

Innovations in Bench to Bedside HIV Prevention

From Hair to Urine: Innovations in Bench to Bedside HIV Prevention

In 2012, a once-a-day-pill ? pre-exposure prophylaxis [1] (PrEP) ? was proven to protect against sexually acquired HIV infection if taken regularly. Now widely accepted (though not always accessible) by many individuals at higher risk for contracting the virus, one of the more pressing emerging research questions is how to measure adherence to the regimen. The answers may offer greater data precision regarding the length of time it takes PrEP to become fully protective (current research suggests 7 to 20 days [2]), and how long-term adherence may impact other elements of an individual?s health.

Monitoring and improving such adherence is critically important for preventing HIV infection in high-risk populations. Since its inception, clinicians and researchers have largely relied on PrEP users reporting their own schedule of maintenance.

Self-reported medication use is complicated ? and unfortunately not always very reliable. Patients frequently self-report higher adherence [3] than is revealed by pharmacological testing [4], so researchers have to seek out other ways of determining whether one is regularly taking their drugs. Innovatively, one of the ways this is being explored in HIV is via testing hair samples [5]. An effective way to objectively measure PrEP adherence [6], it?s in many ways preferable to testing blood samples given the ease of collecting hair strands, and that they do not require cold storage or biohazardous handling.

However, while great for research, hair levels are not practical for routine use in patient care.

The required equipment is expensive, and there are no standard point-of-care (POC) testing methods for hair levels ? meaning results are not immediately available to discuss with patients. Given this, searching for equally accurate but easier to implement solutions has been at the forefront of many researchers? minds. One such investigator at UCSF has found one:

?I?m just so much more excited by urine than hair!? says UCSF Professor of Medicine and Medical Director of Ward 86 Dr. Monica Gandhi [7], with a laugh.



Monica Gandhi,
MD, MPH

Dr. Gandhi and her research collaborators have been working with Abbott [8] (formerly known as Alere, a POC manufacturer) to develop a rapid, low-cost, easy-to-perform urine testing method [9] using an antibody-based test (or immunoassay). Comparable in accuracy to the gold standard test of measuring drug levels via mass spectrometry, this new test is far more suitable for POC testing than either hair or blood tests. It works by detecting antibodies that are directly linked to the PrEP medication *tenofovir*. (Tenofovir is also the most common antiretroviral treatment worldwide, so the urine test can be utilized for monitoring ART adherence).

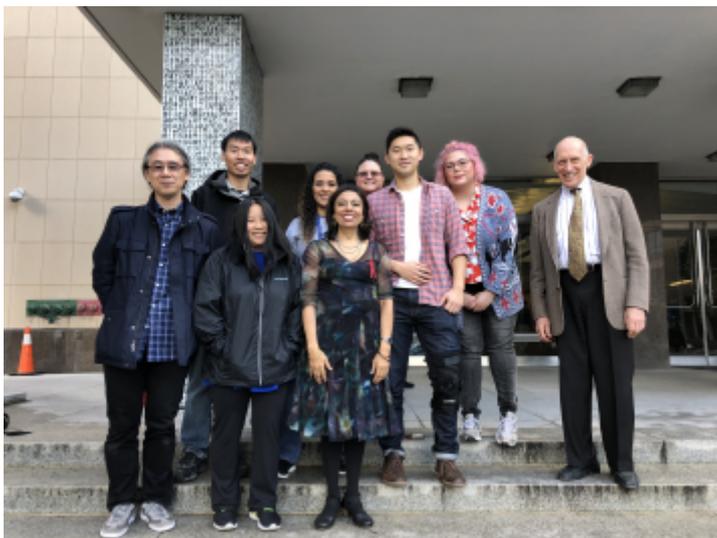
Similar to the way a home pregnancy test works, the test kit is in the form of a dipstick ? after being exposed to urine, it reveals whether the patient has stayed adherent to their PrEP medication or not.

?This is especially ideal for monitoring adherence of patients in resource-limited settings,? notes Gandhi.

Providing immediate feedback to patients is key in regions where making multiple return trips to a clinic for results is not feasible. Urine is easy to obtain in the field, and in rural areas where providers may lack the training or supplies to draw blood ? or the laboratory infrastructure to test such samples ? this is even more essential.

Of course, biomedical measures aren't the only concern when it comes to new prevention approaches. A key subsequent step is effectively communicating non-adherent results to patients in a way that encourages improved maintenance of prophylactic treatment.

The outlook is promising. Evidence shows offering an objective metric of adherence is self-motivating enough for behavior change. In fact, in previous HIV PrEP trials, research participants have shown an interest in immediate drug level monitoring, viewing it as either validating or motivating.



Gandhi's Hair Lab Team

Of notable importance, Gandhi's findings can offer lessons in behavior change far beyond the HIV field. Despite its relevance, therapeutic drug monitoring is not a major focus of many disciplines in medicine. Citing World Health Organization [10] recommendations, Gandhi says more people worldwide would benefit from efforts to improve medication adherence than from the development of new medicines, in line with the National Council on Patient Information and Education [11]'s description of non-adherence as America's "other drug problem."

As Gandhi further details, "adherence issues plague every field. We take at face value that people are taking their drugs, and then they come in with [poor health outcomes]. We *want* to motivate people. In a very non-judgmental way, we want to figure out what is truly happening in terms of adherence with objective tests.

"Drug level monitoring for PrEP adherence is more advanced than other fields of medicine, but the tests are mainly applicable to research settings. We need low-cost easy-to-use tools to get adherence testing to the real world."

Fortunately for the HIV community, Gandhi and colleagues are headed in that direction.

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