

# Safe Conception and Preconception Planning, Counseling and Care

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# Disclosures

- Gilead Pharmaceutical Co: member Scientific Advisory Committee re: PrEP

# Objectives

- **To discuss the rationale for preconception planning, counseling and care (PCC) in the setting of HIV**
- **To discuss PCC interventions that may improve or promote maternal health of women with HIV**
- **To identify research needs in this area**

# ACOG

- *The goal of preconception care is to reduce the risk of adverse health effects for the woman, fetus, or neonate by optimizing the woman's health and knowledge before planning and conceiving a pregnancy.*
  - The importance of preconception care in the continuum of women's health care. ACOG Committee Opinion 313 (reaffirmed 2012):
- Comprehensive family planning and PCC should be offered to all HIV+ women as part of routine primary care (ACOG, CDC, USPHS Perinatal Guidelines)

# Goals of Preconception Care

- Prevention of unintended pregnancy
- Promote appropriate birth spacing
- Optimize maternal before pregnancy and maternal and fetal health during pregnancy
- Prevention of MTCT
- Reduce risk of transmission to uninfected partner

# Representative DHS Data

	TFR	Wanted FR	Unmet need Contracepti on %	HIV % women	HIV % men
Ethiopia (2011)	4.8	3.0	26.3	1.9	1.0
Malawi (2010)	5.7	4.5	26.2	12.9	8.4
Rwanda (2010)	4.6	3.1	20.8	3.7	2.2
Zambia (2007)	6.2	5.2	26.6	16.1	12.3

# Why is PCC Important?

- High rates of unintended pregnancies among HIV+ women
  - Rwanda (n=565 women on ART): after knowing their HIV status 82/132 (62.7%) pregnancies unintended; 85/263 (32.3%) recently sex active not using contraception- (Kikuchi et al. *Biosci Trends* 2011;5:255)
  - Cape Town: 265 HIV+/267 HIV- postpartum women in Cape Town: most recent pregnancy unintended in 61.6% HIV+ and 63.2% HIV- (Crede'. *BMC Public Health*. 2012; 12:197)
  - Uganda: 110 HIV+ (441 men, 659 women): about 1/3 became pregnant, 43% unplanned (53% women, 26% men) (Wanyenze. *JIAS* 2011; 14:35)
  - Sub-Saharan Africa: 66-92% HIV+ women do not want more children, but only 20-43% use contraception (Sarnquist et al. *Curr HIV Res* 2013;11:160)

# Effective Contraception is Under-used

- Kenya HIV+ adolescents (15-19yr): 394/797 (49%) had been pregnant; no difference in PP use of contraception by intendedness (Obare et al. BMC Womens Health. 2012; 12:34)
- Cape Town: 265 HIV+/267 HIV- postpartum women : current contraceptive use 89% in both but largely DMPA-only 6.4% using LARC/LAPC: poor knowledge and lack of provider recommendation (Crede'. BMC Public Health. 2012; 12:197)
- Nationally representative survey of clinicians in S. Africa and Zimbabwe (n=1444): only 14% provide Cu-IUD, 4% LNG-IUD, 16% implants; <5% felt IUDs appropriate for HIV+ women. LARC provision largely limited to physicians, hospitals, urban areas (Morse et al. BJOG 2013; doi: 10.1111/1471-0528.12290 )



# Emergency Contraception

- Should be considered with episode of unprotected sex or broken condom-can reduce pregnancy by approx 75% if taken within 72 hr (preferred method LNG 0.75 mg q 12 hr x 2 )
- 30 in-depth interviews with providers at private and public health facilities in Durban, South Africa: often reluctant to provide EC because felt EC likely to discourage regular use of contraception and increase the risk of unprotected sexual intercourse (Mararaj et al. J Fam Plann Reprod Health Care. 2011; 37:89)

