

# **Planning for Woman's Condom Launch in China: Implications for Broader Access**

Neeti Nundy  
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Family Planning  
Dakar, Senegal  
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# Female condoms – expanding choice

- Female condoms are sheaths that fit inside a woman's vagina made of thin soft film or latex.
- Designed to protect from both pregnancy and STIs, including HIV.
- Male condoms are effective and difficult to negotiate use consistently.
- Female condom use: women can initiate and requires partner cooperation.
- Sales of female condoms were 40 million units in 2010.



## Female condoms products

Top left: FC2® female condom

Top right: Cupid™ Condom

Bottom left: Woman's Condom/O'lavie

Bottom right: VA w.o.w. female condom

Photo credit: PATH



# Woman's Condom – ease of use and good sensation

- User-centered development process.
- Designed for dual protection.
- Acceptability, safety, and performance validated in clinical studies.
- Performs as well or better than other female condoms for acceptability and performance.
- Unique features improve ease of use and sensation.



**Pre-insertion**



**Post-insertion**



# Dahua – high quality manufacturing in China

- In 2008, PATH licensed the Woman's Condom to the Shanghai Dahua Medical Apparatus Company (Dahua).
- Since then, Dahua has focused on technical transfer, production scale-up, building inventory for clinical trials and regulatory submissions.



CE Mark	Complete
Shanghai FDA	Complete
WHO technical review	In process
USFDA	IDE filed

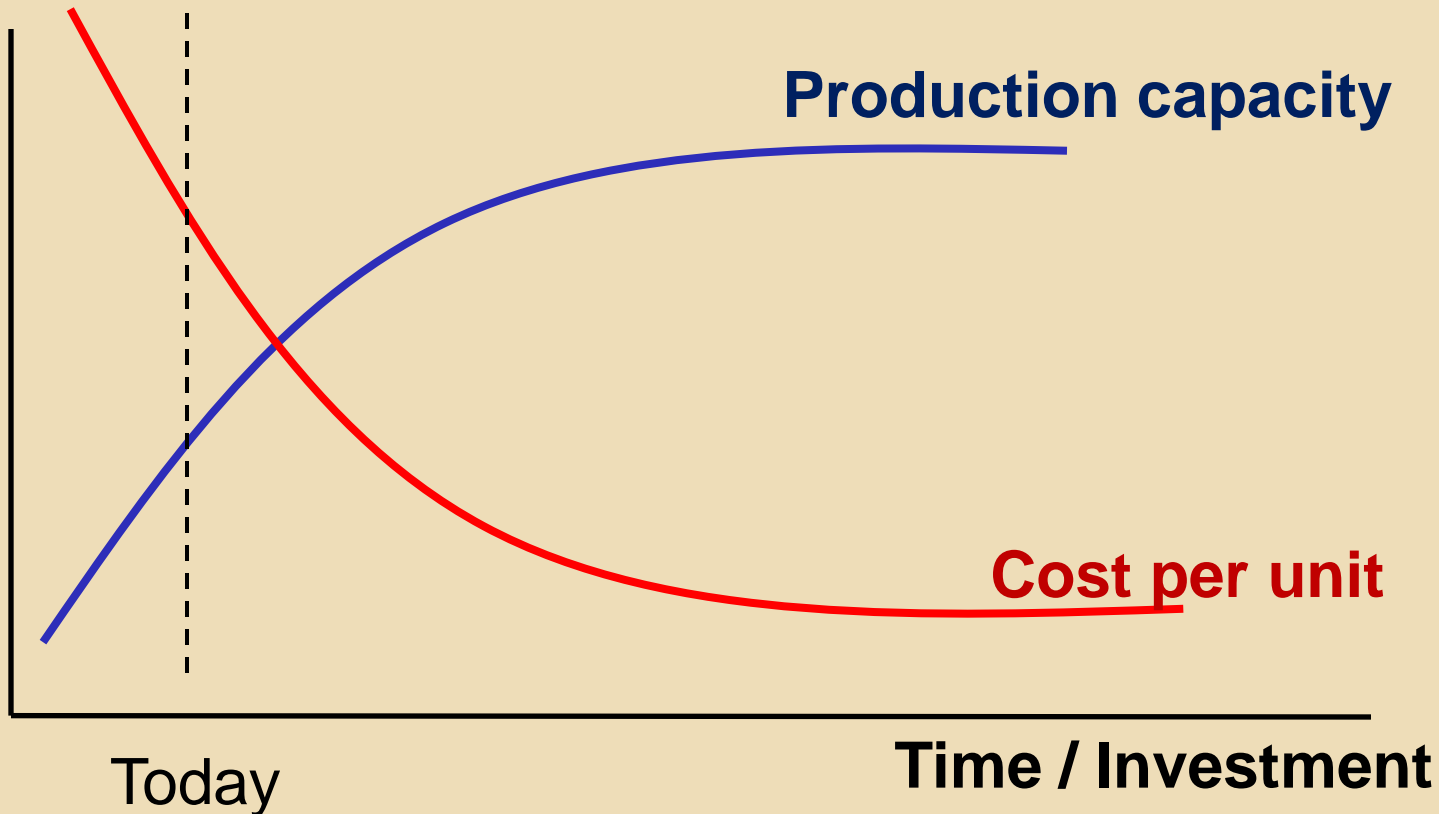
# New partnership to test the total market approach in two countries

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- POW Product Development Partnership (PDP): PATH, Dahua, CONRAD and NICHD.
- Goals:
  - Build evidence of Woman's Condom effectiveness.
  - Focus first on developing markets in China and sub-Saharan Africa.
  - Build toward sustainable markets using a total market approach.
  - Engage in advocacy to raise awareness and build demand globally and regionally.



