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May 13-14, 2011
Orlando, FL

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Women's Health Issues

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Outline

- **Human Papilloma Virus (HPV)**
 - Infection/complications
 - Vaccination recommendations
- **Cervical cancer screening for HIV-infected women**
- **Contraception modalities for HIV-infected women**
- **Reproductive issues in HIV-infected or at risk women**

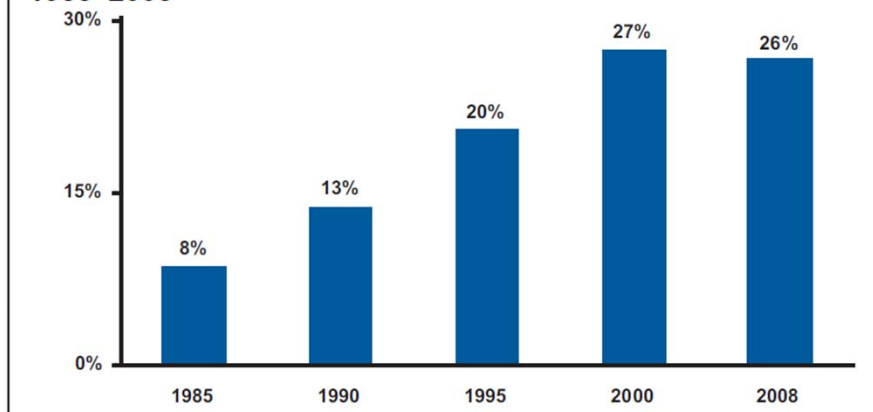


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Figure 1: Women as a Proportion of New AIDS Diagnoses, 1985–2008^{1,2,13}



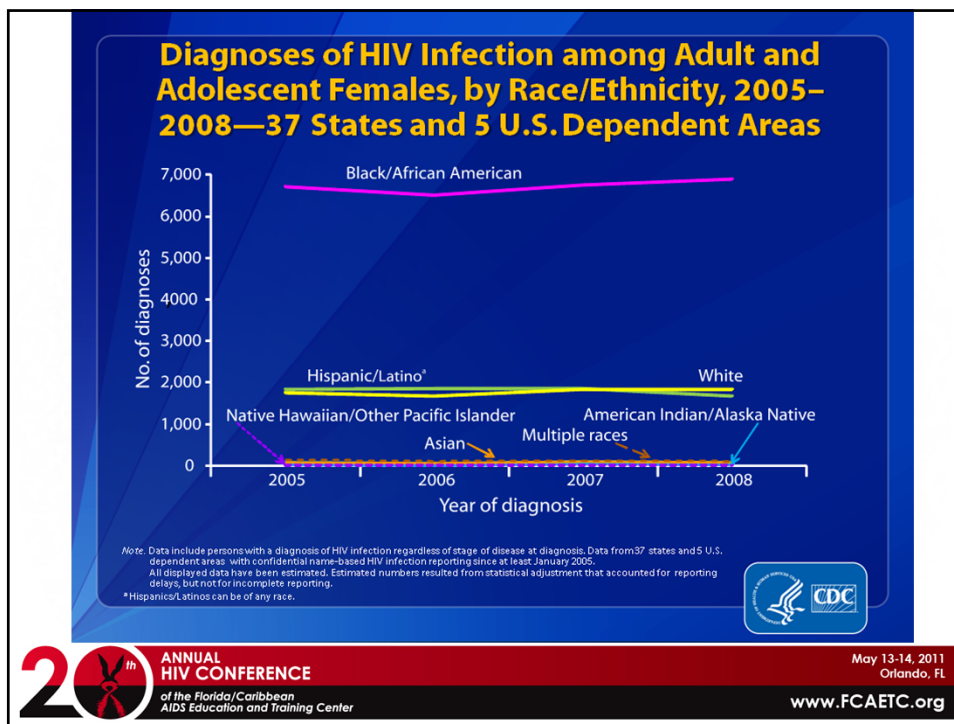
The Henry J. Kaiser Family Foundation. *HIV/AIDS Policy Fact Sheet: Women and HIV/AIDS in the United States*. November 2010. Web. 19 Feb 2011.
<http://www.kff.org/hivaids/upload/6092-08.pdf>.