# Why is Preconception Care Important?

- HIV has an adverse effect on fertility and there is potential improvement in fertility with ART
  - HIV associated with decrease in pregnancy rates and increase in pregnancy loss (JAIDS 2000;25:345; Lancet 1998;351:9096; Am J Epidemiol 2000; 151:1020; Int J STDs/AIDS 2006; 17:842)
  - Prospective cohort (Johannesburg): 4 public sector ART clinics (8/09-3/11):745.2 person-years (PY)-pregnancy incidence rate: 21.6/100 PY [95% CI: 18.5-25.2] (62% unplanned); Unmet need for contraception was 50% higher in women initiating ART in the past year as compared to women on ART>1 year (Schwartz et al. Plos One 2012; 7(4):e36039
    - By 2 yr after ART initiation, approx ¼ women had had at least 1 unintended pregnancy
    - Rates of unintended pregnancy high, including those ART initiating ART with lower CD4 counts and higher viral loads

# Why is Preconception Care Important?

- High rates of HIV serodiscordance (SDC) among sexual partnerships
  - Estimated ~140,000 HIV SDC heterosexual couples in US, about half of whom want more children (Am J Obstet Gynecol 2011;204:488)
  - In Zambia and South Africa, approximately 20% of couples in the general population were found to be discordant (Lurie et al., 2003; McKenna et al. AIDS. 1997 Sep;11 Suppl 1:S103).
  - In Kenya, 50% of spouses of HIV-infected persons are HIV negative (450,000; DHS, 2003)
  - In Botswana, of people who came into VCT center for testing because their partner was HIV positive, 57% were negative (Tebelopele, 2007)

# Why is Preconception Care Important?

- Fertility desires and intentions among HIV+ women
  - Most studies show that pregnancy desires and reproductive decision-making are similar between HIV-infected and HIV-uninfected women (Fam Plann Perspect 2001; 33:144; AIDS Behav 2007; 11:927; AIDS Care 2012; 24:1)
  - Comparison of live birth rates before and in the era of effective ART found 150% increase in live birth rate among HIV+ women versus 5% increase among HIV- women (WIHS) (Sharma et al. AJOG 2007;196:541)
  - Survey of 450 HIV+ women in UK(AIDS Care 2011; 23:1093): 41% who initially reported no desire to have children changed their mind following advances in HIV care
  - High cultural/personal value placed on pregnancy

# Why is Preconception Care Important?

- High rates of comorbidities potentially affecting maternal or fetal health
  - 43% of Canadian HIV+ women report current or history of domestic violence (AIDS Pt Care STDs 2010;24:763)
  - DHS data: 11 sub-Saharan African countries: 46,697 women: 25.1% hx of physical violence, 10.6% hx of sexual violence (Hung et al. Obstet Gynecol. 2012;119:975)
  - Cape Town: 227 HIV+ women receiving ART: 10% hx of verbal or physical abuse since HIV diagnosis (Myer et al. Trop Med Int Health. 2007 ;12:1484)
  - KwaZulu Natal: antenatal depression (n=387): 38.5% with depression, 38.3% had thought of harming themselves; HIV risk factor for depression ( Mannikam et al. S Afr Med J. 2012;102:940)
  - Hepatitis: approx 7-9% of HIV+ pts have chronic HBV infection (PLoS One. 2013;8(3):e58468; PLoS One. 2013;8(3):e59346.)

# Tuberculosis and HIV

- TB-HIV interactions
  - Women of reproductive age have higher rates of progression of TB infection to disease than men in same age range
    - 80% of all mortality due to TB in women occurs in reproductive age
- HIV and TB independent risk factors for maternal mortality
  - S Africa: 3.2X RR death with TB-HIV coinfection; in some tertiary hospitals, TB-HIV account for 14-15% of all maternal mortality (AIDS 2001;15:1857)
  - India: TB incidence 5/100 py postpartum HIV+ women (Gupta.CID 2007)
    - 12% maternal mortality vs 1% HIV infection alone (2.2 RR adjusted for factors independently assoc with mortality)

