Contraception in HIV-Infected Adolescents

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Contraception Use

- **Wide variation in contraceptive prevalence: 15-49yo women - 8% western Africa to 78% in northern Europe**
- **Female sterilization (22%), IUDs (22%), COCs (14%) = >2/3 practice worldwide**
- **Less developed countries 70% contraception relies on female sterilization and IUDs**

Mitchell, 2004

Contraceptive Use and Compliance:

- **Choice dependent on:**
  - Range of methods available
  - Patient choice
  - Prevalent health and religious beliefs
  - Perceptions of method effectiveness
  - Side effects
- **Requires basic knowledge of reproduction and literacy skills to follow written instructions**
- **In some countries, inability to make autonomous decisions d/t political instability, lack of economic independence, prevailing cultural/religious attitudes**

Mitchell, 2004

Need for contraception in HIV infected:

- Fertility not reduced by HIV infection (behavioral change, low BMI, AIDS, intercurrent illness, existing subfertility, IVDU)
- 70% of infected women are sexually active, effective contraception variable, unplanned pregnancy frequent
- Lactational amenorrhea important and effective means of child spacing in developing countries; weighed vs. risk of perinatal transmission

WHO Medical Eligibility Criteria for Contraceptive Use, 2009

1. A condition for which there is no restriction for the use of the contraceptive method.
2. A condition where the advantages of using the method generally outweigh the theoretical or proven risks.
3. A condition where the theoretical or proven risks usually outweigh the advantages of using the method.
4. A condition which represents an unacceptable health risk if the contraceptive method is used.

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WHO Medical Eligibility Criteria for Contraceptive Use, 2009

Category	With Clinical Judgment	With Limited Clinical Judgment
1	Use method in any circumstances	Yes (use the method)
2	Generally use the method	
3	Use of method not usually recommended unless other more appropriate methods are not available or acceptable	No (do not use the method)
4	Method not to be used	

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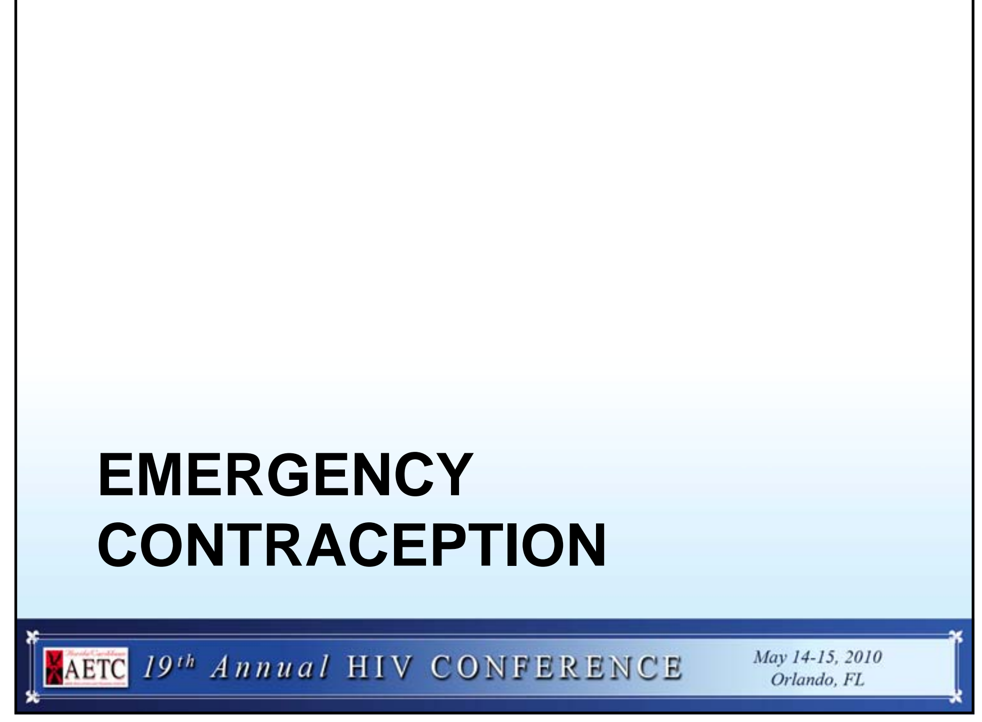


Emergency Contraception

- **Methods: Plan B (high-dose progestin only pills), Yuzpe (high-dose COCs)**
- **Mechanism: inhibits ovulation, may disrupt luteal phase and thicken cervical mucous; NOT an abortifacient**
- **Indications: Intercourse within past 72 hours without contraception, independent of cycle**
  - Lack of contraception
  - Contraceptive mishap (condom break, missed pills etc.)
  - Sexual assault
  - Exposure to teratogen

