Ensuring the Ethical Implementation of the New World Health Organization Pre-Exposure Prophylaxis Recommendations for Men Who Have Sex with Men

Kavita Shah Arora, MD, MBE1,2 and Carl G. Streed, Jr., MD3

Abstract

The World Health Organization’s (WHO) new recommendation to encourage pre-exposure prophylaxis in men who have sex with men (MSM) is an important step towards eradicating the HIV epidemic. However, the ethical issues of stigma, privacy and confidentiality, and access must be addressed in order to ensure the optimal implementation of this important recommendation.

Key words: anti-retroviral, HIV, men who have sex with men (MSM), pre-exposure prophylaxis (PrEP).

Introduction

In July 2014, the World Health Organization (WHO) concluded that, “among men who have sex with men, pre-exposure prophylaxis (PrEP) is recommended as an additional HIV prevention choice.”1 This bold new recommendation takes a step beyond the 2012 conditional recommendation which focused on serodiscordant relations, and acknowledges obstacles to implementation while attempting to balance these potential drawbacks with the known empirical benefits of PrEP in a population considered to be at high-risk for HIV infection.2 The high quality of evidence that is available suggests that PrEP is best offered as a component of a comprehensive HIV prevention package. While the WHO recommendations mention concerns regarding implementation of PrEP due to stigma around HIV, sexual health, and men who have sex with men (MSM); provider attitudes; privacy and confidentiality concerns; and access to basic HIV services, the focus of the updated recommendations is on the empiric evidence. Although any tool to help eradicate HIV is important, further discussion of these barriers to implementation and the ethical ramifications of the updated recommendation is important and has thus far been inadequately addressed.1

Stigma towards HIV, sexual health, and the MSM population is certainly not a new phenomenon.3 However, the PrEP debate has only amplified the dialogue as emtricitabine/tenofovir disoproxil fumarate (Truvada) serves as a lightning rod for the conversation surrounding stigma, both within the population impacted by the new recommendation as well as the medical and public health community. Some in the MSM community have coined the term “Truvada whore,” implying that those using PrEP are doing so for the purpose of engaging in high-risk behavior (e.g., multiple sex partners, condomless sex, etc.). Just as oral contraceptives (e.g., “the pill”) do not promote promiscuity,4 and women who desire contraception to be covered by insurance are not engaging in high-risk behavior as a result of oral contraceptives, those using PrEP are simply making a personal and informed decision regarding their health care.5 Thus, health care providers and the health care field in general need to recommit to ending HIV exceptionalism and stigma towards HIV care. Community mobilization has shown promising leads towards decreasing stigma and other social inequities affecting HIV care.3,6 Future research efforts need to focus on the impact of PrEP on stigma, discrimination, and other social inequities affecting HIV care.

However, we must be careful not to generalize the MSM population as uniformly high-risk rather than accounting for individual risk and various sub-profiles similar to the heterosexual population. For example, many leaders and organizations have called for the repeal of the Food and Drug Administration’s lifetime ban on blood donation by men who have sex with men to account for individual risk profiles.

1Department of Reproductive Biology and Bioethics, Case Western Reserve University and 2Department of Obstetrics and Gynecology, MetroHealth Medical Center, Cleveland, Ohio.
3Department of Internal Medicine, Johns Hopkins Bayview Medical Center, Baltimore, Maryland.
rather than continue to rely on an outdated, discriminatory ban not based on evidence.\textsuperscript{7} Similarly, so too must the healthcare community personalize the WHO recommendations for each individual patient.

Yet, there remain many other practical limitations to implementing the WHO guidance. We need to continue to develop tools to prevent HIV in MSM who are not aware of their HIV exposure risks and have not told their providers of their sexual practices. Given that breaches in confidentiality occur more in regards to people that are HIV positive and/or MSM, it is not surprising that concerns surrounding confidentiality remain an obstacle to seeking care.\textsuperscript{8} Physicians providing PrEP also should be mindful of confidentiality and privacy concerns surrounding disclosure of both MSM behavior and HIV status. For example, it is important to ensure that patients in other exam rooms or in the hallways do not overhear conversations that take place in one exam room. Similarly, permission should be obtained from the patient to discuss all health-related matters, but especially sensitive information such as MSM and HIV status, in front of family members and/or partners, and office staff must be mindful of Health Insurance Portability and Accountability Act (HIPAA) considerations when disclosing health information over the phone. Secondly, adolescents were not included in the PrEP studies and it remains unclear whether individual state policies and laws will allow for adolescents to consent for PrEP medications without parental consent.\textsuperscript{9} This is especially important given that people aged 15–24 comprise over one-third of people newly infected with HIV globally.\textsuperscript{10} The ability for patients to disclose their risk factors and have an open, frank discussion surrounding PrEP is further limited by the fact that in many countries around the world (including many countries with a high prevalence of HIV), homosexuality is expressly illegal.\textsuperscript{11,12}

PrEP is a valuable tool against the spread of HIV. However, education and studies of workforce capacity will be necessary to ensure that MSM patients are offered PrEP as a component of routine, preventative care. The implementation of PrEP must be done in a manner that preserves access to HIV testing, condoms, needle-exchange programs, and other HIV prevention and treatment programs as outlined in the WHO guidelines.\textsuperscript{1} Given that in many areas heterosexual transmission remains the most prominent method of acquiring HIV, it is important that research continue to explore PrEP in all potentially serodiscordant couples and the priority remain on ensuring access to care, both basic as well as innovative, across the spectrum of risk. In areas where resources are limited, the emphasis must ethically remain on treating infected people, potentially through emerging test-and-treat programs.\textsuperscript{12} Long-term study regarding cost, effectiveness, side effects and tolerability, drug resistance, behavioral modification, and adherence will also be necessary to ensure the safe optimization of PrEP recommendations.\textsuperscript{13} It is also important to ensure that the results of studies conducted in resource-poor areas are not simply transplanted to areas with more resources, but that the data inform implementation in the communities that supported the initial research.\textsuperscript{14}

The concept of PrEP has been around for decades (e.g., antimalarial drugs to prevent malaria infection, zidovudine in labor to prevent mother-to-child transmission of HIV, etc.). Yet, the clinical evidence to support the use of a specific regimen in a subpopulation at risk has taken over a decade to generate, and when determined, years to disseminate. While the results of the (Iniciativa Profilaxis Pre-Exposición) iPrEx study, which demonstrated the effectiveness of PrEP in the MSM population, have been available since 2010, the push to make policy recommendations and engage primary care providers as stakeholders is only happening recently.\textsuperscript{15}

While the authors laud the WHO in embracing a promising tool in the fight to prevent HIV and stem the HIV epidemic, it is important that the ethical and social ramifications of this updated recommendation are more fully analyzed. Community-based consensus building, both geographic and within MSM populations, can assist in optimally addressing the ethical and health services complexity of PrEP. In this manner, the implementation of the new WHO recommendations can be conducted in a manner that is both strategic and ethically deliberate.

Author Disclosure Statement
The authors have no conflicts of interest to declare.

References


Address correspondence to:
Kavita Shah Arora, MD, MBE
Department of Obstetrics and Gynecology
MetroHealth Medical Center
2500 MetroHealth Drive
Cleveland, OH 44109

E-mail: kavita.shah.arora@gmail.com