



Increasing Access Through Low-Cost Implants

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Outline of the presentation

- 1) Why Focus on Implants
- 2) Why Zarin
- 3) Quality Assurance
- 4) Registration
- 5) 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

Implant Provision – Kenya Context

Implant program to date

- Norplant registered in 1989
- Over 1,000 trained providers
- High cost of implants has limited scale-up
- Implants now most popular LAPM – Comparative assessment of LAPMs (2008)

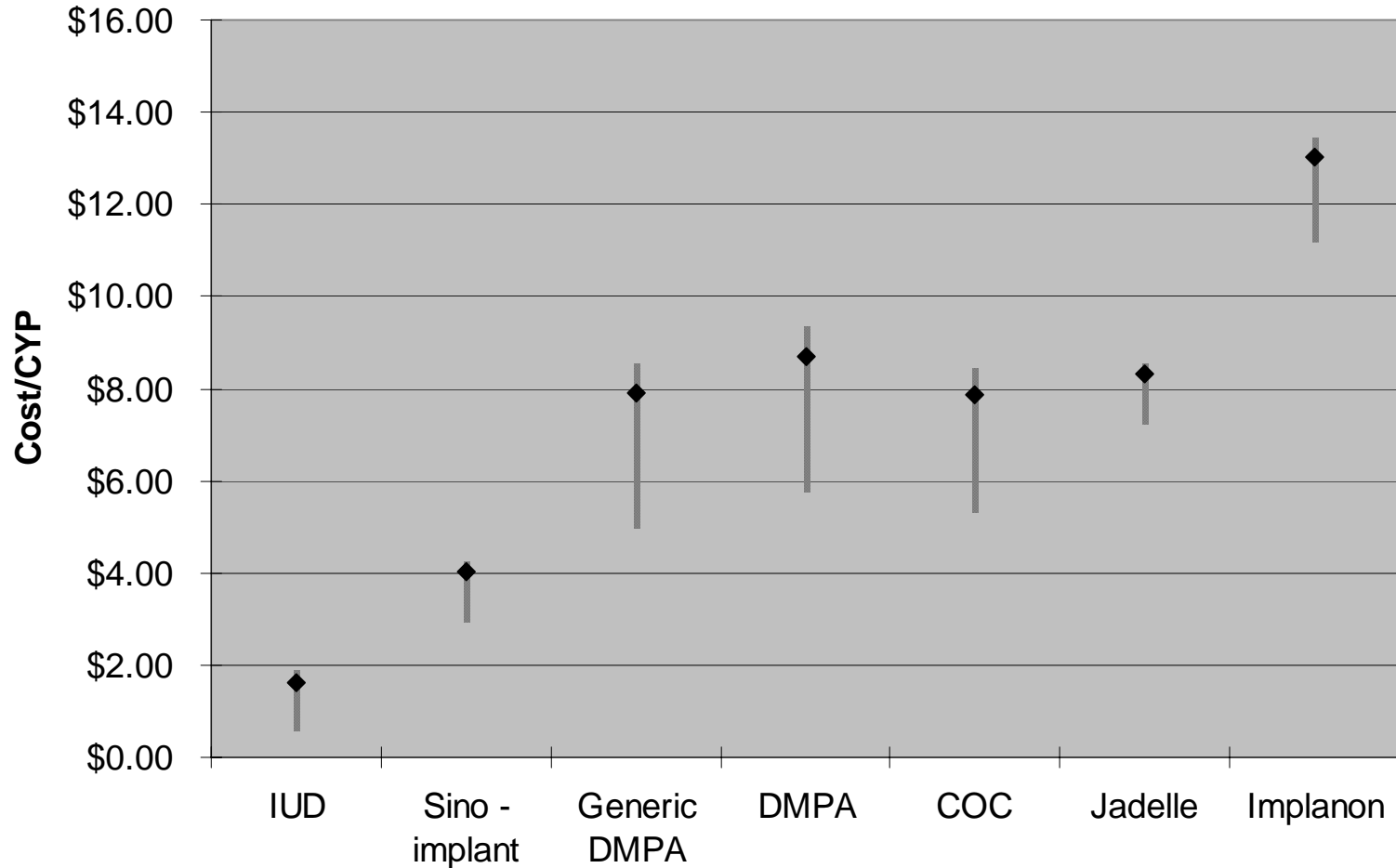
FHI Study-2007-08 (Olawo and Steiner 2009)

- Evaluated 21 private sector/NGO/public sector clinics
- Clients pay median US\$8 for insertion
- Marie Stopes – US\$30 per insertion-implants sustainable
- Access to removal not an issue

Why Zarin?

