LARCs and PMs, and…
New Contraceptive Technologies

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USAID/GH/PRH
Africa Health Officers State of the Art (SOTA) Conference
Johannesburg, South Africa, May 6-10, 2013
LARCs and PMs at a glance

Long Acting Reversible Contraceptives (LARCs)

IUDs
- CuT380A
- Mirena
- LNG-IUS

Implants
- Jadelle
- Implanon

Permanent Methods (PMs)
- Tubal Ligation
- Vasectomy
- Sino-Implant II
QUESTION:

WHAT ARE THE #1 AND THE #2 MOST COMMONLY USED MODERN CONTRACEPTIVE METHODS IN THE WORLD?
Worldwide, there is a wide range of method use... 
...and there is wide variation across and within regions.

**World**

- MCPR = 56%
- LARC/PM share = 63%
- TFR = 2.4

- Not Using: 37%
- Traditional: 7%
- Condom: 8%
- Pill: 9%
- Injectable: 4%
- Vasectomy: 2%
- Female Sterilization: 19%
- IUD: 14%

**Less Developed Countries**

- MCPR = 45%
- LARC/PM share = 56%
- TFR = 2.9

- Not Using: 47%
- IUD: 6%
- Implant: 0%
- Injectable: 5%
- Traditional: 8%
- Condom: 5%
- Pill: 10%

**Least Developed Countries**

- MCPR = 25%
- LARC/PM share = 19%
- TFR = 4.1

- Not Using: 69%
- Female Sterilization: 3%
- Injectable: 7%
- Pill: 11%
- Condom: 2%
- Trad: 6%
- Vasectomy: 1%
- IUD: 1%
- Implant: 1%

* excludes China

Demand for FP is high for spacing and limiting in Africa

<table>
<thead>
<tr>
<th>Country</th>
<th>Total demand</th>
<th>%satisfied</th>
<th>Demand to space</th>
<th>Demand to limit</th>
</tr>
</thead>
<tbody>
<tr>
<td>Rwanda (2010)</td>
<td>79%</td>
<td>60%</td>
<td>33%</td>
<td>46%</td>
</tr>
<tr>
<td>Malawi (2010)</td>
<td>73%</td>
<td>58%</td>
<td>33%</td>
<td>40%</td>
</tr>
<tr>
<td>Kenya (2008/09)</td>
<td>71%</td>
<td>55%</td>
<td>30%</td>
<td>41%</td>
</tr>
<tr>
<td>Zambia (2007)</td>
<td>68%</td>
<td>49%</td>
<td>41%</td>
<td>27%</td>
</tr>
<tr>
<td>Uganda (2011)</td>
<td>64%</td>
<td>41%</td>
<td>35%</td>
<td>29%</td>
</tr>
<tr>
<td>Tanzania (2010)</td>
<td>60%</td>
<td>46%</td>
<td>37%</td>
<td>23%</td>
</tr>
<tr>
<td>Madagascar (2008/9)</td>
<td>59%</td>
<td>50%</td>
<td>29%</td>
<td>30%</td>
</tr>
<tr>
<td>Ghana (2008)</td>
<td>59%</td>
<td>28%</td>
<td>34%</td>
<td>25%</td>
</tr>
<tr>
<td>Ethiopia (2011)</td>
<td>58%</td>
<td>47%</td>
<td>33%</td>
<td>25%</td>
</tr>
<tr>
<td>Mozambique (2003)</td>
<td>45%</td>
<td>25%</td>
<td>27%</td>
<td>18%</td>
</tr>
<tr>
<td>Nigeria (2008)</td>
<td>45%</td>
<td>28%</td>
<td>23%</td>
<td>12%</td>
</tr>
<tr>
<td>Senegal (2010/11)</td>
<td>43%</td>
<td>24%</td>
<td>31%</td>
<td>12%</td>
</tr>
<tr>
<td>Mali (2006)</td>
<td>36%</td>
<td>19%</td>
<td>26%</td>
<td>10%</td>
</tr>
</tbody>
</table>

Who can choose, and use LARCs and PMs?

