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# LARCs and PMs, and... New Contraceptive Technologies



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# LARCs and PMs at a glance

## Long Acting Reversible Contraceptives (LARCs)



CuT380A

IUDs



- Mirena
- LNG-IUS

Implants

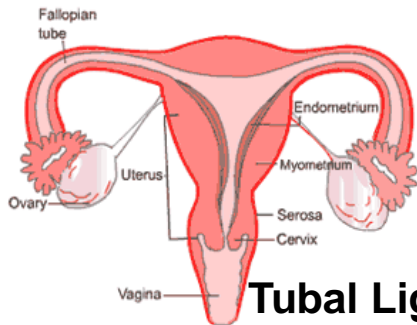


Jadelle



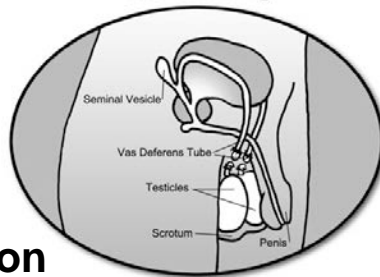
Implanon

## Permanent Methods (PMs)



Tubal Ligation

### Vasectomy



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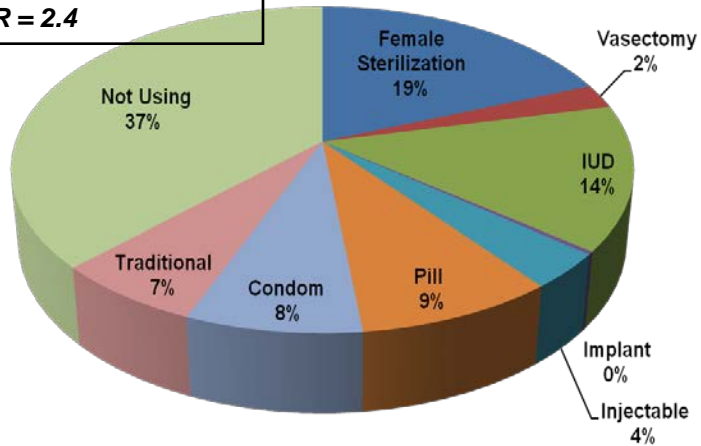
Sino-Implant II

# QUESTION:

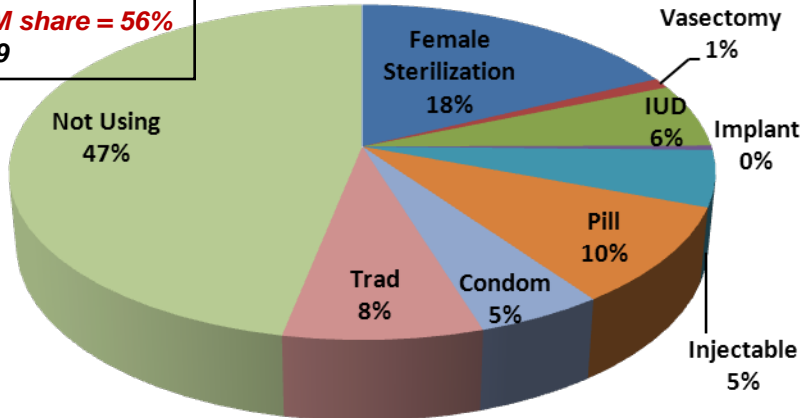
WHAT ARE THE #1 AND THE #2  
MOST COMMONLY USED  
MODERN CONTRACEPTIVE METHODS  
IN THE WORLD?

