Reproductive choices & pregnancy desires

- Want pregnancy now
- Want to avoid pregnancy now
Reproductive choices & pregnancy desires

- **Want pregnancy now**
  - Safer conception counseling and services to reduce own HIV risk or risk of transmitting to partner

- **Want to avoid pregnancy now**
  - Choice of effective, reversible contraception that does not interact with HIV treatment or increase HIV risk

**Supported for desired family building**
A MOMENT TO TALK ABOUT ORAL PrEP FOR WOMEN
Oral PrEP efficacy studies that included women

<table>
<thead>
<tr>
<th>Study</th>
<th>Cohort size</th>
<th>Overall efficacy</th>
</tr>
</thead>
<tbody>
<tr>
<td>Partners PrEP Study</td>
<td>4,747 discordant couples including 1,785 HIV negative women</td>
<td>75% (55-87%) for FTC/TDF 67% (44-81%) for TDF</td>
</tr>
<tr>
<td>TDF2</td>
<td>1,219 men and women including 557 women</td>
<td>62% (22-83%) for FTC/TDF</td>
</tr>
<tr>
<td>Bangkok Tenofovir Study</td>
<td>2,413 injection drug users including 489 women</td>
<td>49% (10-72%) for TDF</td>
</tr>
<tr>
<td>FEM-PrEP</td>
<td>2,120 women</td>
<td>6% (-52%-41%) for FTC/TDF</td>
</tr>
<tr>
<td>VOICE</td>
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<td>-4% (-49-27%) for FTC/TDF -49% (-129-3%) for TDF</td>
</tr>
</tbody>
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Thomson et al. JIAS 2015
Oral PrEP efficacy studies that included women

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Thomson et al. JIAS 2015
DAILY ORAL PREP PREVENTS HIV INFECTION AMONG WOMEN

SUFFICIENT ADHERENCE

Thomson et al. JIAS 2015; Corneli JAIDS 2014; Cottrell Expert Opinion Drug Metab Toxicol 2015; Callahan JAIDS 2015; Van der Straten PlosOne 2014
FACTORS INFLUENCING WOMEN’S ADHERENCE TO DAILY ORAL PrEP DURING EFFICACY TRIALS

- Risk perception and motivation for using PrEP
- Community perceptions about PrEP and stigma about HIV infection
- Clinical trial participant understanding of research methods and participant’s role in proof-of-concept studies

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SUFFICIENT ADHERENCE

DAILY ORAL PREP PREVENTS HIV INFECTION AMONG WOMEN

HYPOTHESIONED BIOLOGICAL FACTORS CONTRIBUTING TO THE LEVEL OF ADHERENCE REQUIRED FOR PREP EFFICACY IN WOMEN

- Pharmacokinetics
- Inflammation / STIs
- Maturity of genital tract
- Infectiousness of HIV infected partners

Thomson et al. JIAS 2015; Corneli JAIDS 2014; Cottrell Expert Opinion Drug Metab Toxicol 2015; Callahan JAIDS 2015; Van der Straten PlosOne 2014
WHO oral PrEP guidelines

<table>
<thead>
<tr>
<th>Target population</th>
<th>Specific recommendation</th>
<th>Strength of the recommendation</th>
<th>Quality of the evidence</th>
</tr>
</thead>
<tbody>
<tr>
<td>HIV-negative individuals at substantial risk of HIV infection&lt;sup&gt;b&lt;/sup&gt;</td>
<td>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</td>
<td>Strong</td>
<td>High</td>
</tr>
</tbody>
</table>
European Medicines Agency Validates Gilead's Type II Variation Application for Truvada® for Reducing the Risk of Sexually Acquired HIV

February 1, 2016

– If Approved, Truvada Would be First Antiretroviral in Europe to be Indicated for Use in Combination with Safer Sex Practices to Reduce the Risk of HIV Infection in Adults –
So, daily oral PrEP works in women, but does it really work for them?
PrEP cannot be one size fits all

There is an exciting pipeline of new PrEP prevention products that could deliver PrEP in ways to meet every woman’s needs and situations.
Pregnancy desires

- Want pregnancy now
  - Safer conception counseling and services to reduce own HIV risk or risk of transmitting to partner
- Supported for desired family building
“We just said even if we have the virus, we will still get the baby.”

- HIV+ woman with an HIV- male partner

Ngure et al. AIDS Care 2014
"Infected women should be advised to consider delaying pregnancy until more is known about perinatal transmission of the virus..."
The concept of “safer conception” is built on the premise that all people have the right to attempt pregnancy in order to realize their reproductive goals.