# Anemia

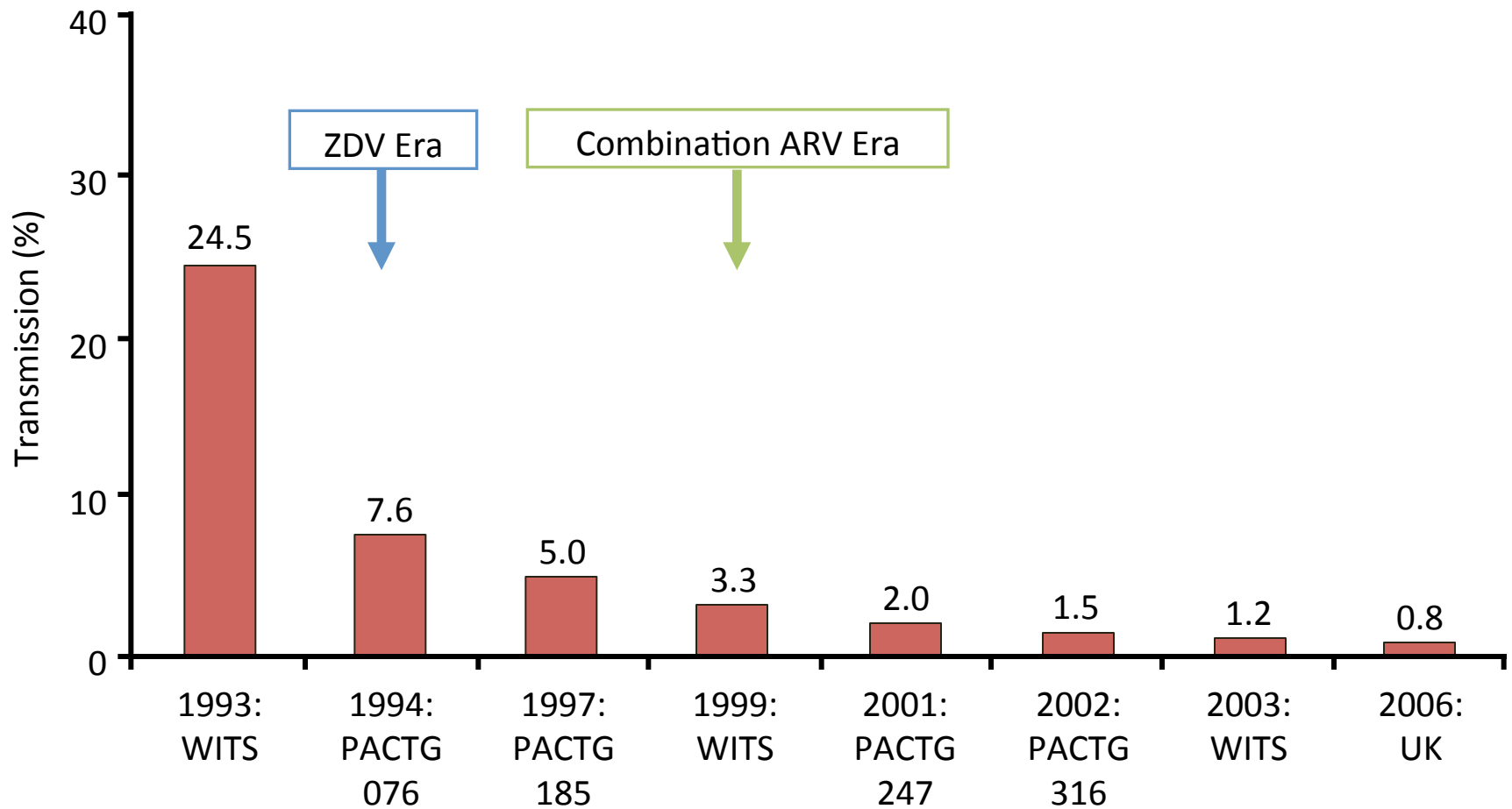
- Anemia is independent predictor of mortality and HIV progression (O' Brien. JAIDS 2005;40:219; Belperio. Am J Med 2004;116:27S)
  - Present in 20-80% HIV+ individuals
- Anemia associated with maternal death, LBW, poor mental development in children
- Rates of anemia high (nutritional, malaria, parasitic infection)
  - Prevalence in HIV+ women high; increased with more advanced disease
  - Nigeria: 985/2318 (42.5%) HIV+ pregnant women had Hgb<11 g/dl; short inter-birth intervals, OIs, use of ZDV, CD4<200 cells/mm<sup>3</sup> independently associated (Ezechi et al. Arch Gynecol Obstet. 2013;287:239)
  - Co-infection with malaria and HIV doubles risk of anemia (Oresh et al. Int J Gynaecol Obstet. 2013;120:23)6
  - 328 HIV+ pregnant women: 38% helminths, 21% malaria,10% both (Rwanda) (Crowther et al. Acta Trop. 2012;124:179)

