Planning for Woman’s Condom Launch in China: Implications for Broader Access

Neeti Nundy
International Conference on Family Planning
Dakar, Senegal
December 2, 2011
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.
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.

Photo credits: PATH/Glenn Austin
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.

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New partnership to test the total market approach in two countries

• 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

- Production capacity
- Cost per unit

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Unmet need exists in China

- 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

- 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

Photo credit: Bang
Working with the Chinese government to reach target users in the public sector

**Target users**
- Youth
- Migrant workers
- Discordant couples
- Commercial sex workers

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

**Promotion**
- Events
- Print media
- TV / Radio
- Outreach

Photo credit: PATH
Implications for broader access

• 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

• 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

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Photo credits: PATH/Glenn Austin
SILCS DIAPHRAGM: POTENTIAL FOR INTRODUCTION IN LOW-RESOURCE SETTINGS

Kyamwanga Imelda Tamwesigire, PhD, Eleanor Turyakira, MSc, Mbarara University of Science and Technology Mbarara Uganda

December 2, 2011
International Conference on Family Planning Dakar, Senegal
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
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
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?”
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.”
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.”
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
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!

Kyamwanga T. Imelda
(kyamwangat@yahoo.com)

For more information about SILCS, please contact SILCS Diaphragm Team at PATH, info@path.org
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)

Used with:
- Hepatitis B vaccine
- Oxytocin
- Tetanus toxoid
- Cyclofem

Single dose
Prefilled and sterile
Non-reusable

Made by BD (Becton, Dickinson and Company)
DMPA IM vs. depo-subQ in Uniject

**DMPA IM 150**
- 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**
- 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

**Benefits**

- Reduced weight and volume
- Non-reusable
- Easier to transport and store, less waste to dispose
- Improved injection safety
- Simplified injection procedures
- Simpler, shorter training
- Eliminates mismatch of syringe/vial supplies

**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.
Sino-implant (II):
Global Introduction of a Low Cost, Highly Effective Contraceptive Implant

International Conference on Family Planning
Dakar, Senegal
December 2, 2011

Laneta Dorflinger, PhD
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

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<th>Jadelle</th>
<th>Implanon</th>
<th>Sino-implant (II)/Zarin</th>
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<tr>
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<td>Bayer Healthcare</td>
<td>Merck/MSD</td>
<td>Shanghai Dahua Pharmaceutical Ltd.</td>
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<td><strong>Formulation</strong></td>
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<td>68 mg etonogestrel in 1 rod</td>
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<td>Pre-loaded disposable</td>
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<td><strong>Cost of implant (US$)(^1)</strong></td>
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\(^1\) FOB price in country of origin.
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¹ FOB price in country of origin.
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

Cumulative Release from Implants

μg Levonorgestrel Released - 2 rods

Days

Jadelle
Sino-implant(I)
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†
Cambodia†
Chile
China
Fiji†
Ghana†
Indonesia
Kenya‡
Madagascar‡
Mali †
Mozambique‡
Malawi ‡
Mongolia†
Nepal
Pakistan†
Sierra Leone‡
Uganda‡
Zambia‡
Zanzibar‡

† Distributed by Marie Stopes International (MSI);
‡ 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

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<td>Tanzania</td>
<td>Approved*</td>
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<tr>
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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.mariestop.es.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!