For people with HIV and at substantial risk of HIV, pregnancy attempts come with heightened risk of sexual HIV transmission (to partners or themselves).

Individual interventions exist to minimize HIV risk while permitting pregnancy - using multiple interventions maximizes risk reduction.

Recognition of pregnancy desire and seeking services is the first step.
Safer conception strategies

- HIV prevention
- Pregnancy optimization
Safer conception strategies

► HIV prevention
  – Pre-exposure prophylaxis (PrEP)
  – Antiretroviral therapy (ART)
  – Condomless sex during peak fertility; condoms at other times
  – Treatment of genital infections
  – Vaginal self-insemination (if HIV+ woman)
  – Semen washing (if HIV+ man)
  – Medical male circumcision (if HIV+ woman and HIV- man)

► Pregnancy optimization
Safer conception strategies

**HIV prevention**
- Pre-exposure prophylaxis (PrEP)
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- Treatment of genital infections
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- Semen washing (if HIV+ man)
- Medical male circumcision (if HIV+ woman and HIV- man)

**Pregnancy optimization**
- Identification of peak fertility using fertility awareness methods
- Simple fertility screening
- Fertility workup and fertility services
Early research on safer conception

Preexposure prophylaxis and timed intercourse for HIV-discordant couples willing to conceive a child

Pietro L. Vernazza\textsuperscript{a}, Irma Graf\textsuperscript{b}, Ulrike Sonnenberg-Schwan\textsuperscript{c}, Maria Geit\textsuperscript{d} and Anja Meurer\textsuperscript{c}

AIDS 2011

- Under the premise of ART use with undetectable HIV viral load, no genital infections, and enough knowledge of menstrual cycle to predict upcoming ovulation
- Use of PrEP (off-label at the time) 24h before ovulation and 24h after – women chose to use/not use
- 46 couples with HIV+ man, HIV- woman
- 0 transmissions to the HIV uninfected woman and 0 transmissions to the babies
Safer conception user preferences

- HIV positive clients in Johannesburg with pregnancy desires needed information about safer conception services but struggled to find providers with knowledge and ability to provide services (Schwartz AIDS 2014)

- In a Johannesburg primary care clinic with HIV positive women, 66% of women with immediate fertility intention spoke with a provider about her fertility intentions (Schwartz JAIDS 2016)

- At entry into a safer conception study for HIV serodiscordant couples in Uganda, timed condomless sex has been used by 15% of HIV serodiscordant couples and was more likely when one perceived willingness of their partner to practice safer conception (Wagner AIDS Behav 2015)

- Stigma, fear of unknown medical procedures, and fear of HIV transmission may prevent people from seeking safer conception services in Kisumu, Kenya (Breitnauer JIAS 2015)
Safer conception user preferences

At enrollment into the Partners Demonstration Project cohort with access to and counseling about PrEP...

Preliminary data: Heffron et al. IDSOG 2014

HIV negative women (n=266)  
HIV positive women (n=535)
Safer conception user preferences

At enrollment into the Partners Demonstration Project cohort with access to and counseling about PrEP...

Preliminary data: Heffron et al. IDSOG

HIV negative women (n=266) vs HIV positive women (n=535)

- PrEP
- ART
- Timed unprotected sex
- STI tx
- Male Circumcision
- Artificial insemination
- Self insemination
- Sperm washing
- None

Knowledge, Willingness, Experience

2014
Provider experiences

- Half of providers surveyed in Uganda felt knowledgeable enough to counsel clients on safer conception strategies (Goggin AIDS Pt Care 2015)

- Clinicians in South Africa concerned about client ART adherence, involvement of male partners, and the potential for underlying fertility issues (Schwartz AIDS 2014)
Safer conception for HIV-affected women desiring pregnancy now

- Many women affected by HIV desire pregnancy; HIV infection doesn’t often change desire
- We have the tools to provide safer conception services
- We are building awareness of tools and experience providing services but need more work in this area
- For providers, cross-specialty training is important - for HIV prevention providers and gynecologists to feel comfortable enough to recommend and refer for options typically in each other’s domains
#GlobalSHARE

Global Community for Sex, HIV and Reproductive Empowerment

www.hiveonline.org/resources/global-share/

*We support healthy sex lives and families.*

A global movement translating emerging science into action supporting every person’s reproductive goals.

