

Literature Review

Physician attitudes toward the ethics of pre-exposure prophylaxis (PrEP): Cost, safety, and resource allocation

Jessica Grippo, MPH, Stacy W. Smallwood, PhD, MPH, Katherine Pincura, MA, MPH, Tamara Wright, MPH, and William A. Mase, DrPH, MPH, MA

Jiann-Ping Hsu College of Public Health, Georgia Southern University, Statesboro, Georgia

Corresponding Author: Stacy W. Smallwood • Georgia Southern University, Statesboro, GA 30460 • (912) 478-2040 • Ssmallwood@georgiasouthern.edu

ABSTRACT

Background: In the United States, human immunodeficiency virus (HIV) remains a substantial public health issue. There is evidence that the use of antiretroviral medications such as pre-exposure prophylaxis (PrEP) can be a safe and effective primary prevention strategy to reduce new cases of HIV infection. Provider practice behavior as it relates to prescribing PrEP and the potential impact on specific vulnerable populations needs increased attention. Few studies have evaluated the attitudes of physicians towards ethical issues related to prescribing PrEP.

Methods: The purpose of the present literature review was to evaluate provider attitudes toward the ethics of prescribing PrEP for individuals at risk of acquiring HIV infection. Searches of the PubMed and Cochrane databases were conducted. Three reviewers independently assessed the relevance of articles and discarded those not directly related to the attitudes of physicians toward ethics of the cost, safety, and resource allocation of PrEP. A total of twenty-one articles were included in the review.

Results: Provider attitudes and perceptions focused on three areas: resource allocation, cost, and safety or effectiveness of PrEP. Providers who were hesitant in prescribing PrEP were concerned with the availability of resources, patient adherence, risk of drug resistance, and toxicity. In the studies reviewed, few providers had prescribed PrEP; however, prescribing practices trended upward with time and awareness.

Conclusions: Realization of the benefits of PrEP will require a utilitarian ethical approach to identifying the populations that will benefit most, monitoring for adverse effects, addressing costs, and educating and training providers to prescribe PrEP responsibly. Ensuring that PrEP fulfills its potential as part of a combination regimen for HIV prevention requires identification of additional evidence, education, support services, and resources that are needed, as well as the regulatory framework and cost scenarios for access to PrEP.

Key words: HIV, pre-exposure prophylaxis, ethics, utilitarianism, PrEP, physician

<https://doi.org/10.21633/jgpha.7.104>

INTRODUCTION

In the United States and around the world, the human immunodeficiency virus (HIV) remains a substantial public health issue. In the United States, there are an estimated 1.2 million people living with HIV (Centers for Disease Control [CDC], 2016a). In 2015, there were 39,513 new diagnoses of HIV (CDC, 2016a). Over recent years, there have been decreases in HIV incidence; however, these decreases are not consistent among all groups. The populations most affected by HIV are gay and bisexual men, who account for 82% of new diagnoses among males (CDC, 2016a). Heterosexuals and injecting drug users also continue to be included in new HIV diagnoses, and African Americans continue to experience the greatest burden of HIV compared to other races (CDC, 2016a).

There is evidence that the use of antiretroviral medications can be a safe and effective way to prevent HIV infection (Sugarman et al., 2014). Pre-exposure prophylaxis (PrEP) is

a method for individuals who are at high risk of acquiring HIV infection to take a daily antiretroviral medication to decrease their risk of infection. The medication consists of two medicines, tenofovir and emtricitabine, in one pill. In July 2012, this medication (brand name Truvada) was approved by the Food and Drug Administration (FDA) for use as PrEP in HIV-uninfected individuals who are at a high risk of acquiring HIV infection (U.S. Food & Drug Administration, 2012). PrEP is taken daily in order to build up and maintain an effective concentration of the medication in the blood system to be protective against the HIV virus. The medication reduces the risk of the virus binding to CD4 cells and replicating (U.S. Food & Drug Administration, 2012). Although PrEP helps to prevent a high-risk individual from acquiring HIV, condoms should continue to be used as an additional barrier to other sexually transmitted infections (CDC, 2016b). According to the CDC, daily use of PrEP can reduce the risk of acquiring HIV from sexual intercourse by up to 90%, and, for

individuals who inject drugs, it can reduce the risk by up to 70% (CDC, 2016b).

