



HPTN

HIV Prevention
Trials Network

Acceptability of HPTN 077

The George Washington University

HPTN Clinical Research Site

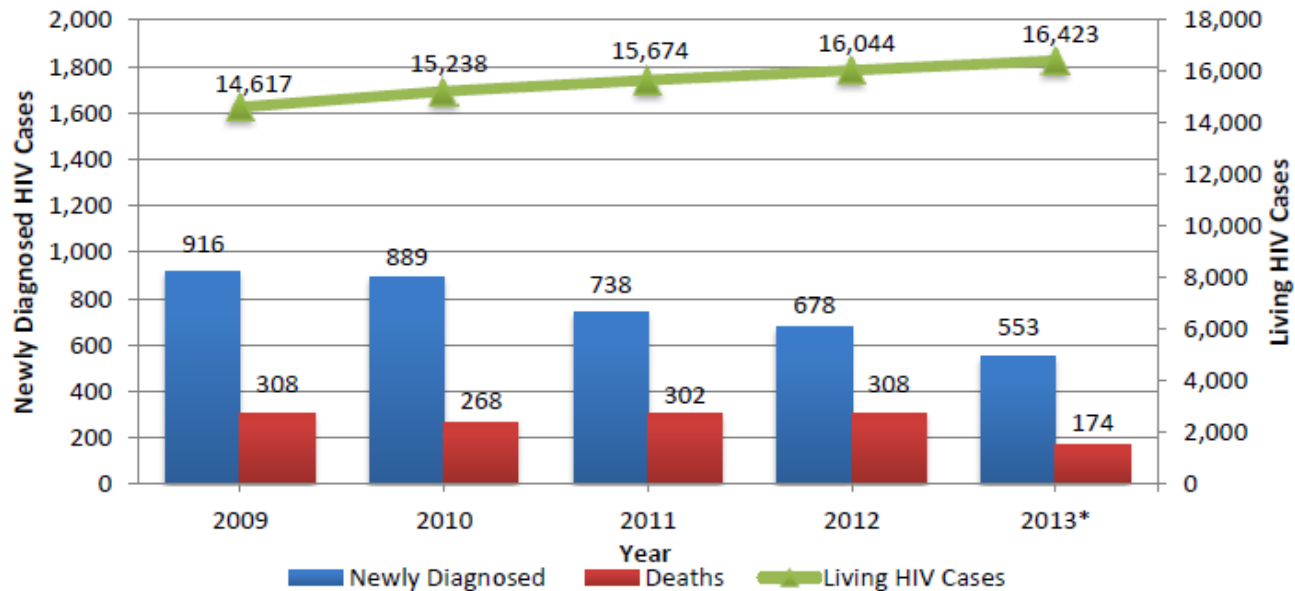
16 June 2016

Outline

- The epidemic in DC
- Prior HPTN studies, the context for injections
- Our experience with HPTN 077
- Discussion