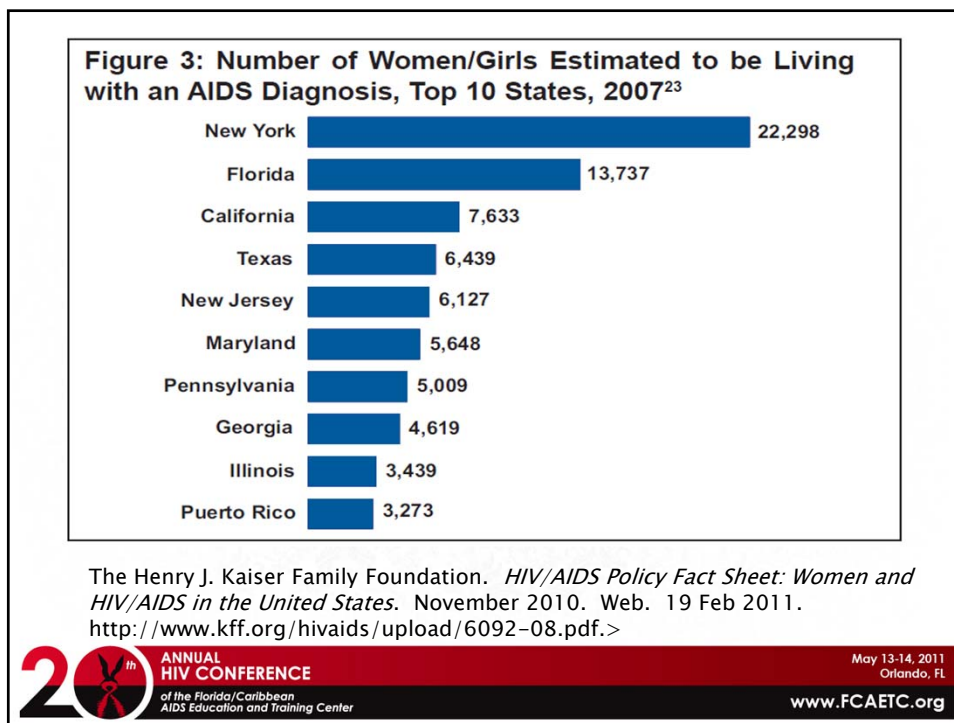
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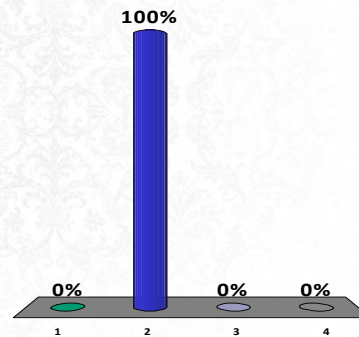
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Case 1

An 18 year old woman, newly diagnosed with HIV infection presents for care. She is concerned about risk for cervical cancer. What do you tell her about the HPV vaccine?

1. **The HPV is safe and effective for HIV-infected women and provides some protection against cervical cancer.**
2. The HPV vaccine provides complete protection against cervical cancer.
3. The HPV vaccine provides complete protection from genital warts as well as cervical cancer.
4. She should get the vaccine so she doesn't have to have PAP smears anymore.



Human Papillomavirus Infection (HPV)

- **Sexually transmitted virus with more than 100 types**
 - Use of condoms can help decrease risk of infection
- **Infection with HPV increases the risk of cervical and anal dysplasia**
 - HPV types 16 and 18 cause cervical cancer as well as anogenital cancers
 - HPV types 6 and 11 are the cause of genital warts and recurrent respiratory papillomatosis

Human Papillomavirus (HPV) and Women with HIV/AIDS

- Increased risk for HPV infection and cervical intraepithelial neoplasia (CIN)
- Increased incidence, prevalence and persistence of HPV, including high risk subtypes, which increases with immunosuppression