PrEP and Ethical Decision-Making

Contemporary public health strategies to prevent disease and promote wellness can be analyzed through the lens of established ethical models for decision making. One of these models, utilitarianism, was developed in the 19th century by Jeremy Bentham and John Stuart Mill to determine which laws were morally best for legislators to provide the greatest balance of good over evil (Velasquez et al., 2015). Utilitarianism has become a widely used ethical approach to decision making. These decisions are most commonly those that affect a large group of people, where the action in question provides the most good and does the least amount of harm. The HIV epidemic and the advent of PrEP provide an instructive example of the complexities of human health behaviors and utilitarian ethical decision-making in public health.

Understanding physicians' attitudes toward the ethical considerations of prescribing PrEP is an essential component in increasing our awareness and understanding of practice patterns impacting population-level administration of PrEP. Primary care providers (PCPs) accomplish the first step in prescribing PrEP to the populations most at risk for acquiring HIV, for physicians must first identify appropriate courses of action. Then, often using utilitarian ethics, they consider the pros and the cons that are the results of the actions and choose the action that will provide the greatest benefit (Velasquez et al., 2015).

The attitudes of physicians towards the cost, safety, and resource allocation aspects of PrEP can either hinder or promote its use. The medications cost an estimated \$12,000 per person per year; however, mathematical modeling suggests that, over time, PrEP programs have the potential to save costs for the healthcare system, showing a positive return on investment (Cappelletti, 2016). Under certain conditions, it is ethical to provide PrEP even when the supply of antiretrovirals available for treatment is low, because maximizing of the overall health benefits means giving priority to those who will respond best to treatment and survive the longest (Rennie, 2013; Macklin et al., 2012). In regards to safety, although some studies have shown that PrEP is effective at reducing the incidence of new HIV infections, it could take years to compile sufficient evidence of the clinical safety and efficacy of PrEP for various populations. These cost and safety considerations can influence decisions on resource allocation. According to Hankins, Macklin, & Warren (2015), cost-effectiveness studies guide resource allocation decisions by indicating where resources can be applied for greatest impact. Hankins et al. (2015) argue that the outcomes-oriented utilitarian principle should guide resource allocation in conjunction with a prioritarian approach, which gives special consideration to socially and economically disadvantaged groups. The combination of prevailing ethical approaches and practical implications such as cost, safety, and resource allocation, can profoundly influence the decisions physicians make regarding PrEP recommendation and prescription.

Although general knowledge about and support for PrEP have increased since the FDA approved Truvada and the CDC released the prescribing guidelines, knowledge of PrEP among providers has increased only slightly, and prescribing rates remain relatively low (Castel et al., 2015). The willingness of physicians to prescribe PrEP has significant implications for PrEP access; however, few studies have evaluated the attitudes of physicians towards the ethics of the cost, safety, and resource allocation of prescribing PrEP.

METHODS

The purpose of this literature review was to evaluate provider attitudes toward the ethics of use of PrEP for individuals at high risk for acquiring HIV infections. Provider concerns regarding the safety, efficacy, and cost-effectiveness of the PrEP intervention were evaluated through the ethical framework of the utilitarian approach to ethical decision-making. All study protocols were reviewed and approved by the Georgia Southern University Institutional Review Board.

This literature review included peer-reviewed journal articles published between 2014 and 2017 reporting on physician attitudes towards prescribing PrEP. Only papers written in English were included. Data were collected by use of the PubMed and Cochrane search engines available through the Georgia Southern University Library GALILEO database system. To ensure that all articles that were eligible for review were captured, a broad initial search strategy was used for literature identification with the terms: "pre-exposure prophylaxis" OR "PrEP," plus "HIV," plus "physician hesitation," and "Ethics" OR "Bioethics" OR "ethical issues" OR "normative" OR "ethical guidelines."

