

Mini Review

The Time is Now for Disruptive Innovation in Pre-Exposure Prophylaxis Adherence Monitoring

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ABSTRACT

Monitoring adherence to pre-exposure prophylaxis is a critical component of reaching ending the human immunodeficiency virus infection (HIV) epidemic goals in the US. Currently, providers still depend on “self-report” pre-exposure prophylaxis (PrEP) adherence, whereby providers ask their patients about their recent pill taking habits. There appears to be growing consensus across the HIV prevention community that “self-report” is an inadequate method of identifying that is in-need of additional adherence support services. In a recent survey, 97% of providers report utilizing self-reported adherence because it is convenient, but only 10% of these providers believe it is accurate. While “self-report” is convenient, evidence and testimonials from diverse stakeholders across the HIV prevention landscape indicate that there is a desire for more accurate, effective adherence monitoring methods. In this mini-review, we will briefly synthesize the emerging evidence and propose a solution to ensure all patients receive the support needed to protect them from HIV acquisition.

Keywords

Pre-exposure prophylaxis; HIV; Adherence; Prevention; Self-report.

INTRODUCTION

Self-reported health behaviors consistently overestimate actual behavior. Those of us who have exaggerated the frequency of our flossing habits to our dentist can attest to this, and yet we still depend on “self-report” for pre-exposure prophylaxis (PrEP) adherence. In a recent survey, 97% of providers report utilizing self-reported adherence because it is convenient, but only 10% of these providers believe it is accurate. This mini-review explores the ramifications of this disconnect and proposes an objective way to monitor and improve PrEP adherence.

Poor Adherence to PrEP Threatens the Success of “Ending the HIV Epidemic”

PrEP is nearly perfect at preventing human immunodeficiency virus infection (HIV) acquisition, but only when taken daily.¹⁻⁵ Inconsistent or low PrEP adherence is shown to reduce PrEP ef-

ficacy, and several PrEP demonstration projects have found that PrEP adherence is often sub-optimal and wanes over time.^{2,3,6-10} One 12-month PrEP demonstration project in Harlem found that adherence was only 52.9% at 3-months, 42.2% at 6-months, 35.8% at 9-months, and 32.4% at 12-months – a trend that is consistent with similar studies across settings and sub-populations.¹¹

Ending the HIV Epidemic

A plan for America Ending the HIV Epidemic (EHE) initiative from the US Department of Health and Human Services (HHS) outlines a strategy to reduce the number of new HIV infections in the US by 75% in the next five-years and by 90% in the next 10-years.¹² A key component of EHE is decreasing seroconversions through a scale-up of PrEP. However, adherence is the biggest determinant of PrEP’s success, and as we saw in the previously mentioned studies, adherence in the real world is sub-optimal.

As Eaton et al's 2018 study of HIV prevalence among African American black men who have sex with men (BMSM) shows, poor PrEP adherence translates to increased seroconversions: across over 4,000 surveyed BMSM, 1 in 3 on PrEP tested positive for HIV, compared to 1 in 5 not on PrEP testing HIV positive.¹³ Without changing current practice and providing improved adherence support for those on PrEP, poor adherence will undermine EHE's ambitious HIV prevention goals.

We Have the Clinical Tools to Accurately Identify and Address Non-Adherence

It is increasingly critical that clinicians are able to accurately determine which of their patients are struggling with their PrEP adherence so that they can allocate additional support services to them. Objective methods of measuring medication adherence have emerged as valuable tools in both research and clinical settings.^{14,15} For example, new innovations enable real-time monitoring of pill taking habits through smart pill bottles and digital pill sensors, facilitating rapid intervention from providers.¹⁴ Novel methods of measuring drug concentrations in various biomatrices (e.g., blood, urine, hair) allow for objective adherence monitoring (OAM) of PrEP and antiretroviral therapy (ART).¹⁴⁻¹⁹ Measuring drug concentrations in biomatrices indicates recent or cumulative exposure to these drug regimens, whereby higher drug concentrations suggest higher adherence and undetectable or low drug concentrations suggest sub-optimal or non-adherence. These biomarker-based OAM methods (i.e., plasma, dried blood spot, urine, and hair-based methods) have been developed and deployed in research settings to quantify and assess PrEP adherence. In one study, 50% of PrEP patients, who were identified as non-adherent by a plasma-based OAM test and then received targeted adherence support, achieved sustained improvement in adherence throughout the remainder of the study. This result indicates that OAM coupled with targeted adherence supports an generate substantial improvements in adherence.²⁰