The HIV Epidemic in DC

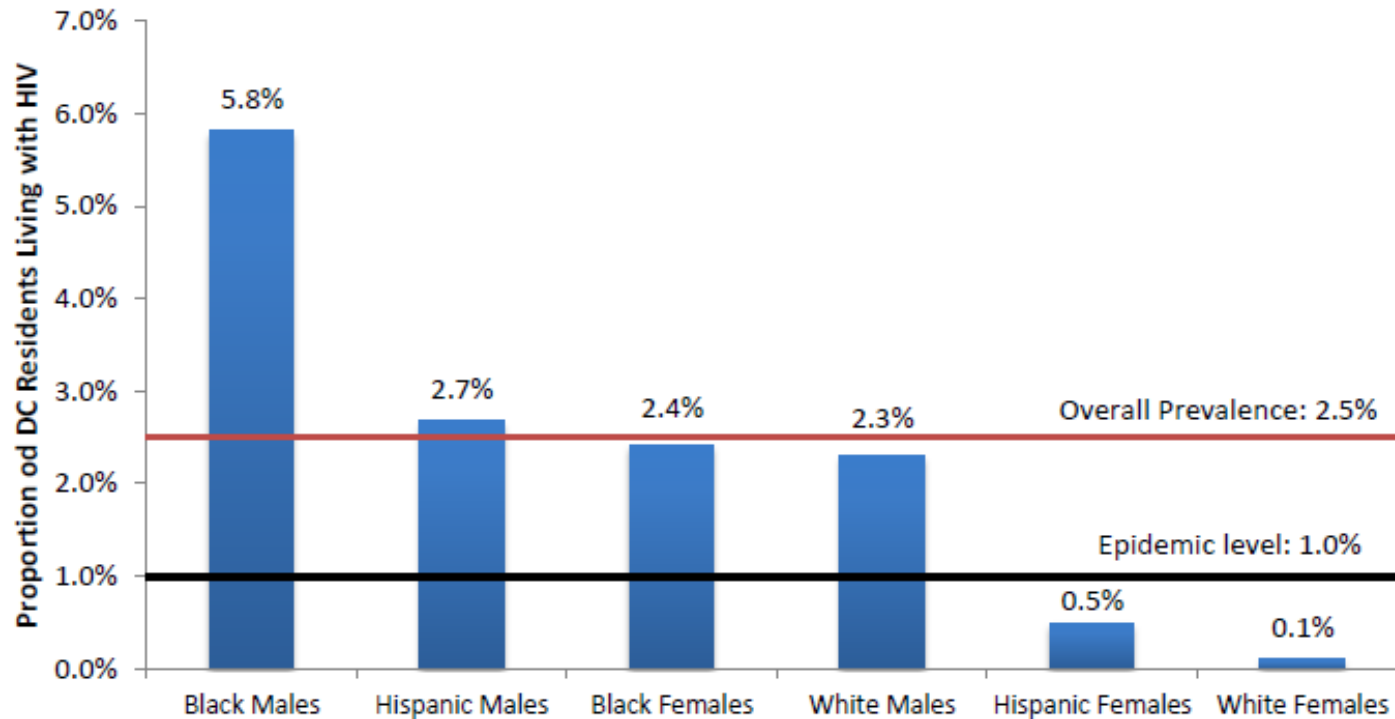
Figure 1. Newly Diagnosed HIV Cases, Deaths, and Living HIV Cases by Year
District of Columbia, 2009-2013



* Information concerning death in 2013 is limited to District of Columbia vital records only. The number of deaths documented in 2013 may increase as information from other sources (i.e., NDI and SSDMF) becomes available.