# 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

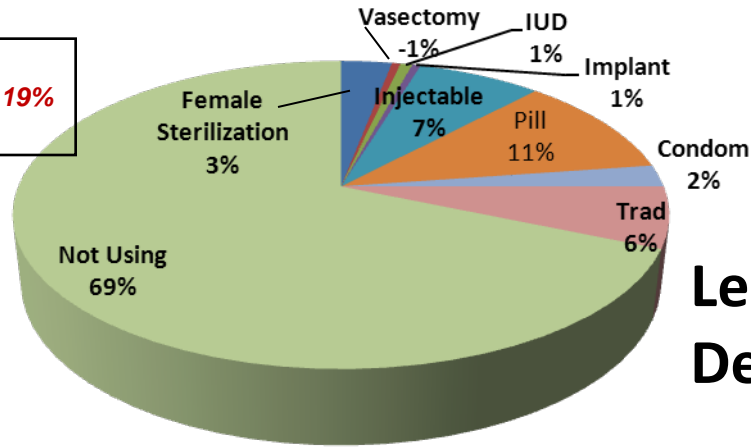


**Less Developed Countries\***  
 MCPR = 45%  
 LARC/PM share = 56%  
 TFR = 2.9



\* excludes China

**Least Developed Countries**  
 MCPR = 25%  
 LARC/PM share = 19%  
 TFR = 4.1



## Least Developed Countries



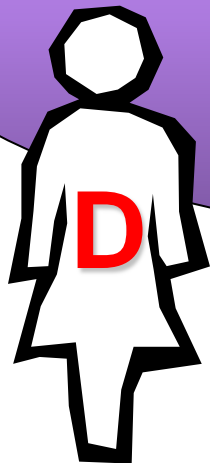
Source: World Contraceptive Use 2011, UN Population Division, 2011.

# Demand for FP is high for spacing and limiting in Africa

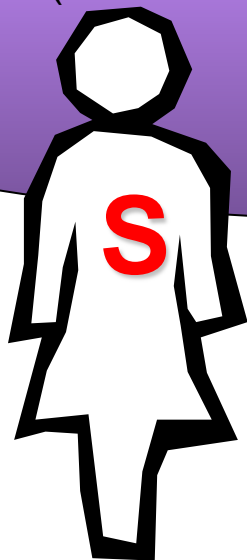
Country	Total demand	%satisfied	Demand to space	Demand to limit
Rwanda (2010)	<b>79%</b>	60%	33%	<b>46%</b>
Malawi (2010)	<b>73%</b>	58%	33%	<b>40%</b>
Kenya (2008/09)	<b>71%</b>	55%	30%	<b>41%</b>
Zambia (2007)	<b>68%</b>	49%	41%	27%
Uganda (2011)	<b>64%</b>	41%	35%	29%
Tanzania (2010)	<b>60%</b>	46%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