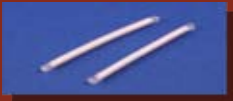




Direct Cost* per CYP by Method, 13 FP/RH USAID Tier One Countries



*Direct 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.

Sino-implant vs. Jadelle and Implanon

	Sino-implant (II) 	Jadelle 	Implanon 
Manufacturer	Shanghai Dahua Pharmaceutical	Bayer HealthCare	Schering Plough/ Organon
Formulation	2 rods; 75 mg levonorgestrel	2 rods; 75 mg levonorgestrel	1 rod; 68 mg etonogestrel
Dimensions	2.4 mm x 44 mm	2.5 mm x 43 mm	2 mm x 40 mm
Labeled length of use	4 years	5 years	3 years
Trocars	Disposable	Autoclavable/ Disposable	Pre-loaded disposable
Cost of implant (US\$)	\$7.50 - \$8.50	\$21 - \$23	\$20 - \$28
Cost per Year*	\$1.90 - 2.10	\$4.20 - \$4.60	\$6.70 - \$9.30

*Cost per Year assumes implant used for labeled duration of use

Eleven published papers

Demonstrate Zarin safe and highly effective

- Annual pregnancy rate under 1%
- About 20,000 women using Zarin studied for up to 7 years
- 3 comparative trials with Norplant control arm
 - Fan 2004: 1,000 per group followed for 5 years
 - 5-year cumulative pregnancy rate 0.7%

Quality Assurance





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 (NQi, UK)
- Registered in China (1994), Indonesia (2002), Kenya and Sierra Leone (2008)
- Over 7 million implants distributed to date



DACA
Ethiopia



Prepared to pass Good Manufacturing Practices
(GMP) inspections

Zarin: Product Quality Evaluation

- Shanghai Dahua Pharmaceutical Co, Ltd.:
 - Internal lot release quality control
 - 4 validated tests (identification, content, dissolution and sterility)
- 10 lots independently verified by FHI and SGS
- Additional tests developed and validated by FHI (metal and organic impurities, sterilization residue, endotoxins, cytotoxicity and package integrity)
- Quality evaluation on-going for next 5 years

Registration & Introduction





Registration Status in 21 Countries



Six year exclusive distribution agreement



Zarin Introduction

- One size doesn't fit all
- **Implant train taken off**
- Zarin jumping on train resulting in significant saving for implant program
- **Partners need to guide speed**
- Introduction \neq Scale-up

Key Concepts

Strategies for Successful Scale-up

Implant Scale-up

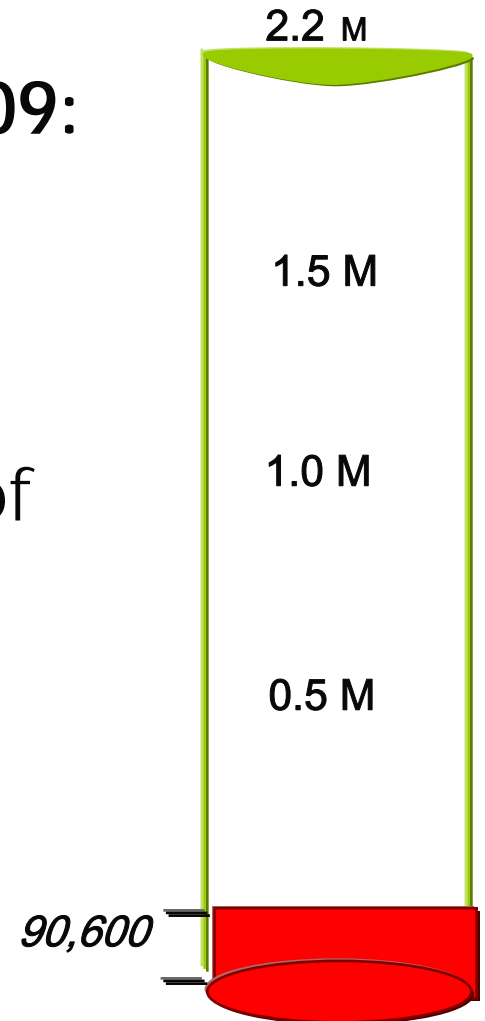
- Advocacy
- Adequate pre-counseling leading to informed choice
- Trained Providers
- A robust clinical infrastructure
- Steady supply of implants
- Reliable access to removal
- Demand creation through Community awareness and participation
- Appropriate supervision and evaluation

