

Oral Pre-Exposure Prophylaxis (PrEP) for HIV Prevention, Clinical Effectiveness, Safety, Adherence, and Risk Compensation in all Populations

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ABSTRACT

Based on WHO and UNAIDS reports in 2021, 38.4 million (33.9-43.8 million) HIV cases in the world, in Indonesia reported by 34 provinces, the number of people living with HIV found in the January-March 2022 period was 10,525 941,973 people have HIV, and 8,784 people are receiving ARV treatment. The aim of this study is to observe the literature on the clinical efficacy, safety, compliance and risk compliance of oral pre-exposure prophylaxis (PrEP) for HIV prevention in all population groups. A literature review was carried out by identifying national and international articles regarding pre-exposure prophylaxis (PrEP) for preventing HIV transmission. The database used was Google Scholar, Pubmed, Science Direct, The Lancet. There were 331 articles searched from the Pubmed online database, 14 articles, Proquest 134, Science Direct 105, The Lancet 2, Google Scholar 105. There were 20 articles that met the inclusion criteria and were processed. In qualitative synthesis. In conclusion, there is very strong evidence that PrEP is safe and effective for HIV prevention in MSM and serodiscordant couples, assuming adequate compliance. The importance of supportive care to ensure that PrEP is effective and the need for frequent HIV testing at warm-up and follow-up to avoid medication antiviral resistance.

Keywords: Human Immunodeficiency Virus (HIV), pre-exposure prophylaxis (PrEP), safety

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BACKGROUND

Based on WHO and UNAIDS reports in 2021, there were 38.4 million (33.9-43.8 million) HIV cases in the world, while in Indonesia, as reported by 34 provinces, the number of people living with HIV found in the January-March 2022 period was 10,525 people out of 941,973 people were tested for HIV, and 8,784 people received ARV treatment. HIV or human immunodeficiency virus is the agent that causes HIV infection, AIDS or acquired immunodeficiency virus is the highest stage of HIV infection. Controlling human immunodeficiency virus (HIV) infection is one development goals in Indonesia. According to the National Medium Term Development Plan (RPJMN) 2020-2024, the target for the incidence of new HIV infections in 2024 is 0.18 per 1,000 population, much lower than the 2018 target of 0.24 per 1,000 population. This is in line with the global goal to end the HIV epidemic by 2030, known as Triple Zero, with zero new infections as one of the main pillars. Antiretroviral therapy (ARV) is widely recommended for all people living with HIV, regardless of level of immunosuppression. In addition, WHO also recommends preventive/prophylactic treatment with ARVs, known as pre-exposure prophylaxis (PrEP), as part of and in addition to the comprehensive preventive measures that have been and are being taken. PrEP has been introduced in several countries and has been shown to reduce HIV infections. (WHO: PrEP Module for Managers, 2017) to avoid contracting HIV. PrEP is used as long as the person is at high risk of contracting HIV. With the right dose, PrEP can reduce the risk of contracting HIV through sexual intercourse by more than 90%.

The level of protection of PrEP is highly correlated with compliance and must be used according to the instructions for use. High adherence to PrEP can provide high protection against HIV infection, while suboptimal adherence does not provide the expected protective benefits. PrEP trials have been conducted widely throughout the world. The results of more than 10 clinical trials covering 18 countries show that PrEP drugs containing tenofovir (TDF) or a combination of TDF and emtricitabine (FTC) can prevent new HIV infections by up to 90% when used continuously. TDF-based PrEP has also been shown to have mild side effects and usually resolve within the first few weeks of use, and is considered safe for pregnant and breastfeeding women (WHO: PrEP Module for Managers, 2017). In 2021, the Indonesian government launched a PrEP trial program for free distribution in Indonesia. This pilot program received financial support to prevent HIV infection in Indonesia, whose prevalence has continued to increase over the last 10 years. Spread across 10 provinces. To receive this, a person must complete an online assessment, after which they will be sent to the nearest Community Health Center to receive PrEP (Ministry of Health 2021).