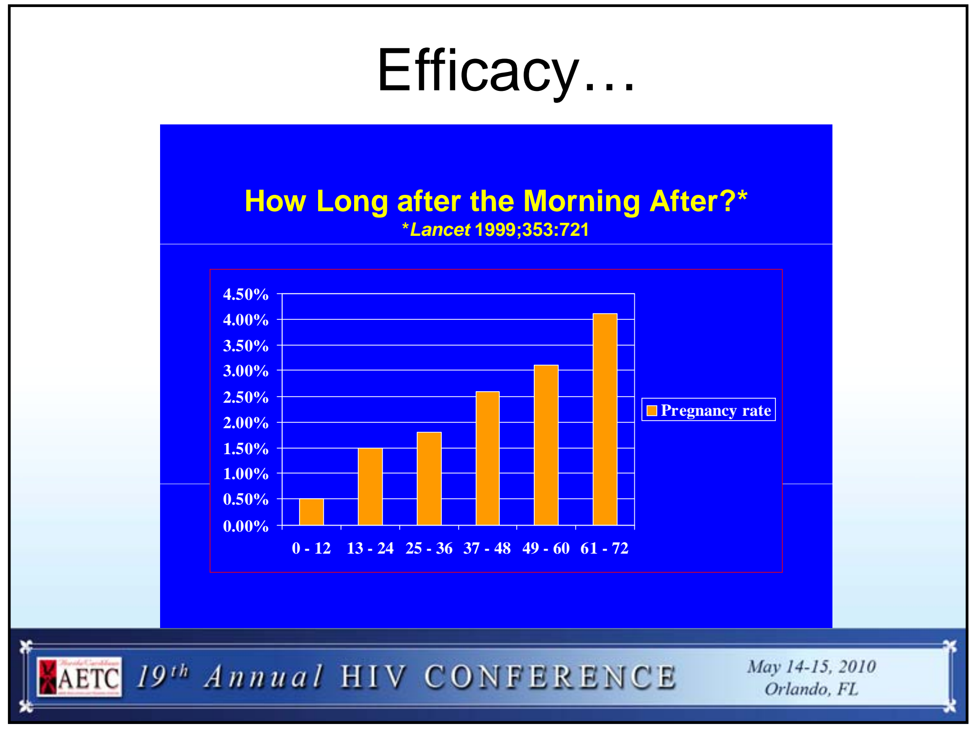
Yuzpe Regimen

- **Two large doses COCs 12 hours apart**
  - (minimum of 100ug estrogen)
- **Risk reduction: 75%**
- **Side-effects: Nausea (50%), emesis (20%), irregular bleeding, breast tenderness**
- **Use anti-emetic 1 hour before 1st dose**
- **Contraindication: pregnancy, estrogen related risks relative contraindications**
- **No evidence of teratogenicity**

Plan B ®

- **Levonorgestrel 0.75mg, 2 doses of single pill, 12 hrs apart (data indicate single dose 1.5 mg equivalent)**
- **Pregnancy rate 1.1% vs. 2-3.2% Yuzpe**
- **Risk reduction 85% vs. 57%**
- **More effective and fewer side-effects than Yuzpe**
- **Limited availability** (<16yo, pharmacy stocking)
- **Contraindication: pregnancy** (not teratogenic)

Efficacy…



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Emergency Contraception: Rx by Telephone

- **3 questions to ask:**
  - Have you had unprotected sex or a problem with your birth control (such as condom breakage) during the last 3 days (rule out sexual assault)?
  - Did your last menstrual period begin less than 4 weeks ago?
  - Was the timing and duration of your last menstrual period normal?
- **If the patient responds "yes" to all 3 questions, a clinician may prescribe emergency contraception over the telephone**
- **Pregnancy test not routinely required**

Adapted from ACOG, Emergency Contraception: A Resource Manual for Providers, 1998.

Advance provision of EC

- **Barriers to use reduce potential effectiveness**
  - FDA approved down to the age of 16yo; limited availability
- **The Alan Guttmacher Institute estimates that in the year 2000 EC prevented 50,000 induced abortions.**
- **Advance provision** *(Delbanco)*
  - Increased (sooner) use of EC, correctly used
  - No decrease in use of regular contraception
  - No increase in unprotected intercourse
- **Burden is on practitioners to provide counseling and advance prescriptions to patients at risk.**

BARRIER AND PERMANENT METHODS

Male Condoms

- High degree of protection against HIV transmission with *consistent, correct use.*
- Most HIV transmission worldwide occurs because condoms are not used at all.
- Method failure rate is 12%; “accidents” 1-12% of users.
- Dual protection (condoms + effective contraception method) advocated