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2 Available HPV Vaccines

- | | |
|---|---|
| <p>➤ Bivalent Vaccine (Cervarix®)</p> <ul style="list-style-type: none"> • HPV types 16 and 18 <ul style="list-style-type: none"> • Cause 70% of cervical cancers | <p>➤ Quadrivalent Vaccine (Gardasil®)</p> <ul style="list-style-type: none"> • HPV types 16 and 18 <ul style="list-style-type: none"> • Cause 70% of cervical cancers • HPV types 11 and 6 <ul style="list-style-type: none"> • Cause 90% of genital warts |
|---|---|

Women who have received HPV vaccine should continue routine cervical cancer screening because 30% of cervical cancers are caused by HPV types other than 16 or 18



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HPV Vaccine

- **Recommended for administration prior to initiation of sexual activity**
- **Can be given to women with abnormalities on cervical cancer screening or genital warts**
 - May protect against types not already acquired
- **Prevaccination tests for HPV are not indicated**
- **The HPV vaccine series consists of three doses**
 - 0, 1-2 months later, and 6 months after 1st dose

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Adult Vaccination Schedule


FIGURE 2. Vaccines that might be indicated for adults, based on medical and other indications — United States, 2011

INDICATION ▶	Pregnancy	Immunocompromising conditions (excluding human immunodeficiency virus [HIV]) ^{3,5,6,13}	HIV infection ^{3,6,12,13} CD4+ T lymphocyte count		Diabetes, heart disease, chronic lung disease, chronic alcoholism	Asplenia ¹² (including elective splenectomy) and persistent complement component deficiencies	Chronic liver disease	Kidney failure, end-stage renal disease, receipt of hemodialysis	Health-care personnel
			<200 cells/μL	≥200 cells/μL					
Influenza ^{1,*}			1 dose TIV annually						1 dose TIV or LAV annually
Tetanus, diphtheria, pertussis (Td/Tdap) ^{2,*}	Td		Substitute 1-time dose of Tdap for Td booster; then boost with Td every 10 years						
Varicella ^{3,*}		Contraindicated	2 doses						
Human papillomavirus (HPV) ^{4,*}			3 doses through age 26 years						
Zoster ⁵		Contraindicated	1 dose						
Measles, mumps, rubella ^{6,*}		Contraindicated	1 or 2 doses						
Pneumococcal (polysaccharide) ^{7,8}			1 or 2 doses						
Meningococcal ^{9,*}			1 or more doses						
Hepatitis A ^{10,*}			2 doses						
Hepatitis B ^{11,*}			3 doses						

* Covered by the Vaccine Injury Compensation Program For all persons in this category who meet the age requirements and who lack evidence of immunity (e.g., lack documentation of vaccination or have no evidence of previous infection) Recommended if some other risk factor is present (e.g., on the basis of medical, occupational, lifestyle, or other indications) No recommendation

MMWR. February 4, 2011;60(4):1-4.

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The incidence of invasive cervical cancer is not higher in those HIV positive women who receive regular screening and recommended follow-up treatment.

Massad LS, et al. *Obstet Gynecol* 2004;104:1077-85.
Massad, LS, et al. *Cancer* 2009;115:524-30.

What is the Recommended Screening for HPV Related Diseases?

- **Inspect the entire genitalia and anal region for visible signs of warts, intraepithelial neoplasia or invasive cancer.**
- **Obtain cervical cytology by PAP testing.**
- **A digital examination of the vaginal, vulvar and perianal region and the anal canal should be performed to feel for masses**

Kaplan JE, et al. *MMWR Recomm Rep* 209;58(RR-4):1-207.



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Cervical Cancer Screening

ACOG	ACS
Start at age 21 (Level A)	Start 3 years after first intercourse, but no later than age 21
Conventional or liquid based PAP acceptable	Same
Screening can be discontinued for women with total hysterectomy for benign reasons and no prior high grade CIN	Same
Consider discontinuing screening at 65-70 if no abnormal cytology in past 10 years and low risk factors	Same, except stop at age 70

www.cancer.org/Healthy/FindCancerEarly/CancerScreeningGuidelines/american-cancer-society-guidelines-for-the-early-detection-of-cancer. Accessed February 28, 2011
Obstet Gynecol. 2009 Dec;114(6):1409-20.