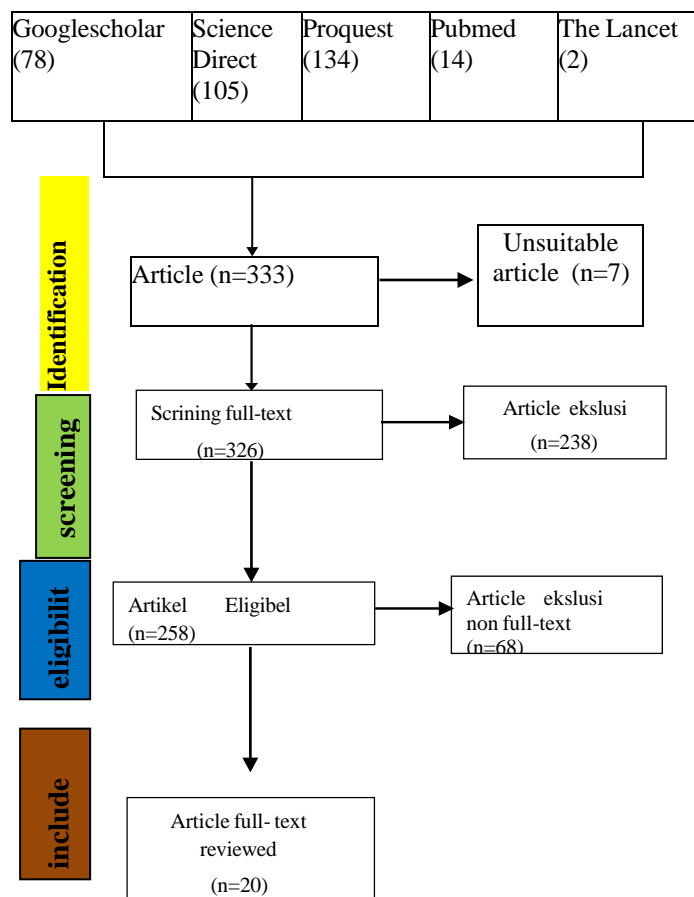
METHODS

A literature review was carried out by identifying national and international articles regarding pre-exposure prophylaxis (PrEP) for preventing HIV transmission. The data bases used are Google Scholar, PubMed, Science Direct, The Lancet. The keywords used in this research are pre-exposure prophylaxis (PPrP), Human Immunodeficiency Virus (HIV). The inclusion criteria in this literature review are articles in full-text form, in English. Indonesian and English published in the last 5 years, research articles in them include two keywords, namely Pre-exposure prophylaxis (PrEP), Human Immunodeficiency Virus (HIV). There were 331 articles searched from the Pubmed online database, 14 articles, Proquest 134, Scindirect 105, The Lancet 2, Google Scholar 105. There were 20 articles that met the inclusion criteria and were processed in a qualitative synthesis. The characteristics of each article included in the qualitative synthesis are in the explanation in table 1.2. Articles that discuss clinical effectiveness, safety, compliance, and risk compensation in all populations. Oral pre-exposure prophylaxis (PrEP), is often found in several online data bases, especially Pubmed, Proquest, Scindirect, The Lancet, Google Scholar, but study articles that

specifically discuss clinical effectiveness, safety, compliance, and risk compensation in all populations. Oral pre-exposure prophylaxis (PrEP) is still limited. Most articles are in English (18 articles) while two (2 articles) are in Indonesian.

RESULTS

Figure 1. Search Algorithm



Research conducted by Eamon O Murchu et.al (2022), states that use of oral pre-exposure prophylaxis (PrEP) to prevent HIV in populations namely MSM, serodiscordant heterosexual couples (individuals whose partners are HIV positive and do not experience viral suppression on antiretroviral drugs), heterosexuals and people who inject drugs (IDUs). The results of this study explain that PrEP containing oral tenofovir is effective and safe in MSM, serodiscordant heterosexual couples, and drug addicts, however it is unclear whether PrEP is effective in heterosexuals. Compliance varied widely across studies, ranging from 25% to 88% with plasma drug monitoring. As expected, efficacy was found to be strongly associated with adherence ($p < 0.01$). On average, a 10% reduction in compliance reduced efficacy by 13%. PrEP was found to be safe, and there was no difference in adverse event rates comparing single-agent tenofovir with the tenofovir/FTC combination. Changes in sexual behavior, or risk compensation, were measured in several ways, including condom use, number of sexual partners, changes in rates of STIs and drug use. Studies consistently show no differences between groups in condom use or number of sexual partners. These studies did not examine all populations. Key people who are at high risk of contracting HIV, such as transgender

women and female sex workers.

Research conducted by Hugo Jourdain, et.al (2022), states that the effectiveness of PrEP is significantly reduced in men younger than 30 years and in those who are socio-economically deprived, both groups show low amounts of PrEP consumption and levels of high PrEP discontinuation, PrEP effectiveness also appears to be lower in real-world conditions than reported in clinical trials. Strengthening efforts to improve monitoring of PrEP adherence will be critical to ensuring the effectiveness of PrEP, especially among young recipients and socioeconomically disadvantaged recipients.

