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Dear Dr. Mermin,

Last year you will recall that NCSD wrote you on two separate occasions raising concerns about the sexually transmitted disease (STD) screening interval for PrEP users as presented in the CDC resource "Pre-exposure Prophylaxis for the Prevention of HIV Infection in the United States-2014." Those letters were sent on February 2nd and April 7th, 2015 and we appreciate the responses we received on each of those letters on February 23rd and July 20th, respectively. We felt then, and feel now, that a lack of clear guidance to providers and patients on recommended routine STD screening intervals for PrEP users would lead to less than optimal screening and in turn, allow asymptomatic STDs to spread, especially rectal and pharyngeal gonorrhea infections, almost 90 percent of which are asymptomatic,[i] and syphilis.

As you noted in your reply correspondence, the issues for making a stronger recommendation on STD screening intervals for persons on PrEP are 1) lack of evidence that a regular screening interval at three months for persons on PrEP was warranted; and 2) not all persons on PrEP may be "high-risk" for "non-HIV" STDs.

First, we concur that not all persons on PrEP are at increased risk for acquiring other STDs such as chlamydia, gonorrhea, and syphilis. For example, for those persons in serodiscordant relationships and only engaging in sexual activity with one another, even a six month interval of STD screening as recommended in the CDC PrEP guidance may be unnecessary. It seems however, as PrEP has seen greater take up in the real world, that this is likely a more extraordinary situation and instead of being the barrier to a stronger recommendation on STD screening intervals for all PrEP users, it ought to become the noted exception.

This leads us to the second point which is the ongoing need to look at the most current evidence that suggests current PrEP guidance on STD screening is not sufficient. As you know, the current PrEP guidance states "STI testing [is] recommended for sexually active adolescents and adults" on PrEP at least every six months (p. 38 of the guidance document), but that STD symptom assessment should be done every three months. As most STIs are asymptomatic,

relying on symptomology is problematic, especially given that a clinical visit to ensure "patients are still HIV negative" is recommended every three months. In other words, there is already a recommended provider interaction at three months so taking advantage of that opportunity to align routine HIV testing and STD screening seems most likely to assure optimal sexual health, and as recent evidence suggests, urgently needed.

At the recent 2016 Conference on Retroviruses and Opportunistic Infections (CROI) in Boston, new data were presented by Dr. Stephanie Cohen and colleagues that looked at patients on PrEP and enrolled in a demonstration project to examine rates of bacterial STD infection, and proportion of cases that would be missed if they had not been screened for STDs at three month intervals. The study reconfirmed that STIs are extremely common among PrEP users, condomless anal intercourse was frequent, and that based on existing PrEP guidance of assessing STD symptoms at the three month interval, 34 percent of gonorrhea, 40 percent of chlamydia, and 20 percent of syphilis infections would have gone undetected. Leaving active infections undetected among PrEP users creates additional opportunities for infections to spread and clinicians should not miss opportunities to screen regularly, detect infections earlier, and adequately treat them to break the chain of transmission. [http://www.croiconference.org/sessions/quarterly-sti-screening-optimizes-sti-detection-among-prep-users-demo-project]

We would also note that Dr. Sarit Golub provided a complimentary presentation at CROI that looked at PrEP users in a community-based PrEP demonstration project in New York City. Her analysis reached similar conclusions as Cohen and colleagues, finding that relying solely on STD symptom assessment would have missed a startling 77 percent of STDs at the three month interval and 68 percent at the nine month interval. Golub and colleagues also went a bit further, essentially to where NCSD recommended the guidance be changed last year: "Routine STI testing at each PrEP prescription visit appears warranted, with particular attention to those with a past STI history." [http://www.croiconference.org/sessions/sti-data-community-based-prep-implementation-suggest-changes-cdc-guidelines]

As you know, the 2014 STD Surveillance report issued by CDC late last year found that for the first time since 2006, rates for all three commonly reported STDs in the United States were on the rise. It is critical that we do not miss existing opportunities to find active infections among persons already accessing care and especially in the face of a rising disease burden that threatens to overwhelm the capacity of public health and other health care providers. The evidence is becoming increasingly clear that the 2014 PrEP guidance must be changed to recommend routine STD screening among PrEP users, with perhaps some exceptions such as that mentioned above, every three months when PrEP prescriptions are being refilled and a user's health is being monitored.

We continue to have interest in engaging you further in this effort. To that end, we would welcome the opportunity to convene a discussion among researchers and clinicians to further shed light on how we can take advantage of PrEP as the astounding bio-medical intervention that

it is and in a way that does not continue to contribute to other adverse sexual health outcomes, such as those we are seeing related to other STDs.

Best,

William (Bill) Smith
Executive Director

CC: Dr. Eugene McCray, Director, Division of HIV/AIDS Prevention, NCHHSTP
Dr. Gail Bolan, Director, Division of STD Prevention, NCHHSTP
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Dr. Laura Cheever, Associate Administrator, HIV/AIDS Bureau, HRSA

[i] Kent CK, Chaw JK, et al, Prevalence of Rectal, Urethral, and Pharyngeal Chlamydia and Gonorrhea Detected in 2 Clinical Settings Among Men Who Have Sex with Men: San Francisco, California, 2003. Clinical Infectious Diseases, 2005: 41:67-74.