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Female Condom

- Difficult to negotiate; female-driven
- Female condom less likely than male condoms to break or leak during intercourse
- Intrusion of outer ring into vagina 2% of coital episodes
- Cumulative probability of vaginal exposure to semen 3% (11.6% w/ male condoms).
- Failure rate 5% (perfect)/21% (typical) per year

Diaphragms, Caps

- Rarely used in adolescents
- Not recommended in discordant couples:
  - Relatively large area of vaginal mucosa exposed
  - Microtrauma during insertion
  - Concomitant use of nonoxynol 9 spermicide
- Epithelial disruption, risk of transmission

Male/Female Sterilization

- Rarely used in adolescents
- Effective, "permanent" (failure rates: 1:2000 males, 1:200 females)
- Do not reduce HIV in genital secretions ("dual protection")
- Studies show a reduction in consistent condom use in couples after sterilization of one partner

Mitchell, 2008

HORMONAL CONTRACEPTION: COMBINED (ESTROGEN + PROGESTIN)

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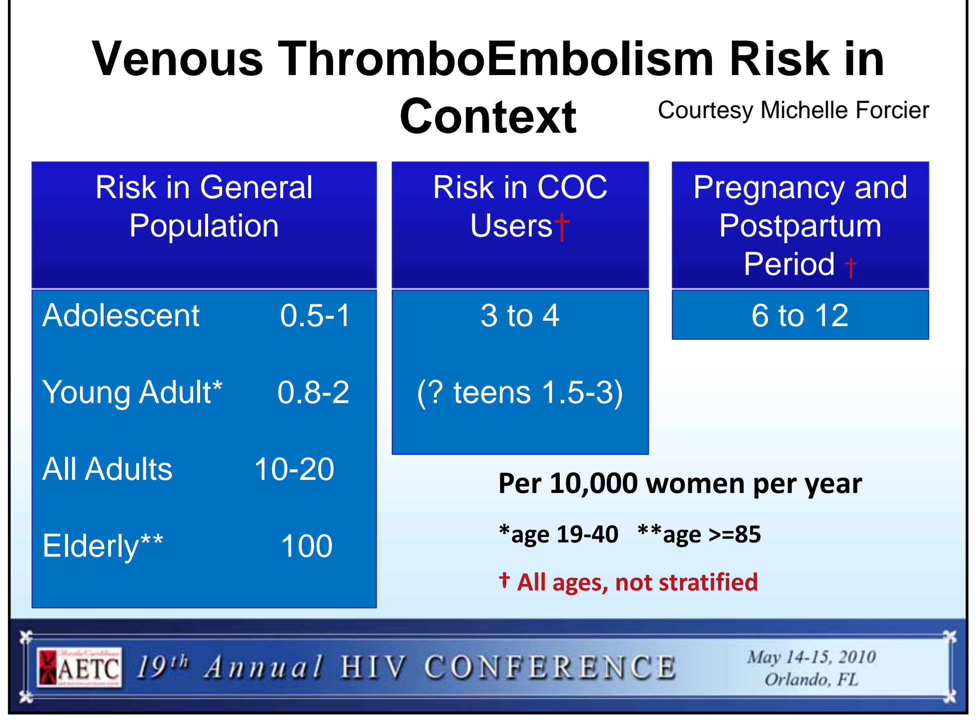
Combined Oral Contraceptives (COCs)

- **Effective method, with non-contraceptive benefits** (dysmenorrhea, irregular menses, acne, fibrocystic breast changes, ovarian cysts, etc)
- **Metabolized in the liver, use contraindicated in women with abnormal liver function** (alcohol abuse, acute or chronic viral hepatitis, ART side-effects and interactions)



Venous ThromboEmbolism Risk in Context

Courtesy Michelle Forcier

Risk in General Population		Risk in COC Users†	Pregnancy and Postpartum Period †
Adolescent	0.5-1	3 to 4	6 to 12
Young Adult*	0.8-2	(? teens 1.5-3)	
All Adults	10-20		
Elderly**	100		

Per 10,000 women per year

***age 19-40   **age >=85**

† All ages, not stratified

Courtesy Michelle Forcier

Activity	Risk death per year
Sky dive	**1 in 1000**
MVC	**1 in 5000**
Older (35-44) smoker OC user	1 in 5200
Pregnancy	**1 in 8700**
Young (15-34) smoker OC user	1 in 57,800
Abortion, medical	**1 in 110,00**
Riding bicycle	**1 in 130,000**
Abortion, surgical 11-12 EGA	**1 in 250,000**
Abortion, surgical <= 8 weeks	**1 in 1,000,000**
Young (15-34) OC user	1 in 1,667,000
Being struck by lightening	**1 in 2,000,000**

Trussel 2006

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Courtesy Michelle Forcier

VTE Risk Summary

Absolute risk VTE (women per year)

General population 10/100,000[1]
2nd generation OC 15/100,000[2]
3rd generation OC 30/100,000[2]
Pregnancy 60/100,000[1]

Incidence of VTE & CV events low in reproductive age women, especially in <30 year olds….
Smoking has greater affect on CV event than OC use in all ages

Absolute risk of VTE on OC is low, allowing majority of women to use and benefit from oral estrogen-progestin contraception

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VTE in HIV?

