



PREP FOR MSM IN THE UNITED STATES: THE WAY FORWARD

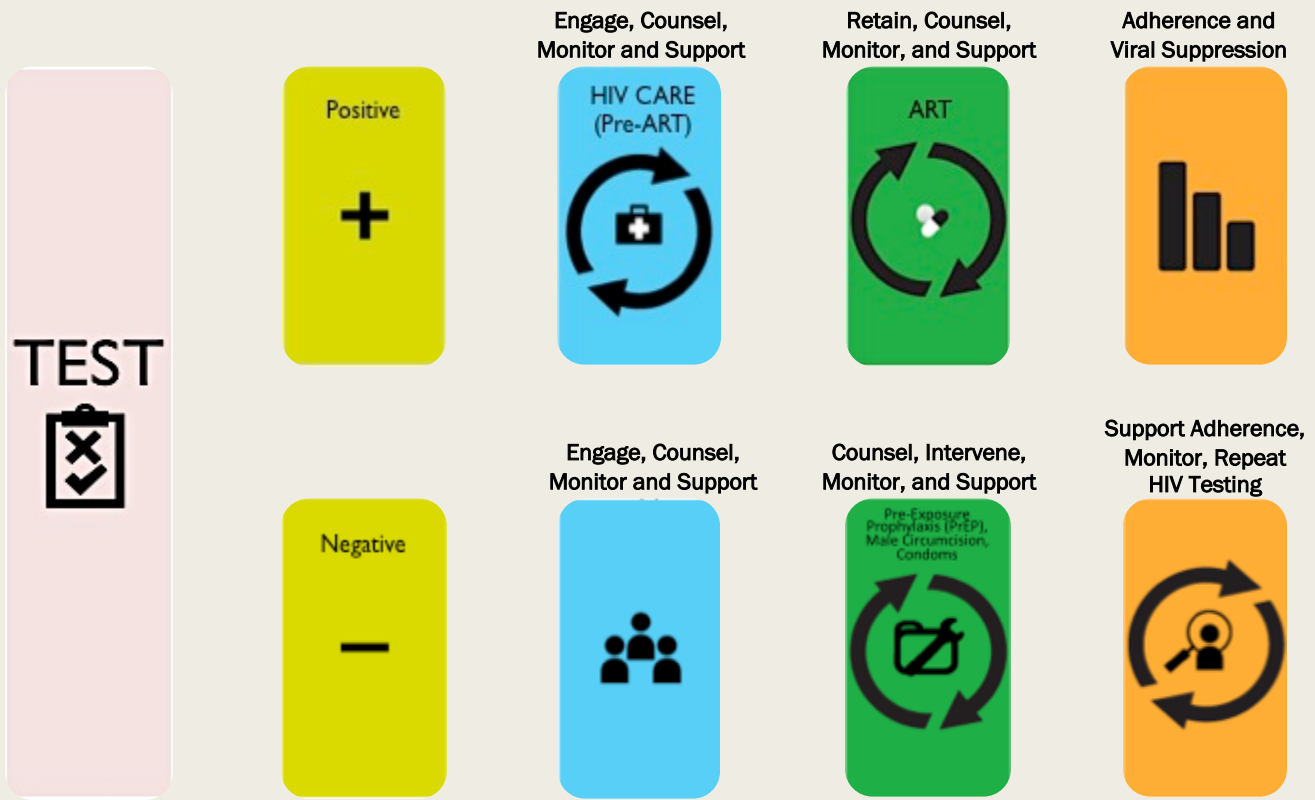
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Wednesday, September 28, 2016

Overview

- Treatment as Prevention (TasP)
- PrEP
 - What We Know
 - What's Coming
- Conclusions

HIV Prevention

- Prior to TasP, PrEP and PEP ways to prevent getting HIV through sex were:
 - Abstinence
 - Having sex with only one person who is HIV negative and who agrees not to have sex with anyone else
 - Using a condom correctly every time you have sex
- New ways to prevent getting HIV are needed
- Recent promising research for HIV treatment and prevention



CARE CONTINUUM FOR HIV+ AND HIV- PERSONS

What is PrEP?

- PrEP (Pre-Exposure Prophylaxis) is an approach that has shown the use of ARV medications can reduce the risk of HIV infection in HIV-negative people.
- In mid-2012 the FDA approved Truvada® to be used for prevention of HIV
- Used as part of a HIV prevention package (risk reduction counseling and condoms)

PrEP Recommendations

- Targeted to individuals at high risk for HIV infection
- Taken as a daily medication consistently
- Women trying to conceive or pregnant should discuss risks/benefits with health care provider
- Delivered as part of a comprehensive package of prevention services
- Must be HIV negative