# 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

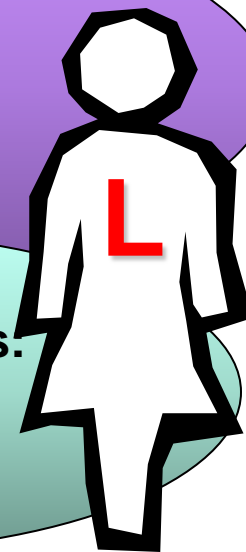


**Spacing**  
between pregnancies  
-Postpartum  
-Postabortion



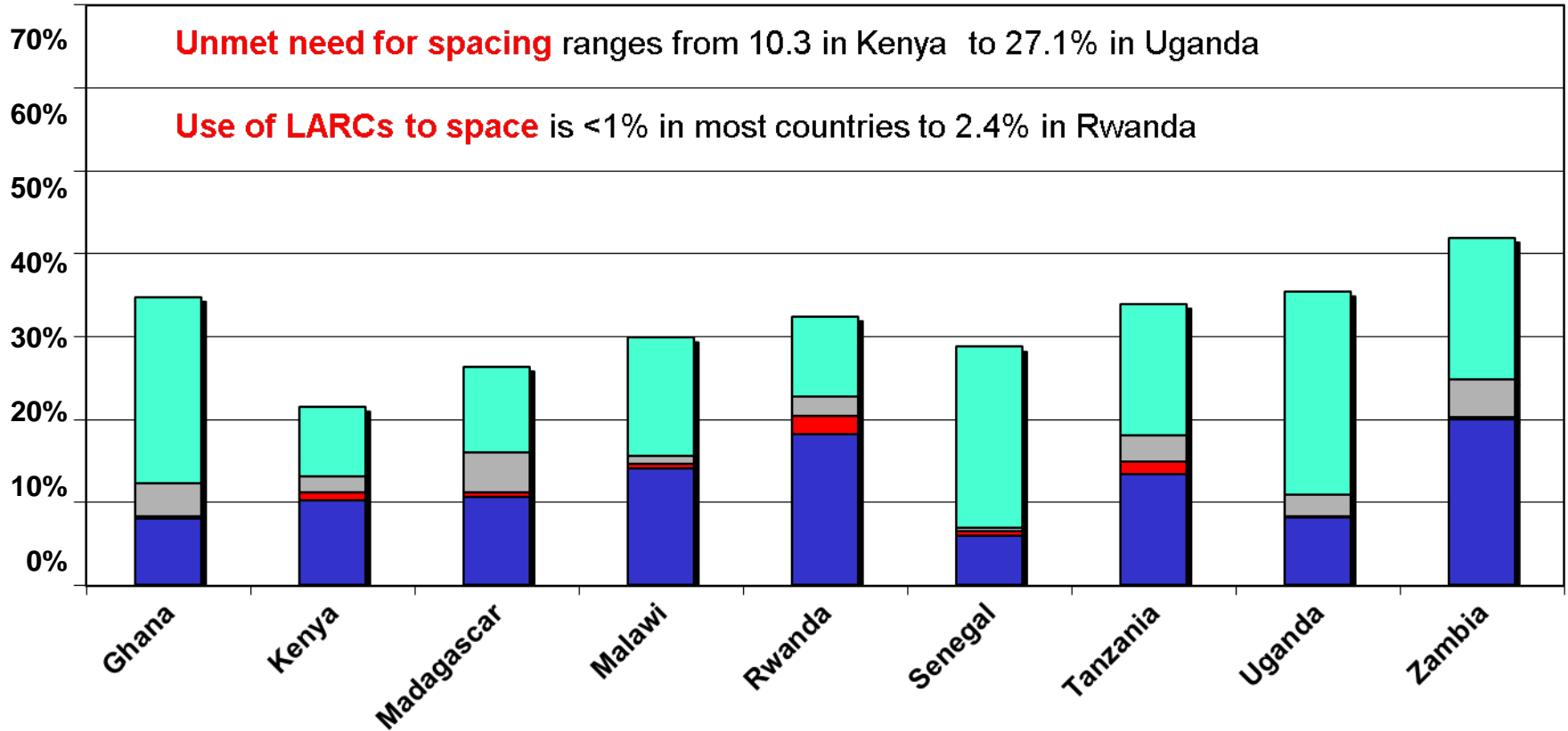
**HIV+**  
women can  
use any  
LARC or PM