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Case 2

- **Your third clinic patient of the morning is a 25 year old woman newly diagnosed with HIV. You do her intake physical including GU/rectal examination and PAP smear. When does her PAP need to be repeated?**



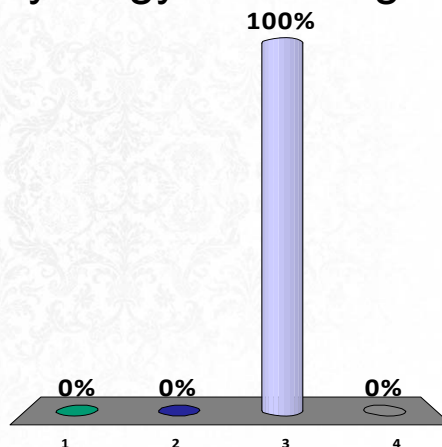
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How often should HIV-infected women undergo cervical cytology screening?

1. **Twice in first year after diagnosis, then annually thereafter**
2. Twice a year
3. Every 2 years, if last screen was normal
4. Every 3 years, if over age 30 and prior 3 PAPs normal



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Cervical Cancer Screening in Women with HIV

- **Current DHHS and ACOG guidelines**
 - Cervical cytology screening twice in the first year after diagnosis of HIV and annually thereafter
 - Refer patients with ASC-US or higher grade abnormality for routine colposcopy
 - Currently, HPV testing has no role in triage of HIV-infected women with abnormal cytology results, though it is used to triage HIV-negative women in this situation

*Obstet Gynecol 2009;114:1409-20. MMWR Recomm Rep 2009;58(RR-4):1-207.



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“All HIV-infected women of childbearing age should be asked about their plans and desires regarding pregnancy upon initiation of care and routinely thereafter (A-III).”

Aberg JA, et al. HIV Primary Care Guidelines. CID 2009;49:651–81.

Birth Control Options



Mirena IUD - Intra Uterine Device

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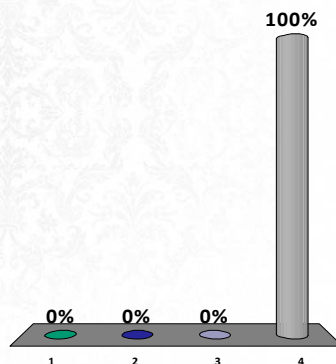
Case 3

- A 25 year old woman on combination antiretroviral therapy (CART) with a ritonavir boosted PI is using condoms. However, she knows that sometimes condoms fail to prevent pregnancy and requests birth control pills. What do you tell her?



Women taking combination antiretroviral therapy (CART) including a ritonavir boosted PI should not rely on which of the following as a sole method of birth control:

1. Oral hormonal contraceptive
2. Depo medroxyprogesterone acetate (Depo-Provera®)
3. Intrauterine device (IUD)
4. None of the above are effective in combination with ritonavir (Norvir®)

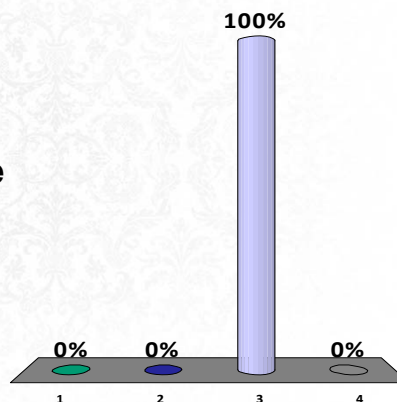


Contraception

- **All contraception methods are effective for HIV-infected women not on ART**
- **HIV positive women on antiretrovirals**
 - Check carefully for potential drug interactions that might decrease effectiveness of birth control or increase risk of side effects

Which of the following forms of contraception prevents transmission of both HIV and STDs?