- **Risks common to HIV-infected:**
  - Smoking,
  - Obesity,
  - Diabetes,
  - Antiphospholipid syndrome,
  - Protein S deficiency
- **Combination of all of these factors?**

Drug Interactions: Hormonal contraception and ART

- **Ethinyl estradiol and progestins – substrates of cytochrome p450 CYP 3A4 systems (microsomes of the liver, small intestine)**
- **ART that:**
  - Induces cytochromes increases hepatic metabolism of hormonal contraception and decreases plasma concentration.
  - Inhibits cytochromes decreases clearance and increases plasma concentration.
- **Both drugs substrates – results uncertain, can be increased or decreased concentrations.**
- **Some drugs have multiple properties (i.e., efavirenz)**

COCs and ART

Medical Eligibility Criteria for Contraceptive Use, WHO, 2009; Mitchell, 2008

- Few data from small, mostly unpublished studies
- Pharmaceutical industry sponsored research using plasma levels to assess total exposure and assess interactions with ethinyl estradiol and norethindrone
- Suggest that, *in general*, PK of a single dose of COCs may be altered by various ARTs

COCs and ART

Medical Eligibility Criteria for Contraceptive Use, WHO, 2009; Mitchell, 2008

- No information on ART interactions in long term contraceptive use and efficacy/clinical outcome studies
- Clinical significance, especially when COCs have not been allowed to reach steady state, unknown

COCs and ART

Medical Eligibility Criteria for Contraceptive Use, WHO, 2009

- **Large decreases in contraceptive steroid level in the blood are seen with rPIs, potential to:**
  - Compromise contraceptive effectiveness
  - Increase ARV toxicity
- **Smaller effects with NNRTIs**
  - Clinical significance unknown
- **To date, no clinically significant interactions reported b/t contraceptive hormones and NRTIs**

COC-ARV Drug Interactions

PIs: COC levels / ART effects
- **ATV/r: EE, NET incr / No data**
- **DRV/r: EE decr, NET no change / DRV no change**
- **FPV/r: EE, NET decr / FPV no change, r incr, incr LFTs**
- **IDV: EE, NET no change / No data**
- **LPV/r: EE decr, NET no change / No data**
- **NFV: EE decr, NET no change / No data**
- **SQV: No data / No change**
- **TPV/r: EE decr ; incr skin and MS Aes, ? drug hypersensitivity**

NNRTIs: COC levels / ART effects
- **EFV: EE incr no change, NGM decr, LNG decr / EFV no change**
- **Etravirine: EE, NET no change / etavirine incr**
- **NVP: EE, NET no change / NVP no change**

NRTIs
- **TDF: EE, NGM no change / TDF no change**
- **ZDV: no data / ZDV no change**

WHO Medical Criteria Eligibility, 2009

Compliance:

- **Relatively strict to achieve desired efficacy**
- **Absorption affected by diarrhea and vomiting**

Summary:

- Risk of perinatal transmission and ART related birth defects (eg, efavirenz)

  VS
- Altered ART levels – risk for development of resistance or toxicity

BIG risks!

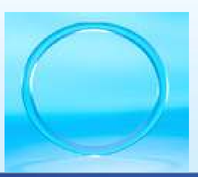
Patch

© OrthoMcNeil
ORTHO EVRATM Transdermal System

- **In U.S.: Ortho EVRA®**
- **3 consecutive 7-day patches are** followed by a patch-free week
- **Norelgestromin 150 mcg/day, ethinyl estradiol 20 mcg/day (higher E2 AUC?)**
- **Compared to COC – higher compliance, similar** efficacy, higher break-through bleeding
- **Availability limited by cost**
- **Weight limit** (“caution” >90kg)
- **Bypass first pass liver metabolism**
  - ?reduce drug interaction issues
  - ?reduce effects on clotting factors

Contraceptive Ring

- **In U.S.: Nuva Ring®**
- **Etonogestrel (3-keto-desogestrol) 120mcg/d, ethinyl estradiol 15 mcg/day**
- **Leave in vagina for 3 weeks, remove for 1 week to allow withdrawal bleeding**
- **Highly effective, few side effects, rapid return of fertility**



Pertinent to HIV?