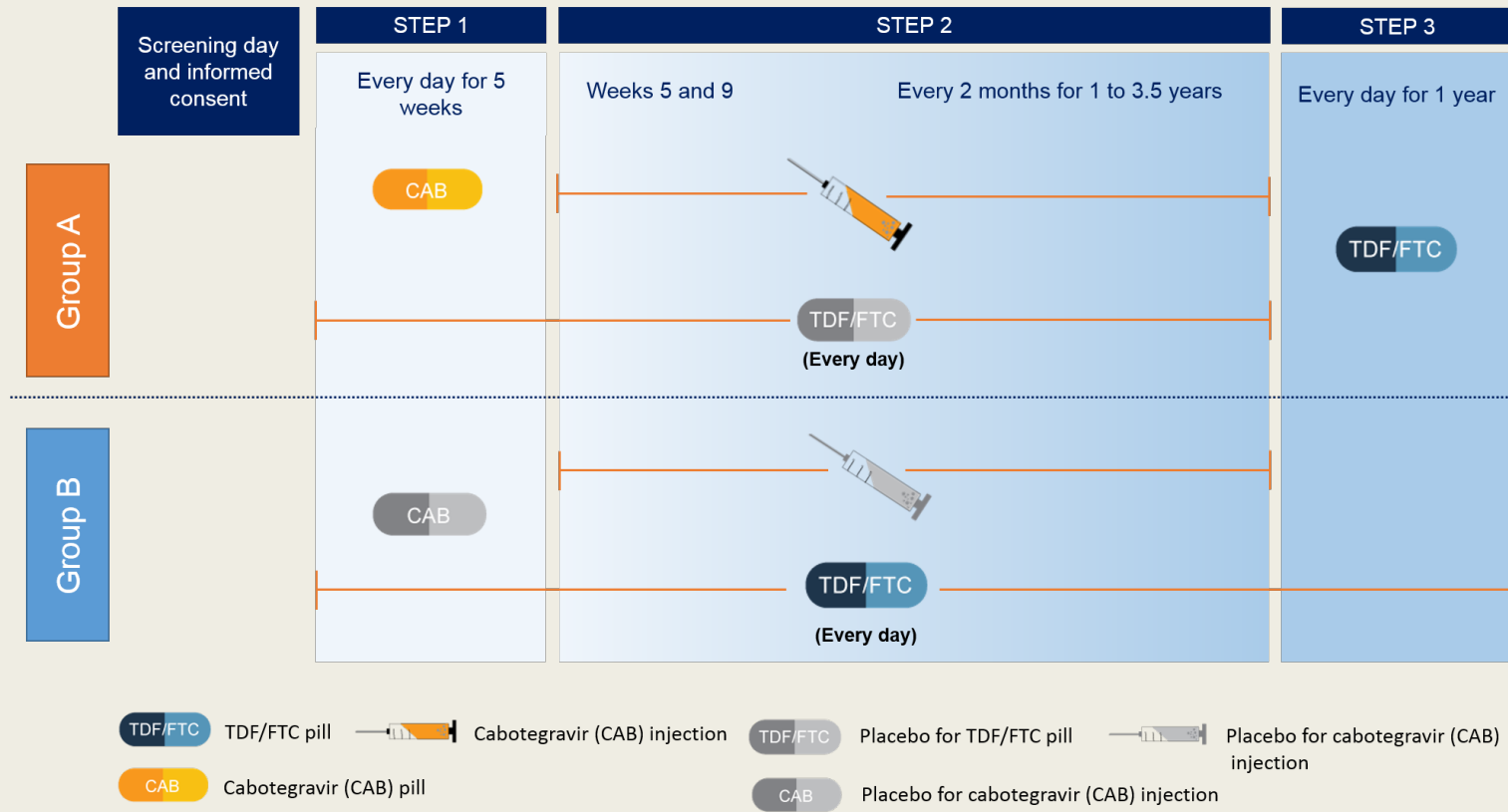
www.cdc.gov/hiv/pdf/guidelines/PrEPguidelines2014.pdf

Injectable PrEP



- Investigational injectable products
 - TMC278LA (long lasting formulation of rilpivirine)
 - GSK1265744 (long lasting formulation of cabotegravir)
- Treatment and prevention
- Long-acting
- Better drug penetration

HPTN 083



Rectal Microbicides (Topical PrEP)

- Tested as daily use and at the time of sex
- Provides delivery of drug to tissue where cells are easy targets for HIV
- Drug absorption into the body low, therefore less potential for toxicity
- Broad range of formulations under evaluation:
 - Gels (\pm applicator)
 - Enemas
 - Rectal inserts (suppositories)