1. Hormonal birth control pills
2. Intrauterine devices
3. **Condoms**
4. Depo-medroxyprogesterone acetate (Depo-Provera®)



Condoms

- **Recommend with each sexual act to prevent pregnancy as well as HIV and sexually transmitted infections (STIs)**
- **Associated with higher risk of failure than other contraceptive methods**
 - 15% failure over 1 year
- **Women should be counseled about the greater effectiveness of using a second method of birth control prevention**



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Condoms and Spermicides

- **Condoms**
 - Remind women to use only water based lubricant with latex condoms
- **Spermicides**
 - Nonoxynol-9
 - Does not protect against HIV
 - Mucosal inflammation, irritation, damage
 - Reduces vaginal lactobacilli



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Condoms

- **Female Condoms**

- **Pros**

- Used correctly, can protect against pregnancy and HIV
 - May be option if man refuses male condom
 - Can be inserted up to 8 hours prior to intercourse
 - Many nonlatex for those with latex allergies
 - No spermicides

- **Cons**

- Expensive
 - May make noise during intercourse
 - Outer ring or frame visible outside the vagina



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Intrauterine Devices (IUDs)

- ▶ **2 types in US**

- Paragard®T380A Intrauterine Copper Contraceptive
 - Mirena® (levonorgesterol – releasing intrauterine system)

- ▶ **Safe and effective for HIV infected women**

- ▶ **No increased risk of infection in HIV infected women**

- ▶ **Rapid return to fertility after removal**

- ▶ **No apparent ART interactions, increased viral shedding or increased risk of HIV transmission**

- Does not prevent spread of HIV or other STIs, condom use still advised

Estes CM and Potter JE. FCAETC CareLink. September 21, 2010;11(7).



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Contraception

- **Diaphragm/cervical cap**
 - Spermicides often used that may increase risk of HIV transmission
- **Sterilization**
 - Recommendations are no different than for non-HIV infected women
 - Optimize health status prior to elective surgery
- **These 2 options do not protect against the spread of HIV or other STIs**



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Hormonal Contraception

- **Safe and effective in women with HIV**
- **While hormonal contraception may not change progression of HIV, there are interactions with ARVs and hormonal contraceptives that could affect pregnancy risk**

Richardson BA, et al. AIDS 2007;21:749-53. Cejtin HE, et al. AIDS 2003;17:1702-4.



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Depot Medroxyprogesterone Acetate (DMPA)

- **Dose: 150 mg IM every 3 months**
- **No significant interactions with ARVs**
- **Most common side effects (same as in HIV negative women)**
 - Menstrual irregularities or amenorrhea
 - Weight gain
 - Headaches
 - Abdominal discomfort
 - Dizziness
 - Mood changes

Watts DH, et al. Contraception 2008;77:84–90.



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ACTG A5093: Safety and Tolerability of DMPA Among HIV-Infected Women on ART

Proportion of subjects with HIV RNA levels <400 copies/mL and median CD4+ cell counts at each sampling

HIV RNA < 400 copies/mL	Control ^a (n=16)	Nelfinavir (n=21)	Efavirenz (n=17)	Nevirapine (n=16)
Baseline	7/15 (47%)	19/21 (90%)	16/17 (94%)	13/16 (81%)
Week 2	5/14 (36%)	15/21 (71%)	16/17 (94%)	11/13 (85%)
Week 4	7/16 (44%)	12/19 (63%)	16/17 (94%)	14/16 (88%)
Week 8	6/13 (46%)	13/16 (81%)	15/16 (94%)	8/10 (80%)
Week 12	6/15 (40%)	15/17 (88%)	15/16 (94%)	12/12 (100%)
<i>Median CD4+ cell count (cells/μL)</i>				
Baseline	704	718	725	620
Week 4	692	620	650	671
Week 12	668	702	774	740

Watts DH, et al. Contraception 2008;77:84–90.



