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Expanding Contraceptive Options

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TOPICS:

- Unmet Need
- LAPMs
- Sino-Implant (Zarin)
- NES/EE Vaginal Ring
- LNG-IUS
- Depo-Provera SubQ
- SILCS Diaphragm
- Women’s Condom
- Male Methods
- New Technology
  - Biodegradable Implants
Long-Acting & Permanent Methods
Zarin® (Sino-implant II)

- Subdermal Contraceptive Implant
If 20% of OC users switched to implants in Africa...over next 5 years would avert:

- 1.8 million unwanted pregnancies
- 576,000 abortions
- 10,000 maternal deaths

The impact would be even more dramatic with new users.
Oral contraceptives

- Highly effective
- Reduction of menstrual loss
- Reduction of pelvic inflammatory disease

Intrauterine devices

- No daily motivation
- Long-acting
- Estrogen-free
- Rapidly reversible

Levonorgestrel intrauterine system
The levonorgestrel intrauterine system

- Rate-controlling membrane
- Hormone cylinder
- Uterine wall
- Section of system
- Levonorgestrel intrauterine system
- Detail
Change in hemoglobin during 5 years of use

Levonorgestrel intrauterine system

Cu IUD
DEPO-PROVERA SubQ 104
The LD Formulation of Depo-Provera — Improving Contraceptive Options for Women

- Suppresses ovulation while lowering drug exposure
  - Lower dose (104mg) potentially leads to greater tolerability
- Rapid onset of action
- The subcutaneous administration offers the potential for in home-injection
- Could be a “game changer” for community-based access to DMPA

LD = lower dose.
What is Uniject*?

The Uniject device is a prefillable injection system developed by PATH in 1987 in response to WHO’s call for improved injection delivery designs

Key features:

- **Single dose** in a **single package** for minimal waste of drug or vaccine.
- **Prefilled** and **sterile** for use by a wide variety of health workers.
- **Nonreusable** to prevent the spread of HIV/AIDS and other diseases.
- **Easy to use** to facilitate community-based distribution by health workers who do not ordinarily administer injections.
- **Compact size** for transport, storage, and disposal

*Uniject is a registered trademark of BD*
NES 150µg/EE 15 µg CVR

Nestorone/Ethynyl Estradiol core

channels
3 x 25 mm

8.4 mm in cross section
56 mm in diameter

Nestorone core

Designed to last one year
The CVR is an effective, convenient, easily-used new contraceptive method – Phase III FDA Trial Completed

**Strengths**
- Monthly ring - good for one year
  - Has health benefits
  - Not coitus dependent
  - Eliminates need for repeated visits to doctor & pharmacy
- Effective
- Lack of androgen effect
  - Weight / lipids favorable
- High level of user satisfaction
- Under a woman’s control
  - She decides when to stop & start
  - No need for a trained health provider
  - Rapid return to fertility if desired

**Challenges**
- Medical risks & side effects similar to currently available hormonal contraceptives
- Need for pre-introductory studies in developing countries
- Manufacturing process improvements underway - advancement from pilot scale production to development of commercial process
- Unless it can be provided at low cost it would not be available in the public sector

Population Council
SILCS Diaphragm: “One size fits most”

- Firm insertion edge
- Cervical cup membrane
- Grip dimples
- Fingertip removal dome
SILCS Advantages

- One size fits most women
- Easy insertion/removal (grip dimples, removal dome)
- Improved comfort (soft spring in the rim)
- No pelvic exam or fitting required
- Simplified supply logistics
- Made of silicone rather than latex
- Designed to be as effective as traditional diaphragm
Woman’s Condom
Product Features

- Insertion Capsule
- Foam Ellipses
- Condom Pouch
- Outer Ring

PATH

USAID
Current Options for Men

- Condom
- Vasectomy
- Withdrawal
- Fertility Awareness Methods
  - SDM (CycleBeads)
Male Contraception
Research and Development

- Use of existing male methods is low, with regional and country differences
- Men are aware of family planning methods
- Men approve of the use of family planning
- Low levels of use may be related to the negative characteristics of existing methods
- Example: In a study conducted in Fiji, Iran, India and Korea, men considered a male pill or injection to be more acceptable than vasectomy
Approaches to Male Contraception: Targeting the sperm

Hormonal regimens are designed to inhibit sperm production in the testes

Source: Image House Medical, Copenhagen
Sperm suppression and contraceptive protection provided by norethisterone enantate (Net-En) combined with testosterone undecanoate (TU) in healthy men

A WHO and CONRAD Multicentre Phase IIb clinical trial

- Norethisterone enantate (Net-En) - Strong progestational & some androgenic activity
- Testosterone Undecanoate (TU) - Well-tolerated long-acting testosterone ester
- Recruitment of 400 couples, 10 centers, 7 countries
  - Recruitment - July 2008 – June 2009
  - Efficacy phase ends Dec 2011
  - Recovery phase ends Dec 2012
  - Data analysis and study report 2013
New Contraceptive Methods Needed

While tremendous success can be achieved by expanding access to existing methods, some additional methods would likely have immediate application if they were of low cost:

1. Non-hormonal, non-steroidal or novel estrogen or progestin oral contraceptives
2. New long-acting injectables in novel delivery systems
3. Non-surgical methods of male and female sterilization
4. Biodegradable implants
5. Novel dual protection methods
Picture shows actual size of Anterion Therapeutic’s injector and medicinal pellets. The area on the arm indicated by a circle and arrow illustrates the lack of scarring post implantation.
Dual Protection

Ethiopia Sex Workers

<table>
<thead>
<tr>
<th></th>
<th>Used for pregnancy prevention</th>
<th>Used for STD prevention</th>
</tr>
</thead>
<tbody>
<tr>
<td>Consistent Condom Use</td>
<td>65% *</td>
<td>24%</td>
</tr>
<tr>
<td>HIV infection rate</td>
<td>55% *</td>
<td>86%</td>
</tr>
<tr>
<td>Would not have sex with client who refuses to use condoms</td>
<td>54% *</td>
<td>10%</td>
</tr>
</tbody>
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* p< 0.001