Reproductive Health Care:

An Integrated Approach

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Family Planning Council

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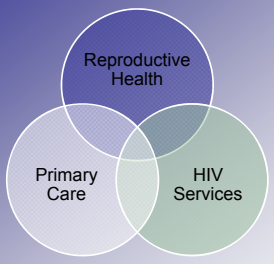
Reproductive Health Care: *Agenda*



- Context for Integrative Services
- Contraceptive Care
- Preconceptive Care
- Case Studies
- Discussion/Q&A

Reproductive Health Care: *Need for integrative approach*

- Half of all pregnancies in US are unintended.
- 70% HIV positive women report being sexually active.
- 25%-30% HIV positive women express desire to conceive.

Aaron, E & Criniti, S, 2007

Reproductive Health Care: *Reproductive Life Plans*

- Plan for when, how and whether to have children.
- Helps to ensure the healthiest outcome.
- Empowers clients to manage their reproductive choices and decisions.

CDC, 2006

Reproductive Life Plans: *Client Prospective*

"Creating a Reproductive Life Plan will help you think about how you would like to live your life and care for your health before you become pregnant…It also helps you set personal health goals so you are physically and emotionally prepared, as well as healthy for pregnancy."

GHIHMO, 2010

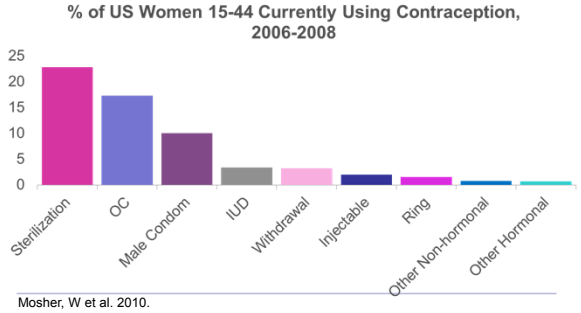
Reproductive Life Plans: *Provider Prospective*

- Reproductive planning should be addressed with everyone of reproductive age.
- Maintain fluid, client responsive approach.
- Utilize "holistic", preventive model of care.
- Ensure cultural competence

Typical Effectiveness of Contraception

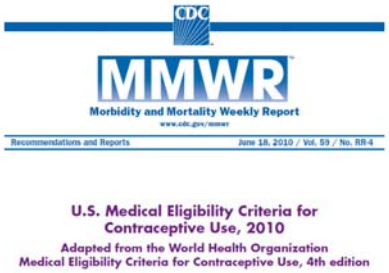
Adapted from: WHO. Family Planning: A Global Handbook

Contraception Use



Mosher, W et al. 2010.

US Medical Eligibility Criteria for Contraceptive Use



US Medical Eligibility Criteria for Contraceptive Use

- CDC published criteria in June '10
- Based on the 4th edition of the World Health Organization guidelines from '09
- Adapted for US women by panel of experts and CDC
- Recommendations for the use of specific contraceptives by women who have particular characteristics/medical conditions

http://www.cdc.gov/reproductivehealth/UnintendedPregnancy/USMEC.htm

US Medical Eligibility Criteria: Organization

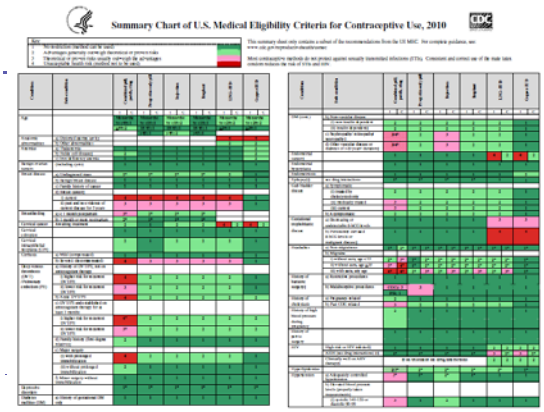
- Criteria are organized according to:
  - Contraceptive method
  - Patient characteristics (age, smoking status, etc.)
  - Preexisting conditions (hypertension, epilepsy, etc.)
- Criteria use a numeric scheme to provide the recommendations for contraceptives being used for contraceptive purposes only, *not* for *treatment* of medical conditions

http://www.cdc.gov/mmwr/pdf/rr/rr5904.pdf

US Medical Eligibility Criteria: Categories

1	No restriction for the use of the contraceptive method for a woman with that medical condition
2	Advantages of using the method generally outweigh the theoretical or proven risks
3	Theoretical or proven risks of the method usually outweigh the advantages – or that there are no other methods that are available or acceptable to the women with that medical condition
4	Unacceptable health risk if the contraceptive method is used by a woman with that medical condition

http://www.cdc.gov/mmwr/pdf/rr/rr5904.pdf



US Medical Eligibility Criteria: ↑ Risk for Adverse Health Events

Conditions Associated w/ ↑ Risk for Adverse Heath Events as a Result of Unintended Pregnancy