A second search was conducted to screen articles for keywords contained in titles and abstracts using the search terms: "PrEP allocation" OR "high risk" OR "PrEP plus efficacy" OR "PrEP plus HIV plus high risk" OR "PrEP plus resource plus allocation" OR "resource" AND "ethics" OR "ethical" OR "utilitarian" OR "utilitarianism" OR "physician" OR "provider" OR "safety" OR "effectiveness" OR "cost PLUS benefit" OR "debate" OR "dilemma." Then a search was conducted through PubMed for the terms "pre-exposure prophylaxis" AND "HIV" AND "physician" OR "provider" AND "ethics" AND "attitudes." Finally, a search was conducted in PubMed using the terms "pre-exposure prophylaxis" OR "PrEP" AND "HIV" AND "physician" OR "provider" AND "ethics" OR "ethical" OR "bioethics." Duplicate articles were eliminated.

Three reviewers independently assessed the relevance of articles and discarded those not directly related to physician's attitudes towards the ethics of the cost, safety, and resource allocation of PrEP. The first reviewer conducted the initial analysis. The second and third analyses were conducted, separately, by two additional reviewers. The criteria for inclusion were that each article must explicitly address considerations of PrEP treatment allocation, cost, safety, and/or efficacy, and must report on

healthcare provider perspectives. Articles that did not initially meet criteria were discussed by the reviewers, and only those articles that had full agreement were included. Twenty-one articles were ultimately included in this literature review.

RESULTS

The literature review focused on provider attitudes regarding prescribing PrEP, including resource allocation, cost, and safety or effectiveness of the drug. Several of the researchers cited in the literature had formulated their own literature reviews or had conducted their own research on prescriber attitudes towards PrEP.

Resource Allocation

Some authors argued that resources allocated to the distribution of PrEP can negatively affect the availability of resources for HIV treatment. Sugarman & Mayer (2014) concluded that questions regarding resource allocation will not be easy to address if related factors, including cost, safety, and efficacy, remain in question. A notable consideration is that there are other effective HIV prevention methods, such as educational forums, counseling, and condom use. Sugarman & Mayer (2014) raised the point that funding for HIV prevention and treatment can be considered a draw on a larger, limited pool of general funding for health concerns – a consideration that demands a more complex and broad assessment of PrEP funding allocation. A second aspect of resource allocation is the problem of determining which demographic – not medical – groups should be prioritized for PrEP, as insufficient resources exist to distribute the treatment regimen equally to all who may benefit from it.

Cost

Several studies focused on cost-effectiveness, investigating whether the benefits of preventing HIV through administering PrEP outweigh the costs of PrEP (Hankins et al., 2015; Hakre et al., 2016; Karris et al., 2014). Funding PrEP while other potentially more cost-effective HIV prevention interventions remain underfunded may have high opportunity costs, diverting resources from early initiation of anti-retroviral therapy or other prevention strategies (Hankins, Macklin, and Warren, 2015).

Puro et al. (2013), through a focus group and literature review, developed a questionnaire that was administered to a convenience sample of Italian HIV specialists during educational courses in two regions and an online survey in February-May 2012. The participants were asked if they would allocate the costs of PrEP to the National Health System (NHS). Most respondents believed that NHS should sustain PrEP costs entirely, in all (28%) or selected (9%) cases (i.e., conception), or partially, based on patient's income (29%) (Puro et al., 2013). Regarding financial sustainability, although it was deemed too expensive, most specialists advocated NHS support of PrEP costs to ensure equity of access, consistent with other studies in which healthcare providers recognized cost as a major barrier for patients and would like for public programs to pay for PrEP if patients cannot afford it (Puro et al., 2013).

A systematic review of 13 studies found that key considerations in assessing cost-effectiveness of PrEP are cost, the epidemic context, individual adherence, PrEP program coverage, and prioritization strategy (Hankins, Macklin, and Warren, 2015). The researchers felt that PrEP could be a cost-effective addition to HIV prevention programs, particularly when those at highest risk of HIV exposure are prioritized (Hankins, Macklin, and Warren, 2015). They also felt that paying for PrEP, when access to antiretroviral therapy is not universal, is an issue that requires reflection. To fulfill the public health need for PrEP, the researchers felt that PrEP introduction activities will enable policy-makers and program planners to answer the questions of who can benefit most from PrEP, how to provide it safely and efficiently, how to integrate PrEP into combination treatment and prevention programs, and what kind of health system support is needed to ensure implementation (Hankins, Macklin, & Warren, 2015).