# Using the private sector to support public sector introduction



# Unmet need exists in China

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- China has a strong family planning system, however this system was largely built to serve married couples.
- Although China's STI and HIV epidemic remains one of low prevalence overall, there are pockets of high infection among specific subpopulations and regions.
- IUDs and sterilization are the most commonly used methods and male condom use is growing.
- Female condom awareness is low, though studies of female condoms in the country show that it is acceptable to various users (Xu et al., 1999; Zhou et al., 2000; Jiang et al., 2004; Yimin et al., 2002).





# Formative research confirmed interest in the Woman's Condom

- Focus group discussions among nine potential user groups.
  - Notable interest in using the Woman's Condom for STI prevention and pregnancy prevention.
  - Men were interested in using this product (maybe more so than women).
  - Biggest challenge: lack of familiarity with product.
- Phase I Couples' use and performance study among 60 couples in Shanghai.
  - The Woman's Condom performed well in terms of acceptability and performance. Similar failure rates to studies in other countries.





# Market research helped set the introduction strategy

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- PATH and Dahua supported a number of market research studies to understand the potential of the Woman's Condom in both the private and public sectors.
  - market segmentation
  - target audience profiles
  - positioning and branding
  - distribution and promotion channel analysis
  - stakeholder mapping



# Fashionable Chinese youth could be the first adopters in the private sector

## Target users

University students  
Young professionals



## Distribution

Online  
Pharmacy and other retail outlets  
Hotel chains  
Clinics

## Promotion

Product website  
Online advertising  
Events  
Print media  
TV / Radio



# Creating positive perceptions of the Woman's Condom

## Current Belief

Male condom is the only choice for dual protection



## Desired Belief

Woman's Condom is another choice to provide dual protection and offers good sexual experience



# Working with the Chinese government to reach target users in the public sector

## Target users

Youth  
Migrant workers  
Discordant couples  
Commercial sex workers



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## Distribution

Family Planning System  
MOH - CDC System  
Social marketing and local NGOs

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## Promotion

Events  
Print media  
TV / Radio  
Outreach



# Implications for broader access

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- Follow methodology used in China to conduct market research in priority regional markets beginning in South Africa.
- Use the POW PDP to form partnerships in sub-Saharan Africa to build demand and grow markets.
- Draw lessons learned and capture market data from China and sub-Saharan Africa introduction to build the case for broader market introduction.
- Continue to advocate and build support for female condoms globally while raising awareness about the Woman's Condom.



# Conclusions

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- The POW PDP aims to test various market strategies to build toward a more sustainable market.
- Supply can not be built overnight; it must grow with demand.
- Success in the private sector can facilitate cost recovery and support public sector programming .
- Developing a total market approach takes careful planning which must be informed by market research.
- By getting the economic model right, we can build a sustainable mechanism to provide an important protection option to women and men who need it most.



# Thank you!

## PATH-Dahua Protection Options for Women Product Development Partnership

Please contact us for more information

### **Woman's Condom project:**

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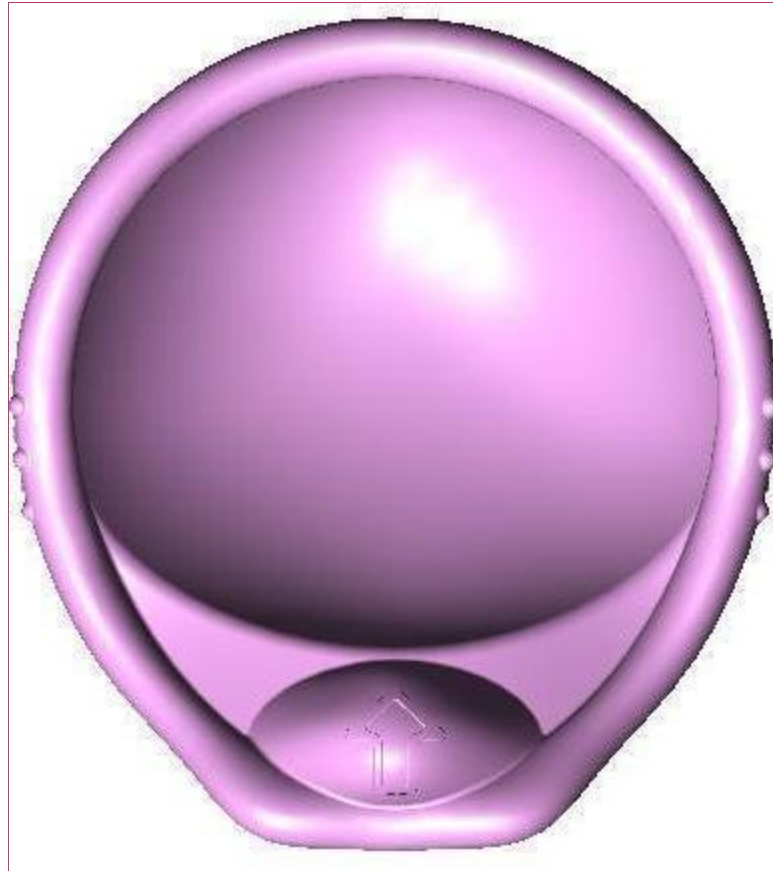
# SILCS DIAPHRAGM: POTENTIAL FOR INTRODUCTION IN LOW-RESOURCE SETTINGS