Breast cancer	Malignant liver tumors (hepatoma) and
Comp	
Diabe nephr or of	
Endo	
Epilep	
Hype	
Histo	
HIV/A	
Ische	
Malignant gestational trophoblastic disease	Tuberculosis

Should consider long-acting, highly-effective contraception for these patients

http://www.cdc.gov/mmwr/pdf/rr/rr5904.pdf

Reproductive Health Care: *Goals of Preconception Counseling*

- Improve the knowledge, attitudes and behaviors of men & women related to preconception health.
- Assure all women of childbearing age in U.S. receive preconception care that will enable them to enter pregnancy in optimal health.
- Reduce risks indicated by previous pregnancy which can prevent or minimize problems for mother and her future children.
- Reduce the disparities in adverse pregnancy outcomes.

CDC, 2006

Reproductive Health Care: *Fertility Issues*

- Menstrual Calendar
- Cervical Mucus Evaluation
- Support/Advocacy
- Build Provider Referral Network

Special Considerations When Working with HIV Infected Women

Oral contraceptives

- Same medical criteria as for HIV-uninfected women if woman is NOT on ART
- Drug-drug interactions are possible between ARVs and hormonal contraceptives (HCs)
  - HCs are metabolized by same pathways and cytochrome P450 enzymes as many PIs and NNRTIs
  - These interactions can cause changes in the efficacy of the ARV or contraception

ACOG (2010), *Gynecologic care for women with human immunodeficiency virus*. Practice Bulletin #117.

Hormonal Contraception: Alternate Delivery Methods

- Combined Patch is a thin plastic square worn on body
- Releases estrogen and progestin through the skin
- Works by preventing ovulation
- Efficacy
  - Limited research suggests may be more effective than COCs
  - Decreased efficacy in women over 90 kg

Hormonal Contraception: Alternate Delivery Methods

- Limited research suggests health risks and benefits are similar to COCs
- Side Effects
  - Skin irritation or rash where patch is applied
  - Changes in bleeding pattern
  - Headaches
  - Nausea
  - Vomiting
  - Breast tenderness
  - Abdominal pain

Hormonal Contraception: Alternate Delivery Methods

- Combined Vaginal Ring is placed into the vagina
  - Releases estrogen and progestin
  - Works by preventing ovulation
  - Efficacy
  - Limited research suggests may be more effective at preventing pregnancy than COCs

Alternative Delivery Methods

- Limited research suggests risks and benefits similar to COCs
- Side effects
  - Changes in bleeding pattern
  - Headaches
  - Nausea
  - Breast tenderness
  - Vaginitis
  - Leukorrhea/increase in Lactobacillus

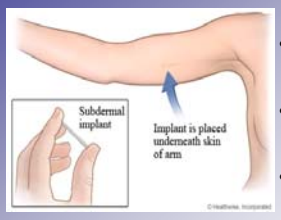
Alternate Delivery Methods

- These delivery methods also vulnerable to drug interactions
- One small study found significant interaction between the estrogen and progestin hormones of the patch and lopinavir/ritonavir
- More research needed on these delivery methods

DMPA

- Injectable (IM,SQ) progestin only contraception
- Given every 3 months
- Works by preventing ovulation
- Efficacy
  - 97% effective as commonly used
  - Over 99% effective when used as directed (3 pregnancies per 1000 women)

Contraceptive Implants



- Thin rods or tubes containing a progestin hormone.
- Provide effective contraception for at least 3 yrs.
- Suppresses ovulation and changes cervical mucus.
- Menstrual irregularities in most users.