**Permanent Methods.**  
Tubal Ligation  
Vasectomy



**Limiting** births  
after desired fertility  
goals are reached  
- High Parity  
- Low Parity  
-Postabortion

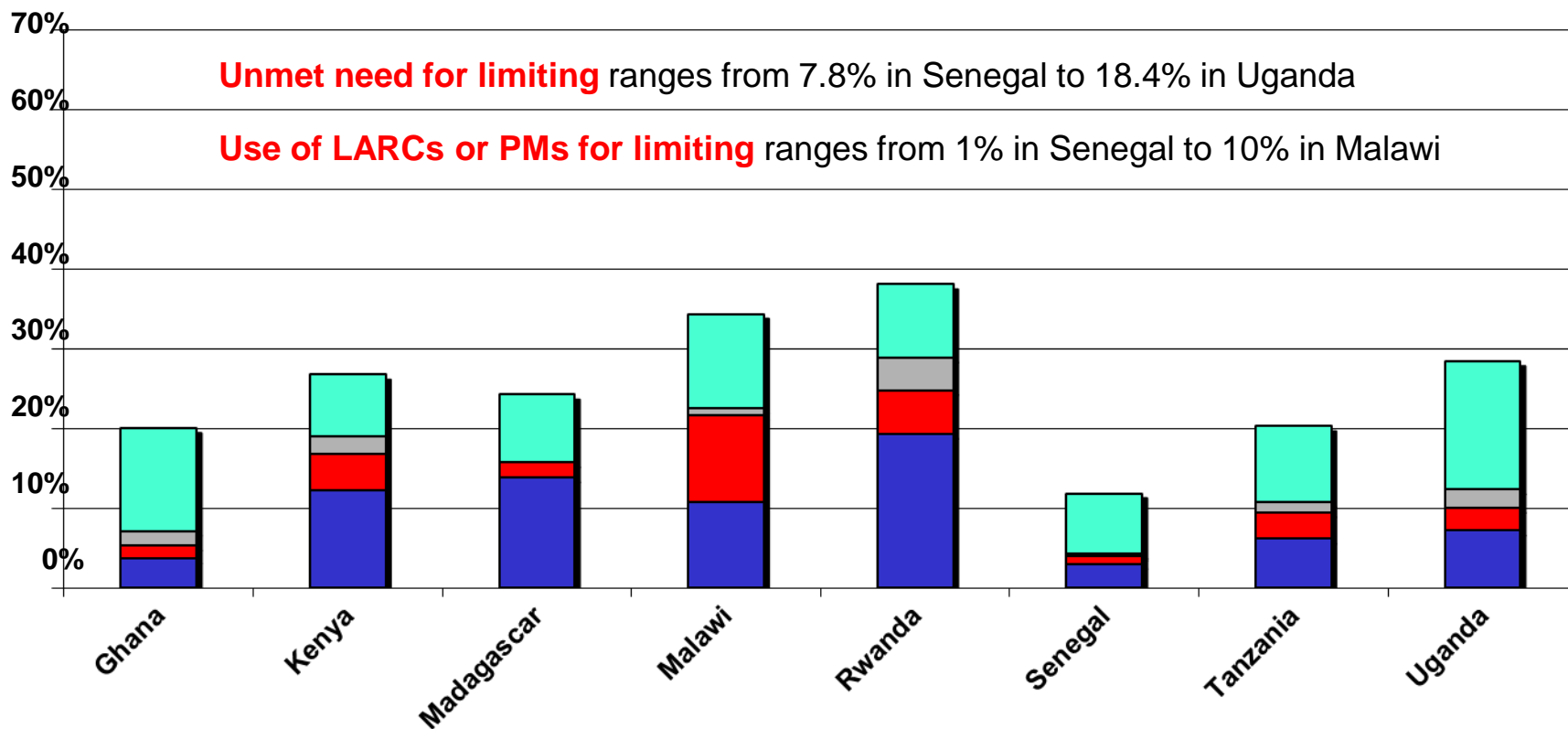
# Total demand, unmet need and method use among all women in select SSA countries, with demand to **space**



Height of bar = Total demand for FP to space

■ + ■ = Unmet need for modern FP to space  
■ = Long-acting reversible method (IUD or implant) to space  
■ = Other modern method use (resupply method) to space  
■ = No method use, or Unmet need to space  
■ = Traditional method use to space