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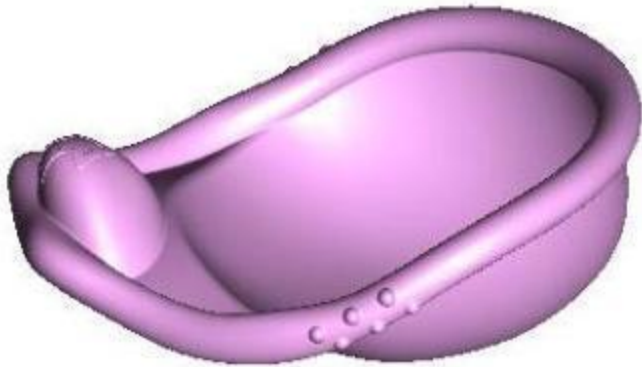
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# SINGLE-SIZE SILCS DIAPHRAGM

Top view



Side view



# THE ASSESSMENT

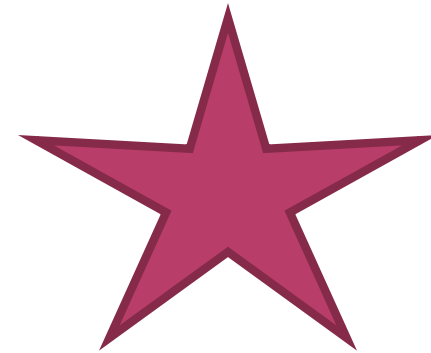
## Objective

- To identify and evaluate opportunities and potential challenges of introducing the SILCS Diaphragm into the existing service delivery system in Uganda

## Methods

- 53 key informant interviews and 31 focus group discussions (FGDs)
- Participants: men and women (potential users) reproductive health service providers, marketing groups, religious and community representatives, policymakers, regulatory authorities, and donors

FIGURE 1: MAP OF UGANDA SHOWING THE DISTRICTS WHICH PARTICIPATED IN THE ASSESSMENT



East: Mbale  
Central: Kampala  
Southwest: Mbarara

# WHY CONDUCT THIS ASSESSMENT IN UGANDA?

- ◉ Outcomes of high fertility
  - Morbidity due to frequent childbearing or unsafe abortions
  - High maternal mortality (435 per 100,000)
  - High infant mortality (76 per 1,000)
- ◉ Low contraceptive use
- ◉ High unmet need for family planning (FP)
  - 25% for birth spacing and 16% for limiting



# FOCUS OF THE ASSESSMENT

- ◉ Current status of family service delivery and use
  - Service delivery logistics and supply chain management for family planning products
  - Women's and men's experiences with family planning
- ◉ Women's/men's interest in a female-initiated cervical barrier contraceptive method and concerns about SILCS
- ◉ Opportunities/challenges regarding future introduction of SILCS
- ◉ Regulatory pathways for introduction of a new medical device
- ◉ Appropriate channels for introduction of a new female-initiated contraceptive

# FAMILIARITY WITH DIAPHRAGMS

- ◉ Most participants unfamiliar with the diaphragm
  - Much awareness-raising needed before ready to introduce this new method
- ◉ FP trainers remembered diaphragms as a safe and effective method
- ◉ Diaphragms still part of the FP guidelines, so would be revitalization of the diaphragm into the method mix



# QUESTIONS FROM WOMEN AND MEN

## ◉ Ease of use

*"Insert-remove-insert every time...Isn't it difficult to remove?"*

*"Can one urinate with it?"; "Suppose it fits badly?"; "Can't it disappear inside?"; "Is it possible to walk/work with it for six hours?"*

## ◉ Cost and reliability of SILCS supplies

*"How much will it cost?", "You have to put it at our level."*

*"Provide this diaphragm free of charge, so that people can first appreciate it."*

## ◉ Alternatives to contraceptive jelly

*"If the contraceptive jelly is finished and I do not yet have money, can I use ordinary vaseline for lubrication...can I use cooking oil...can I use the diaphragm without the jelly?"*

# QUESTIONS FROM WOMEN AND MEN

## ◉ Effect on sexual pleasure

*“What are the chances of appetite when one uses the diaphragm?...sometimes the reason people do not use some methods is that they want to enjoy sex as it is, naturally.”*

*“Does it affect the sex position?”*

*“Can it hurt the man?”*

*“Do you feel the woman?”*

*“Does it affect vaginal lubrication?”*

*“The contraceptive jelly may make things messy!”*

## ◉ Risk of HIV infection

- The need for methods that offer dual protection was recognized but,

*“Our men do not use condoms...they want us pregnant...Preventing AIDS is not easy for us who are married.”*