Long Acting Reversible Contraceptives:
- Implants (Implanon, Jadelle, Sino-Implant II)
- IUDs (Cu T 380A, ML-375, LNG-IUS, Mirena)

Delaying first births
- Youth
- Nulliparous

Spacing between pregnancies
- Postpartum
- Postabortion

HIV+ women can use any LARC or PM

Permanent Methods:
- Tubal Ligation
- Vasectomy

Limiting births after desired fertility goals are reached
- High Parity
- Low Parity
- Postabortion
Total demand, unmet need and method use among all women in select SSA countries, with demand to space

Unmet need for spacing ranges from 10.3 in Kenya to 27.1% in Uganda

Use of LARCs to space is <1% in most countries to 2.4% in Rwanda

Height of bar = Total demand for FP to space
- 0% = No method use, or Unmet need to space
- 10% = Traditional method use to space
- 20% = Long-acting reversible method (IUD or implant) to space
- 30% = Other modern method use (resupply method) to space

Source: Most recent DHS; data for all women. Secondary analysis by EngenderHealth & Futures Institute (The RESPOND Project), 2012
Total demand, unmet need and method use among all women in select SSA countries with demand to limit

Unmet need for limiting ranges from 7.8% in Senegal to 18.4% in Uganda

Use of LARCs or PMs for limiting ranges from 1% in Senegal to 10% in Malawi

Source: Most recent DHS; data for all women. Secondary analysis by EngenderHealth & Futures Institute (The RESPOND Project), 2012.
FP2020: “Bending the curve”

To reach the 120 million goal means bending the curve upward in reaching more women with life-saving family planning information, services, and supplies.

This can be achieved through:

- increased country commitments
- increased donor engagement
- high impact/best practices
- new technologies

Historical progress

Accelerated progress following the Summit

120 million additional women
Successful programs can achieve a 1 point increase in MCPR per year. Of the 34 countries tracked, half have achieved/exceeded this increase over the last inter-survey period. Nine of the original 13 priority countries have achieved this success.

Note: 13 original priority countries are noted with purple bars.

Source: two most recent DHS surveys.
# Effectiveness of specific FP methods in preventing pregnancy

<table>
<thead>
<tr>
<th>Method</th>
<th># of unintended pregnancies among 1,000 women in 1st year of typical use</th>
</tr>
</thead>
<tbody>
<tr>
<td>No method</td>
<td>850</td>
</tr>
<tr>
<td>Withdrawal</td>
<td>220</td>
</tr>
<tr>
<td>Female condom</td>
<td>210</td>
</tr>
<tr>
<td>Male condom</td>
<td>180</td>
</tr>
<tr>
<td>Pill</td>
<td>90</td>
</tr>
<tr>
<td>Injectable</td>
<td>60</td>
</tr>
<tr>
<td>IUD</td>
<td>8 / 2 (Cu-T / LNG-IUS)</td>
</tr>
<tr>
<td>Female sterilization</td>
<td>5</td>
</tr>
<tr>
<td>Vasectomy</td>
<td>1.5</td>
</tr>
<tr>
<td>Implant</td>
<td>0.5</td>
</tr>
</tbody>
</table>
LARCs and PMs: Characteristics & Service Requirements

Characteristics:
- Highly effective
- Most cost-effective over time
- Popular when accessible (good fit with reproductive intentions)

Service Requirements:
- Ensure voluntary, informed choice
- Skilled, motivated, enabled providers
  “Provider-dependent”
  “No provider, no program”
- Contraceptives, essential medical instruments expendable medical supplies
  “No products, no program”
- Suitable service setting
### Typical unit costs of contraceptive methods in public sector FP programs

<table>
<thead>
<tr>
<th>Method</th>
<th>Unit Cost</th>
</tr>
</thead>
<tbody>
<tr>
<td>Condoms</td>
<td>$0.025</td>
</tr>
<tr>
<td>Pill</td>
<td>$0.21</td>
</tr>
<tr>
<td>Female condom</td>
<td>$0.77</td>
</tr>
<tr>
<td>Injectable</td>
<td>$0.87</td>
</tr>
<tr>
<td>LNG-IUS</td>
<td>$0.00*</td>
</tr>
<tr>
<td>IUD-CuT</td>
<td>$0.56</td>
</tr>
<tr>
<td>Sino-implant I</td>
<td>$8.00</td>
</tr>
<tr>
<td>Jadelle</td>
<td>$8.50</td>
</tr>
<tr>
<td>Implanon</td>
<td>$8.50</td>
</tr>
<tr>
<td>Male sterilization</td>
<td>$4.95</td>
</tr>
<tr>
<td>Female sterilization</td>
<td>$9.09</td>
</tr>
</tbody>
</table>