# Total demand, unmet need and method use among all women in select SSA countries with demand to **limit**



Height of bar = Total demand for FP to limit

Using no method to limit

Using traditional method to limit

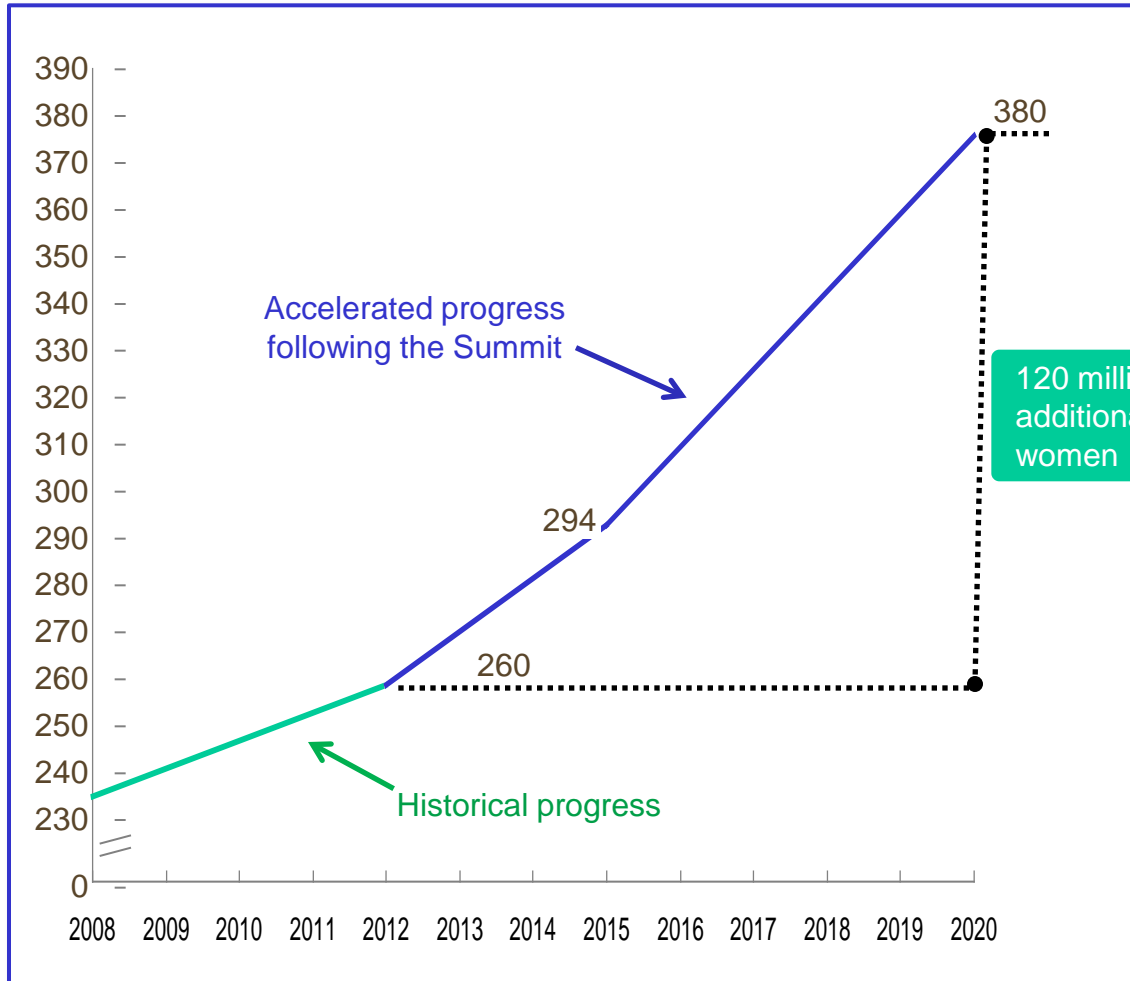
Using no method to limit + Using traditional method to limit = Unmet need for modern FP to limit

