

PreExposure Prophylaxis (PrEP) in Vulnerable Populations: Annotated Bibliography

Pérez-Figueroa, R. E., et al. (2015). "ACCEPTABILITY OF PrEP UPTAKE AMONG RACIALLY/ETHNICALLY DIVERSE YOUNG MEN WHO HAVE SEX WITH MEN: THE P18 STUDY." *AIDS education and prevention : official publication of the International Society for AIDS Education* 27(2): 112-125.

Pre-exposure prophylaxis (PrEP) is considered an effective biomedical approach for HIV prevention. However, there is limited understanding of PrEP uptake among racially/ethnically and socioeconomically diverse young men who have sex with men (YMSM). This study examined attitudes and perceptions toward PrEP uptake among YMSM by conducting semistructured interviews with a sample (N = 100) of YMSM in New York City. Thematic analysis was employed to explore key issues related to attitudes and perceptions toward PrEP utilization. Findings suggest that self-perceived risk for HIV transmission, enjoying unprotected sex, and being in a romantic relationship were associated with PrEP uptake. The most prominent barriers to PrEP uptake included costs, adherence regimen, and access. In summary, these findings underscore the importance of addressing behavioral and structural factors in maximizing the effectiveness of PrEP. In addition, PrEP implementation programs ought to consider the role of social and structural challenges to PrEP uptake and adherence among YMSM.

<https://www.ncbi.nlm.nih.gov/pmc/articles/PMC4550097/>

Krakower, D. S. and K. H. Mayer (2015). "Pre-Exposure Prophylaxis to Prevent HIV Infection: Current Status, Future Opportunities and Challenges." *Drugs* 75(3): 243-251.

As the global incidence of HIV exceeds 2 million new infections annually, effective interventions to decrease HIV transmission are needed. Randomized placebo-controlled studies have demonstrated that daily oral antiretroviral pre-exposure chemoprophylaxis (PrEP) with a fixed-dose combination tablet containing tenofovir disoproxil fumarate and emtricitabine can significantly reduce HIV incidence among diverse at-risk populations. In these studies, the efficacy of PrEP was correlated with levels of adherence. Official guidelines recommend provision of PrEP to persons at greatest risk of HIV acquisition, and demonstration projects suggest that high levels of uptake and adherence are possible outside of controlled studies. However, several potential barriers to implementing PrEP remain. These challenges include low awareness and utilization of PrEP by at-risk persons, uncertainty about adherence in "real-world" settings, the majority of healthcare providers being untrained in PrEP provision, limited data about potential adverse effects from long-term use of tenofovir-emtricitabine, high costs of PrEP medications, and stigma associated with PrEP use and the behaviors that would warrant PrEP. Innovative pharmacologic chemoprophylactic approaches could provide solutions to some of these challenges. Less-than-daily oral dosing regimens and long-acting injectable medications could reduce pill burdens and facilitate adherence, and local delivery of PrEP medications to genital compartments via gels, rings and films may limit systemic drug exposure and potential toxicities. As the portfolio of chemoprophylactic agents and delivery systems expands to meet the diverse sexual health needs and product preferences of individuals who may benefit from PrEP, it is hoped that antiretroviral chemoprophylaxis could become an acceptable, feasible, and highly effective addition to existing HIV prevention strategies. <https://www.ncbi.nlm.nih.gov/pmc/articles/PMC4354703/>

Kelley, C. F., et al. (2015). "Applying a PrEP Continuum of Care for Men Who Have Sex With Men in Atlanta, Georgia." *Clinical Infectious Diseases* 61(10): 1590-1597.

Reductions in human immunodeficiency virus (HIV) incidence with pre-exposure prophylaxis (PrEP) for men who have sex with men (MSM) will require significant coverage of those at risk. We propose a simplified framework, similar to the HIV care continuum, to achieve protection with PrEP as follows: 1. At-risk MSM; 2. Awareness of and willingness to take PrEP; 3. Access to healthcare; 4. Receiving a prescription; and 5. Adhering to effective PrEP. We evaluated the PrEP care continuum on an Atlanta cohort of MSM and projected how many MSM might achieve protection from HIV. Even with optimistic estimates, few Atlanta MSM (15%) are projected to achieve protection from HIV with PrEP given the significant barriers described. Each continuum step represents an important point for intervention that could substantially increase the overall effectiveness of PrEP. In addition, novel strategies for PrEP delivery are needed to achieve the necessary effectiveness for Atlanta MSM at risk of HIV. <https://academic.oup.com/cid/article/61/10/1590/302887/Applying-a-PrEP-Continuum-of-Care-for-Men-Who-Have>

