Bioethical Challenges With HIV Treatment as Prevention

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To best realize the opportunities afforded by treatment as prevention, important ethical challenges must be addressed, including those related to acceptability, safety, and effectiveness, as well as alternatives. Absent universal access to quality antiretroviral treatment, safety, fairness, and allocation must also be considered.

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With mounting scientific evidence, substantial enthusiasm appropriately accompanies the use of human immunodeficiency virus (HIV) treatment as prevention (TasP) as a means of helping to curtail the HIV pandemic. As demonstrated by epidemiological and clinical research, the early treatment of HIV infection can have salutary effects not only for those treated but also in diminishing the chance of HIV transmission. In addition, TasP promises to diminish morbidity and mortality related to tuberculosis [1]. Accordingly, major efforts are being directed at implementing TasP. To best realize the opportunities afforded by TasP, several important ethical challenges must be addressed. Some of these challenges relate to TasP in general, while others are especially relevant due to the current lack of universal access to antiretroviral treatment (ART).

ETHICS AND TASP

TasP involves ethical issues related to acceptability, safety and effectiveness, as well as alternatives.

Acceptability

Acceptability of initiating ART among both those who are infected with HIV and those who are not infected and rely on TasP as a means of prevention is obviously critical in order for TasP to meet its dual goals of treatment and prevention. For those who are HIV infected, early treatment with ART may involve medicalization of infection prior to when they perceive themselves to be sick, which may be accompanied by reluctance to initiate treatment [2]. Since lifelong adherence is generally understood to be important in the treatment of HIV infection, it is essential that upon starting ART there is a genuine commitment to adhere as well as an ability to do so. As with all medical treatments, ART can have side effects that may be especially relevant in weighing the risks and benefits for particular individuals in deciding to initiate treatment. In addition to possible physical reactions to ART, in some settings social risks and stigma associated with treatment need to be considered. This range of concerns underscores the importance of informed and voluntary uptake of ART for TasP [3].

Since TasP aims to benefit not only the individuals being treated but also their sexual partners, it is necessary to consider the acceptability of TasP as a means of prevention for these partners. Considered as such, TasP is different from other forms of prevention in which at-risk individuals take some type of measure that is intended to afford a prevention benefit, such as ensuring condom use or using antiretroviral agents as preexposure prophylaxis (PrEP). In contrast, TasP is predicated on the actions of others. Therefore, uninfected individuals must trust that their HIV-infected sexual partners are adherent to ART and that the ART is sufficiently effective to mitigate transmission risk. While in some mutually monogamous dyadic relationships such trust
may be justified, in particular at-risk populations it may not, raising concerns about the safety and well-being of those at risk.

Safety and Effectiveness
The safety and effectiveness of TasP is dependent upon having sound and reliable ART delivery systems. This includes the ability to provide appropriate care and monitoring at a reasonable cost. In addition, safety and effectiveness in preventing new infections will be influenced somewhat by risk behaviors; and perhaps to the certainty ascribed to the ability of TasP to prevent transmission of HIV [4]. Finally, while efficacy data regarding TaSP are convincing in dyadic heterosexual couples, effectiveness information in this setting is arguably lacking as are data in other at-risk populations.

Alternatives
In considering the use of TasP for the prevention of new infections, it is important to keep in mind that there are other evidence-based means of prevention, including other ART-based means, such as PrEP, and that no single approach to HIV prevention is likely to be sufficient [5]. Indeed, a combination of preventive measures is likely to be needed [6]. In addition, data are emerging regarding the possible safety and efficacy of alternative means of prevention, such as vaginal microbicides, that are within the control of at-risk individuals. Also, there are the aspirations of identifying an effective HIV vaccine that could afford durable prevention benefits that would not require assiduous adherence to ART [7]. Similarly, another aspirational approach relates to achieving an “HIV cure” [8] that, if realized in a way that could be practically implemented, would obviously provide profound benefits for treatment and in turn prevention.

CONSIDERATIONS DUE TO A LACK OF UNIVERSAL ACCESS TO ART

Without universal access to quality ART, especially in resource-limited settings, there are special ethical considerations related to safety, fairness, and allocation. While these considerations are largely emblematic of global disparities in wealth and power that will unfortunately not be easily resolved, they necessarily shape the contours of health-related programs such as TasP.

Safety
Safety must be the initial consideration in initiating TasP. Although maintaining safety while on ART can be difficult in any setting, doing so in resource-poor settings where HIV prevalence is high can be expected to be especially challenging due to the need to ensure consistent access to suitable ART [9]. Similarly, it will be critical to establish context-appropriate systems of maintaining adherence and conducting monitoring. Moreover, these programs and processes need to be sustainable and insulated to the extent possible from political whim and inevitable changes in economic conditions.

Fairness
While many communities would stand to derive substantial benefit from the implementation of TasP when universal access to ART is lacking, questions of fairness arise in determining where TasP should be initiated first. As TasP is implemented, further questions of fairness will arise in relation to which individuals will be selected for treatment. Although what precisely constitutes fairness at both of these levels is unclear and complex, it is essential that mechanisms of selection be procedurally fair and transparent [10].

Allocation
Across the globe, there are clear and unmet needs for access to HIV treatment and prevention services, not to mention other non-HIV–related global health priorities. At one level are concerns about the allocation of resources to ART- and non-ART–based means of HIV prevention. At another level are concerns about allocating ART for a variety of uses, such as treatment of those who are ill, early treatment of those who are infected for TasP, and prevention (including prevention of maternal-to-child transmission [PMTCT], PrEP, and postexposure prophylaxis [PEP]). As long as there is true scarcity of ART, allocation decisions will be particularly difficult and it will be difficult to find easy answers. While some have advocated that when ART is scarce, priority should be given to treatment, then TasP, and then PrEP [11], others have illustrated the flaws of this intuitive conclusion [12–14]. It is beyond the scope of this article to examine the related arguments and counterarguments in detail, yet it is clear that additional attention needs to focus on the ethics of allocation. Recent scholarship in social justice theory [15, 16] may provide the necessary tools to help navigate appropriate paths forward.

CONCLUDING COMMENTS

TasP is an extremely promising means of helping to end the HIV pandemic. Nevertheless, like most, if not all, biomedical interventions, TasP involves ethical challenges that are exacerbated by global disparities in health, wealth, and the particular vulnerabilities of those infected with HIV and at heightened risk of becoming infected. Transparent and explicit deliberation about these issues along with meaningful engagement of the relevant stakeholders should help to address them in order to mitigate unintended actions and consequences as TasP is implemented.

Notes

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