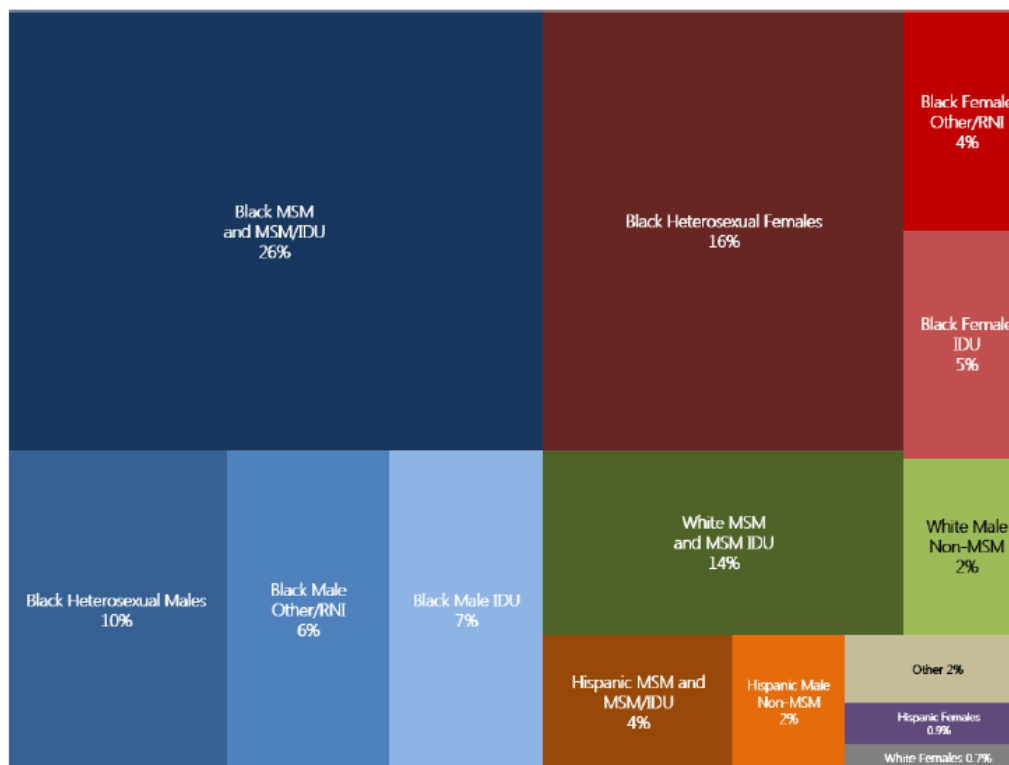
The HIV Epidemic in DC

Figure 4. Proportion of Residents Diagnosed and Living with HIV by Race/Ethnicity and Sex
District of Columbia, 2013



The HIV Epidemic in DC

Figure 5. Proportion of Living Cases of HIV Diagnosed in DC, by Race/Ethnicity, Sex and Mode of Transmission, District of Columbia, 2013 (N=16,423)



*MSM: includes men who have sex with men;
IDU: injection drug use;
RNI: risk not identified;

Other: perinatal transmission, hemophilia, blood transfusion, and occupational exposure (healthcare workers); Non-MSM: All modes of transmission excluding MSM and MSM/IDU.

Hispanic Male non-MSM: Heterosexual, IDU, RNI and other modes of transmission

Black Female Other: RNI and other modes of transmission

Black Male Other: RNI and other modes of transmission

Hispanic Female: All modes of transmission

White Female: All modes of transmission

Other: All persons of other race with all modes of transmission

Completed HPTN Studies at GW

- HPTN 061
 - To determine the feasibility and acceptability of a multi-component intervention for Black MSM, including peer health system navigation (N=227 in DC)
- HPTN 064
 - To determine the feasibility of estimating HIV incidence in women at risk for HIV and evaluate feasibility of enrolling/following cohort of women (N=210 in DC)
- HPTN 069
 - Phase II study of safety and tolerability of maraviroc as PrEP (N=70 in DC)
- HPTN 073
 - Truvada as PrEP + C4 counseling among black MSM (N=75 in DC)

Ongoing and new HPTN Studies at GW

- HPTN 077
 - Early Phase II study of safety and tolerability of long acting injectable PrEP using GSK744LA (N=23 in DC, follow up ongoing)
- HPTN 085
 - A phase 2b study of VRC01 in reducing acquisition of HIV-1 infection among men and transgender persons who have sex with men (just opened!)
- HPTN 083
 - Phase study of injectable cabotegravir in reducing acquisition of HIV-1 infection among men and transgender persons who have sex with men (coming soon!)

Other studies being conducted in our public health research clinic

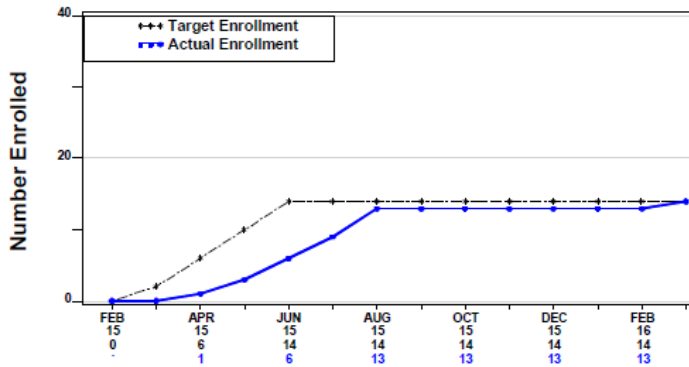
- Telemedicine for transgender women of color
- Overcoming structural barriers to HIV prevention utilization by Black MSM
- Sexual violence / biomarkers in pre- and post menopausal women
- Molecular epidemiology
- Survey research
- Culturally-tailored PrEP resource center for young Black MSM



We are having a great experience with HPTN 077...

Figure 1E. GWU CRS

Total Enrolled: 14 Enrollment Target: 14 Enrollment Needed: 0



Enrolled 23 out of target 22!