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Combined Contraceptive

- **Vaginal Ring (NuvaRing®)**
 - Insert for 3 weeks, then remove for 1 week
 - Safe in HIV+ women
 - Drug interactions with ARVs not well studied
- **Transdermal Patch (Ortho Evra®)**
 - Less variability of hormone levels
 - Interactions with ART not well studied.
- **These may have interactions with ARVs much like oral hormonal contraceptives**

Oral Hormonal Contraceptives

- **Primarily metabolized by sulphate and glucuronide conjugation in the liver as well as cytochrome P450 enzymes**
 - Antiretrovirals can influence metabolism by these pathways

Oral Contraceptives and Antiretroviral Interactions: Ritonavir Boosted PIs

Atazanavir (Reyataz®)/r	Lowers ethinyl estradiol levels. Oral contraceptives should contain at least 35 micrograms ethinyl estradiol.
Other ritonavir boosted PIs	Use alternative or additional method of birth control

DHHS Adult and Adolescent Guidelines. Jan 10, 2011:1-166.
www.aidsinfo.nih.gov/contentFiles/AdultandAdolescentGL.pdf.
 Accessed February 28, 2011



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Oral Contraceptives and ARV Interactions: Unboosted PIs

Atazanavir (Reyataz®)	Oral contraceptives should contain no more than 30 micrograms of ethinyl estradiol or use alternative method
Fosamprenavir (Lexiva®)	Use alternative method

DHHS Adult and Adolescent Guidelines. Jan 10, 2011:1-166.
www.aidsinfo.nih.gov/contentFiles/AdultandAdolescentGL.pdf.
 Accessed February 28, 2011



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Oral Contraceptives and ARV Interactions: NNRTIs

Efavirenz (Sustiva®, Atripla®)	Ethinyl estradiol ↔ Levonorgestrel AUC ↓ 83% Norelgestromin AUC ↓ 64%	Use alternative or additional methods. Efficacy of emergency postcoital contraception with Levonorgestrel may be diminished.
Etravirine (Intelligence®)	Ethinyl estradiol AUC ↑ 22% Norethindrone no significant effect	No dosage adjustment necessary
Nevirapine (Viramune®)	Ethinyl estradiol AUC ↓ 20% Norethindrone AUC ↓ 19%	Use alternative or additional methods

DHHS Adult and Adolescent Guidelines. Jan 10, 2011:1-166.
www.aidsinfo.nih.gov/contentFiles/AdultandAdolescentGL.pdf. Accessed February 28, 2011



Efavirenz Use In Fertile Women

- Pregnancy category D
- Pregnancy testing should be done before using in women of childbearing potential
- Due to teratogenic effects, use of efavirenz should be avoided in women at risk of pregnancy
 - Use should be avoided in 1st trimester
 - Use in 2nd – 3rd trimester only when benefits exceed risks

DHHS Adult and Adolescent Guidelines. Jan 10, 2011:1-166.
www.aidsinfo.nih.gov/contentFiles/AdultandAdolescentGL.pdf. Accessed February 28, 2011



Oral Contraceptives and ARV Interactions: Other Agents

- There are no significant interactions with NRTIs, enfuvirtide, maraviroc or raltegravir



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Contraception and Preconception Care

- Discussion needed if:
 - Patient expresses desire for future pregnancy
 - Patient is not trying to conceive, but is not using appropriate contraception, either
 - Patient expresses uncertainty about reproductive plans
- **GOAL: ensure informed decisions about contraception with prevention of unintended pregnancy and offer preconception counseling if pregnancy is desired**



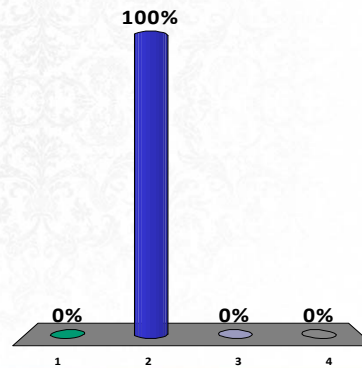
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Which of the following antiretrovirals should be avoided in fertile women not using effective birth control?

1. Emtricitabine/tenofovir (Truvada®)
2. Lopinavir/ritonavir (Kaletra®)
3. Ritonavir boosted atazanavir (Reyataz®)
4. Efavirenz (Sustiva®, Atripla®)



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Women at Risk for Pregnancy

- Review all medications and avoid drugs with potential reproductive toxicity
 - For example efavirenz, lithium, ribavirin, statins, ACE inhibitors and warfarin
- Remember that risks are highest early in pregnancy and may occur before pregnancy recognized



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Case 4

- A 35 year old HIV+ man who has a CD4 count of 560 and a viral load of 120 copies/mL presents with his wife who is HIV negative.
- They desire a child together, but want to minimize the risk of HIV infection in the wife and child. What do you do?