Research conducted by Debra C. ten Brink, et.al (2022) In this study, the implementation and scale-up of PrEP among MSM could have a major impact on public health in eight countries that account for more than 70% of new HIV infections in Asia. If PrEP is implemented and scaled up by 2022 in the eight Asian countries considered in this study, with an additional 15% MSM coverage achieved by the end of 2026, an additional 100,000 (66,000–130,000) HIV infections (17%) and 300,000 (198,000–390,000) HIV-related disability (3%) averted over the period 2022 to 2031 compared with initial PrEP coverage. In addition to preventing HIV infection and disability, this could result in cumulative savings of nearly US\$12.3 million in ART costs over a five-year period for these countries. It is estimated that HIV prevalence could increase among MSM in Cambodia, China, Indonesia, and Vietnam, but may decline in India, Myanmar, and Thailand, while leveling off in Nepal, if previous trends are projected into the future.

Research conducted by Andrew N Phillips, et.al (2022) mentioned that average additional annual costs incurred in the context of country population adults 10 million is \$23.5 million per year (6.5 million–56.0 million), resulting in a mean cost per infection prevented of \$1297 (356–5719). Considering the budgetary impact of PrEP, in context the average HIV prevalence in our setting scenario is approximately 10%. Over a 50-year period (2021–2071, the modeled increase in PrEP across scenarios is estimated to result in 0.51 times (90% range 0.22 to 0.77). The results suggest that making PrEP easily accessible in the community (e.g. over the counter and at no cost at pharmacies or through community distribution) for all adults during the risk season (i.e., risk-informed PrEP) is likely to be cost-effective in communities with HIV viral load prevalence greater than 1000 copies per mL among all adults (HIV positive and negative) higher than 2%.

Research conducted by Xiaojie Huang, et.al (2018), states that PrEP is most effective in reducing the incidence of HIV among users with a high level of PrEP adherence. Adherence support interventions for PrEP should be designed, based on the experience of HIV treatment studies that adopted several behavioral interventions to help increase and maintain adherence treatment, Psychological counseling focused on developing strategies should also be tested as a strategy to increase adherence to PrEP treatment. In addition, research has shown that some MSM prefer long-acting injectable formulations, which may also be beneficial for increasing PrEP adherence. Hence the research in Future work is needed to evaluate the efficacy of PrEP in combination with appropriate behavioral and psychological interventions or different PrEP formulations among MSM.

Research conducted by Eamon O Murchu et.al (2021) states that the PrEP program is considered to save costs and provide significant health benefits for the community. Univariate sensitivity analysis showed that PrEP efficacy and HIV incidence had the greatest impact on cost-effectiveness. Including increases in sexually transmitted infections had negligible impact on outcomes. Efficacy was a significant driver in the model. PrEP was cost-saving at all efficacy values above 60%, and at the lowest efficacy reported in MSM. Event-based dosing (administration during high-risk periods only) was associated with additional cost savings. It was estimated that 1705 people (95% CI:

617-3452) will join this program in the first year. The impact of the additional budget is V 1.5 m (95% CI: V0.5m to V3m) in the first year and V5.4 million over 5 years (95% CI: V1.8m to V11.5m), with 173 HIV cases prevented during 5 years.

Research conducted by Ni Kadek Diah Purnamayanti¹, et al. (2019) stated that various strategies were applied based on the type of administration process, dose variants, and partner preference variants. Preferences for PrEP dosage and type of application were related to their heterosexual or homosexual orientation and social commitments. This study describes the benefits of monitoring M-health levels and biomarkers. Tenofovirs as a biomarker of PrEP adherence, a biomarker of Tenofovir blood levels to assess adherence. Tenofovir plasma levels equal to or greater than 52.0 mg/mL indicate regular daily consumption. Comparison of PrEP adherence using m-Health using Wisepill, showing significant differences between the control and intervention groups. However, compliance based on measurements of plasma Tenofovir levels did not differ significantly between the control and intervention groups. M-Health is one approach that can be used to assess Pre Exposure Prophylaxis (PrEP) compliance. The types of m-health services reviewed in this research are SMS, Medication Event Monitoring System (MEMS), Wisepill.