- **Paracrine effect:**
  - Less sensitive to drug interactions causing decreased contraceptive efficacy?
- **Lower overall systemic estrogen exposure** (Wilhelmus, 2005)
- **Improved VTE risk?**

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Pertinent to HIV?

- **Hemostasis variables:** ***(Rad, 2006)***
  - Comparable with minor differences b/t CVR/nestorone vs COC/LNG (Factor VIIt, act. Protein C resistance, protein S, global act PTT-based protein C resistance)
  - Less androgenic Ps of the CVR oppose the E effects on the liver < more androgenic 2nd generation P of the COCs
  - Findings likely reflect comparison b/t steroids rather than delivery method

ART Drug Interactions

ART	COC* /P/R	CIC	POP	DMPA	LNG/ETG implants	Cu-IUD		LNG-IUD	
						I	C	I	C
NRTIs	**1**	1	1	1	1	2/3	2	2/3	2
NNRTIs	**2**	2	2	1	2	2/3	2	2/3	2
rPIs	**3**	3	3	1	2	2/3	2	2/3	2

*Mimimum of 30ug must be used.

COC - Combined Oral Contraceptive; P – Patch; R – Ring; CIC – Combined Injectable Contraceptives; POP – Progestin Only Pill; DMPA – Depo Medroxy Progesterone Acetate; LNG/ETG – Levonorgestrel/Etonorgestrel; Cu-IUD – Copper IUD; LGN-IUD – Levonorgestrel IUD

HORMONAL CONTRACEPTION: (PROGESTIN ONLY)

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Progestin Only Pills (POPs)

- **Can be used by women with contraindications to estrogen use.**
- **Effective if used correctly and consistently, ovulation is not inhibited in all users, inconsistent use results in pregnancy – not frequently used in adolescents.**
- **New POP, Cerazette, 75ug desogestrel, inhibited ovulation in 97% cycles at 7, 12 mos, enhanced efficacy?**

Long-acting Progestins

Can be used if contraindications to estrogen use.
Highly effective, non-user dependent, not intercourse dependent, reversible.

Injectables:

- **Require access to health care**
- **Main type in U.S.:**
  - DMPA 150mg IM q12 wks

  Less common: SQ DMPA (104mg q 13 mos), can be self-delivered

Implants:

- **Must be inserted by trained health professional**
- **Two types:**
  - Implanon – 3yrs
  - Jadelle – 5yrs

New Implants
Not Available in U.S.

Implanon
Etonogestrel
(3-ketodesogestrel)

Jadelle
Norplant II
levonorgestrel

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DMPA-ARV Drug Interactions

PIs: COC levels / ART effects

- **NFV: DMPA no change / NFV no change**

NNRTIs: COC levels / ART effects

- **EFV: DMPA no change / EFV no change**
- **NVP: DMPA no change / NVP incr (no change VL or CD4+, no grade 3- or 4-AEs)**

NRTIs

- **ZDV: no data / ZDV no change**

WHO, 2009

ART Drug Interactions

ART	COC* /P/R	CIC	POP	DMPA	LNG/ETG implants	Cu-IUD		LNG-IUD	
						I	C	I	C
NRTIs	1	1	**1**	**1**	**1**	2/3	2	2/3	2
NNRTIs	2	2	**2**	**1**	**2**	2/3	2	2/3	2
rPIs	3	3	**3**	**1**	**2**	2/3	2	2/3	2

*Mimimum of 30ug must be used.

COC - Combined Oral Contraceptive; P – Patch; R – Ring; CIC – Combined Injectable Contraceptives; POP – Progestin Only Pill; DMPA – Depo Medroxy Progesterone Acetate; LNG/ETG – Levonorgestrel/Etonorgestrel; Cu-IUD – Copper IUD; LGN-IUD – Levonorgestrel IUD

***Bone Density in Adolescents: Depo Provera, Norplant, COCs vs. Condoms Cromer BA et al, J Peds 1996; 129:671

After 1 year:

- 1.5% **decrease** in BMD c Depo Provera
- 2.9%, 2.5%, & 1.5% **increase** in BMD in controls, Norplant, & COC users respectively

After 2 years:

- 3.1% **decrease** in BMD c Depo Provera
- 9.5% & 9.3% **increase** in BMD in controls & Norplant users, respectively

(Similar dramatic findings by Berenson and colleagues, 2008)

Cundy et al: substantial BMD recovery 1 year after discontinuation in ***adult*** women…

Depo-provera: FDA Black Box warning November 2004

"Women who use Depo-provera contraceptive injection may lose significant BMD. Bone loss is greater with increasing duration of use and may not be completely reversible. It is unknown if the use of DMPA during adolescence or early adulthood, a critical period of bone accretion, will reduce peak bone mass and increase the risk of osteoporotic fracture later in life. DMPA should be used as a long-term birth control method (e.g. longer than 2 years) only if other birth control methods are inadequate."