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Preconception Planning

- Improve health before conception
- Safe sex practices and avoidance of sexually transmitted infection
- Counsel to discontinue smoking and substance abuse – refer if needed
- Recommend folic acid before conception
- Ensure vaccinations are up to date

*ACOG. Obstet and Gynecol. 2010;117:1492-1509.



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Preconception Planning

- **Discordant couples hoping to conceive**
 - HIV infected woman with HIV non-infected man
 - Insemination of partner's sperm at time of ovulation
 - HIV non-infected woman with HIV infected man
 - Donor insemination with sperm from non-HIV infected male
 - Limit intercourse to fertile period of woman's cycle (0-4% risk of seroconversion*)
 - Sperm washing – ACOG gives as option, CDC recommends against at this time

*Mandelbrot L, et al. Lancet 1997;349:850-1.

Barreiro P, et al. J Acquir Immune Defic Syndr 2006;43:324-6.



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Preconception Planning

- **Discuss the following:**
 - Ways to optimize mother/child long-term health
 - Possible effects of ART on the fetus
 - Efavirenz is pregnancy category D
 - should be avoided in the first trimester and only used otherwise in pregnancy if benefits outweigh potential risks
 - Goal of CART treatment is undetectable HIV RNA level at the time of delivery
 - If possible, refer to a provider with expertise in preconception counseling

ACOG. Obstet and Gynecol. 2010;117:1492-1509.



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Preconception Planning

- **Discuss the following:**
 - Interventions to reduce risk of mother-to-child transmission
 - In the absence of ART, risk of vertical transmission is about 25%
 - With AZT risk decreases to 5-8%
 - With AZT and scheduled cesarean risk decreases to 2%
 - With effective HAART treatment, maternal HIV RNA less than 1,000 copies/mL and without scheduled cesarean, risk is 2%

ACOG. Obstet and Gynecol. 2010;117:1492-1509.
Int J Gynaecol Obstet. 2001 Jun;73(3):279-81



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Preconception Planning

- **Discuss the following:**
 - Cesarean delivery for HIV infected women with HIV RNA over 1,000 copies/mL
 - Avoidance of breastfeeding
 - Prophylactic ART for the newborn for several weeks

*ACOG. Obstet and Gynecol. 2010;117:1492-1509.



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Already Pregnant?

- **Review the Perinatal Guidelines**
 - aidsinfo.nih.gov/ContentFiles/PerinatalGL.pdf
 - Resistance testing if HIV VL > 500 copies/mL
- **Currently, the preferred ART regimen in pregnant women is**
 - zidovudine/lamivudine (Combivir®) + lopinavir/ritonavir (Kaletra®)



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“With the implementation of recommendations for universal prenatal HIV counseling and testing, antiretroviral prophylaxis, scheduled cesarean delivery and avoidance of breastfeeding, the rate of perinatal HIV transmission has dramatically declined to less than 2% in the United States and Europe.”

DHHS Perinatal Guidelines. May 24, 2010;1-117. Available at <http://aidsinfo.nih.gov/ContentFiles/PerinatalGL.pdf>. Accessed February 23, 2010.



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Summary

- **Screening for HPV related diseases is an important part of care of women with HIV**
 - Cervical cytology should be done every 6 months in the first year after HIV diagnosis and annually thereafter
 - Women with ASC-US or higher pathology should be referred for colposcopy
- **Many women with HIV are of childbearing age and discussion regarding fertility is important**



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Summary

- **Discuss contraception with all HIV + women**
 - Many interactions between ARTs and oral hormonal contraceptives
 - IUDs, depo medroxyprogesterone, and surgical sterilization are effective and safe in HIV infected women on ART
 - Condoms are less effective for birth control but prevent spread of HIV and STIs
- **Conception and safe delivery of health baby is possible for women with HIV who receive good care and are compliant with HAART**



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