Using one of the four LAPMs to limit

Other modern method use (resupply method) to limit



# FP2020: “Bending the curve”

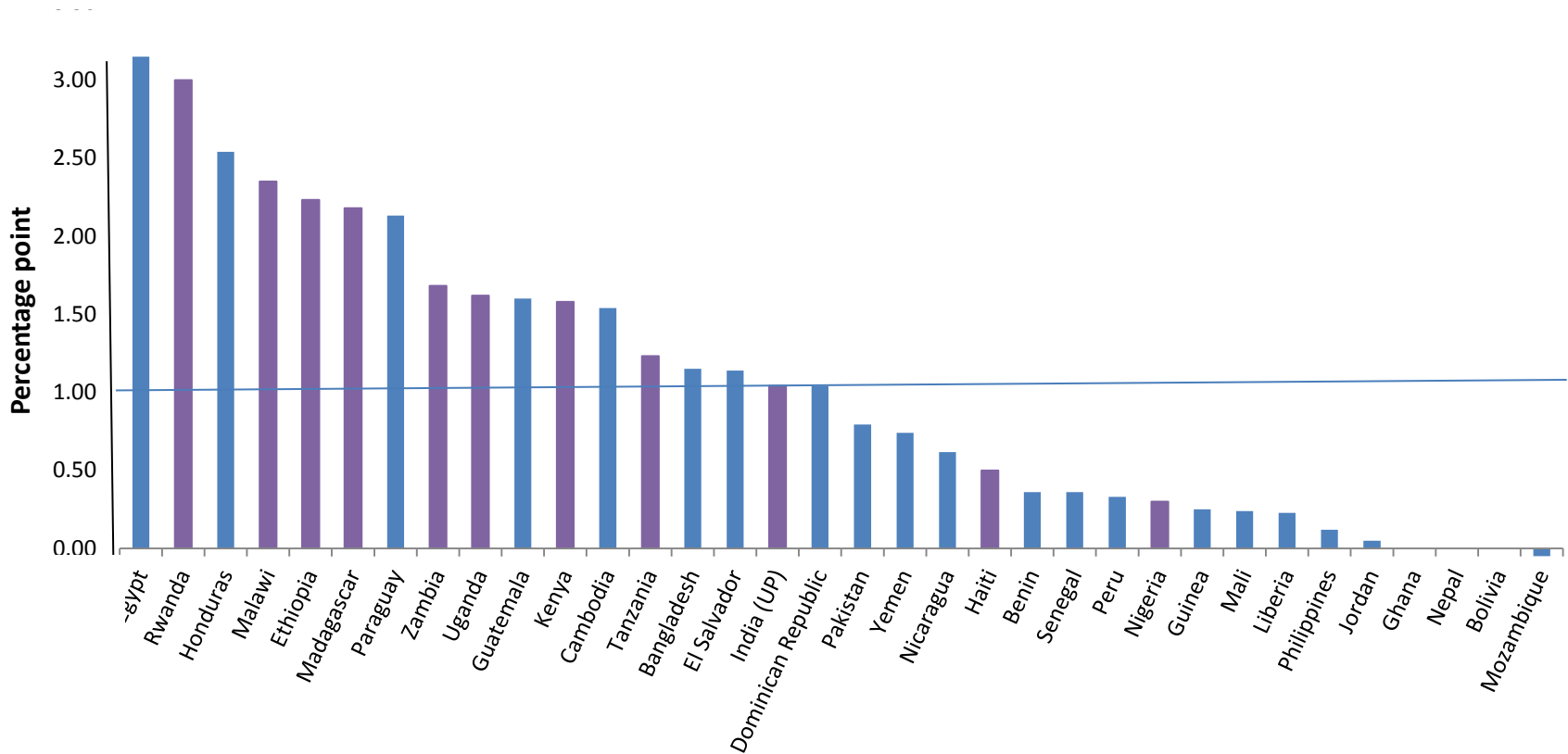


To reach the 120 million goal means bending the curve upward in reaching more women with life-saving family planning information, services, and supplies.

This can be achieved through:

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

# Performance: Average annual change in MCPR



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.*

# Effectiveness of specific FP methods in preventing pregnancy

Method	# of unintended pregnancies among 1,000 women in 1 <sup>st</sup> year of typical use
No method	850
Withdrawal	220
Female condom	210
Male condom	180
Pill	90
Injectable	60
IUD	8 / 2 (Cu-T / LNG-IUS)
Female sterilization	5
Vasectomy	1.5
Implant	0.5