PCPs and infectious disease physicians in the US Air Force (USAF) participated in a cross-sectional survey examining knowledge, attitudes, and beliefs toward HIV and PrEP (Hakre et al., 2016). Barriers to PrEP utilization included concerns about costs, viral resistance, patient adherence, and side effects of medication. The low uptake of PrEP by USAF providers may be related to concerns reported in the survey and uncertainty about costs.

A study by Castel et al. (2015) examined PrEP knowledge, experience, and likelihood of prescribing PrEP among HIV providers in Miami, FL, and Washington, DC. As stated in this report, 53% of the providers were concerned about the cost of the drug and reimbursement procedures (Castel et al., 2015). Latent class analysis was conducted to divide the providers into two groups: class one, who were identified as perceiving PrEP as less effective with substantial barriers; and class two, who perceived PrEP as being moderately effective with few barriers. Class two had a slightly higher probability of agreeing that cost might pose a substantial barrier (Castel et al., 2015). Both groups of providers also identified the risk for drug resistance and risk compensation as potential barriers to PrEP use—findings that were consistent with the results of other studies of potential physician providers of PrEP (Blumenthal et al., 2015; Caceres et al., 2015; Castel et al., 2016; Hakre et al., 2016; Hankins et al., 2015; Karris et al., 2014; Krakower et al., 2014; Krakower et al., 2015; Krakower and Mayer, 2016; Puro et al., 2013; Smith et al., 2016).

Safety/Effectiveness

Prescribers were hesitant in prescribing PrEP because the effectiveness of the drug was considered equivocal (Blumenthal et al., 2015; Caceres et al., 2015; Castel et al., 2016; Hakre et al., 2016; Hankins et al., 2015; Karris et al., 2014; Krakower et al., 2014; Krakower et al., 2015; Krakower and Mayer, 2016; Puro et al., 2013; Smith et al., 2016). PCPs reported lack of knowledge or training about PrEP as the main barrier in prescribing PrEP and in providing PrEP education to patients (Hakre et al., 2016).

A study by Blumenthal et al. (2015) explored prescriber attitudes about efficacy through a 35-question, self-administered survey that was given to clinicians (N=233) who attended HIV-related conferences and meetings in New York, San Diego, and Los Angeles. The survey focused on knowledge and experience with PrEP and evaluated perceived advantages and disadvantages of PrEP being provided by clinicians who did and did not generally care for HIV-infected persons and high-risk, HIV-uninfected individuals (Blumenthal et al., 2015). The results showed that 40% of these providers were hesitant to prescribe PrEP because of patient resistance to the drug. Most (>80%) providers agreed that new studies showing efficacy, patient request, ease of patient obtaining PrEP, and recommendations from CDC would likely increase their use of PrEP (Blumenthal et al., 2015). Many of the reports indicated that patients would become resistant to the drug and that it would essentially be ineffective, which limited their willingness to prescribe PrEP (Blumenthal et al., 2015; Caceres et al., 2015; Castel et al., 2016; Hakre et al., 2016; Hankins et al., 2015; Karris et al., 2014; Krakower et al., 2014; Krakower et al., 2015; Krakower and Mayer, 2016; Puro et al., 2013; Smith et al., 2016).

A study by Karris et al. (2013) examined prescriber attitudes towards the safety of PrEP through a 10-question survey that was given to infectious disease specialists (N = 573) who belonged to The Emerging Infections Network of the Infectious Diseases Society of America. The survey inquired about the participants' HIV practice, to whom they had provided or would provide PrEP, how they assessed eligibility, how they measured adherence, when PrEP would be discontinued, and what perceived barriers existed (Karris et al., 2014). When asked why physicians would not provide PrEP, 77% were worried about adherence and the risk for future resistance, 53% did not want to use potentially toxic drugs for healthy persons, and 53% felt there was insufficient evidence for the efficacy of PrEP (Karris et al., 2014).