Join the GlobalSHARE Google Group to share ideas, best practices, and challenges. *All are welcome.*
Pregnancy desires

- Want to avoid pregnancy now
- Choice of effective, reversible contraception that does not interact with HIV treatment or increase HIV risk

Supported for desired family building
HORMONAL CONTRACEPTION AND HIV
Contraception reduces maternal mortality & could do more if unmet need is satisfied


Expected reduction in maternal deaths if unmet needs for contraception are fulfilled

Simulation results, presented at the aggregated level, of number of maternal deaths per year if anticipated contraceptive demand is met (red bars) or not met (blue bars).
Unanswered research questions (some of them)

For HIV positive women:
Do any ARVs and contraceptives interact to reduce the efficacy of contraceptives to prevent pregnancy?

For HIV negative women:
Does the use of any hormonal contraceptive by HIV negative women increase the risk of HIV acquisition in uninfected women?
Unanswered research questions (some of them)

For HIV positive women:
Do any ARVs and contraceptives interact to reduce the efficacy of contraceptives to prevent pregnancy?
Real world contraceptive effectiveness

► 5,153 African HIV positive women with HIV negative male partners participating in 3 large prospective studies and followed for ~1.8 years

► 1,248 total pregnancies; overall pregnancy incidence = 14.8 per 100 person years

► All methods prevent pregnancy; With efavirenz, all methods have diminished effectiveness, especially implants, but power is low for efavirenz comparisons

Pyra et al. AIDS 2015
Real world contraceptive effectiveness

- Retrospective analysis of clinic data from western Kenya including 24,560 HIV positive women
- 3,337 incident pregnancies; overall incidence = 8.9 per 100 person years
- Implant users had lowest pregnancy rates
- Pregnancy rate is 3 times higher among implant users using efavirenz relative to implant users using nevirapine

Patel et al. Lancet HIV 2015
For HIV negative women:
Does the use of any hormonal contraceptive by HIV negative women increase the risk of HIV acquisition in uninfected women?
Early epidemiologic studies of HIV asked:

How are people who get HIV different from people who don’t get HIV?

- Sexual behavior
- Injection drug use
- Blood transfusions
- Exposure to infected breast milk
- Other sexually transmitted infections
- Male circumcision
- Occupation
- Contraception
- Religion
- Income level
- Geographic residence
Primary objective: Compare HIV incidence during periods with injectable or oral contraceptive use to periods without hormonal contraceptive use

- Prospective cohort study of 1314 HIV uninfected women in serodiscordant partnerships from East and southern Africa (14 sites, 7 countries)

- All women knew their study partner was HIV infected; clinical and behavioral data collected from HIV infected partners

- Quarterly follow up visits for ≤24 months

- 24-month retention: >90%

Contraception and HIV acquisition among women

<table>
<thead>
<tr>
<th></th>
<th>Incidence rate*</th>
<th>HR (95% CI)</th>
<th>p-value</th>
<th>OR (95% CI)</th>
<th>p-value</th>
</tr>
</thead>
<tbody>
<tr>
<td>No hormonal contraception</td>
<td>3.78</td>
<td>1.00</td>
<td>1.00</td>
<td>1.00</td>
<td></td>
</tr>
<tr>
<td>Injectable</td>
<td>6.85 (1.04-4.04)</td>
<td>2.05</td>
<td>0.04</td>
<td>2.19 (1.01-4.74)</td>
<td>0.05</td>
</tr>
<tr>
<td>Oral</td>
<td>5.94 (0.55-5.82)</td>
<td>1.80</td>
<td>0.33</td>
<td>1.63 (0.47-5.66)</td>
<td>0.44</td>
</tr>
</tbody>
</table>

*per 100 person years

**Adjusted for age, enrollment plasma viral load level of the HIV infected partner and time dependent unprotected sex and pregnancy.

Female hormonal contraceptive linked to higher HIV risk

Women who use hormonal contraceptives are roughly twice as likely to become infected with HIV or pass on the virus to their partner, according to a new study published Tuesday.

The most popular contraceptive for women in eastern and southern Africa, a hormone shot given every three months, appears to double the risk the women will become infected with HIV, according to a large study published Monday. And when it is used by HIV-positive women, their male partners are twice as likely to become infected than if the women had used no contraception.
Studies of injectable contraception and HIV acquisition meeting “minimum quality criteria”

WHO 2014 Guidance

► Women at high risk of acquiring HIV can use all hormonal contraceptive methods without restriction.

► Women at high risk of HIV using progestogen-only injectables should be informed that available studies have important methodological limitations.