# LARCs and PMs: Characteristics & Service Requirements

## Characteristics:

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



## Service Requirements:

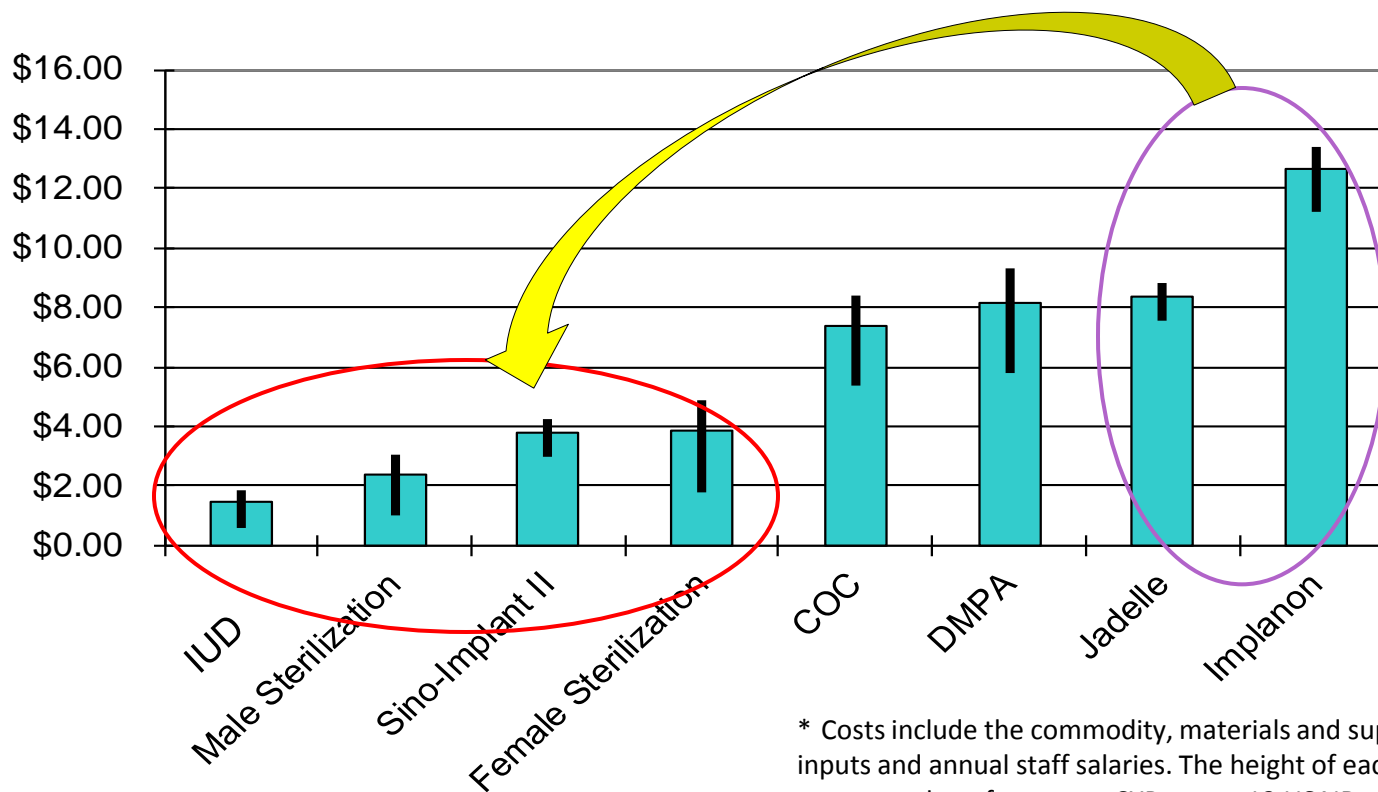
- Ensure **voluntary, informed choice**
- Skilled, motivated, enabled providers  
“Provider-dependent”  
**“No provider, no program”**
- Contraceptives, essential medical instruments expendable medical supplies  
**“No products, no program”**
- Suitable service setting

# Typical unit costs of contraceptive methods in public sector FP programs

Method	Unit Cost
Condoms	\$0.025
Pill	\$0.21
Female condom	\$0.77
Injectable	\$0.87
LNG-IUS	\$0.00*
IUD-CuT	\$0.56
Sino-implant I	\$8.00
Jadelle	\$8.50
Implanon	\$8.50
Male sterilization	\$4.95
Female sterilization	\$9.09

\* 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.