Prescriber Practices

Even though prescribers were aware of PrEP and its use, many were reluctant to prescribe it (Castel et al., 2015; Hakre et al., 2016; Krakower et al., 2015; Karris et al., 2015; Krakower and Mayer, 2012; Krakower and Mayer, 2016; Puro et al., 2013; Smith et al., 2016). For example, a survey of 184 clinicians working for a New England AIDS Educational and Resource Center was conducted to investigate prescribing practices (Krakower et al., 2015). The results indicated that clinicians were not readily prescribing PrEP. Of the respondents, 75% reported being aware of CDC PrEP guidelines, but only 19% had prescribed it. Having a higher percentage of patients infected with HIV was associated with a history of prescribing PrEP. This study was conducted at an institution specializing in HIV care, rather than in a primary care setting, a fact pointed out by survey respondents who believed that primary care and sexual health clinics may be more appropriate settings for prescription of PrEP.

Several studies indicated that some prescribers supported PrEP but had not prescribed it because it was not relevant to

their patient population. In a survey given to clinicians, 74% of respondents reported support for provision of PrEP, but only 9% had prescribed it. Of those surveyed, 34% reported that PrEP was not germane to their practice (Karris et al., 2013).

Puro, et al., (2013) assessed prescribers' knowledge about PrEP and their willingness to prescribe it. HIV specialists (N=311) responded to a survey regarding attitudes toward PrEP. Of these, 69% rated their own familiarity with PrEP as being minimum or sufficient, and 70% reported that they would prescribe PrEP. These results support broader findings indicating a higher willingness to prescribe PrEP among HIV specialists (Puro et al., 2013).

A survey was given to providers treating individuals with HIV to evaluate their willingness to prescribe PrEP (Castel et al., 2015). Of the participants, 50% reported that they were infectious disease specialists, and 75% reported that they were PCPs. However, only 17% of the HIV providers reported that they had prescribed PrEP, with slightly over half of the respondents reporting belief in the efficacy of PrEP.

Several studies suggested that PrEP awareness and willingness to prescribe it are generally increasing (Castel et al., 2015; Hakre et al., 2016; Karris et al., 2015; Krakower et al., 2015; Krakower and Mayer, 2012; Krakower and Mayer, 2016; Puro et al., 2013; Smith et al., 2016). In one study conducted before and after the release of PrEP trial results, primary care clinicians reported that awareness of PrEP had increased from 24% in 2009 to 66% in 2015 (Smith et al., 2015). In 2009, 1% of participants reported having prescribed PrEP; in 2015, 7% reported having prescribed PrEP. Willingness to prescribe PrEP was associated with experience in treating patients with antiretroviral medications for HIV.

DISCUSSION/CONCLUSIONS

The studies included in this review discussed the importance of resource allocation, safety, effectiveness, and cost benefits for prescribing PrEP. Realization of the societal value of PrEP will require identifying individuals who are most likely to benefit from it, monitoring for adverse effects, addressing costs, and training providers to prescribe PrEP responsibly (Krakower and Mayer, 2012). Many prescribers are hesitant in prescribing PrEP, mainly due to lack of knowledge and efficacy of the drug. Ensuring that PrEP fulfills its potential as part of a HIV prevention regimen requires establishing additional evidence, education, support services, and resources, as well as the regulatory framework and cost scenarios for access to PrEP (Hankins, Macklin, and Warren, 2015).

The cost of PrEP has been cited as a provider concern, but the extent to which cost acts as a barrier remains unclear. Perception of cost as a barrier was associated with specialization in infectious diseases and/or HIV care. In a study of 573 infectious disease specialists, cost was cited as the main barrier and, in another study of 311 HIV specialists, was cited as the second largest barrier. Two

other studies ($N = 403$, $N = 233$), surveying a wider mix of providers, found that cost concerns were not among the highest perceived barriers (Blumenthal et al., 2015; Hakre et al., 2016; Karris et al., 2014; Puro et al., 2013).

Due to the considerable expense of the drug, the issue of cost as a prohibitive factor in utilization of PrEP for patients is substantial. However, a utilitarian analysis of cost factors would aim to place these concerns in the broader context of healthcare accessibility, particularly for the high-risk populations that the drug regimen would benefit. The cost-effectiveness of PrEP, from a utilitarian standpoint, would be determined by evaluating its effect on populations rather than individuals (Mandal, Ponnambath, & Parija, 2016). A limitation of the current body of research is that provider survey items regarding cost are likely to be interpreted at the individual level, imputing the cost to each patient. Further research investigating the barrier of price on high-risk populations most likely to derive the greatest benefits from the drug is warranted to clarify the relationship between individual and population-level ethical issues.