Golub, S. A., et al. (2013). "From Efficacy to Effectiveness: Facilitators and Barriers to PrEP Acceptability and Motivations for Adherence Among MSM and Transgender Women in New York City." *AIDS Patient Care and STDs* 27(4): 248-254.

This study examined potential facilitators and barriers to pre-exposure prophylaxis (PrEP) use and their association with PrEP acceptability and motivations for adherence among 184 MSM and transgender women living in New York City. Participants were presented with educational information about PrEP and completed a computerized survey. Overall, 55.4% of participants reported willingness to take PrEP. The most highly endorsed barriers to PrEP use were health concerns, including both long-term impacts and short-term side effects, questions about PrEP's impact on future drug resistance, and concerns that PrEP does not provide complete protection against HIV. The most highly endorsed facilitator was free access to PrEP, followed by access to support services such as regular HIV testing, sexual health care/monitoring, and access to one-on-one counseling. Participants of color rated both barriers and facilitators as more important than their White counterparts. In multivariate models, barrier and facilitator scores significantly predicted not only PrEP acceptability, but also motivation for PrEP adherence among those who were likely to use PrEP. PrEP implementation programs should consider addressing these barriers and facilitators in protocol and policy development. Findings underscore the importance of support services, such as sexual health counseling, to the success of PrEP as a prevention strategy. <https://www.ncbi.nlm.nih.gov/pmc/articles/PMC3624632/>

Frankis, J., et al. (2016). "Who Will Use Pre-Exposure Prophylaxis (PrEP) and Why?: Understanding PrEP Awareness and Acceptability amongst Men Who Have Sex with Men in the UK – A Mixed Methods Study." *PLoS ONE* 11(4): e0151385.

BACKGROUND: Recent clinical trials suggest that pre-exposure prophylaxis (PrEP) may reduce HIV transmission by up to 86% for men who have sex with men (MSM), whilst relatively high levels of PrEP acceptability have been reported to date. This study examines PrEP awareness amongst sub-groups of MSM communities and acceptability amongst MSM in a low prevalence region (Scotland, UK), using a mixed methods design. **METHODS:** Quantitative surveys of n = 690 MSM recruited online via social and sociosexual media were analysed using descriptive statistics and multivariate logistic regression. In addition, n = 10 in-depth qualitative interviews with MSM were analysed thematically. **RESULTS:** Under one third (29.7%) of MSM had heard of PrEP, with awareness related to living in large cities, degree level education, commercial gay scene use and reporting an HIV test in the last year. Just under half of

participants (47.8%) were likely to use PrEP if it were available but there was no relationship between PrEP acceptability and previous PrEP awareness. Younger men (18–25 years) and those who report higher risk UAI were significantly more likely to say they would use PrEP. Qualitative data described specific PrEP scenarios, illustrating how risk, patterns of sexual practice and social relationships could affect motivation for and nature of PrEP use. CONCLUSION: These findings suggest substantial interest PrEP amongst MSM reporting HIV risk behaviours in Scotland. Given the Proud results, there is a strong case to investigate PrEP implementation within the UK. However, it appears that disparities in awareness have already emerged along traditional indicators of inequality. Our research identifies the need for comprehensive support when PrEP is introduced, including a key online component, to ensure equity of awareness across diverse MSM communities (e.g. by geography, education, gay scene use and HIV proximity), as well as to responding to the diverse informational and sexual health needs of all MSM communities. <https://www.ncbi.nlm.nih.gov/pmc/articles/PMC4836740/>

Deutsch, M. B., et al. (2015). "HIV pre-exposure prophylaxis in transgender women: a subgroup analysis of the iPrEx trial." *The Lancet HIV* 2(12): e512-e519.