Source: Tumlinson, K., Steiner, M., Rademacher, K., Olawa, A., Solomon, M. and Bratt, J., 2011. The promise of affordable implants: is cost recovery possible in Kenya? *Contraception*, Jan; 83(1):88-93.

# 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

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



# 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



- “Twinning” IUD and Implants services
- Single nurse or midwife provides outreach

- 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

# CYP CONVERSION FACTORS - UPDATED 2011

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

\*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



### 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



### 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.
- Pfizer product: Patent until 2020.



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*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:
  - 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



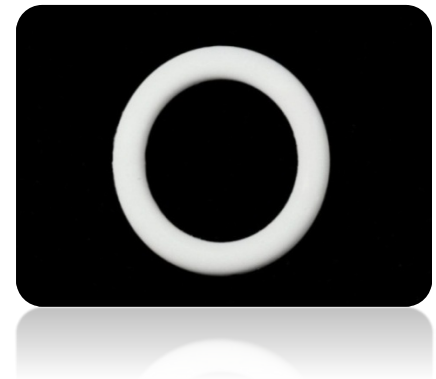
# New “gap-filling” FP Methods

## ➤ 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)

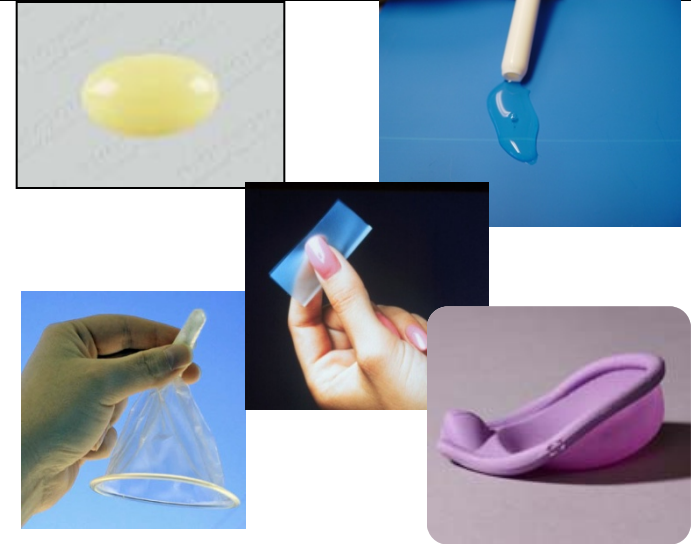
- Effective contraceptive placed under the skin, similar to but much smaller than an implant
- Biodegradability would eliminate the need for removal at the end of one year
- Landscape analysis of manufacturers underway



### 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*



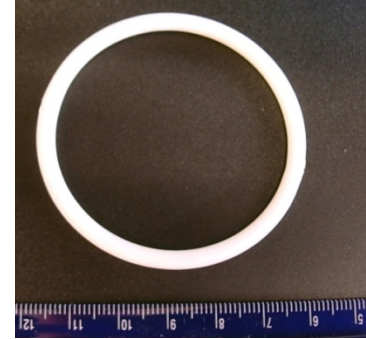
## ❖ **MZL Combination Topical Gel** (Population Council)

- 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*



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# Subsidy-free, affordable OCs

## 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**

## RESOURCES:

- LARCs / PMs: Trish MacDonald - [pmacdonald@usaid.gov](mailto:pmacdonald@usaid.gov)
- New Technologies: Judy Manning - [jmanning@usaid.gov](mailto:jmanning@usaid.gov)
- Sayana Press: Victoria Graham - [vgraham@usaid.gov](mailto:vgraham@usaid.gov)
- Microgynon Fe: Andrea Harris – [aharris@usaid.gov](mailto:aharris@usaid.gov)
- K4Health Toolkits: [www.k4health.org](http://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**



Photo by Staff/EngenderHealth



Photo by R. Mowil/EngenderHealth



Photo by C.Svingen/EngenderHealth





# **COUNTRY EXAMPLES of Service Delivery Approaches:**

**Malawi  
Mali  
Senegal**

# Thank you

