Adolescent MSM participation in biomedical HIV prevention trials: toward a model for shared decision making

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Abstract:

The objective of this study is to explore the feasibility and acceptability of shared decision making between minor YMSM and their parents during the enrollment process for biomedical HIV prevention trials.

While rates of new HIV infection are declining globally, they have remained stagnant in the U.S. for more than a decade. Youth are at the heart of the persistent U.S. epidemic, accounting for an estimated 26% of all new HIV infections. Young men who have sex with men (YMSM) are at especially high risk. There are new biomedical approaches to HIV prevention that dramatically decrease the risk of infection. One is pre-exposure prophylaxis, or PrEP, which involves prescribing an HIV treatment medication, tenofovir-emtricitabine (TDF-FTC), to individuals at risk of HIV acquisition. Randomized clinical trials of PrEP have demonstrated 95% efficacy among adherent users, suggesting PrEP may be a useful prevention tool for American YMSM. However, the PrEP clinical trials were conducted with adults. There are several concerns about the risks of PrEP use in adolescents, including the possibility of reduced bone mineral density, difficulty with adherence, and behavioral risk compensation. Clinical studies are needed to better understand whether and how these potential harms manifest in adolescents, but there is pervasive reluctance to enroll them in biomedical prevention trials due to ethical and regulatory complexities. Investigators and their institutional review boards must protect minors from risk of harm associated with research, which typically means requiring parental consent for participation. But for YMSM, parental consent may introduce the risk of social harms if parents learn their son is engaged in same-sex sexual relationships. Our project will assess the feasibility of shared decision making between minor YMSM and their parents, in hopes of improving minors’ access to biomedical trials for HIV prevention.