Sino-implant (II) Initiative: 2.2 million implants over 5 years

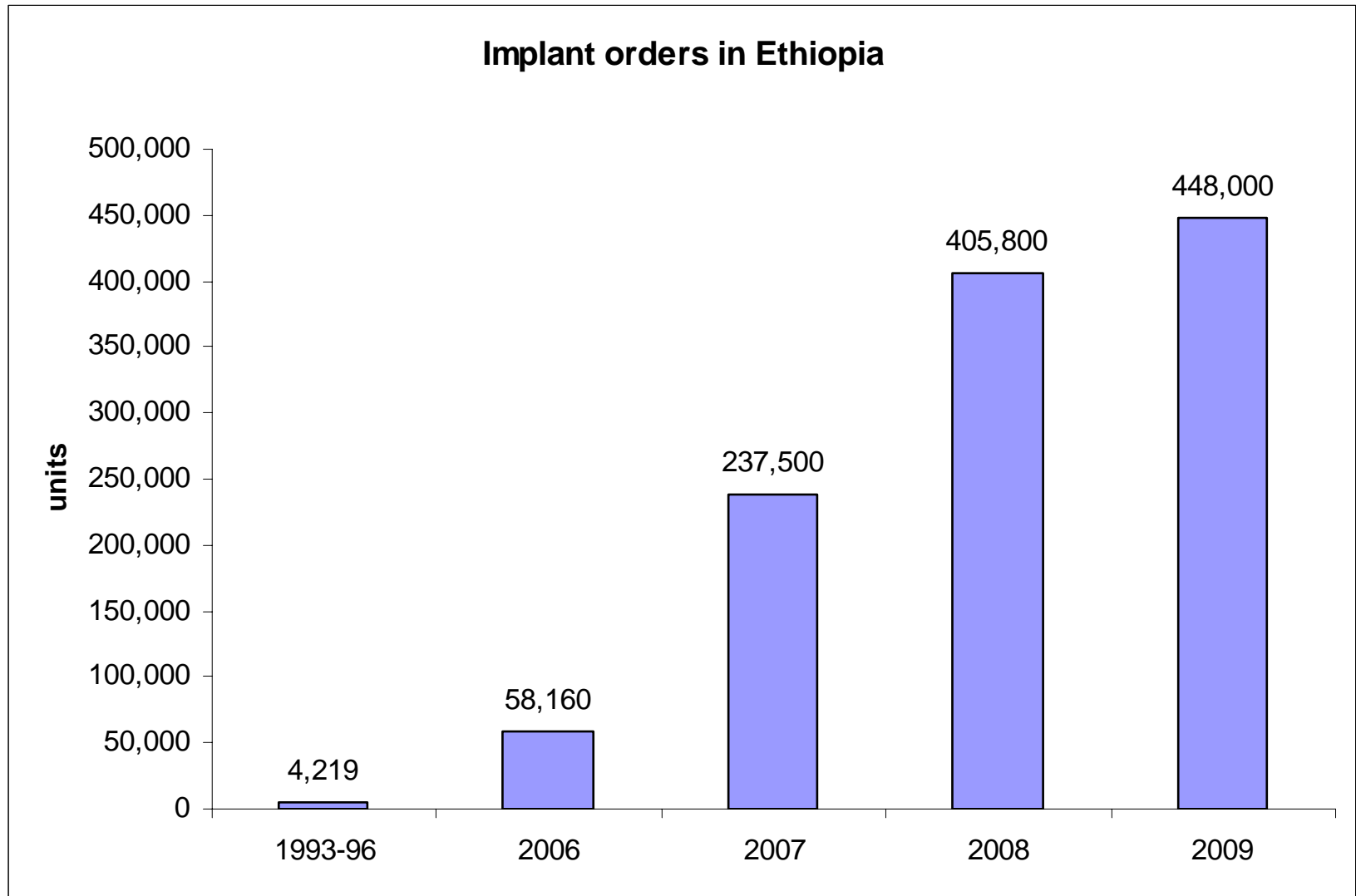
90,600 units in first four months of 2009:

- 15,400 for Kenya
- 5,000 for Sierra Leone
- 70,200 ordered in anticipation of approvals for other countries

Cost saving: US\$1.36 million



Dramatic increase in Ethiopia



Actual figures for first 4 months of 2009

Growing Team

Core Team

- Markus Steiner
- Aida Cancel
- Heather Vahdat
- David Jenkins
- David Asante
- Haizhen Meng
- David Hubacher
- Diane Luo (consultant)

Program Representatives

- Karin Ganter (PROGRESS)
- Trinity Zan (RESPOND)
- Laura Raney (CRTU/K4H)

FHI Country Offices

Growing Team - Partners

• Registration Partners

- Pharm Access Africa
- DKT
- Marie Stopes
- Profamilia
Colombia/DR

• Other Partners

- EngenderHealth
- IntraHealth
- Ipas
- Population Council
- PSI
- WHO



Thank you!