Intrauterine devices (IUDs)

- No known drug interactions
- No increase in shedding of HIV
- 2 types
  - Copper (Paragard) works for 10 years, may be associated with heavier menses, periods regular)
  - Levonorgestrel IUD (Mirena) works for 5 years, reduces menstrual blood loss (is FDA-approved as a treatment for menorrhagia), periods scant and not regular

Medical Eligibility Criteria for IUD

	LNG-IUD	LNG-IUD	Cu-IUD	Cu-IUD
	Initiation	Continuation	Initiation	Continuation
High Risk for HIV	2	2	2	2
HIV Infection	2	2	2	2
AIDS	3	2	3	2
Clinically Well on ARV Therapy	2	2	2	2

Category 2: A condition for which the advantages of using the method generally outweigh the theoretical or proven risks.

Category 3: A condition for which the theoretical or proven risks usually outweigh the advantages of using the method.

Adapted from: U.S. medical eligibility criteria for contraceptive use.

IUD and HIV Considerations

- **No higher risk** in HIV-positive women over uninfected women for
  - Complications
  - Infections
- IUD use **not associated** with increased risk for transmission to sex partners
- Women with IUD in place who develop AIDS should be monitored for pelvic infection

Hormonal Contraception and NNRTI Interaction Table

Efavirenz **(EFV)**	No effect on oral ethinyl estradiol Decreased active metabolites of norgestimate (levonorgestrel AUC ↓ 83%; norelgestromin ↓64%) Implant: ↓ etonogestrel Levonorgestrel AUC ↓58%	A reliable method of barrier contraception must be used in addition to HC due to decreases in progestin levels. A reliable method of barrier contraception must be used due to reports of contraceptive failure. Effectiveness of emergency contraception may be diminished
Etravirine (ETR)	Ethinyl estradiol AUC ↑22% Norethindrone: no significant effect	No dosage adjustment necessary
Nevirapine (NVP)	Ethinyl estradiol AUC ↓20% Norethindrone AUC ↓19% DMPA: no significant change	Use alternative or additional methods No dosage adjustment needed

Adapted from: Recommendations for use of antiretroviral drugs in pregnant HIV-1-infected women for maternal health and interventions to reduce perinatal HIV transmission in the United States

Hormonal Contraception and Ritonavir-boosted PI Table

Atazanavir/ritonavir (ATV/r)	↓ Ethinyl estradiol ↑ Norgestimate	Oral contraceptive should contain at least 35 mcg of ethinyl estradiol. OCs containing progestins other than norethindrone or norgestimate have not been studied.
Darunavir/ritonavir (DRV/r)	Ethinyl estradiol ↓44% Norethindrone AUC ↓14%	Use alternative or additional method.
Fosamprenavir/ritonavir (FPV/r)	Ethinyl estradiol AUC ↓ 37% Norethindrone AUC ↓34%	Use alternative or additional method.
Lopinavir/ritonavir (LPV/r)	Ethinyl estradiol AUC ↓42% Norethindrone AUC ↓17%	Use alternative or additional method.
Saquinavir/ritonavir (SQV/r)	↓Ethinyl estradiol	Use alternative or additional method.
Tipranavir/ritonavir (TPV/r)	Ethinyl estradiol AUC ↓48% Norethindrone: no significant change	Use alternative or additional method.

Adapted from: Recommendations for use of antiretroviral drugs in pregnant HIV-1-infected women for maternal health and interventions to reduce perinatal HIV transmission in the United States

Hormonal Contraception and PIs without Ritonavir Table

Atazanavir (ATV)	Ethinyl estradiol AUC ↑48% Norethindrone AUC ↑110%	Oral contraceptive should contain no more than 30 mcg of ethinyl estradiol or use alternative method. OCs containing less than 25 mcg of ethinyl estradiol or progestins other than norethindrone or norgestimate have not been studied.
Fosamprenavir (FPV)	With APV: ↑Ethinyl estradiol and ↑norethindrone; ↓APV 20%	Use alternative method.
Indinavir (IDV)	Ethinyl estradiol AUC ↑25% Norethindrone AUC ↑26%	No dose adjustment.
Nelfinavir	Ethinyl estradiol AUC ↓47% Norethindrone ↓18%	Use alternative or additional method.