In clinical settings, a liquid chromatography tandem-mass spectrometry (LC-MS/MS) urine adherence test is presently the only commercialized OAM method available for PrEP and has been introduced at >25 clinics nationwide. Preliminary data suggests that routine clinical use of the LC-MS/MS urine adherence test is useful in improving adherence and predicting future non-retention.²¹ These results showed that 74% of individuals initially identified as non-adherent by the urine OAM test demonstrated recent adherence on the same test at their next visit after receiving targeted adherence counseling.²¹ Moreover, non-adherent patients were 70% more likely to miss their next visit and 114% more likely to have dropped out of care within the next six months compared to adherent individuals. This demonstrates a further role for adherence testing in predicting future non-retention in care.²¹

Despite the Availability of OAM, "self-report" Still Prevails Clinically

Though OAM capabilities have dramatically advanced since PrEP got its Food and Drug Administration (FDA) approval, current PrEP clinical practice has not adopted this disruptive technology.

PrEP clinics still depend on "self-report" to monitor adherence, whereby providers ask their patients about their recent pill taking habits. "Self-report" is free, easy to implement, and enables providers to rapidly triage individuals, who self-report non-adherent, to the appropriate support services. Nevertheless, research suggests that "self-report" is prone to social desirability and recall biases, and it is heavily influenced by the trust that patients do or do not feel for their providers²²⁻²⁶ Like the flossing example above, self-report dramatically overestimates actual adherence behavior.

Key Stakeholders Align in their Denouncement of Self-Report

There appears to be a growing consensus across the HIV prevention community that "self-report" is an inadequate method of identifying who is in-need of additional adherence support services. While "self-report" is convenient, evidence and testimonials from diverse stakeholders across the HIV prevention landscape indicate that there is a desire for more accurate, effective adherence monitoring methods. In this mini-review, we will briefly synthesize the emerging evidence from four distinct sources (the FDA, clinical trials, PrEP patients, and providers) and propose a solution to ensure all patients receive the support needed to protect them from HIV acquisition.

FDA's initial approval of Truvada: Citing the importance of adherence in determining PrEP's utility, the FDA acknowledged the significance of using accurate monitoring methods and describes the inadequacy of relying on self-reported adherence. When the FDA first approved Truvada for use as PrEP in 2012, they noted that *"self-reported adherence and adherence by pill count were unreliable... high self-reported adherence was poorly predictive of measurable intracellular concentrations of the active forms of the Truvada components whereas low self-reported adherence was predictive of non-measurable drug concentrations."*²⁷

Clinical trials: Several PrEP demonstration projects internationally and in the United States collected both self-reported and biomarker-based adherence data to assess the association between adherence and protection from HIV-acquisition.^{24,9,26,28} In a 2018 meta-analysis of PrEP adherence studies, Sidebottom et al list 6 unique studies that collected both self-reported and plasma-based adherence testing data from disparate patient populations (i.e., men who have sex with men, transgender women, heterosexuals, people who inject drugs, adolescents etc.) (Table 1). There was a consistent and

Table 1. PrEP Studies That Measured both Self-Reported and Plasma-Based Adherence

Year	Study Name	% with Detectable TDF or FTC in Plasma	Self-report (%)
2010	iPrEx	51	95
2012	TDF2	80	94
2012	FEM-PrEP	24	95
2013	Bangkok tenofovir study	67	94
2013	ATN 082 (Project PrEPARE)	20	62
2015	VOICE	30	87-90

Adapted from Sidebottom et al⁹

substantial divergence between self-reported adherence and detectable drug levels in plasma, with discrepancies as high as 95% self-reported adherence and 24% adherence per plasma drug levels.⁹