► Women at high risk of HIV infection should be informed that progestogen-only injectables may or may not increase their risk of HIV acquisition.
Individual participant meta analysis of DMPA and HIV acquisition

Pooled hazard ratio 1.50 (1.24-1.83)

Comparing one injectable contraceptive to another

- 3,141 South African women participating in VOICE (trial of oral and vaginal gel PrEP) using injectable contraceptives

<table>
<thead>
<tr>
<th>Primary comparison in whole cohort (n=3141)</th>
<th>Number of HIV-1 seroconversions/person-years</th>
<th>Incidence per 100 person-years (95% CI)</th>
<th>Unadjusted Cox proportional hazards regression analysis</th>
<th>Adjusted Cox proportional hazards regression analysis</th>
</tr>
</thead>
<tbody>
<tr>
<td></td>
<td></td>
<td></td>
<td>Hazard ratio (95% CI) p value</td>
<td>Hazard ratio (95% CI) p value</td>
</tr>
<tr>
<td>NET-EN</td>
<td>55/970.8</td>
<td>5.67 (4.35-7.38)</td>
<td>Reference --</td>
<td>Reference --</td>
</tr>
<tr>
<td>DMPA</td>
<td>152/1763.0</td>
<td>8.62 (7.35-10.11)</td>
<td>1.53 (1.12-2.08) 0.007</td>
<td>1.41 (1.06-1.89)* 0.02</td>
</tr>
<tr>
<td>Total</td>
<td>207/2733.7</td>
<td>7.57 (6.61-8.68)</td>
<td>--</td>
<td>--</td>
</tr>
</tbody>
</table>

Noguchi et al. Lancet HIV 2015
Comparing exogenous and endogenous progestins

- 432 South African women tested for HIV twice per week to characterize immune determinants of HIV acquisition risk
- Women using injectable contraception (DMPA and Net-En) were more likely to acquire HIV
- Injectable contraception was associated with higher frequencies of HIV target cells in cervical swab samples

Byrne et al. Lancet ID 2015
Another recent analysis...

- 2,830 women in the HPTN 035 study of vaginal microbicide gel for HIV prevention from Malawi, Zambia, Zimbabwe, and South Africa

<table>
<thead>
<tr>
<th></th>
<th>Number of HIV infection per person-years</th>
<th>Incidence</th>
<th>Unadjusted hazard ratio&lt;sup&gt;a&lt;/sup&gt; (95% CI)</th>
<th>p Value</th>
<th>aHR (95% CI)</th>
<th>p Value</th>
</tr>
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<tbody>
<tr>
<td>All participants&lt;sup&gt;b&lt;/sup&gt;</td>
<td>106/2605</td>
<td>4.07</td>
<td></td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td>No HC</td>
<td>29/481</td>
<td>3.95</td>
<td>Ref</td>
<td>-</td>
<td></td>
<td>-</td>
</tr>
<tr>
<td>Injectable</td>
<td>72/1543</td>
<td>4.66</td>
<td>1.26 (0.76, 2.10)</td>
<td>.37</td>
<td>1.17 (0.70, 1.96)</td>
<td>.56</td>
</tr>
<tr>
<td>Oral</td>
<td>15/580</td>
<td>2.58</td>
<td>0.77 (0.38, 1.57)</td>
<td>.47</td>
<td>0.76 (0.37, 1.55)</td>
<td>.45</td>
</tr>
</tbody>
</table>

<sup>a</sup> Cox proportional hazards models stratified by site.

<sup>b</sup> Adjusted models = time-varying Cox proportional hazards models stratified by site and adjusted for baseline age (as a continuous variable), living with a partner, HSV-2 status and time-varying unprotected sex at last vaginal sex act with censoring at the first positive pregnancy test.

Balkus et al. Contraception 2016
Complexities with observational data

- Long inter-survey interval
- Loss to follow up and missing visits
- No or insufficient adjustment for confounding factors
- Inability to distinguish between types of hormonal contraceptives
- Self report of contraceptive use and sexual behavior
Complexities with observational data

- Long inter-survey interval
- Loss to follow up and missing visits
- No or insufficient adjustment for confounding factors
- Inability to distinguish between types of hormonal contraceptives
- Self report of contraceptive use and sexual behavior

Yc DNA detected in vaginal swabs of women reporting 100% condom use: a cross sectional study among 440 HIV-women within the Partners PrEP Study