MTN-017

Truvada®

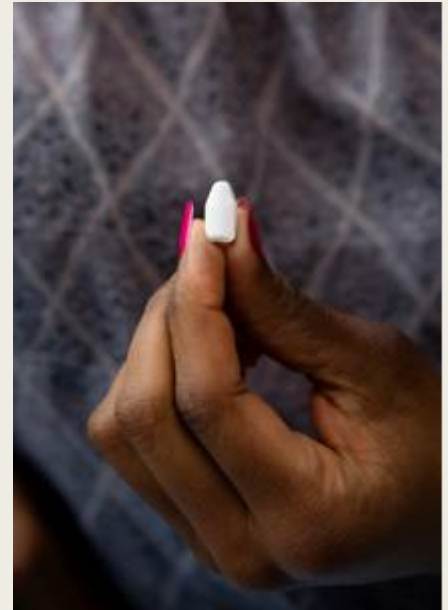


Tenofovir reduced
glycerin gel



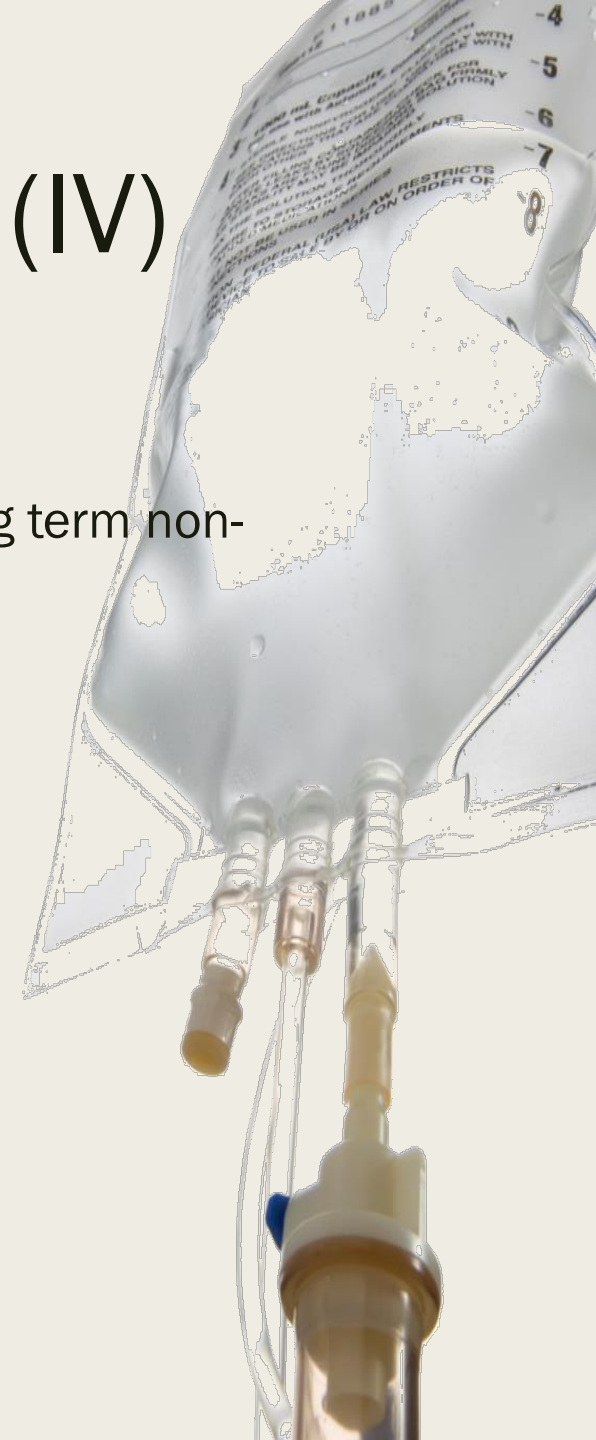
Rectal Studies Being Developed

- MTN Phase 1 study of a combination fast dissolving tablet (rectal insert)
 - CONRAD collaboration
 - Men and women (N = 30)
 - Single dose study under development
 - Elvitegravir vs. Elvitegravir & tenofovir
- MTN Adonis Phase 1 study
 - Is digital/phallic insertion equivalent to applicator insertion of a microbicide?
 - HIV uninfected MSM & TGW (N = 16)
 - Dapivirine gel

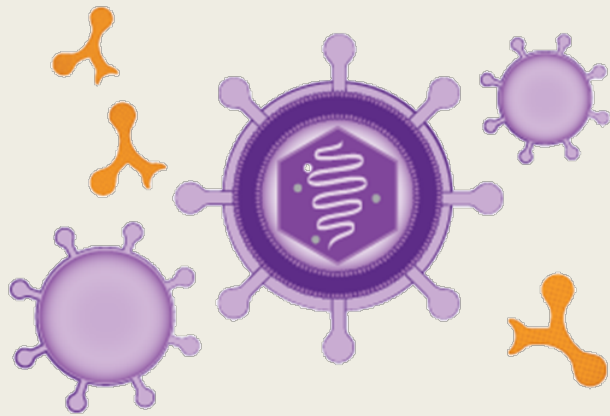


Antibody Infusion (IV)

- Monoclonal antibody VRC01 identified in long term non-progressor
- Reduced HIV transmission by 90% in lab
- Prevention and therapeutic potential
- IV administration



How VRC01 Works



Healthy HIV

VS.



HIV neutralized
w/ VRC01

The AMP Studies

Regimen	Cisgender Women in sub-Saharan Africa	MSM & TG People in the Americas	Total
VRC01 10 mg/kg	500	900	1400
VRC01 30 mg/kg	500	900	1400
Control	500	900	1400
Total	1500	2700	4200

10 infusions total and Infusions every 8 weeks
Study duration: approximately 22 months

Final Thoughts

- Development and testing of new biomedical interventions is necessary
- May be several years away from an efficacious vaccine, microbicide or cure
- Need appropriately tailored interventions that consider real world practices

Additional Information

- www.HPTN.org
- www.MTNstopsHIV.org
- www.HVTN.org
- www.NIH.gov