SummaryBackground Pre-exposure prophylaxis (PrEP) with oral emtricitabine and tenofovir disoproxil fumarate is used to prevent the sexual acquisition of HIV in groups at high risk such as transgender women. We used data from the iPrEx study to assess PrEP efficacy, effectiveness, and adherence in transgender women. **Methods** The iPrEx trial was a randomised controlled trial of PrEP with oral emtricitabine plus tenofovir disoproxil fumarate compared with placebo in men who have sex with men (MSM) and transgender women, followed by an open-label extension. Drug concentrations were measured in blood by liquid chromatography and tandem mass spectroscopy. We did unplanned exploratory analyses to investigate differences in PrEP outcomes among transgender women and between transgender women and MSM. **Findings** Of the 2499 participants enrolled in the randomised controlled trial, 29 (1%) identified as women, 296 (12%) identified as trans, 14 (1%) identified as men but reported use of feminising hormones, such that 339 (14%) reported one or more characteristics and are classified as transgender women for the purpose of this study. Compared with MSM, transgender women more frequently reported transactional sex, receptive anal intercourse without a condom, or more than five partners in the past 3 months. Among transgender women, there were 11 HIV infections in the PrEP group and ten in the placebo group (hazard ratio 1.1, 95% CI 0.5–2.7). In the PrEP group, drug was detected in none of the transgender women at the seroconversion visit, six (18%) of 33 seronegative transgender women ($p=0.31$), and 58 (52%) of 111 seronegative MSM ($p<0.0001$). PrEP use was not linked to behavioural indicators of HIV risk among transgender women, whereas MSM at highest risk were more adherent. **Interpretation** PrEP seems to be effective in preventing HIV acquisition in transgender women when taken, but there seem to be barriers to adherence, particularly among those at the most risk. Studies of PrEP use in transgender women populations should be designed and tailored specifically for this population, rather than adapted from or subsumed into studies of MSM. <http://www.sciencedirect.com/science/article/pii/S2352301815002064>

Buchbinder, S. P., et al. (2014). "Who should be offered HIV pre-exposure prophylaxis (PrEP)?: A secondary analysis of a Phase 3 PrEP efficacy trial in men who have sex with men and transgender women." *The Lancet infectious diseases* 14(6): 468-475.

BACKGROUND: Pre-exposure prophylaxis (PrEP) has been proven to reduce HIV acquisition in men who have sex with men and transgender women (MSM/TGW). For maximal impact, PrEP should be

targeted to subpopulations accounting for the largest proportion of infections (population attributable fraction, PAF) and for whom the number needed to treat (NNT) to prevent infection is lowest.

METHODS: The iPrEx study was a randomized controlled efficacy trial of tenofovir-disoproxil-fumarate/emtricitabine PrEP in 2499 MSM/TGW on 4 continents. We calculated the association between demographic and risk behavior during screening with subsequent seroconversion among placebo recipients using a Poisson model, and the PAF and NNT for risk behavior subgroups.

FINDINGS: Of 1248 placebo participants enrolled, 83 became HIV infected in follow-up. Participants reporting non-condom receptive anal intercourse (ncRAI) seroconverted significantly more often than MSM/TGW reporting no condomless anal sex (adjusted hazard ratio (AHR) 5.11, 95% CI 1.55-16.79). The overall PAF for MSM/TGW reporting ncRAI was 64% (prevalence=60%). Most of this risk came from ncRAI with unknown serostatus partners (PAF 53%, prevalence=54%, AHR 4.76); in contrast, the PAF for ncRAI with an HIV positive partner, an uncommon practice, was only 1% (prevalence 1%, AHR=7.11). The overall NNT per year for the cohort was 62 (95% CI 44-147). NNTs were lower for MSM/TGW self-reporting ncRAI, cocaine use, or a sexually transmitted infection (NNT= 36, 12, and 41 respectively). Having a single partner or non-condom insertive anal sex had the highest NNTs.

INTERPRETATION: PrEP may be most effective at a population level if targeted toward MSM/TGW reporting ncRAI, even with partners perceived to be HIV negative. Substance use history and testing for STIs may also inform individual decisions to start PrEP. Considering PAF and NNT can aid in discussing the benefits and risks of PrEP with MSM/TGW.

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<https://www.ncbi.nlm.nih.gov/pmc/articles/PMC4133171/>