# HEALTH PROVIDER CONCERNS

- Invest in provider training and supervision so provider attitude does not bias SILCS introduction

*"You know people come with fixed ideas about FP methods. Some methods die in the hands of health workers."*

*"You have to target the providers to deal with their attitudes and get them on board early."*

- Ability of users to wear and care for diaphragm

*"Imagine the women in the community, what facilities do they have to keep it clean?...the dirty water and lack of soap will encourage introduction of infection related to hygiene."*

# POLICYMAKER PERSPECTIVES

- ◉ While no policies exist that prevent introducing SILCS as a contraceptive, identifying a source of funding to support a new product is a concern

*“Who is going to support this product? ...can we sustain its supply?”*

- ◉ Concern about nonoxynol-9 spermicide
  - Need for an alternative contraceptive gel or evidence of effectiveness without gel

# POLICYMAKER PERSPECTIVES

## HIV prevention

- ◉ Policymakers worried about the risk of HIV infection

*"We have just re-launched the female condom and uptake has been slow, why would you like to take us backwards?"*

*"There are many people who do not know their HIV sero status...how do we provide a method that does not ensure dual protection?"*

- ◉ However, stakeholders concede that most women currently use FP methods that do not offer HIV protection

*"Ok it does not prevent HIV/AIDS but what about the Depo, IUD and pills we are providing...that should not prevent the introduction of the method."*

## NEXT STEPS

- ◉ MOH needs evidence of country-level acceptability before willing to support introduction
- ◉ Need to identify an alternative to nonoxynol-9 contraceptive gel
- ◉ Identify opportunities to provide gender-based education about:
  - Sexual health and reproductive anatomy
  - Device insertion and removal
  - Effect on sexual pleasure for partner

# POTENTIAL MARKET SEGMENTS

- ⦿ Young, married women for birth spacing
  - First introduce to educated, elite women in the city to gain awareness
  - Then expand to rural areas
- ⦿ Women who have discontinued use of other methods, especially the injection
- ⦿ Women currently not using any contraceptive method and who do not want a pregnancy



# STRATEGY FOR BRINGING SILCS TO UGANDA

- ◉ Complete product registration and market clearance
- ◉ Generate awareness and support from FP providers
- ◉ Provide consumer education/raise awareness
- ◉ Create demand
- ◉ Introduce in private-not-for-profit sector first to raise awareness and show acceptability
- ◉ Include diaphragm in the contraceptive catalogue so it can be included in the public-sector FP program

# SUMMARY

- ◉ All stakeholders recognized that SILCS could increase choice and fill a gap in the method mix
  - Expressed eagerness because it is nonhormonal and woman initiated
- ◉ Client and provider education will be key to help raise awareness about this new method and address questions
- ◉ SILCS introduction provides an opportunity for educating women about their sexual health and anatomy
- ◉ MOH and other policymakers suggest introducing SILCS in the private-not-for-profit sector first to build awareness and demonstrate that women can use this method

# ACKNOWLEDGEMENTS

- ◉ PATH
- ◉ USAID
- ◉ CONRAD
- ◉ MOH, UNFPA; and other FP donors
- ◉ Policymakers, planners and implementers, researchers, community leaders and health workers, and the potential users of the SILCS diaphragm who provided this invaluable information

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# Thank You!

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For more information about SILCS,  
please contact **SILCS Diaphragm Team**  
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# Introduction strategies for Depo-subQ Provera 104™ in Uniject™

Dr. Bocar Daff

Director, Reproductive Health  
Senegal Ministry of Health

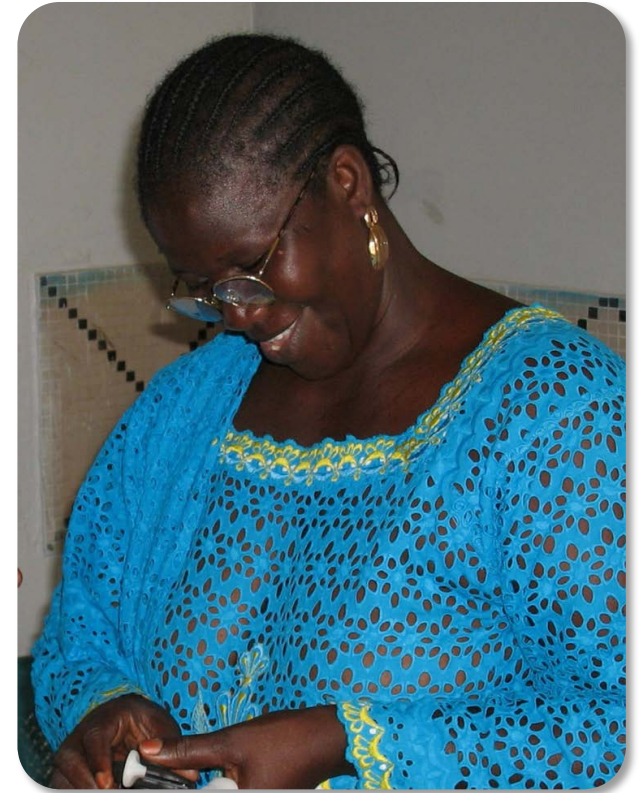
# Background

- 2009: Senegal Ministry of Health and PATH partnered to plan for introduction of depo-subQ provera 104™ in Uniject.™
- Strategy development included analysis of:
  - Senegal family planning data.
  - Public, private and NGO distribution systems.
  - Regulatory approval requirements.
  - Price and procurement needs.