# Why is Preconception Care Important?

- **Advances in HIV care and prevention of perinatal transmission**
  - **MTCT rates <1% achievable with preventive interventions, including effective ART (AIDS 2008;22: 973)**
  - **Life expectancy and ART:**
    - **Resource-rich settings:**
      - **ATHENA cohort<sup>3</sup>: Modeled life expectancy for asymptomatic pts who remained naive and without AIDS at Wk 24 after Dx similar to age- and sex-matched uninfected controls: 52.7 vs 53.1 years (Van Sighem et al. AIDS 2010;24: 1527)**
    - **Resource-limited settings:**
      - **Data from 6 S. African ART cohorts (n=37,740): with baseline CD4>200 cells/mm<sup>3</sup>, life expectancy 70-86% of HIV- adults of same age/sex; increased by 15-20% when survived 2 yrs after starting ART (Johnson et al. PLoS 2013;10:e1001418)**
      - **KwaZulu Natal population cohort (n>101,000): increase in adult life expectancy from 49.2-60.5 yr from 2003-2011 (Bor et al. Science 2013;339:961)**



# Change in MTCT in Resource-Rich Countries



# Core PCC Interventions

- Counseling: tobacco, alcohol, substance abuse, safer sexual practices, and other risk behaviors
- Contraception to reduce unintended pregnancy and achieve appropriate birth spacing
- Identify and treat anemia
- Nutritional assessment and interventions
- Screen and treat genital tract infections
- Diagnose, treat or optimize other medical conditions
  - Opportunistic infections (e.g., TB) treatment or prophylaxis
- Avoid drugs with teratogenic potential, radiation or other environmental exposures

# Core PCC interventions (cont)

- Immunizations (e.g., rubella, tetanus, HBV)
- Family history/genetic risk
- Assess CD4 cell count/HIV-RNA and HIV status of partner
- Initiate/modify ART, if indicated
  - Ensure tolerability, lack of toxicity, effectiveness
- Address other psychosocial and mental health issues (depression, interpersonal violence, etc)
- Safe conception: interventions to reduce risk to uninfected partners
- Long term care plans

# CDC: Contraceptive Categories

	<b>COC/ P/R</b>	<b>POP</b>	<b>DMPA</b>	<b>LNG- impl</b>	<b>Cu- IUD</b>	<b>LNG -IUD</b>	<b>Spermi cides</b>
High risk	1	1	1	1	2	2	4
HIV	1	1	1	1	2	2	3
AIDS	1	1	1	1	3/2	3/2	3

- Category 1: no restriction on use
- Category 2: advantages generally outweigh risks
- Category 3: risks usually outweigh advantages
- Category 4: unacceptable health risk if used

CIC = combined injectable contraceptives; COC/P/R = low-dose combined oral contraceptives/patch/ring; Cu-IUD = copper intrauterine devices; LNG-impl = levonorgestrel implants; LNG-IUD = levonorgestrel-releasing intrauterine devices; POC = progestogen-only pills.

# Hormonal Contraception: Issues to Consider

- High efficacy
- Alternate routes of delivery: oral, transdermal, vaginal ring, subdermal implant, injection, intrauterine system
- Based on route of delivery, longer duration of action and greater convenience
- No effect on HIV progression (Heffron et al. AIDS. 2013 Jan 14;27(2): 261)
- Potential non-contraceptive benefits:
  - Decrease in menstrual blood loss and anemia
  - Decreased risk of pelvic inflammatory disease and ectopic pregnancy
  - Decreased incidence of ovarian, endometrial, colorectal cancers
  - Menstrual control

# Unintended and Unwanted Pregnancies Among HIV+ Women

**Table 2** Number of unintended and unwanted HIV-positive births per year in the absence of antiretroviral prophylaxis and cost savings associated with family planning relative to preventing mother-to-child transmission of HIV (PMTCT) services, by PEPFAR country