Adapted from: Recommendations for use of antiretroviral drugs in pregnant HIV-1-infected women for maternal health and interventions to reduce perinatal HIV transmission in the United States

Hormonal Contraception and CCR5 antagonist/integrase inhibitor table

CCR5 antagonist		
Maraviroc (MVC)	No significant effect	Safe to use in
Integrase inhibitor		
Raltegravir	No significant drug effect	No dose adjustment necessary

Adapted from: Recommendations for use of antiretroviral drugs in pregnant HIV-1-infected women for maternal health and interventions to reduce perinatal HIV transmission in the United States

WHO Recommendations

- No restriction on the use of any hormonal contraceptive method for HIV-positive women or women at high risk for HIV infection
- Critical importance must be placed on the consistent and correct use of condoms for the prevention of HIV acquisition or transmission
- Most concern is focused on the evidence of HIV acquisition and DMPA because a causal relationship is neither established nor ruled out
- Voluntary use of contraception by HIV positive women who wish to prevent pregnancy continues to be an important strategy for the reduction of MTCT

Condoms

- Efficacy
  - Pregnancy prevention as commonly used
    - Male condom 85%
    - Female condom 79%
  - Pregnancy prevention when used correctly and consistently
    - Male condom 98%
    - Female condom 95%
  - Male condom is 80-95% effective at preventing HIV transmission when used correctly and consistently

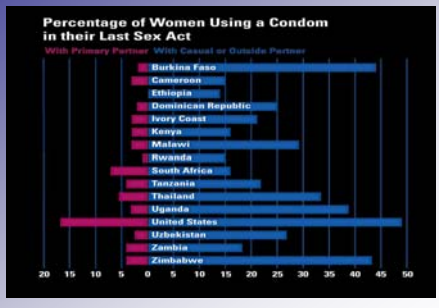
Dual Contraceptive Use

- Condom use should be encouraged for women
  - To prevent HIV/STI acquisition
- Condom use should be encouraged in HIV-positive women
  - To prevent HIV transmission
  - Prevent STI acquisition
  - As an adjuvant to contraceptives
- Condoms alone have a failure rate of 15%-21% at preventing pregnancy

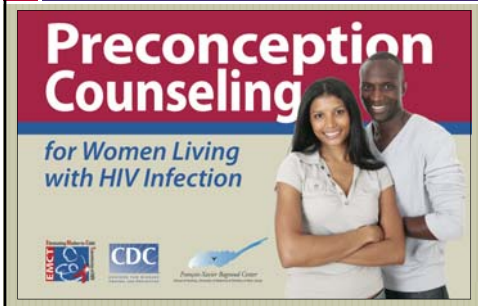
Reproductive Health Care:

Global Campaign for Microbicides, Statistics

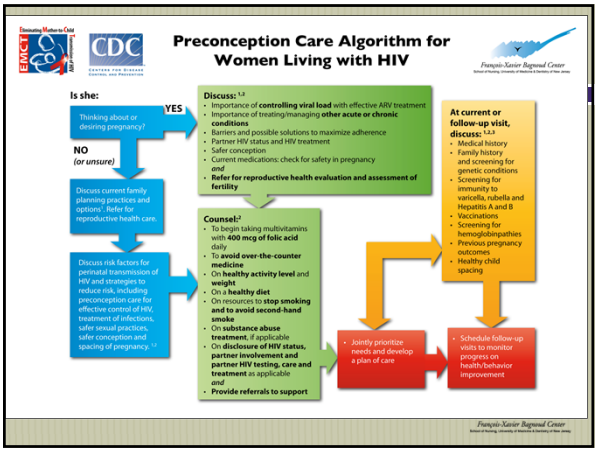
Measure Evaluation. 1997–2002. http://www.measuredhs.com.

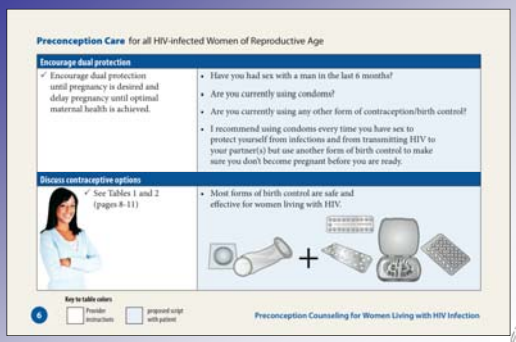


Support tools: Counseling Guide

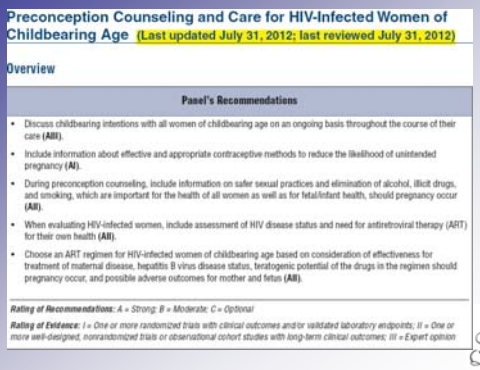


A counseling guide for providers with suggested scripts for discussing fertility desires and preconception care with women of reproductive are living with HIV.