Patient preferences: Importantly, several studies suggest that many patients want closer adherence monitoring. Hunt et al describe the acceptability of urine adherence monitoring with the vast majority of patients at their Philadelphia PrEP clinic claiming urine adherence testing would be a helpful component of routine PrEP care.²⁹ Moreover, Koester et al studied the acceptability of drug detection feedback among participants in the iPrEx Open Label Extension (OLE) study. Half of the participants found biomarker based adherence monitoring to be useful and motivating with no negative reactions recorded from the 59 patients who were interviewed.³⁰ This speaks to the potential for OAM to not only facilitate adherence interventions for non-adherent individuals but also incite a positive feedback loop that keeps adherent clients sustainably protected from HIV acquisition. As one 22-year-old African American patient from Chicago claimed:

“It’s just that it solidifies that all your efforts are being... So you know you’re taking this pill, you see it in your bloodstream. You know it’s working. You know it’s there. You know you’re not doing it just in vain.”

Provider preferences: A recent survey of 30 PrEP-prescribing providers across the United States illustrates a disconcerting trend in providers’ perceived ability to adequately monitor PrEP adherence. These 30 providers were approached *via* a third-party survey service to gauge their perceptions of the importance of PrEP adherence and their preferences for adherence monitoring methods. 80% of providers (24/30) claimed that they are “worried about the potential of patients seroconverting after being initiated on PrEP, due to non-adherence.” Nevertheless, 97% of providers (29/30) consistently use “self-report” to assess PrEP adherence, despite only 10% (3/29) believing this method is accurate. Conversely, only three of the 30 providers use biomarker-based adherence monitoring to assess adherence, all of whom believe this method is accurate.

Call to Action: Use Objective Methods to Monitor PrEP Patients’ Adherence

In sum, insights from the FDA, clinical trials, patients, and providers all indicate that “self-report”, the current standard of care adherence monitoring method, is insufficient in identifying those struggling with PrEP adherence. Initiating at-risk individuals on PrEP is an important factor in curbing new HIV infections in the United States; however, these PrEP uptake gains will be nullified if we lack the tools to accurately identify non-adherence and allocate the appropriate support services.

There are certainly populations and research settings in which self-report does correlate with actual adherence. Still, having an objective test removes the onus of “truth telling” and “lie detection” from patients and providers. The results of OAM provide an empirical foundation upon which to build trust and mitigate the barriers to adherence that all patients inevitably face at some point in their PrEP journey. For adherent individuals, per the Koester et al study mentioned above, OAM can provide positive feedback

that their diligence is “working” and that they are succeeding in taking the daily pill that will keep them protected from HIV acquisition.

Introducing OAM for PrEP has a corollary in the field of HIV-viral load testing for people living with HIV on ART. With ART, providers rely on viral load monitoring to determine if the medications are “working” (e.g., the virus is suppressed and the patient is unlikely to acquire opportunistic infections or transmit HIV to others). In the United States, it would be unusual for an infectious disease doctor to make a clinical decision regarding ART support (i.e., allocating adherence support services or referring to additional resistance testing) without first conducting a routine viral load test. While discussing patients’ unique lifestyle and barriers to adherence is surely indispensable, having an objective data point to complement and contextualize these qualitative descriptions is integral to making informed clinical decisions. Optimal PrEP care should be no different; objective adherence data empowers providers to make informed clinical decisions and ensure PrEP is “working” for their at-risk patients.

CONCLUSION

Taking a pill every single day for an extended period of time is inherently difficult, particularly for otherwise-healthy people. The barriers to optimal adherence, especially for those who are traditionally-marginalized or vulnerable to HIV infection, are numerous, diverse, and ever-changing.^{9,29,31-34} We all face occasional lulls in health-seeking behavior. Thus, we cannot settle for antiquated adherence monitoring tactics that are subjective and prone to biases, even if they are cheap and easy. We need to equip our PrEP providers with the most accurate and patient-friendly tools available. These tools can help PrEP achieve its potential to end the HIV epidemic.

CONFLICTS OF INTEREST

Giffin Daughtridge, Elijah Kahn-Woods, Casper Enghuus, and Shane Hebel are paid employees of UrSure, Inc.

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