# Family planning in Senegal

- Population: 12.6 million.
- Unmet need for family planning: 35%
- Contraceptive prevalence:
  - All methods: 13.1%
  - Modern methods: 12.1%
  - Injectables: 5.2%
- Public sector provides over 90% of injectables.





# Community-based distribution in Senegal

- Community health workers in Senegal now provide an array of services and products, including rapid diagnostic tests and artemisinin-based combination therapy for malaria, and the initial offer of oral contraceptives.
- If proven feasible and acceptable in Senegal through current pilot studies, injectables can be added to the range of products offered by community health workers.

# What is Uniject™?

Developed by PATH  
in 1984



Made by BD (Becton,  
Dickinson and Company)

Single dose  
Prefilled and sterile  
Non-reusable

Used with:

- Hepatitis B vaccine
- Oxytocin
- Tetanus toxoid
- Cyclofem

# DMPA IM vs. depo-subQ in Uniject

## DMPA IM 150



### DMPA IM 150

**Depo-Provera®**  
Contraceptive Injection  
medroxyprogesterone acetate injectable suspension

- 150 mg DMPA
- Delivered every 3 months
- Glass vial with syringe
- Intramuscular injection
- 1" needle
- 99% contraceptive efficacy
- Depo-Provera brand: Pfizer Inc.
- Generic manufacturers generic equivalents

Current standard



**depo-subQ  
provera 104**  
medroxyprogesterone acetate injectable suspension  
(104 mg/0.65 mL for subcutaneous use)

## depo-subQ provera 104

- 104 mg DMPA
- Delivered every 3 months
- Prefilled in Uniject
- Subcutaneous injection
- 3/8" needle
- Equivalent contraceptive efficacy, safety, side effects
- Pfizer Inc. product: patent until 2020

New option

# Non-clinic access using depo-subQ in Uniject

## Features

Single, exact dose, all-in-one presentation

Subcutaneous injection

Reduced weight and volume

Non-reusable

## Benefits

Simplified injection procedures

Simpler, shorter training

Eliminates mismatch of syringe/vial supplies

Easier to transport and store, less waste to dispose

Improved injection safety

## Value

**Increased acceptability and use by lower-level health care workers**

**Uniquely suited to home and self-injection**

# Depo subQ in Uniject: Senegal introduction strategy (1)

- Community-based distribution (CBD) is an important delivery system for family planning.
- Injectables are delivered through CBD in dozens of countries around the world.
- Senegal has current pilot of DMPA IM through CBD.
- If feasible and acceptable in Senegal, then followed by Depo-subQ introduction.



# Depo subQ in Uniject:

## Senegal introduction strategy (2)

- Depo subQ in Uniject presentation is easy and safe for providers.
- Has the potential for home-based and self-injection if policies were favorable.
- Introduction will depend on perceived value in relation to price.



# Introduction planning process

- Depo subQ in Uniject is part of the Senegal Ministry of Health Maternal Health Technical Working Group.
- Additional requirements for Senegal introduction:
  - Information on product's delivery system costs and benefits.
  - Public sector price.
  - Experience with product in similar country settings.



# Introduction challenges



- Lengthy international regulatory approval process:
    - European regulatory approval is pre-requisite to country registration.
    - European approval is anticipated mid-to late 2012.
  - Uncertainty about public sector price:
    - October 2011: Product offered at US\$1.55 per unit for 12 million units to international institutional buyers.
- 



# Introduction opportunities

- Reinforcing training of community health workers and strengthen CBD system.
- Reviewing national policies in related to home and self-injection.
- Contributing to government's goals of increasing contraceptive use through new users.