GWU CRS
Site ID 260

12
100% (12/12)
0% (0/12)
83% (10/12)
17% (2/12)
0% (0/12)
0% (0/12)
0% (0/12)
10
100% (10/10)
0% (0/10)
100% (10/10)
0% (0/10)
0% (0/10)

Retention currently 100%!

A lot of it was new since low risk, healthy people...

Notes about recruitment and engagement

- CAB meetings, CAB mailing list
- Fliers at campuses
- Word of mouth
- Social media
- Craigslist

- *Did not use our typical venue based approaches since for low risk people*

- Differentiation between *injectable vaccine vs. long acting ARV injectable*

Are you interested in helping prevent HIV?

The George Washington University is conducting a NIH-funded study testing the safety and tolerability of a new non-vaccine injectable drug that may one day be able to prevent the spread of HIV

Low risk, HIV-negative persons ages 18 to 65 may be eligible to receive up to \$1,175 for participating in a two year study

To learn more and to see if you are eligible
call (202) 652-4709 | email gwuphc@gwu.edu

Participants are seen by appointment only at the
GW Public Health Research Clinic
2013 H Street, NW, Washington, DC, 20006
and the GW Medical Faculty Associates, Inc.
2150 Pennsylvania Avenue, NW, Washington, DC 20037

GWU Public Health Clinic (202) 652-4709 gwuphc@gwu.edu	GWU Public Health Clinic (202) 652-4709 gwuphc@gwu.edu	GWU Public Health Clinic (202) 652-4709 gwuphc@gwu.edu	GWU Public Health Clinic (202) 652-4709 gwuphc@gwu.edu	GWU Public Health Clinic (202) 652-4709 gwuphc@gwu.edu	GWU Public Health Clinic (202) 652-4709 gwuphc@gwu.edu	GWU Public Health Clinic (202) 652-4709 gwuphc@gwu.edu	GWU Public Health Clinic (202) 652-4709 gwuphc@gwu.edu	GWU Public Health Clinic (202) 652-4709 gwuphc@gwu.edu	GWU Public Health Clinic (202) 652-4709 gwuphc@gwu.edu	GWU Public Health Clinic (202) 652-4709 gwuphc@gwu.edu	GWU Public Health Clinic (202) 652-4709 gwuphc@gwu.edu	GWU Public Health Clinic (202) 652-4709 gwuphc@gwu.edu
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Short social media (e.g., facebook, twitter, , craigslist, grinder, etc.) script and print media with low risk specified

Are you interested in helping to end the HIV epidemic? We are conducting a new NIH funded study of injectable medications that may one day help stop the spread of HIV and we are looking for a few HIV-negative, low risk, and healthy individuals. Eligible participants may be able to receive up to \$1,175 over 2 years. If you or anyone you know might be interested in participating, please call 202 652 4709 or email gwuphc@gwu.edu

Shorter social media (e.g., facebook, twitter, craigslist, grinder, etc.) script and print media

Help prevent HIV! Join HPTN 077. Eligible participants may receive up to \$1,175 over 2 years. Interested in participating? gwuphc@gwu.edu

Shorter social media (e.g., facebook, twitter, craigslist, grinder, etc.) script and print media

Are you at low risk for HIV? Join HPTN 077. Participants may receive up to \$1,175 over 2 years. Interested in participating? gwuphc@gwu.edu

HPTN 077 to help stop HIV. Participants may receive up to \$1,175 over 2 years. Interested? gwuphc@gwu.edu
Are you at low risk for HIV? Join HPTN 077 & test an injectable medication to prevent HIV. Interested in participating? gwuphc@gwu.edu

Join HPTN 077 & test a non-vaccine injectable medication to prevent HIV. Interested in participating?
gwuphc@gwu.edu

Issues about implementation

- Once understood not a vaccine, more acceptable
- Preferred more injections x 1 to fewer injections x 2
- No one discontinued due to negative injection perception
- Easy to manage in pharmacy, clinic, data
- Very few AEs
- Clear protocol
- Excellent support of CMC and protocol team

Discussion and Q&A

ACKNOWLEDGEMENTS

The HIV Prevention Trials Network is sponsored by the National Institute of Allergy and Infectious Diseases, the National Institute of Mental Health, and the National Institute on Drug Abuse, all components of the U.S. National Institutes of Health.

Thank you

We are looking forward to working together on HPTN 083!

Questions?