Research conducted by Steven Maxwell, et.al (2022) states that the majority of gay and bisexual men who engage in chemsex, initiate PrEP in recognition of the potential risk of HIV transmission and report high levels of PrEP adherence. They use a variety of strategies to support effective PrEP access and adherence. These findings support growing evidence that PrEP is a viable prevention tool for gay and bisexual men who engage in chemsex, and that chemsex does not negatively impact PrEP adherence.

Research conducted by Teddy Tjahyanto¹, et.al (2019) states that PrEP is effective as an HIV preventive measure in MSM and can function properly if it is well received and used obediently. However, the use of PPrP has obstacles in terms of costs and negative stigma. PPrP can be a prevention option in an effort to prevent HIV infection and reduce the spread of HIV among MSM.

Research conducted by Long Hoang Nguyen et al. (2021) states that there is a high desire to use PrEP among MSM in Vietnam. Strategies to increase awareness and support positive perceptions of PrEP will help reduce stigma towards PrEP/ART and should be considered when implementing a comprehensive PrEP program in Vietnam. Online communication strategies are preferred among MSM. The preferred implementation modality for MSM is through MSM-friendly clinics and MSM civil business organizations, while pharmacies are considered inappropriate due to concerns about counterfeit medicines.

Research conducted by Jeffrey Adams, et.al (2019) stated that To increase uptake among Asian gay men, increased literacy around HIV and pre-exposure prophylaxis is needed. This knowledge needs to be increased both at the individual level in primary care services and collectively through health promotion initiatives. These services and health promotion initiatives need to be provided in a way that encourages engagement of gay Asian men. The results of the study indicate several barriers to PrEP uptake among gay Asian men, and present several areas where primary health care and public action may be needed to ensure PrEP uptake.

Knowledge of PrEP was low across the sample. As mentioned elsewhere, gay and bisexual men are not necessarily aware of the efficacy of PrEP, or understand the dosing

schedule, and should not be too confident that PrEP will offer adequate protection.

Research conducted by Renee Heffron, et al (2022) found 1,381 HIV-serodiscordant couples registered at 12 ART clinics in Kampala and Wakiso, Uganda, including 730 registered before and 651 after the launch of PrEP delivery from 1 June 2018-15 December 2020). During the baseline period, 99.4% of partners living with HIV initiated ART and 85.0% were virally suppressed at 6 months. Among HIV-negative couples who enrolled after PrEP launch, 81.0% (527/651) initiated PrEP within 90 days of enrollment; among these 527, 11.2% requested a refill 6 months later.

Research conducted by Susan S. Witte, et al (2022) stated that higher perceived social support from one's family and fewer years in sex work were associated with a higher desire to use PrEP. Age and years of sex work are often correlated but represent different factors. While we found that women in sex work for less than five years were more likely to receive PrEP, we agree with others targeting women whose sex work is more recent and that the tool may strengthen acceptance and subsequent uptake.

Research conducted by Grant Murewanhema, et al (2020) states that HIV is among women living in Sub-Saharan Africa. Due to the lack of studies, more studies are needed and factors that may influence effectiveness such as adherence need to be further explored.

Research conducted by Vasiliki Papageorgiou, et al (2022) states that there is none There is consistent evidence that PrEP use increases ciswomen's risk of contracting bacterial STIs, with some studies suggesting that it may be associated with a reduced risk. This is in line with similar findings in MSM and transgender women, described in a pilot study pilot observational study. Based on findings, adolescent girls and young women in sub-Saharan Africa have a high prevalence and incidence of bacterial STIs (especially chlamydia and gonorrhea) which are associated with higher susceptibility based on age-differentiated gender, transactional gender, gender norms, and age-based gender. life.

Research conducted by Kayla Stankevitz, et al (2020) states that continuity varies based on population and across time. The combined estimate at 12 months is actually higher than previous time points. This may be due to different studies reporting at different time points, and some studies reporting very low continuation at only 1 and 6 months. Continuity also varies within populations.

Some of this variation can likely be attributed to differences in types of studies, intervention models, and mechanisms for client support.

Research conducted by Zixin Wang, et al (2020), stated that Chinese gays, bisexuals and MSM with experience of using sexual drugs have the potential to be good candidates for PrEP implementation. Group *Chinese gays, bisexuals and MSM* these reported a high prevalence of uptake and willingness to use PrEP.