Among providers, the effectiveness of PrEP and its potential for toxic side effects were oft-cited concerns. In a study of 39 HIV care providers, participants discussed the issue of patient adherence to medication regimens as a barrier to PrEP efficacy (Krakower et al., 2014). Whether provider concerns over PrEP efficacy in all the studies reviewed were related to adherence, rather than efficacy of the drug regimen, is unclear; however, patient adherence was frequently cited as a reservation.

A generally positive attitude toward the provision of PrEP was associated with provider knowledge and experience with PrEP, suggesting that provider education will be involved in shaping how PrEP is positioned as a preventive intervention for high-risk populations. Blumenthal et al. (2015) found that 80% of 233 providers reported that they would be more open to prescribing PrEP if more data on safety and efficacy become available. As levels of provider education increase, a demand for comparative data between established HIV prevention methods and PrEP intervention is likely to arise among professionals seeking a more complete understanding of whether the benefits of PrEP and other methods justify the costs.

At present, PrEP provision is generally low (Karris et al., 2014; Castel et al., 2015; Krakower & Mayer, 2016; Hakre et al., 2016). In keeping with reports that providers would be more open to prescribing PrEP after gaining greater certainty of its safety and efficacy, Smith et al. (2016) reported a slow increase in PrEP provision over a three-year span as PrEP awareness grew among the medical community. Still, as of 2015, only 7% of participants reported having prescribed PrEP, suggesting that some providers may be finding compelling reasons not to provide it. Inquiries should focus on how the oft-cited factors of adherence, toxicity, and the substantial cost of the drug regimen might be affecting provider perspectives on the potential for PrEP to reduce HIV transmission.

Overall, few participants reviewed cited the issue of resource allocation among their chief concerns about PrEP. In the context of the provider-patient relationship, the distal, population-level impact of PrEP resource provision on availability of other HIV treatments may be a less salient consideration in provider decision-making. Further, resource allocation for healthcare varies considerably by country, suggesting that the question of how providers view the practice of drawing from limited funding for PrEP may vary according to culture-specific perceptions of resource availability and distribution (Davis, Stremikis, Schoen, & Squires, 2014).

Considering disease burden, costing information, and efficacy, cost-effectiveness studies that illustrate the utilitarian principle at work can provide an initial indication of the potential effects of PrEP programs. In regard to administration of PrEP and ethics, cost-effectiveness becomes an issue. Unlike the context of private prescriptions, if PrEP becomes a state-recommended intervention, the question of cost versus benefit arises. Some of the questions posed by PrEP are not specific to HIV prophylaxis, but are standard public health considerations about resource allocation and striking a balance between individual benefits and public good. To increase access to PrEP, we need to understand the cost of PrEP and establish who is going to pay for it. Clinicians who prescribe PrEP have an ethical obligation to be aware of the current and emerging data concerning PrEP and the ethical issues associated with its use.

Regarding ethics and PrEP, prescribers may have a moral issue in which they believe that prescribing PrEP will encourage risky behavior (Puro et al., 2013; Krakower et al., 2015). There is also a concern that PrEP may lead to drug resistance, with resulting decreased efficacy of population-level treatment; if this is the case, it may be argued that it is not ethical to prescribe it (Venter, Allais, and Richter, 2014). The urgent-need principle states that medical needs of people give rise to moral claims to the health care resources necessary to meet those needs, that equally urgent needs give rise to equal moral claims, and that more urgent needs give rise to stronger moral claims (Brock et al., 2003). The urgent-need principle can be combined with the utilitarian principle in setting priorities for allocating PrEP, with the principle of equity giving priority to stigmatized and marginalized populations, such as men who have sex with men, sex workers, people who inject drugs, and young women and serodiscordant couples (Hankins, Macklin, and Warren, 2015). Introduction of PrEP will enable policy-makers and program planners to answer the questions of who can benefit most from PrEP, how to provide it safely and efficiently, how to integrate PrEP into combination treatment and prevention programs, and what kind of health system support is needed to ensure implementation (Hankins, Macklin, and Warren, 2015).