* Available from the ICA Foundation
Cost effectiveness per couple year of protection

* Costs include the commodity, materials and supplies, labor time inputs and annual staff salaries. The height of each bar shows the average value of costs per CYP across 13 USAID priority countries.

Price-Volume Guarantees for Implants

**Jadelle (Bayer)**
- Price reduced to $US 8.50
- 27 million over 6 years
- Incremental increases: 3m/Y1, 4m/Y2, 5m/Y3…
- Expand country registrations

**Implanon (Merck)**
- Price reduced to $US 8.50
- 13 million over 6 years
- Same quantity per year (2.17m)
- New NXT inserter phase-in
- Expand country registrations

**Implications for Programs:**
- 40 million implants over 6 years; 69 countries are eligible
- Plan and coordinate service scale-up with forecasting / procurement
- Ensure informed and voluntary choice, quality care, management of side-effects, removal services
# Comparison of available implants

<table>
<thead>
<tr>
<th></th>
<th>Sino-implant (II)</th>
<th>Jadelle</th>
<th>Implanon</th>
</tr>
</thead>
<tbody>
<tr>
<td><strong>Manufacturer</strong></td>
<td>Shanghai Dahua Pharmaceutical</td>
<td>Bayer Schering Pharma</td>
<td>Merck</td>
</tr>
<tr>
<td><strong>Formulation</strong></td>
<td>150 mg levonorgestrel in 2 rods</td>
<td>150 mg levonorgestrel in 2 rods</td>
<td>68 mg etonogestrel in 1 rod</td>
</tr>
<tr>
<td><strong>Mean Insertion &amp; Removal time</strong></td>
<td>Insertion: 2 min, Removal: 4.9 min</td>
<td>Insertion: 2 min, Removal: 4.9 min</td>
<td>Insertion: 1.1 min, Removal: 2.6 min</td>
</tr>
<tr>
<td><strong>Labeled duration of product use</strong></td>
<td>4 years</td>
<td>5 years</td>
<td>3 years</td>
</tr>
<tr>
<td><strong>Trocars</strong></td>
<td>Disposable</td>
<td>Disposable</td>
<td>Pre-loaded disposable; NXT inserter phasing-in</td>
</tr>
<tr>
<td><strong>Cost of implant (US$)</strong></td>
<td>$8.00</td>
<td>$8.50</td>
<td>$8.50</td>
</tr>
<tr>
<td><strong>Product Cost per Year (if used for duration)</strong></td>
<td>$2.00</td>
<td>$1.70</td>
<td>$2.80</td>
</tr>
<tr>
<td><strong>WHO Prequalification</strong></td>
<td>Application submitted</td>
<td>Yes</td>
<td>Yes</td>
</tr>
</tbody>
</table>
What are the New Frontiers for LARCs/PMs?

• 2014: WHO review of Medical Eligibility Criteria (MEC) for Progestin-only methods, for immediate postpartum use

• Task Shifting for LARCs and PMs – WHO “Optimizing the health workforce for effective family planning services”

• Reaching youth and first time parents with LARC counseling and services – for delaying and spacing pregnancy (an ACOG recommendation)

• Offer LARCs / PMs with PAC services

• LNG-IUS for contraception, dysmenorrhea, anemia

• Female Sterilization for younger, low parity women
  —or—

• Vasectomy for their partners
Service Delivery Strategies for Expanding Access to & Choice of LARCs and PMs

- Trained, dedicated providers in facilities or communities
- Task Shifting
- Mobile Clinical Outreach
- Integrated with MNCH, Nutrition, PMTCT, HIV
- Special “event days”
- Social franchises of private clinics
- Financing schemes, vouchers
- Contracting-out, contracting-in
- CHW referrals

