Somewhat Accepting Sexual Orientation Identity			
Primary Caregiver	52 (57.8%)	34 (56.6%)	86 (57.3%)
Secondary Caregiver	34 (37.7%)	18 (.30%)	53 (35.3%)

Note. Significant TM/TF differences based on Chi Square analyses indicated by

*
 $p < .05$

**
 $p < .01$

 $p < .001$

Sexual history, HIV testing and attitudes, and sexual health services as facilitators and barriers to participation in a PrEP HIV prevention study for transgender male (TM) and transgender female (TF) youth and emerging adults

Table 2

	TM N = 90	TF N = 60	All Transgender Youth N = 150	Correlation with PrEP Study Participation
Would you Participate in a PrEP Study?				
Definitely – probably yes	36 (40.0%)	27 (45.0%)	53 (42.0%)	
I don't know	19 (21.1%)	10 (16.7%)	29 (19.3%)	
Definitely – probably no	35 (38.9%)	23 (38.3%)	58 (38.6%)	
Sexual History				
Lifetime number sexual partners ^a	M = 5.17 SD = 5.752 Range 0 -25	M = 3.95 SD = 4.312 Range 0 - 25	M = 4.68 SD = 5.242 Range 0 - 25	.25**
Sexual partner past 12 months ^a	M = 2.76 SD = 3.135 Range 0 -25	M = 2.13 SD = 1.346 Range 0 - 6	M = 2.51 SD = 2.585 Range 0 - 25	.24**
Cisgender male sexual partner	59 (65.6%)	36 (60.0%)	95 (63.3%)	.22**
Health Services				
Tested for HIV	24 (26.7%)	21 (35.0%)	45 (30.0%)	.25**
Tested for STI	36 (40.0%)	17 (28.3%)	53 (35.3%)	.41**
HIV infection extremely or somewhat unlikely ^a	48 (53.3%)	27 (45.0%)	75 (50.0%)	-.17*
Never or rarely worry about HIV ^a	62 (68.9%)	38 (63.4%)	100 (66.7%)	-.32***
Discussed PrEP with doctor	2 (2.2%)	5 (8.3%)	7 (4.7%)	.05
Comfortable asking doctor about HIV prevention ^a	28 (31.1%)	32 (53.3%)	60 (40.0%)**	.24**
Discussed transgender identity with a doctor	46 (51.1%)	25 (41.7%)	71 (47.3%)	.10
Discussed sexual orientation with a doctor	43 (47.8%)	32 (53.3%)	75 (50.0%)	.23**
Puberty Blocking Therapy	3 (3.3%)	18 (30.0%)	21 (14.0%)***	.10
Hormone Replacement Therapy	27 (30.0%)	21 (35.0%)	48 (32.0%)	.20*

Note. Significant TM/TF differences based on Chi Square analyses and for correlations between survey responses and likelihood of PrEP study participation indicated by

* $p < .05$,

** $p < .01$,

Author Manuscript

Author Manuscript

Author Manuscript

Author Manuscript

100% < *p*

Indicates item measured with 5-point Likert-type scale response and dichotomized for reporting percentages. All other items were yes-no responses.

Table 3
Study factors facilitating and presenting barriers to participation in a PrEP HIV prevention study for transgender male (TM) and transgender female (TF) youth and emerging adults

Items	TM N = 90	TF N = 60	All Youth N = 150	Correlation with Decision to Participate in PrEP Study
Facilitators for Participation				
HIV Protection				
HIV Protection on a daily basis ^a	47 (52.2%)	38 (63.3%)	85 (56.7%)	.46***
Getting the PrEP medication for free	48 (53.3%)	28 (46.7%)	76 (50.7%)	.26**
Learning more about how to protect myself from getting HIV	41 (45.6%)	26 (43.3%)	67 (44.7%)	.33***
Not having to rely on my partner to ^a protect me against getting HIV	41 (45.6%)	18 (30.0%)	67 (44.7%)	.32***
Relationship with Research Staff				
I would trust researcher to protect my confidentiality	54 (60.0%)	32 (53.3%)	86 (57.3%)	.25**
Being able to talk to research staff who are affirming of my gender identity	53 (58.9%)	30 (50.0%)	83 (55.3%)	.18*
Being able to talk to a researcher about my sexual health	40 (44.4%)	26 (44.0%)	66 (44.0%)	.27***
I would have a doctor check my health every 3 months	39 (43.3%)	17 (28.3%)	56 (37.3%)	.28***
More likely to get an HIV test ^b				
As part of a PrEP study	56 (62.2%)	27 (45.0%)	83 (55.3%)	.30***
PrEP study or on my own	20 (22.2%)	38 (63.3%)	43 (28.7%)	
On my own	14 (15.2%)	10 (16.7%)	24 (16.0%)	
Barriers to Participation				
Health concerns				
Frequent minor side effects: e.g. gastrointestinal, headache ^b				
Extremely worried	4 (4.40%)	5 (8.30%)	9 (6.0%)	
Somewhat worried	44 (48.9%)	24 (40.0%)	68 (45.3%)	
Not at all worried	42 (46.7%)	31 (51.7%)	73 (48.7%)	
Rare side effects: e.g. kidney, bone health ^b				
Extremely worried	15 (17.7%)	11 (18.3%)	26 (17.3%)	
Somewhat worried	46 (51.1%)	28 (46.7%)	74 (49.3%)	
Not at all worried	29 (32.2%)	21 (35.0%)	50 (33.3%)	
I'm already taking medication and don't want to add another	22 (24.4%)	13 (21.7%)	35 (23.3%)	-.20*
Logistics and Disclosure				
It would be too difficult to get to the appointments every few months	43 (47.8%)	23 (38.3%)	66 (44.0%)	-.38***
I don't think I would remember to take the pills everyday	28 (31.1%)	23 (38.3%)	51 (34.0%)	-.22**
I don't want to talk to researchers about my gender identity	12 (13.3%)	9 (15.0%)	21 (14.0%)	-.20**

Note. Significant TM/TF differences based on Chi Square analyses and for correlations between survey responses and likelihood of PrEP study participation indicated by

*
 $p < .05,$

**
 $p < .01,$

 $p < .001$

^aIndicates item measured with 5-point Likert-type scale response and dichotomized for reporting percentages

^bIndicates item measured with 3-point Likert-type scale response and dichotomized for reporting percentages. All other items were yes-no responses.

Author Manuscript

Author Manuscript

Author Manuscript

Author Manuscript