Heffron CROI 2016 poster #865

<table>
<thead>
<tr>
<th>DMPA</th>
<th>No hormonal contraception</th>
</tr>
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<tbody>
<tr>
<td>34.3%</td>
<td>29.8%</td>
</tr>
</tbody>
</table>

p = 0.2
Research Priorities

► Higher quality data from a randomized trial of contraceptives

► Biologic studies to understand changes in vaginal tissue, immune function and HIV receptor cells with use of hormonal contraceptives, when different levels of exogenous hormones are present and for varying lengths of time

► Observational analyses with high quality datasets following recommended “best practices”
The ECHO Trial

A Multi Center, Open-Label, Randomised Clinical Trial Comparing HIV Incidence and Contraceptive Benefits in Women using Depot Medroxyprogesterone Acetate (DMPA), Levonorgestrel (LNG) Implant, and Copper Intrauterine Devices (IUDs)

The Evidence for Contraceptive Options and HIV Outcomes (ECHO) Trial
ECHO Trial Design

7,800 women ages 16-35 wanting to prevent pregnancy and willing to be randomized

Randomize (1:1:1 ratio)

- DMPA (2,600 women)
- LNG implant (2,600 women)
- Copper IUD (2,600 women)
Objectives

Primary objective
• To compare the risks of HIV acquisition between women randomised to injectable DMPA, levonorgestrel (LNG) implants, and copper IUDs

Secondary objectives
• Pregnancy, safety, contraceptive continuation
Study Population

- Sexually active, HIV-negative women
- Seeking effective contraception
- Willing to be randomised to any of the study arms
- Ages 16-35 years old
- Able and willing to provide written informed consent
- Not having any medical condition that would make use of the contraceptive methods unsafe
Study Setting

12 sites:
- South Africa (9 sites)
- Kenya
- Swaziland
- Zambia
Key Metrics

- To do this study well, it has to be done right.

- Key metrics are being monitored in real-time:
  - Refusal of contraceptive method assigned just after randomization
  - Retention
  - Rate of contraceptive discontinuation
Consider some possible outcomes and their implications

• No difference in HIV risk with any method
  • Reassurance to continue these methods in use.

• Some difference in HIV risk
  • LNG implant lowest risk: Strengthen access to LNG
  • Copper IUD lowest risk: Strengthen access to IUD
  • DMPA highest risk: Weigh how to use less DMPA, including messaging, delivery, alternatives
Learn more about ECHO

- http://www.echo-consortium.com/

Open-Label Randomised Clinical Trial

The Evidence for Contraceptive Options and HIV Outcomes (ECHO) Study
Reproductive choices & pregnancy desires

- **Want pregnancy now**
  - Safer conception counseling and services to reduce own HIV risk or risk of transmitting to partner

- **Want to avoid pregnancy now**
  - Choice of effective, reversible contraception that does not interact with HIV treatment or increase HIV risk

**Supported for desired family building**
Conclusions

► For women affected by HIV who desire pregnancy, pregnancy without HIV transmission is very possible

► We need to work to increase discussion with women about safer conception methods and comfort among providers to offer services

► For women wanting contraception, important unanswered questions remain about interactions between specific antiretrovirals and hormonal contraceptives

► Whether DMPA or other hormonal contraceptives increase a woman’s risk for HIV acquisition – and to what extent – remains an open question relevant for women with HIV risk
Reproductive choices & pregnancy desires

- **Want pregnancy now**
  - Safer conception counseling and services to reduce own HIV risk or risk of transmitting to partner and baby

- **Want to avoid pregnancy now**
  - Choice of effective, reversible contraception that does not interact with HIV treatment or increase HIV risk

- **Ambivalent about pregnancy**
  - How to support these women?

Supported for desired family building
Acknowledgements

► **International Clinical Research Center (Seattle, USA)**
  Jared Baeten, Connie Celum, Ruanne Barnabas, Deborah Donnell, Kathy Thomas, Jennifer Morton, Caitlin Scoville, Susan Morrison, Harald Haugen, Lara Kidoguchi, Kerry Thomson, Jennifer Velloza, Kerry Hancuch

► **Partners in Health Research and Development Team (Thika, Kenya)**
  Nelly Mugo, Kenneth Ngure, Njambi Njuguna, Elizabeth Irungu

► **GlobalSHARE catalysts**
  Shannon Weber, Lynn Matthews, Angela Kaida, Natasha Davies, Shelia Eshiwani

► **Study Teams from the Partners Demonstration Project, Partners PrEP Study, Partners in Prevention HSV/HIV Transmission Study, and the ECHO Trial**

► **So many dedicated research participants**