- “Twinning” IUD and Implants services
- Single nurse or midwife provides outreach
<table>
<thead>
<tr>
<th>Method</th>
<th>CYP Per Unit</th>
</tr>
</thead>
<tbody>
<tr>
<td>Copper-T 380-A IUD</td>
<td>4.6 CYP per IUD inserted (3.3 for 5 year IUD e.g. LNG-IUS)</td>
</tr>
<tr>
<td>3 year implant (e.g. Implanon)</td>
<td>2.5 CYP per implant</td>
</tr>
<tr>
<td>4 year implant (e.g. Sino-Implant)</td>
<td>3.2 CYP per implant</td>
</tr>
<tr>
<td>5 year implant (e.g. Jadelle)</td>
<td>3.8 CYP per implant</td>
</tr>
<tr>
<td>Emergency Contraception</td>
<td>20 doses per CYP</td>
</tr>
<tr>
<td>Fertility Awareness Methods</td>
<td>1.5 CYP per trained adopter</td>
</tr>
<tr>
<td>Standard Days Method</td>
<td>1.5 CYP per trained adopter</td>
</tr>
<tr>
<td>LAM</td>
<td>4 active users per CYP (or .25 CYP per user)</td>
</tr>
<tr>
<td>Sterilization*</td>
<td></td>
</tr>
<tr>
<td>Global (India, Nepal, Bangladesh)</td>
<td>10</td>
</tr>
<tr>
<td>Oral Contraceptives</td>
<td>15 cycles per CYP</td>
</tr>
<tr>
<td>Condoms (Male and Female)</td>
<td>120 units per CYP</td>
</tr>
<tr>
<td>Vaginal Foaming Tablets</td>
<td>120 units per CYP</td>
</tr>
<tr>
<td>Depo Provera (DMPA) Injectable</td>
<td>4 doses per CYP</td>
</tr>
<tr>
<td>Noristerat (NET-En) Injectable</td>
<td>6 doses per CYP</td>
</tr>
<tr>
<td>Cyclofem Monthly Injectable</td>
<td>13 doses per CYP</td>
</tr>
<tr>
<td>Monthly Vaginal Ring/Patch</td>
<td>15 units per CYP</td>
</tr>
</tbody>
</table>

*The CYP conversion factor for sterilization varies because it depends on when the sterilization is performed in the reproductive life of the individual. For more specific data on CYPs and sterilization, consult with national DHS and CDC reproductive health survey records which may provide a historical calculation based on a specific country’s context.
WHAT ELSE IS NEW IN THE WORLD OF CONTRACEPTIVES?
Sayana Press - What is it?
How is it different from DMPA IM?

Current standard

DMPA IM 150

- 150 mg DMPA.
- Delivered every 3 months.
- Glass vial with syringe.
- Intramuscular injection.
- 1” needle.
- Site: deep muscle tissue.
- 99% contraceptive efficacy.
- Depo-Provera® brand: Pfizer, Inc.
- Generic equivalents made by various manufacturers.

Sayana Press

- 104 mg DMPA.
- Delivered every 3 months.
- Prefilled in Uniject.
- Subcutaneous injection.
- 3/8” needle.
- Site: subcutaneous fat.
- Equivalent contraceptive efficacy, safety, and side effects.

Sayana Press is a registered trademark of Pfizer, Inc.
Pilot introduction of Sayana® Press

• Sayana Press pilot introduction announced at London Summit on Family Planning (FP2020): Innovative partnership to deliver convenient contraceptives to up to 3 million women

• Sayana Press pilot introduction consortium:
  o DFID, USAID, Bill & Melinda Gates Foundation, PATH, UNFPA, Pfizer

Objectives
• Deliver up to 12 million units of Sayana Press in four to six countries in Sub-Saharan Africa and South Asia, 2013–2016.
• Expand access to injectables for new users, improve continuation, and reduce delivery costs.
• Evaluate the value proposition of Sayana Press: Inform decision-making about whether to include Sayana Press in family planning programs in the future.