"BMD should be evaluated when a woman needs to continue to use DMPA long term. In adolescents, interpretation of BMD results should take into account patient age and skeletal maturity."

Changes in Density w/ Use, D/C of Depo in Adolescent Girls

Scholes D., et al. Arch Pediatr Adolesc Med. 2005 Feb;159(2):139-44.

N=170 girls, 14-18yo, at 12 months s/p d/c:

Bone Density	Hip	Spine	Body
Depo Provera	-1.81%*	-0.97%*	0.73%
Discontinuers	1.34%**	2.86%**	3.56*
Controls	-0.19%	1.32%	0.88%

* p<0.001, ** p=0.004

- **Cromer et al., estradiol supplementation in adolescent DMPA users eliminated BMD decrease**
- **No e/o menopausal osteoporosis or fractures in users**
- **Effect similar to lactation (no known long-term impact on skeletal health)?**
  - No need to supplement with estradiol?
- **Calcium supplementation helpful independent of contraception use**

DMPA Use in Adolescents

- **Caution is warranted for use in girls younger than age 15 or within 3 years of menarche**
- **Carefully weigh risk/benefit ratio for:**
  - thin Caucasian or Asian girls
  - smokers
  - girls who had late menarche (> age 14)
  - girls with cancer, limited mobility, endocrinopathy, anorexia, or steroids
- **Opportunity to counsel on calcium intake, exercise, avoiding smoking**

DMPA Use in HIV-infected?

Multiple data on decreased BMD in HIV-infected

- **HIV infection**
- **ART (TDF)**
- **Smoking, alcohol**
- **Sedentary lifestyle**

Additive effects…

Obesity

- **DMPA vs. COCs vs. controls: DMPA users > 2x as likely to become obese over the following three years** ***(Berenson, 2009)***
- **Considerable problem in populations at risk for and infected with HIV**
- **Inflammatory and cardiovascular risk factors inherent to both HIV/AIDS and obesity**

Menstruation and Irregular Vaginal Bleeding

- **DMPA:**
  - Irregular bleeding common first 3 mos of use
  - Regardless of duration of use, 1/3 with bleeding in last 3 mos
  - Decreases with time
    - 50% no bleeding during at least one cycle by one year and 68% at 24 mos *(Bigrigg, 1999)*
  - Discontinuation rate 45% at one year, with most commonly cited reason being irregular bleeding

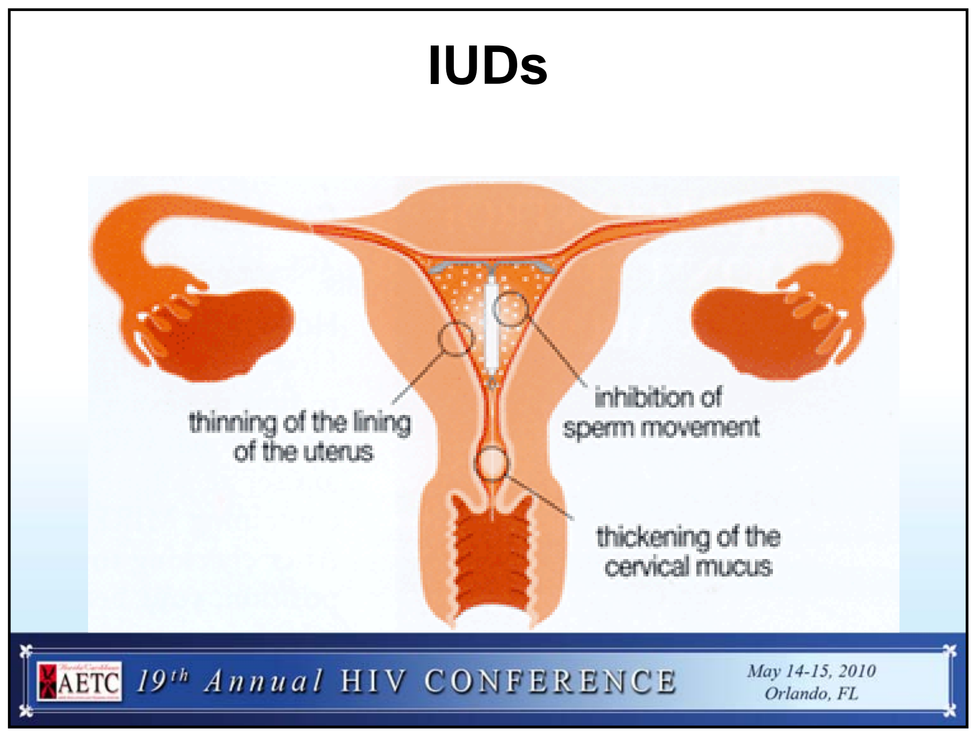
Menstruation and Irregular Vaginal Bleeding