Conducting a comprehensive literature review, rather than a systematic review, allowed review and evaluation of a wide range of literature. This approach provided the flexibility to engage the broad knowledge base in the published literature; however, it has limitations. A comprehensive literature

review is subject to misinterpretation of data. Additionally, although broad search terms were used, some literature may have been overlooked. PrEP is relatively new as a prevention approach, having been approved by the FDA in 2012. Most of the studies cited in this review were published between 2014 and 2016. Therefore, even the most recent studies published on this topic may not reflect the most up-to-date research and information pertaining to PrEP.

The innovative use of Truvada for the prevention of HIV infection represents a new development in the fight against the spread of HIV. If PrEP can be shown to have a positive net benefit to high-risk populations and these communities, public health professionals can lead the call for policies and programs that make the drug regimen more accessible to vulnerable populations. Current data suggest that decision-making at the provider level is stalled by the lack of data pertaining to PrEP safety and efficacy. Further, providers are hesitant to support the prevention method because it simply is not affordable for many patients. Further research into the safety and efficacy of PrEP is needed in order to build a case for the public benefit of devoting resources to the allocation of PrEP that would withstand a utilitarian analysis. If data demonstrate that spending on PrEP is likely to reduce HIV transmission rates in high-risk communities, advocates can push for policies that would help lower the cost of PrEP for patients, and efforts to educate providers on the benefits of PrEP will meet with greater success.

Acknowledgements

A doctoral student research team conducted this research as part of the course requirements for PUBH 9331—Health Policy, Regulation, and Ethics at the Jiann-Ping Hsu College of Public Health. The authors extend appreciation to faculty mentors from the Department of Community Health Behavior and Education and the Department of Health Policy and Management.