Anticipated countries for pilot introduction
• Bangladesh, Burkina Faso, Niger, Senegal, Uganda
New “gap-filling” FP Methods

One-Year Contraceptive Methods

- Help to fill the gap between 3-month injectables and five-year implants
- Eliminate the need for repeated visits to the doctor or pharmacy for re-supply

NES+EE Contraceptive Vaginal Ring (Pop Council, NICHD, BMGF)

- First long-term hormonal method completely under the woman’s control
- Used “3-wks in/1-wk out” to mimic normal cycle
- Proven very effective in two large Phase III clinical trials
- FDA approval expected 2014

Biodegradable Contraceptive Pellets (FHI 360)

- Effective contraceptive placed under the skin, similar to but much smaller than an implant
- Biodegradability would eliminate the need for removal at the end of one year
- Landscape analysis of manufacturers underway
3. Multipurpose Prevention Technologies (MPTs)

- **“On demand” products:**
  - Used at the time of intercourse
  - Appropriate for women who have infrequent sex, or who would like more direct control over their own protection

- **Sustained release devices:**
  - User-initiated, but not requiring daily action
  - Should increase adherence, and therefore overall effectiveness
MPTs: “On Demand” Barriers and Gels

- **SILCS Diaphragm + TFV Gel** (CONRAD)
  - Uses the SILCS diaphragm as a delivery device for TFV gel
  - Designed for effective protection for up to 24 hours
  - Most advanced in terms of FDA approval for the individual components, and bridging studies for combined use
  - *Would be a non-hormonal method to prevent pregnancy, HIV and HSV-2*

- **MZL Combination Topical Gel** (Population Council)
  - Combines MIV-150 + Zinc Acetate + the progestin LNG in carrageenan gel
  - Provides effective protection for up to 24 hours
  - Gel optimization and initial PK in vivo underway
  - *Would prevent pregnancy, HIV, HSV-2 and HPV*
**MPTs: Sustained-Release Devices: Combination Intravaginal Rings (IVRs)**

- **MZL Combination IVR** (Population Council)
  - Combines MIV-150 + Zinc Acetate + LNG in a vaginal ring
  - Designed for **30 days** of continuous use
  - Formulation and in-vitro testing are underway
  - **Would prevent pregnancy, HIV and HSV-2**

- **Dapivirine + LNG IVR** (IPM)
  - Combines the ARV Dapivirine + LNG
  - Designed for **60 days** of continuous use
  - Formulation and in-vitro testing are underway
  - **Would prevent pregnancy and HIV**

- **Tenofovir + LNG IVR** (CONRAD)
  - Combines tenofovir (TFV) with LNG
  - Designed for **90 days** of continuous use
  - In-vivo testing underway; clinical studies to begin late 2013
  - **Would prevent pregnancy, HIV and HSV-2**
Bayer-USAID Contraceptive Security Initiative details:

- Microgynon Fe brand
- Launching in 11 countries in middle band of Africa
- Targets middle income consumers who prefer to purchase in pharmacies
- Price band +/- $1 USD per cycle pack
- Fully sustainable
- Bayer LT commitment to brand

Benefits of Manufacturer’s Model Partnership:

- No need for USG subsidy – product is fully commercially sustainable after initial period of brand awareness building
- Allows missions to more effectively target subsidized product to the poorest
- Moves contraceptive market toward greater sustainability
- Makes room to concentrate on LARC-PMs, other technologies

Subsidy-free, affordable OCs
RESOURCES:

- LARCs / PMs: Trish MacDonald - pmacdonald@usaid.gov
- New Technologies: Judy Manning - jmanning@usaid.gov
- Sayana Press: Victoria Graham - vgraham@usaid.gov
- Microgynon Fe: Andrea Harris – aharris@usaid.gov
- K4Health Toolkits: www.k4health.org
Here’s the “health payoff” if expanded access to FP, and choice of LARCs/PMs, are increased

- 222 million women in the developing world have an unmet need for FP
- Meeting this need would prevent 54 million unintended pregnancies
  - 26,000,000 fewer abortions
  - ~80,000 fewer maternal deaths
  - 2,400,000 fewer serious morbidities
  - 1,100,000 fewer infant deaths
  - >300,000 fewer children lose mother
- Many other family, societal and national benefits.
- A matter of social justice
COUNTRY EXAMPLES of Service Delivery Approaches:

Malawi
Mali
Senegal
Thank you