- Implanon: anovulation, amenorrhea in 30-40% of users by 12mos; 10% w/ frequent or prolonged bleeding
- POPs: menstrual irregularities, prolonged bleeding

Risk of transmission:

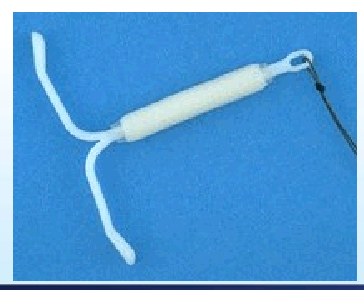
Irregular bleeding less tolerated in HIV-infected…

IUDs



Intrauterine Devices

Cu IUD
- **Highly effective**
- **Long term (8yrs for Safe-T 380)**
- **Cost effective**



LNG- IUS
- **Highly effective**
  - failure 0.1-0.2/100 women years
- **Last for up to 5 years**
- **Lower risk of PID, ectopic than Cu IUD**
- **Endometrial thinning, initial irregular bleeding; 94-97% ↓ menstrual blood loss at 12mos (10-15% amenorrhea)**

Intrauterine Devices in Adolescents

- **Adolescent population notorious for poor compliance and continuation of any contraceptive method – need longer-acting and less demanding method(s)**
- **Main concern: PID, infertility; adolescent females with the highest STI rates of any age group**
- **Grimes et al, 2000.: Previously reported risk of PID exaggerated d/t inappropriate comparison groups, diagnostic bias, and failure to control for sexual behavior**

PID

- **WHO analysis: PID 6x > first 20 days post insertion, thereafter, low and constant for 8 yrs** ***Farley, 1992***
- **Mechanism = inadvertent insertion in presence of GC, CT.**

PID

- **? PID risk higher in women with STI, IUD users vs non-IUD users? - no data**
  - Incidence of PID in IUD users w/in range reported for natural h/o chlamydia ***Grimes, 2000; Mohllagee, 2006***
  - Limited evidence suggests not more severe in IUD users, nor is treatment compromised if IUD is left in. ***Grimes, 2000***
- **Sequelae: infertility, ectopic pregnancy not increased in IUD users** ***Grimes, 2000, 2001; Hubacher, 2001; Randic, 1992***

PID

- **Screening and awaiting negative result prior to insertion decreases risk of PID**
- **Prophylactic antibiotics not helpful (metaanalysis of RCTs)** ***Grimes, 1999***
- **Educate, and encourage condom use!**

PID in HIV-infected?

- **Studies show increased rates in infected women, but rates still low 0-5%** ***Grimes, 2000; Mohllajee, 2006; Shelton, 2001.***
  - Conducted in countries with delay in results of diagnostic screening for GC & CT, cost of screening is prohibitive
  - Clinical and historical screening used, unreliable

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PID risk in infected IUD users

Sinei et al., 1998, 2001

- **N= 649 Kenyan women (156 HIV infected, 493 not infected)**
- **F/u at 1, 4, 24 months p insertion**
- **No *significant* differences b/t infected, non-infected, nor by immune status (CD4 count) in infected or non-infected complication rates**
- **Rates of PID rare (2.0% infected, 0.4% non-infected)**

Other concerns with adolescents:

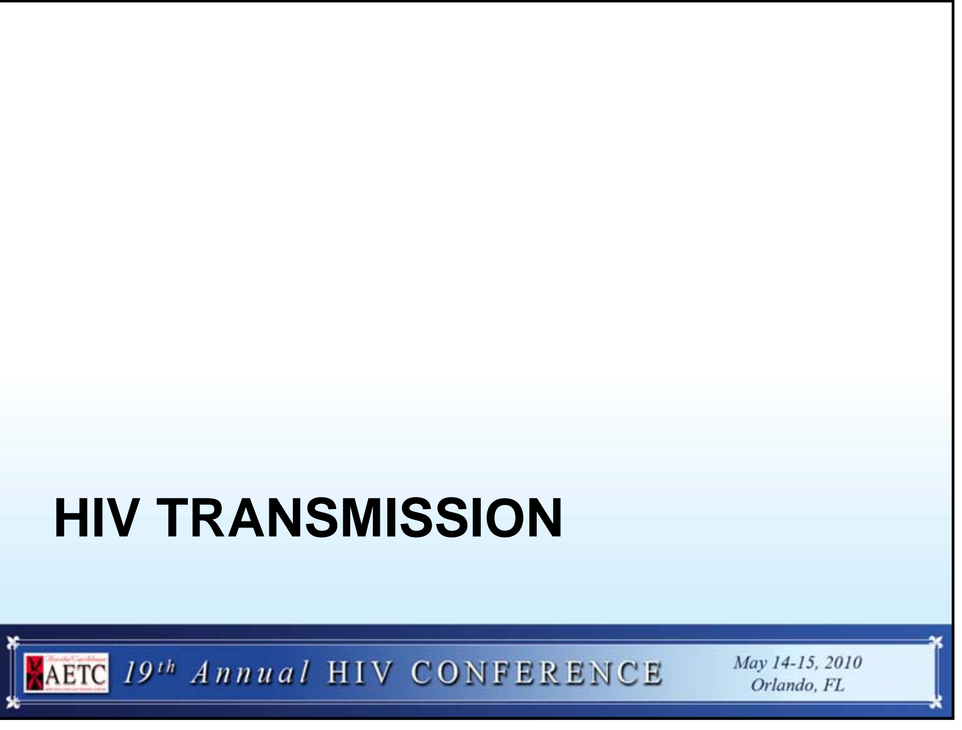
- **Difficulty/discomfort with insertion**
  - Likely d/t nulliparity rather than age
- **Address by…**
  - Misoprostol to soften cervix prior to insertion
  - Pre-insertion counseling

Other concerns with adolescents:

- **Increased expulsion rate**
  - Higher rates of expulsion in parous women 10yrs younger, but still w/in typical range *Diaz, 1993*
  - Two studies in teens with high expulsion rates (17%, 20%) *Kulig, 1980; Weiner, 1985*
  - Several studies show nulliparous women able to use them well *Duenas, 1993; Lete, 1998; Veldhuis, 2004*
- **Although expulsion rates higher in nulliparous women, still "low" (2-10%)**

Intrauterine Devices in HIV

- **Theoretical risk of decreased contraceptive efficacy caused by reduced endometrial inflammatory response in advanced immunosuppression (based on failures in renal transplant patients) - ?** ***Mitchell, 2008***



Intrauterine Devices in HIV

- **Sexual transmission of HIV**
  - ? Incr. d/t increase volume and duration of menses, genital inflammation, microtrauma to the penile epithelium from IUD threads *Mitchell, 2008*
  - No change in cervical shedding of HIV-1 DNA at 4 mos post insertion (Kenya, 98 women) *Richardson, 1999*
  - Cohort study with IUD users, incr with advanced infection, unprotected sex during menses; decr. with condom use *Mitchell, 2008*

Hormonal Contraception & HIV Transmission/Acquisition

- Increased cervical ectropion with COC use
- Long-acting progestins thin the vaginal epithelium, decr efficacy of this barrier?
- Genital shedding of HIV

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Biological Factors Increasing Susceptibility of Female Adolescents to HPV Infection

- Inadequate production of cervical mucus, which may act as a barrier against infection[1,2]
- Immature columnar epithelial cells in the transformation zone of the cervix are especially susceptible to HPV[1,2]
- Incomplete local immunity against certain infections[1,2]
- Increased susceptibility to minor trauma during sexual intercourse[1,2]

Photo courtesy of Daron Ferris, MD

1. Kahn JA. *Curr Opin Pediatr.* 2001;13:303–309. **2.** Rager KM, Kahn JA. *Curr Women Health Rep.* 2002;2:468–475.

Genital Shedding

- **Effective HAART reduces infectivity of genital secretions**
- **Genital shedding demonstrated in 25% of women with undetectable viral loads.** **Fiore, 2003**

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Genital Shedding

- **Additional effect of contraception methods?**
  - COCs, DMPA ? incr shedding of HIV1 infected cells from the cervix and vagina (did not measure free HIV1 virions or cell associated HIV1 RNA) *Mostad, 1998*
  - No association b/t hormonal contraception, IUDs after adjusting for plasma RNA. Kovacs, 2001
  - Ongoing multi-site longitudinal observation study California, Zimbabwe – genital shedding, effects of hormonal contraception on parameters of infectivity of women with HIV

Effects on Disease Progression

- **Recent comprehensive review: results mixed**
- **2 studies demonstrate more rapid CD4+ Tcell depletion**
- **No studies demonstrate sustained or substantial effects on viral load**
- **Interactions b/t sex steroids and the immune system quite complex, involve numerous interactions along the HIV lifecycle**

Stringer and Antonsen, 2008

Take Home Message…

- **COCs – consider alternate methods if rPI**
- **Consider alternate methods in general for infected teens:**
  - Ring
  - Implants and IUDs (LNG)

Questions?