References

- Blumenthal, J., Jain, S., Krakower, D., Sun, X., Young, J., Mayer, K., ... the CCTG 598 Team. (2015). Knowledge is Power! Increased Provider Knowledge Scores regarding Pre-exposure Prophylaxis (PrEP) are Associated with Higher Rates of PrEP Prescription and Future Intent to Prescribe PrEP. *AIDS and Behavior*, 19(5), 802–810. <http://doi.org/10.1007/s10461-015-0996-z>
- Brock, D. W. (2003). Separate spheres and indirect benefits. *Cost Effectiveness and Resource Allocation: C/E*, 1, 4. <http://doi.org/10.1186/1478-7547-1-4>
- Cappelletti, A. (2016). Ethics of pre-exposure prophylaxis in high-risk HIV patients. *University of Western Ontario Medical Journal*, 85(2), 53-55.
- Castel, A. D., Feaster, D. J., Tang, W., Willis, S., Jordan, H., Villamizar, K., Metsch, L. (2015). Understanding HIV Care Provider Attitudes Regarding Intentions to Prescribe PrEP. *Journal of Acquired Immune Deficiency Syndromes*, 70(5), 520–528. <http://doi.org/10.1097/QAI.0000000000000780>
- Centers for Disease Control and Prevention. (2016a). HIV in the United States: At a Glance. Retrieved from <https://www.cdc.gov/hiv/statistics/overview/ata glance.html>.
- Centers for Disease Control and Prevention. (2016b). HIV/AIDS PrEP. Retrieved from <https://www.cdc.gov/hiv/basics/prep.html>.
- Davis, K., Stremikis, K., Schoen, C., & Squires, D. (2014). Mirror, mirror on the wall, 2014 update: How the U.S. health care system compares internationally. *The Commonwealth Fund*. Retrieved from <http://www.commonwealthfund.org/publications/fund-reports/2014/jun/mirror-mirror>
- Hakre, S., Blaylock, J. M., Dawson, P., Beckett, C., Garges, E. C., Michael, N. L., ... Okulicz, J. F. (2016). Knowledge, attitudes, and beliefs about HIV pre-exposure prophylaxis among US Air Force Health Care Providers. *Medicine*, 95(32), e4511. <http://doi.org/10.1097/MD.0000000000004511>
- Hankins, C., Macklin, R., & Warren, M. (2015). Translating PrEP effectiveness into public health impact: key considerations for decision-makers on cost-effectiveness, price, regulatory issues, distributive justice and advocacy for access. *Journal of the International AIDS Society*, 18(4Suppl 3), 19973. <http://doi.org/10.7448/IAS.18.4.19973>
- Karris, M. Y., Beekmann, S. E., Mehta, S. R., Anderson, C. M., & Polgreen, P. M. (2014). Are We Prepped for Preexposure Prophylaxis (PrEP)? Provider Opinions on the Real-World Use of PrEP in the United States and Canada. *Clinical Infectious Diseases: An Official Publication of the Infectious Diseases Society of America*, 58(5), 704–712. <http://doi.org/10.1093/cid/cit796>
- Krakower, D., & Mayer, K. H. (2012). Engaging Healthcare Providers to Implement HIV Pre-Exposure Prophylaxis. *Current Opinion in HIV and AIDS*, 7(6), 593–599. <http://doi.org/10.1097/COH.0b013e3283590446>
- Krakower, D., Ware, N., Mitty, J. A., Maloney, K., & Mayer, K. H. (2014). HIV Providers' Perceived Barriers and Facilitators to Implementing Pre-Exposure Prophylaxis in Care Settings: A Qualitative Study. *AIDS and Behavior*, 18(9), 1712–1721. <http://doi.org/10.1007/s10461-014-0839-3>
- Krakower, D. S., & Mayer, K. H. (2016). The Role of Healthcare Providers in the Roll-Out of PrEP. *Current Opinion in HIV and AIDS*, 11(1), 41–48. <http://doi.org/10.1097/COH.0000000000000206>
- Macklin, R. & Cowan, E. (2012). Given resource constraints, it would be unethical to divert antiretroviral drugs from treatment to prevention. *Health Affairs*, 31(7), 1537-1544.
- Mandal, J., Ponnambath, D. K., & Parija, S. C. (2016). Utilitarian and deontological ethics in medicine. *Tropical Parasitology*, 6(1), 5–7. <http://doi.org/10.4103/2229-5070.175024>
- Puro, V., Palummieri, A., De Carli, G., Piselli, P., & Ippolito, G. (2013). Attitude towards antiretroviral pre-exposure prophylaxis (PrEP) prescription among HIV specialists. *BMC Infectious Diseases*, 13, 217. <http://doi.org/10.1186/1471-2334-13-217>
- Rennie, S. (2013). Ethical use of antiretroviral resources for HIV prevention in resource poor settings. *Developing World Bioethics*, 13(2), 79-86.
- Smith, D. K., Mendoza, M. C. B., Stryker, J. E., & Rose, C. E. (2016). PrEP Awareness and Attitudes in a National Survey of Primary Care Clinicians in the United States, 2009–2015. *PLoS ONE*, 11(6), e0156592. <http://doi.org/10.1371/journal.pone.0156592>
- Sugarman, J. & Mayer, K. H. (2014). Ethics and pre-exposure prophylaxis for HIV infection. *Journal of Acquired Immune Deficiency Syndrome*, 63(02), S135-S139.
- Velasquez, M. A., C; Shanks, T; S.J.; Meyer, M. (2015). Thinking Ethically. Retrieved from <https://www.scu.edu/ethics/ethics-resources/ethical-decision-making/thinking-ethically/>
- Venter, F., Allais, L., & Richter, M. (2014). Exposure Ethics: Does HIV Pre-Exposure Prophylaxis Raise Ethical Problems for the Health Care Provider and Policy Maker? *Bioethics*, 28(6), 269-274.
- U.S Food & Drug Administration. (2012). FDA Approves first drug for reducing the risk of sexually acquired HIV infection. Retrieved from <http://www.fda.gov/NewsEvents/Newsroom/PressAnnouncements/ucm312210.htm>

© Jessica Grippo, Stacy W. Smallwood, Katherine Pincura, Tamara Wright, and William A. Mase. Originally published in jGPHA (<http://www.gapha.org/jgpha/>) December 20, 2017. This is an open-access article distributed under the terms of the Creative Commons Attribution Non-Commercial No-Derivatives License (<http://creativecommons.org/licenses/by/4.0/>), which permits unrestricted use, distribution, and reproduction in any medium, provided the original work ("first published in the Journal of the Georgia Public Health Association...") is properly cited with original URL and bibliographic citation information. The complete bibliographic information, a link to the original publication on <http://www.gapha.jgpha.org/>, as well as this copyright and license information must be included.