

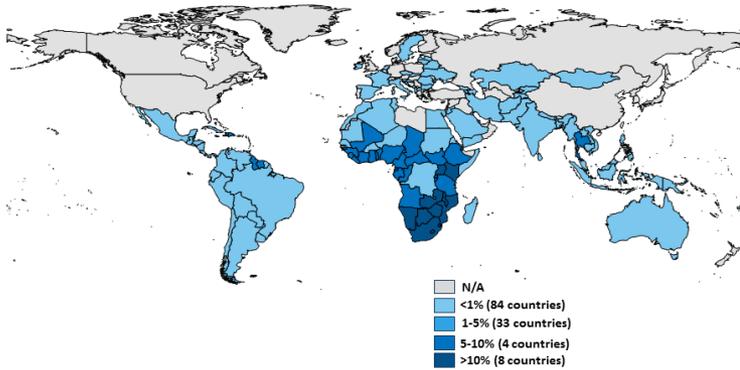
PrEP for all women: no way!!

Women and HIV
Boston, March 2 2018

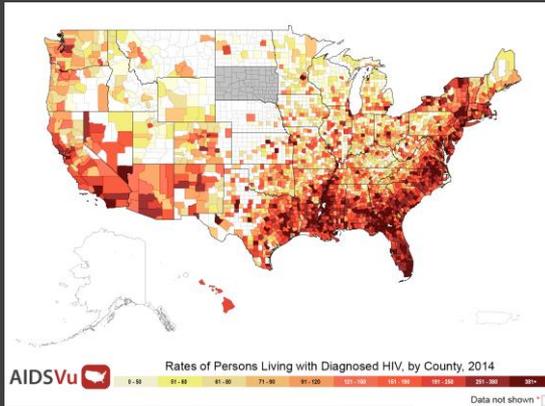
Figure 1

Adult HIV Prevalence, 2016

Global HIV Prevalence = 0.8%



NOTES: Data are estimates. Prevalence includes adults ages 15-49.
SOURCES: Kaiser Family Foundation, based on UNAIDS, AIDInfo, Accessed July 2017



Right thing, Right place, Right time!!

“Oral PrEP (containing TDF) should be offered as an additional prevention choice for people at **substantial risk** of HIV infection as part of combination prevention approaches” WHO Guidelines 2015

Substantial risk of HIV infection is provisionally defined as HIV incidence greater than 3 per 100 person-years in the absence of PrEP.

Poor adherence is a problem

- Adherence in women, especially young women, has been poor.
 - Two placebo-controlled trials that targeted women in high prevalence settings showed very low uptake of PrEP (less than one third) in the active arm and no effectiveness on an intent-to-treat basis
- Among sex workers in South Africa, high rates of loss to follow-up were observed: 71% (n = 156/219) at 12 months. (Eakle R, et al.. [PLoS Med.](#) 2017 Nov 21;14(11):e1002444.)
- Need very high adherence in women for it to be effective-- Little forgiveness for missed doses.
- Less uptake of drug in vaginal than rectal tissue (*Patterson KB et al. Sci Transl Med 2011*)



PrEP

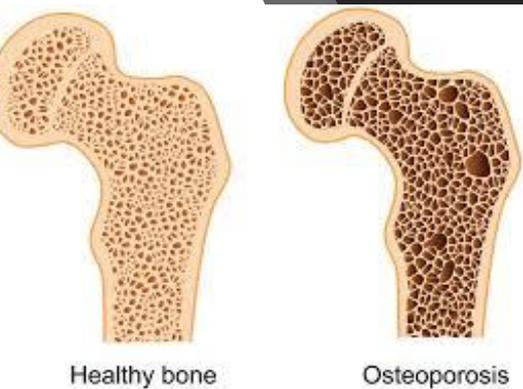


Not Cost Effective for All Women

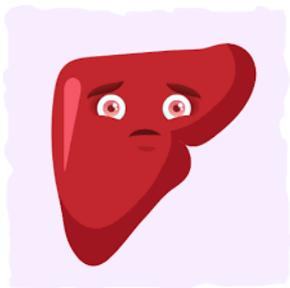
- **PrEP costs are substantial, and include costs for clinic staff, medications, laboratory testing, pharmacy services, community education, provider education and monitoring and evaluation.**
- **Cost effective for serodiscordant couples in Uganda** (Ying R, et al. [J Int AIDS Soc.](#) 2015)
- **Cost saving for high risk young women in South Africa- 18-26 years, incidence of 5-9%** (Wallensky R, et al. JID 2016)
- **Need infrastructure to support PrEP for all-- regular HIV testing, creatine and Hep B testing, adherence support**



There are risks when healthy people take drugs: risk vs benefit



- While Severe long-term toxicity of TDF for HIV treatment is rare, surveillance of large-scale use of PrEP could identify rare but important clinical adverse events. Active surveillance during PrEP scale-up is warranted.
- Lack of safety data on long-term use
- GI disturbances: nausea, vomiting, diarrhea
- Bone density decreases observed in young women using PrEP (Kasonde, et al *PLoSOne* 2014)
- Creatinine testing is preferred before starting PrEP and quarterly during PrEP use (first 12 months) then annually
- Hepatitis B is endemic in many parts of the world where HIV is transmitted. The medications used for PrEP are active against hepatitis B. Withdrawal of active therapy against HBV infection can lead to virological and clinical relapse.



Drug resistance

- How implementing PrEP on a large scale affects resistance overall is unknown, and active surveillance during PrEP scale-up warranted.
- Resistance is rare but does occur
 - Risk with AHI at PrEP initiation
 - 1 HIV multiclass resistance despite good PrEP adherence (Knox CROI 2016)
- Risks that increase resistance:
 - Starting PrEP without knowing that you are already HIV positive.
 - Become infected during a break from PrEP and then not having an HIV test before restarting.
 - Missing too many PrEP doses, so that drug levels are too low to prevent HIV infection.



Prep use during menopause, pregnancy and adolescence?

- Menopause: ex-vivo study, suggests lower concentrations of TFV/TFVdp and FTC/FTCtp in post-menopausal women suggesting higher doses may be needed for post-menopausal women (Nicol MR, et al. The role of menopause in tenofovir diphosphate and emtricitabine triphosphate concentrations in cervical tissue. [AIDS](#). 2018 Jan 2;32(1):11-15.)
- Is the drug as efficacious in pregnancy? Among adolescents? How do hormones effect efficacy?



Proper Implementation requires ALL IN!!

- Even among populations with high incidence and interest in PrEP there have been substantial challenges with rollout.
- PrEP awareness among providers and users needed
- Must address stigma around use
- Adherence and adequate support services are not trivial– insurance and access to drugs issue in low prevalence areas
- Need to do this right so that individuals will use it and adhere!

STIGMA STOPS HERE



PrEP holds promise for women
but it must be offered to those
at greatest risk