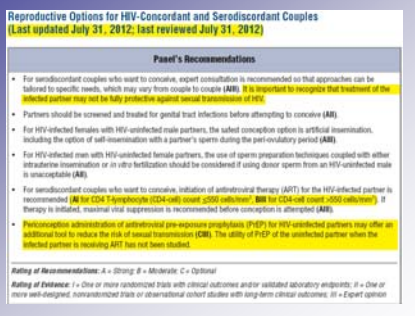




Preconception Counseling and Care



Preconception Counseling and Care



Reproductive Health Care: *Preconception Opportunity. (ACOG, 2006)*

- Optimize maternal HIV stability.
- Choose "safe" ARV's
- Ed/Counsel HIV MTCT risks.
- For HIV Discordant Couples discuss optimal risk reduction techniques.
- Evaluate need for vaccination/OI prophylaxis.
- Optimize Nutritional Health
- PNV/Folic Acid.
- Genetic Screening/Compile OB History.

AETC NATIONAL RESOURCE CENTER

AIDS Education and Training Centers National Resource Center

U.S. Public Health Service Perinatal Guidelines

Recommendations for Use of Antiretroviral Drugs in Pregnant HIV-1-Infected Women for Maternal Health and Interventions to Reduce Perinatal HIV Transmission in the United States

Introduction (3)

Strength of Recommendation	Quality of Evidence
A: Strong **B:** Moderate **C:** Optional	**I:** One or more randomized trials w/ clinical outcomes and/or validated lab endpoints **II:** One or more well-designed, nonrandomized trials or observational studies with long-term clinical outcomes **III:** Expert opinion

Recommendations in these guidelines are based on scientific evidence and expert opinion. Each recommended statement is rated with a letter of **A**, **B**, or **C** that represents the strength of the recommendation and with a numeral **I**, **II**, or **III**, according to the quality of evidence.

Preconception Counseling and Care (1)

- Preconception care is part of routine primary care and is recommended by CDC, ACOG, and other national organizations.
- Purpose:
  - Prevention of unintended pregnancies
  - Optimization of maternal health prior to pregnancy
  - Prevention of perinatal transmission
  - Prevention of HIV-transmission to an uninfected partner while trying to conceive

Reproductive Options for HIV-Concordant and Serodiscordant Couples (1)

All couples:

- Both partners should be screened for genital tract infections.(AII)
- Semen analysis is recommended for HIV-infected men. HIV, and possibly ART, may be associated with a higher prevalence of abnormalities.

Reproductive Options for HIV-Concordant and Serodiscordant Couples (2)

Serodiscordant couples:

- Expert consultation is recommended. (AIII)
  - No single method of safer conception is fully protective against transmission of HIV.
- Initiation of ART for the HIV-infected partner is recommended (AI for CD4 count ≤550 and BIII for CD4 count >550).
  - Maximal viral suppression is recommended before attempting conception. (AIII)
  - HPTN 052 trial showed ART can significantly decrease HIV transmission to uninfected partners

Reproductive Options for HIV-Concordant and Serodiscordant Couples (3)

- HIV-infected female with uninfected male partner: The safest option is artificial insemination, including the option of self-insemination, during the periovulatory period. (AIII)
- HIV-infected man with uninfected female: Sperm preparation techniques + either intrauterine insemination or *in vitro* fertilization should be considered if using donor sperm from an uninfected male is unacceptable. (AII)

Reproductive Options for HIV-Concordant and Serodiscordant Couples (4)

- Preconception administration of PrEP for HIV-uninfected partners may offer an additional tool to reduce the risk of sexual transmission. (CIII)
  - The utility of PrEP of the uninfected partner when the infected partner is receiving ART has not been studied.
  - Outcome studies are needed to examine adverse events, including risk of congenital abnormalities.

Reproductive Health Care: *FIMR Project*

FIMR/HIV PREVENTION METHODOLOGY
NATIONAL RESOURCE CENTER

FIMR, 2010

Expert Consultation (at no cost)

- **Perinatal HIV Hotline**
  - **National Perinatal HIV Consultation and Referral Service**
  - **1-888-448-8765**
- **Warmline**
  - **National HIV/AIDS Telephone Consultation Service**
  - **1-800-933-3413**

Reproductive Health Care: *Questions & Discussion*

Thank you,
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