Research conducted by KB Biello, et al (2018) stated that IDUs have a high risk of contracting HIV due to risky injection and sexual behavior. With recent evidence of HIV transmission and outbreaks related to injection drug use especially in the context of increasing prevalence of injection drug use and injection. Maximizing the accessibility of all HIV prevention tools available to PWID should be a public health priority. The efficacy of antiretroviral PrEP for HIV prevention among PWID has been established in major clinical trials but, to date, PrEP uptake in this socially marginalized population has remained low.

Research conducted by Graham Shaw, et al (2023) states that 27 countries where PrEP services are provided or planned for people who inject drugs, most of which are high-income countries; however, in many countries, PrEP services are small-scale and

limited to certain geographic areas or cities and data regarding coverage are limited.

DISCUSSION

Clinical Effectiveness

Eamon O Murchu, et.al (2022) explains that PrEP containing oral tenofovir is effective and safe in MSM, serodiscordant heterosexual couples, and drug addicts, however it is unclear whether PrEP is effective in heterosexuals. Hugo Jourdain, et.al (2022) The effectiveness of PrEP was significantly reduced in men younger than 30 years and in those who were socioeconomically disadvantaged, both groups showed a low amount of PrEP consumption and a high PrEP discontinuation rate, the effectiveness of PrEP was also appears to be lower in real-world conditions than reported in clinical trials, meanwhile (Indonesian Ministry of Health 2021) PrEP can reduce the risk of HIV through sexual transmission by more than 90% if used according to rules and good adherence. ten Brink, et.al (2022) If PrEP were implemented and scaled up this could result in a cumulative savings of nearly US\$12.3 million in ART costs over a five year period for countries It is estimated that HIV prevalence may increase among MSM in Cambodia, China, Indonesia, and Vietnam, but may decrease in India, Myanmar, and Thailand, while leveling off in Nepal. Considers the budgetary impact of PrEP, in the context of HIV prevalence.

Safety

Eamon O'Murchu, et.al (2022) safe on LSL, partner serodiscordant heterosexuals, and drug users and there was no difference in side effect rates comparing single-agent tenofovir to the tenofovir/FTC combination. (WHO: PrEP module for leaders, 2017). PrEP containing Tenofovir (TDF) or a combination of TDF and Emtricitabine (FTC) can prevent new HIV infections by up to 90% when taken consistently.

Adherence

Eamon O'Murchu, et.al (2022) Adherence varied widely across studies, ranging from 25% to 88% with plasma drug monitoring. As expected, efficacy was found to be highly related to adherence ($p < 0,01$). On average, a 10% reduction in adherence reduces efficacy by 13%. PrEP was found to be safe, and there was no difference in side effect rates comparing single-agent tenofovir to the tenofovir/FTC combination. Steven Maxwell, et.al (2022) In this study, the majority of gay and bisexual men involved in chemsex started PrEP in recognition of the potential risk of HIV transmission and reported high levels of PrEP adherence. They use a variety of strategies to support effective PrEP access and adherence. These findings support growing evidence that PrEP is a viable prevention tool for gay and bisexual men who engage in chemsex, and that chemsex does not negatively impact PrEP adherence. (Ministry of Health RI 2021) High adherence to PrEP is able produce a high level of protection from HIV infection, while suboptimal adherence will not provide the expected protective benefits.

CONCLUSION

Risk compensation across all populations

Eamon O Murchu, et.al (2022) explains Change in sexual behavior, or risk compensation, is measured in a number of ways method, including condom use, amount partner sex, changes in rates of STIs and drug use, Education regularly consistently showed no difference between groups in condom use or number of sexual partners. Susan S. Witte, et.al (2022) perceived social support more height from one's family and fewer years in the job six linked with desire Which more height to take PrEP. Age and years of sex work often correlated but represent different factors. While we found that women in sex work for less than five years were more likely to receive PrEP, we agree with Which another targeting women who are newer sex workers and tools can strengthen acceptance and next absorption. Zixin Wang, et.al (2020), found that Chinese gay, bisexual and MSM with experience using

sexual drugs are potential candidates for good PrEP implementation. Groupgay Chinese, bisexual and MSM these report a high prevalence of uptake and willingness to use PrEP. Graham Shaw, et al (2023) identified 27 countries where PrEP services are provided or planned for people who inject drugs, most of which are high-income countries; however, in many countries, PrEP services are small-scale and limited to certain geographic areas or cities and data regarding coverage is limited. The target audience for PrEP according to WHO is MSM, FSW, Transgender/Transgender, Injecting Drug Users and syrodiscordant couples or couples of different HIV status (WHO: PrEP Module for Managers, 2017).

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