Increasing Access by Introducing a Low-Cost Contraceptive Implant

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Outline of the Presentation

1) Why Focus on Implants?
2) Why Sino-implant (II)?
3) Quality Assurance
4) Registration/Introduction
Why Focus on Implants?
If 20% of OC users switched to implants in Africa, over next 5 years would avert:

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

Hubacher, Mavranezouli, and McGinn 2008

The impact would be even more dramatic with new users.
Dramatic Increase in Ethiopia

Actual figures for first 4 months of 2009, RH Interchange website
Why Sino-implant (II)?
## Sino-implant vs. Jadelle and Implanon

<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</td>
<td>Bayer</td>
<td>Schering Plough/</td>
</tr>
<tr>
<td></td>
<td>Pharmaceutical</td>
<td>HealthCare</td>
<td>Organon</td>
</tr>
<tr>
<td><strong>Formulation</strong></td>
<td>2 rods; 75 mg levonorgestrel</td>
<td>2 rods; 75 mg levonorgestrel</td>
<td>1 rod; 68 mg etonogestrel</td>
</tr>
<tr>
<td><strong>Labeled length of 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>Autoclavable/Disposable</td>
<td>Pre-loaded disposable</td>
</tr>
<tr>
<td><strong>Cost of implant (US$)</strong></td>
<td>$7.50 - $8.50</td>
<td>$21 - $23</td>
<td>$20 - $28</td>
</tr>
<tr>
<td><strong>Cost per year</strong></td>
<td>$1.90 - 2.10</td>
<td>$4.20 - $4.60</td>
<td>$6.70 - $9.30</td>
</tr>
</tbody>
</table>

Assumes implant used for labeled duration of use
Service Delivery Costs per CYP by Method, 13 FP/RH Tier One Countries

*Costs include the commodity, materials and supplies, labor time inputs and annual staff salaries. The height of each bar represents the range of cost per CYP across the 13 USAID priority countries, while the diamond shows the average value.
15 Published Studies

Demonstrate Sino-implant (II) safe and highly effective

- Annual pregnancy rate under 1%
- Over 20,000 women using Sino-implant (II) studied for up to 7 years
- 3 comparative trials with Norplant in control arm
- Review paper in press, *Contraception* (Steiner, Lopez, Grimes et al.)
FHI Quality Assurance

- FHI over 20 years experience testing products for donors and service delivery groups

- Testing facilities in US and Thailand

- Ensure global distribution of high quality public health commodities (condoms, DMPA, oral contraceptives, bed netting, malaria drugs etc)
Manufactured exclusively by:

Shanghai Dahua Pharmaceutical Company, Limited
Shanghai Dahua Pharmaceutical Co., Ltd., Shanghai, China

- New facility opened 2004
- Built to GMP standards: Chinese State Drug Administration certified
- ISO 9001 and ISO 13485 certified: National Quality Institute, UK
- Over 7 million implants distributed to date
Prepared to pass Good Manufacturing Practices (GMP) inspections

- **Independent GMP audits** by SGS Group, a leading Swiss international inspection, verification, testing and certification organization
- **GMP audits** by multiple National Drug Regulatory Authorities: Ethiopia, Kenya, Uganda, Malawi and Madagascar
- **PSI prequalification audit**
- **Pakistan MOH visit**
- **On-going inspections in coming years**
Sino-implant (II) Product Quality Evaluation

- **Shanghai DaHua Pharmaceutical:**
  - Internal Lot release quality control
  - 4 validated tests (identification, content, dissolution and sterility)

- 10 lots independently verified by FHI and SGS in first year

- Each lot independently tested prior to distribution

- Additional tests by FHI (metal and organic impurities, sterilization residue, endotoxins, cytotoxicity and package integrity)

- On-going quality evaluation for 5 years
Registration Status in 35 Countries

Registered
- Kenya
- Sierra Leone
- Indonesia
- China

In Progress (n=20)
- Argentina
- Bangladesh
- Bolivia
- Brazil
- Burkina Faso
- Chile
- Colombia
- Dominican Republic
- Ecuador
- India
- Mali
- Mexico
- Mozambique
- Nigeria
- Peru
- Russia
- South Africa
- Sudan
- Venezuela
- Zimbabwe

Under Review (n=11)
- Burundi
- Ethiopia
- Ghana
- Madagascar
- Malawi
- Nepal
- Pakistan
- Rwanda
- Tanzania
- Uganda
- Zambia

FHI Grant supporting 33 countries
FHI’s Role as Global Coordinator

- **Shanghai Dahua Pharmaceutical Co., Ltd.**
  - Manufacturer

- **Family Health International Global Coordinating Center**

- **Pharm Access Africa Distributors**
  - Exclusive Distribution Agreements
  - Price Ceiling Negotiation (Public and NGO)
  - Technical Assistance
Sino-implant (II)

Introduction

• One size doesn’t fit all
• Introducing Sino-implant (II) role of FHI and distribution partners
• Realizing substantial cost-savings
• Scaling-up role of existing service delivery partners

Key Concepts
Strategies for Successful Scale-up

- Advocacy
- Adequate pre-counseling leading to informed choice
- Trained Providers
- A robust clinical infrastructure
- Steady supply of implants
- Reliable access to removal
- Demand creation through Community awareness and participation
- Appropriate supervision and evaluation
Sino-implant (II) Initiative: 2.2 million implants over 5 years

112,200 units in 3 countries with approvals/pre-approvals:

- Kenya
- Sierra Leone
- Ethiopia

Cost saving: ~US$1.6 million
Partners

Registration Partners
- Pharm Access Africa
- DKT
- Marie Stopes
- Progyne
- WomanCare Global

Other Partners
- EngenderHealth
- IntraHealth
- Ipas
- Population Council
- PSI
- WHO
Thank you!