PEPFAR country*	Unintended births to all women <sup>4 17 18</sup> (%)	Unwanted births to all women <sup>4 17 18</sup> (%)	Annual no of births to HIV+ women <sup>23</sup>	No of unintended HIV+ births <sup>†</sup>	No of unwanted HIV+ births <sup>†</sup>	Cost savings of averting unintended HIV+ births <sup>‡</sup> (US\$)	Cost savings of averting unwanted HIV+ births <sup>‡</sup> (US\$)
Botswana	58.4	6.2	11370	1992	211	384839	40856
Mozambique	19.7	3.7	95482	5643	1060	1090169	204752
Namibia	33.7	23.3	9316	942	651	181956	125803
South Africa	52.8	17.3	222415	35231	11543	6806187	2230058
Zambia	40.3	18.9	73668	8906	4177	1720639	806950
Ethiopia	34.9	17.3	65585	6867	3404	1326587	657592
Kenya	44.5	19.6	77799	10386	4575	2006504	883763
Rwanda	39.8	12.5	14107	1684	529	325405	102200
Tanzania	23.5	5.2	99775	7034	1556	1358925	300698
Uganda	45.8	12.5	79950	10985	2998	2122217	579208
Côte d'Ivoire	28.7	4.9	30412	2618	447	505863	86367
Nigeria	14.5	5.0	187544	8158	2813	1576076	543474
Haiti	47.4	29.8	4946	703	442	135875	85423
Vietnam	22.9	11.9	3796	261	136	50381	26181

\*Guyana is excluded due to lack of data.

†Calculated as: proportion of unintended (or unwanted) births × annual number of births to HIV-positive women × 30% vertical transmission rate in absence of prophylaxis.<sup>16</sup>

‡Calculated as: [number of unintended (or unwanted) births × \$857] − [number of unintended (or unwanted) births × \$663].<sup>24</sup>

# Safer Conception Strategies for Serodiscordant Couples

- Screen/treat GTIs
- Timed intercourse during most fertile period
- PrEP/ART
- HIV+ woman
  - Home insemination
- HIV+ man
  - Assisted reproductive technology

# Pre-exposure Prophylaxis (PrEP)

- Mixed results in terms of efficacy
- PrEP works but...it has to be taken
  - FEM-PrEP: although reporting 95% adherence, <40% women had evidence recent TDF/FTC use at visits matched to HIV infection window for women with HIV seroconversion (NEJM 2012)
  - VOICE: only 28-29% had detectable drug blood levels when randomized to drug (CROI 2013)



**Table 2. Who can provide which PCC components?**

PCC Components	Type of Provider				
	OB/GYN	HIV provider (MD or mid-level provider)	Primary care provider	Nurse	Lay provider
Assess childbearing plans/desires	X	X	X	X	X
Assess partner HIV status, including HIV testing	X	X	X	X (rapid tests)	X (rapid tests)
Counsel re: importance of planned childbearing	X	X	X	X	X
Screen for and Counsel re: drug, alcohol, smoking and effect on pregnancy	X	X	X	X	X
Counsel re: contraceptive options	X	X	X		
Provide contraception	All (including implant, IUD, tubal sterilization, Essure)	Condoms, combined oral, patch, ring; DMPA	Condoms, combined oral, patch, ring; DMPA	Condoms*	Condoms*
Counsel re: HIV and pregnancy	X	X	X	X	X
Comprehensive HIV, medical and reproductive history	X	X	X		
Counsel re: ART/PrEP as prevention	X	X	X	X	X
Implement ART		X	X **	X***	
Implement PrEP	X	X	X		
Screen for STIs/semen analysis	X	X	X		
Counsel re: medical /surgical and obstetrical/gyn history re: effect on pregnancy/pregnancy outcome	X				
Optimize medical conditions prior to conception	X	X	X		
Counsel re: medications in pregnancy and possible adverse effects on fetus	X				
Discuss /manage infertility	X				
Screen for depression/abuse	X	X	X	X	X

# Research Issues

- How to motivate uptake and sustained use of longer acting, less user-dependent contraception for women who do not desire pregnancy
- How to implement and integrate PCC interventions into HIV care
- The role of PrEP/ART in safe conception-implementation, supporting adherence
- Outcomes research re: PCC effectiveness for maternal health