Beginning with the End in Mind: Multiple Meanings for Contraceptive Research & Development

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Begin with the end in mind in order to achieve...

- Availability
- Quality
- Equity
- Choice
Strategy #1: Conduct acceptability research at all phases of development and introduction

A conceptual framework

Callahan R, et al. 2017
Strategy 2: Reflect service delivery contexts when designing and developing new products

Condoms by Drone, NPR
Strategy 3: Include actionable, binding terms in contractual agreements
Strategy 4: At all stages, work to keep Cost of Goods Sold as low as possible
Strategy 5: Be flexible & embrace change
Contraceptive Technology Innovation at FHI 360

Expanding Access to Underutilized Contraceptive Methods
Levoplant/Sino-implant (II)
Prequalified by the World Health Organization in June 2017

- Manufactured by Shanghai Dahua Pharmaceutical
- “Levoplant” is global trade name for product with new levonorgestrel supplier; currently being re-registered
- DKT International is new global marketing partner
- WHO Prequalified for 3 years of use
Contraceptive Implant Prices 2009-2013: Changes Since Global Introduction of Sino-implant (II)

Key Milestones

- **2009**: Sino-implant (II) registered in Kenya under trade name Zarin; first registration outside of Asia
- **2011-2012**: Under agreement with partners, Merck/MSD reduces price of Implanon to $18/unit, with retro-active reduction to $16.50 when volume thresholds reached in Dec 2012
- **2011-2012**: Bayer HealthCare reduces price of Jadelle to $19/unit and then subsequently to $18/unit
- **2012-2013**: Bayer HealthCare and Merck/MSD lower the prices of Jadelle and Implanon to US$8.50 per unit as part of volume guarantees
- **2009-2014**: Over 1 million Sino-implant (II) units procured in countries under Gates initiative since 2009, resulting in over $10 million in commodity savings

2009-2010 prices based on weighted averages from RH Interchange in Kenya, Ethiopia and Sierra Leone. 2011-2013 prices from RHSC and press releases issued by the manufacturers.

Prices established through volume guarantees last through 2019

Bayer HealthCare and Merck/MSD have committed to $8.50 price through 2023
Levonorgestrel Intrauterine System (LNG-IUS): Access to Method Remains Limited

LNG-IUS added to WHO EML in 2015

Global learning agenda developed in 2016

First approved for use in 1990, the LNG-IUS has a nearly 30-year research-to-practice gap in FP 2020 countries

Landscape may be changing as more affordable products become available
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New Methods Under Development
Development of a 6-month injectable

- Currently, no injectable is labeled more than 3 months
- Discontinuation rates are high, in part due to late or missed re-injection visits

A longer-acting injectable would likely:

- Improve re-injection compliance
- Reduce time & travel costs for clients
- Reduce burden on health system

FHI 360 and collaborators are currently evaluating multiple formulations
Development of a Biodegradable Implant

Currently, implants require removal by a skilled provider

A biodegradable implant would address current problems including:

- Lack of trained personnel
- Inability among women to access or afford the procedure
- Burden on health system
- In addition, product with “intermediate” duration of efficacy would fill method mix gap

FHI 360 and collaborators are evaluating multiple designs/formulations
Adapting microneedle patches for contraception

Targeting contraceptive steroid hormones to the dermal versus subcutaneous space

Microneedle patch is applied to skin
Microneedles dissolve and release the contraceptive
Sharps-free backing is removed and discarded

Polymer Microneedles

Adapted from Micron Biomedical and Mark Prausnitz
Microneedles Acceptability Research

**Goal:** Incorporate end user feedback into product design decisions

**Study objectives:**

- Explore initial acceptability of the microneedle patch for contraceptive delivery and potential barriers to use;
- Define desired qualities or characteristics of a microneedle patch for contraceptive use;
- Quantify relative importance of various contraceptive microneedle patch attributes

**Study sites:** New Delhi, India and Ibadan, Nigeria
Contraceptive Technology Innovation

Global Knowledge Sharing
CTI Exchange

CALLIOPE

Contraceptive Pipeline Database

CAPRI

Contraceptive Active Pharmaceutical Ingredient Database

Calliope, the Contraceptive Pipeline Database, includes information on potential contraceptive targets and leads, products in development, and a selection of products only available in limited markets.

CAPRI, the Contraceptive Active Pharmaceutical Ingredient Database, lists biological and chemical properties for 27 active pharmaceutical ingredients found in contraceptives, along with data on their pharmacology, toxicology, impurities, metabolites, and use in marketed products.

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