Umit Kartoglu

# Sino-implant (II):

## Global Introduction of a Low Cost, Highly Effective Contraceptive Implant

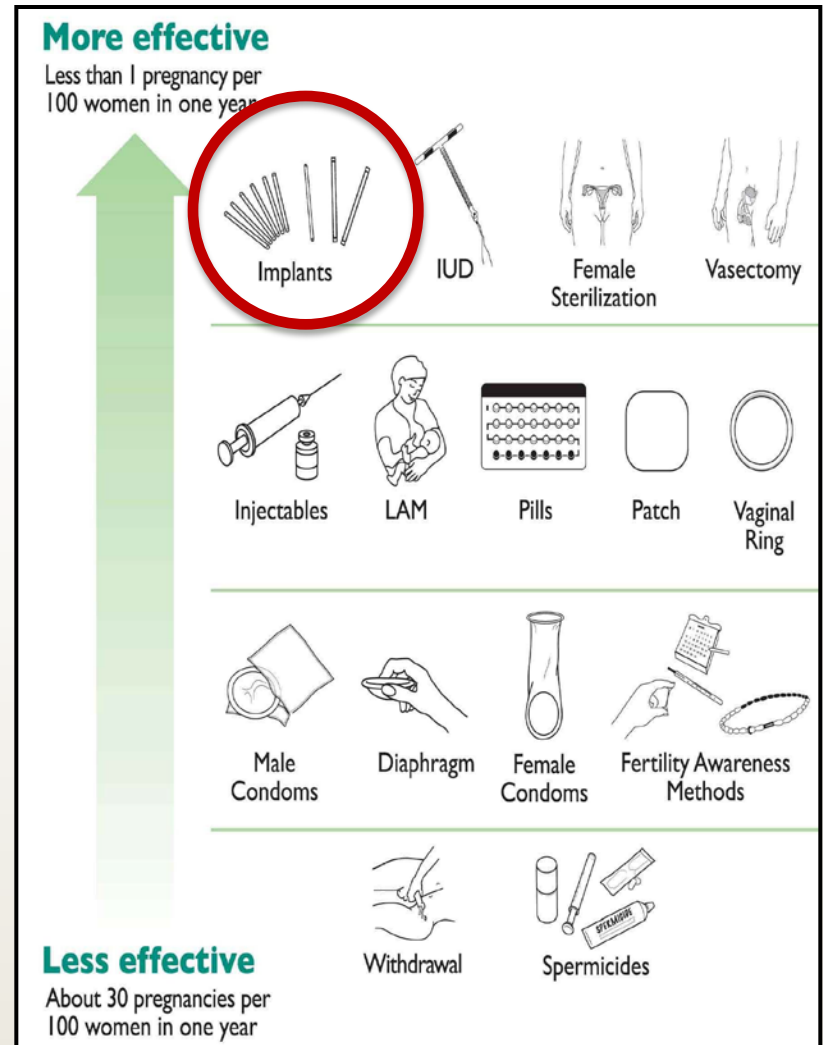
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Kate Rademacher, MHA  
Heather Vahdat, MPH  
Derek Owen, PhD  
David Hubacher, PhD  
Haizhen Meng, MS  
David Asante, MD, MPH  
Marsden Solomon, MD  
Markus J. Steiner, PhD






# Benefits of Implants

- Highly effective
- Do not fail because of user error
- Continuation rates higher than shorter-acting methods
- No regular action needed by user
- Avoids need for resupply
- Over time, less burden on health system because fewer visits required
- Cost-effective






# Comparison of Hormonal Implants

	Jadelle 	Implanon 	Sino-implant (II)/Zarin 
<b>Manufacturer</b>	Bayer Healthcare	Merck/MSD	Shanghai Dahua Pharmaceutical Ltd.
<b>Formulation</b>	150 mg levonorgestrel in 2 rods	68 mg etonogestrel in 1 rod	150 mg levonorgestrel in 2 rods
<b>Mean Insertion &amp; Removal time</b>	Insertion: 2 min Removal: 5 min	Insertion: 1 min Removal: 2-3 min	Insertion: 2 min Removal: 5 min
<b>Labeled duration</b>	5 years	3 years	4 years
<b>Trocars</b>	Autoclavable / Disposable	Pre-loaded disposable	Disposable
<b>Cost of implant (US\$)<sup>1</sup></b>	\$21.00	\$18.00	\$8.00
<b>Cost per Year (if used for duration)</b>	\$4.20	\$6.00	\$2.00
<b>WHO Prequal</b>	Yes	Yes	Application submitted

<sup>1</sup> FOB price in country of origin.

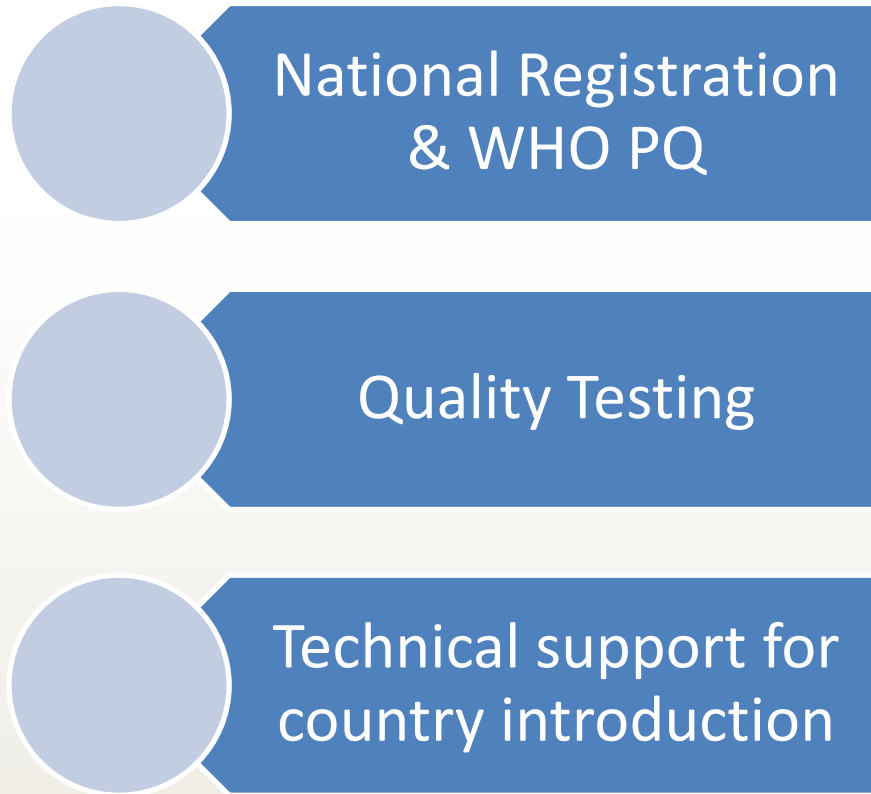
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# Sino-implant (II): What is FHI 360's Role?

A global initiative to help increase access to safe and affordable contraceptive implants by providing technical assistance to support the introduction of Sino-implant (II) in resource-constrained settings.



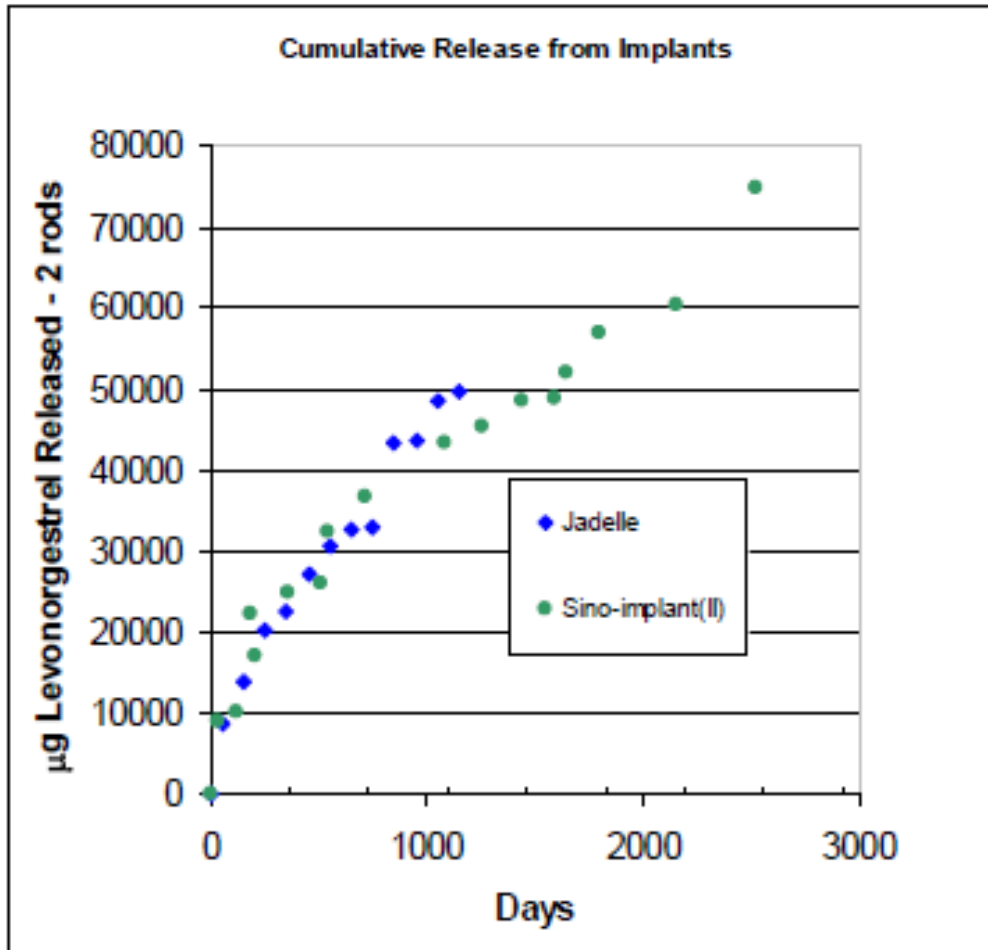
Funding for the Sino-implant (II) initiative comes from the Bill & Melinda Gates Foundation

# Clinical Data on Sino-implant (II)

- **15 published studies demonstrate that Sino-implant (II) is highly effective:**
  - Over 15,000 women in 4 randomized trials using Sino-implant (II) for up to 5 years
  - Annual pregnancy rate under 1%
- **New clinical trial being initiated in the Dominican Republic**
  - Evaluate the contraceptive effectiveness through 5 years of use



# Analysis of Rods Removed After Various Durations of Use





# WHO Prequalification Programme

- Application for prequalification submitted to WHO by Dahua with technical assistance from FHI 360.
- Application accepted for formal review in October 2010. Review is ongoing.
- Process includes clinical dossier review, CMC dossier review, and GMP inspection.
- Only 1 non-SRA contraceptive method approved to date.



# Sino-implant (II) Registration Status

Nov 2011

## Registered (n=19)

Burkina Faso <sup>†</sup>	Mozambique <sup>‡</sup>
Cambodia <sup>†</sup>	Malawi <sup>‡</sup>
Chile	Mongolia <sup>†</sup>
China	Nepal
Fiji <sup>†</sup>	Pakistan <sup>†</sup>
Ghana <sup>†</sup>	Sierra Leone <sup>‡</sup>
Indonesia	Uganda <sup>‡</sup>
Kenya <sup>†</sup>	Zambia <sup>‡</sup>
Madagascar <sup>‡</sup>	Zanzibar <sup>‡</sup>
Mali <sup>†</sup>	

Under Review in an  
additional 10 countries

<sup>†</sup>Distributed by Marie Stopes International (MSI);

<sup>‡</sup> Distributed by Pharm Access Africa Ltd. (PAAL)

# Inspections and Audits

- GMP inspections by countries as part of registration process
- Independent GMP audits by SGS, PSI, and other groups

Country	GMP Status
Kenya	Approved
Uganda	Approved
Malawi	Approved
Madagascar	Approved
Ghana	Approved
Nepal	Approved
Tanzania	Approved*
Ethiopia	Approved*



Since 2007, 16 inspections:

- Resource-intensive for manufacturer
- GMP guidelines are open to interpretation
- Less than 10% of findings overlapped between GMP inspections

\* Final registration pending. In Ethiopia, product has provisional status.

# Sino-implant (II) Product Quality Evaluation

- **Lot-Release Testing:** Every lot tested by Dahua and independent Swiss-based company (SGS)
- **Annual Evaluation:** API, metal impurities, sterilization residue, endotoxins, cytotoxicity, and package integrity



**Years 1, 2, 3 & 4:**  
**Product met all  
international quality  
standards**

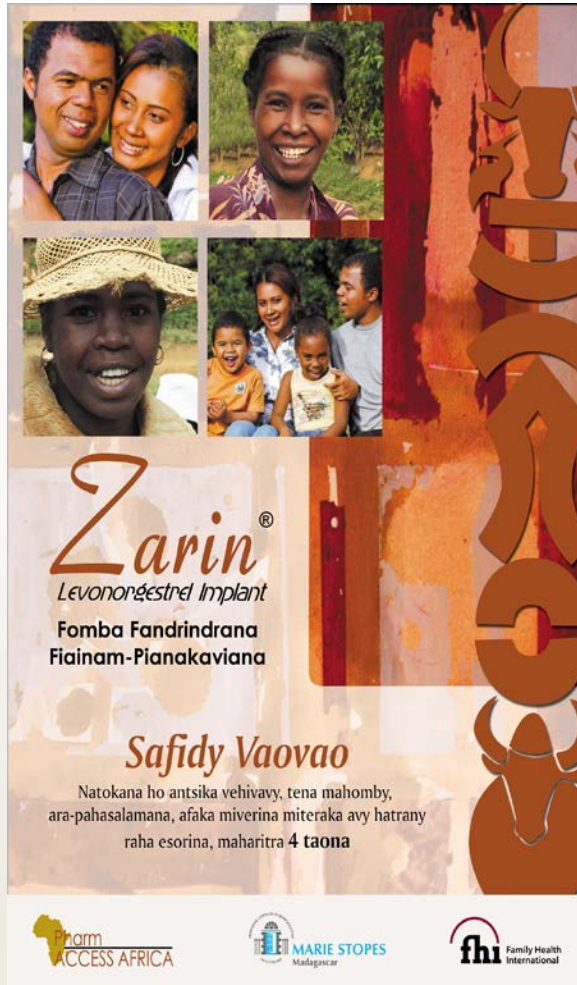
# Post-marketing Studies

- **Studies underway in Kenya, Madagascar, and Pakistan**
  - Studies will monitor effectiveness, safety & acceptability
  - Each study will follow 600 new users of Sino-implant (II) for 12 months
  - First 3 months of data from Madagascar: no post-insertion pregnancies or serious insertion complications





# Country-Level Introduction



- **Country registration** is obtained.
- **Product launch meetings** are held with stakeholders in focus countries.
- **Training materials** are available on K4Health platform.
- **Technical assistance provided** (e.g. support responding to tenders)
- **Price ceilings** with distributors help keep public sector prices low.
- **Despite efforts, public sector procurement remains a challenge**

# Project Impact to Date

- As of mid-2011, **516,300 units** have been procured in countries with approvals/pre-approvals

Estimated impact of 516,300 units\*:

- **1.8M couple-years of protection from pregnancy**
- **608,000 pregnancies averted**
- **2,000 maternal deaths averted**
- **71,000 abortions averted**

**\$7.4 M dollars in cost savings\***

\*Public health impact is estimated from MSI Impact Calculator available at [www.maristopes.org](http://www.maristopes.org). Saving is calculated based on a price of \$8 for Sino-implant assuming the alternative is to purchase Jadelle (average Jadelle was \$24 in 2009 and \$22 in 2010). Prices were calculated using data from the RH Interchange: <http://rhi.rhsupplies.org/>

# Lessons Learned

- ✓ **Support from global coordinating entity has been valuable** especially in areas of dossier submission and quality testing.
  - Language barriers have been particularly challenging.
- ✓ **Sustainability is priority** so transition plan is critical.
- ✓ **Challenges of overcoming negative perceptions of Chinese products exist.** These challenges can impact product introduction.
- ✓ **WHO Prequalification is valued highly** at the country level but the process for non-SRA-approved drugs can be **lengthy and costly.**
- ✓ Strategy of **pursuing national registration in parallel has been effective.**



# Thank you!

