Developing a Resilient Product Introduction Ecosystem: Lessons Learned from the Global Scale-Up of the Hormonal IUD

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Moderator: Andrée Sosler, Technical Director
FHI 360
What is the hormonal IUD?

A highly effective long-acting reversible contraceptive (LARC) with non-contraceptive benefits

<table>
<thead>
<tr>
<th>Looks Like:</th>
<th>Works By:</th>
<th>Provides:</th>
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</thead>
</table>
| Plastic T-frame with 52 mg* of levonorgestrel | • Thickening cervical mucus  
• Inhibiting sperm movement & survival | • 99% contraceptive efficacy  
• Potential treatment for heavy menstrual bleeding |

Possible side effects include:

- Changes in Periods
- Cramping During & Right After Insertion
- and less commonly
  - Headaches
  - Breast Tenderness
  - Acne

*13.5 mg and 19.5 mg IUDs available in limited contexts
There has been a 30+ year gap between initial approval of the hormonal IUD and widespread availability in LMICs.

- **1970s**: Product developed
- **1990**: Mirena approved in Finland
- **2000**: Mirena approved in U.S.
- **2003**: ICA Foundation founded
  - Has donated nearly 200K units in 39 countries to date
- **2015**: Method added to WHO EML
  - Global working group launched
  - Global learning agenda (GLA) developed
- **2015**: Liletta/Avibela approved in U.S.
- **2020**: Newly structured Hormonal IUD Access Group launched
  - GLA refreshed
- **2021**: USAID & UNFPA add method to catalogs
  - Suppliers lower per unit prices to ensure global accessibility
- **2022**: First mover countries begin national rollout of method
#Hormonal IUD Access Group Structure & Goals

**Launched:** 2015  
**Restructured:** 2020

## Steering Committee

**Purpose:** Develop, monitor and implement global strategy to expand access to hormonal IUD and strengthen hormonal IUD market; identify and mitigate risks in market health; maintain relationships with suppliers; review demand forecasts.

## Operations Group

**Purpose:** Forum that supports monitoring of market health, development of communications, identifying and tracking country needs.

## Partners Exchange

**Purpose:** Technical working group to discuss/share lessons learned related to rollout; address country rollout issues; share information to support steering committee

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Governments  
Donors  
Researchers  
Suppliers  
Procurers  
Implementers

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#RHSUPPLIES2023
Kai Risse, Global Head - Institutional Supply Partnerships
Bayer AG
Bayer’s Sustainability Strategy: Strategic Elements, Impacts and 2030 Targets

Target for Pharma: We aim to provide 100m Women in LMIC with access to modern contraception annually by 2030

1 Those targets are accounted for in the long-term variable compensation (LTI) of our Board of Management and our LTI-entitled managerial employees.
Family Planning with modern Contraceptives
Securing Essential Contraceptive Supplies
Bayer has been supporting Family Planning Programs for more than 50 Years

Bayer offers a broad range of high-quality, hormonal contraceptives

- Implants
- Injectables
- Oral Contraceptives
- Hormonal IUDs
Facts about Mirena®

- was first launched in 1990
- is available worldwide with marketing authorization in over 120 countries\(^1\)
- has over 218 million women-years of experience\(^1\)
- more than 6000 publications related to levonorgestrel-releasing intrauterine systems or levonorgestrel in over 20 different languages

Mirena® can offer a number of benefits making it a suitable choice at different stages of a woman’s reproductive life

<table>
<thead>
<tr>
<th>Properties of Mirena®</th>
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<tbody>
<tr>
<td>Maximum duration of use (years)</td>
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<tr>
<td>Efficacy (Pearl Index)</td>
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<tr>
<td>Average \textit{in vivo} LNG release rate over the first year</td>
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<tr>
<td>Total LNG content (mg)</td>
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<tr>
<td>T-frame dimensions (mm)</td>
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<tr>
<td>Insertion tube diameter (mm)</td>
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<tr>
<td>Silver ring/ MR compatibility</td>
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<tr>
<td>Color of the monofilament threads</td>
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</tbody>
</table>
Mirena® has 4 approved indications
(not all indications are approved in all countries)

// Contraception (up to 8 years);

// Treatment of idiopathic menorrhagia (heavy menstrual bleeding without structural cause);

// Protection from endometrial hyperplasia during estrogen replacement therapy (ERT);

// Treatment of dysmenorrhea.
Mirena® - The EvoInserter®

EvoInserter®

- was assessed to have a user-friendly design
- is associated with a high placement success rate, ease of placement
- may remove some concerns among HCPs about difficult placement of LNG-IUSs, thereby encouraging increased uptake of an effective contraceptive method

Gemzell et al: Contraception 96 (2017) 426-431
Training Resources: Slide Deck

Intended to provide a basis for effective training Mirena®, covering important topics such as clinical data, counseling, placement procedure and FAQ.

Proprietary Information

Mechanism

LNG-IUS releases a low, slow dose of LNG

Due to the low release rate, LNG-IUS is less likely to cause irritation than other IUS devices

Studies of LNG-IUS have shown it to be well tolerated

- The LNG-IUS is made from inert materials
- Intended for long-term use
- Suitable for all women who need or want hormonal contraception

How to approach counseling on IUS

Step 5: Deploy the side arms

Open the arm

While holding the arm down to the side

Wait 30 seconds

If completely deployed

Summary of evidence

Fundal positioning of Mirena is important in order to reduce the risk of expulsion. However, there is no evidence defining the allowable distance from the fundus to ensure maximum safety and efficacy for Mirena.  

In one study, over half of the women who had become pregnant while using an IUC had malpositioned device (n=42).  

In another study of women with malpositioned IUC (n=182), no pregnancies occurred with the device in place.  

The position of Mirena did not influence pain scores or bleeding patterns (n=43) suggesting these symptoms are not reliable predictors of malpositioning.  

The efficacy of Mirena may be less affected by its position in the uterine cavity than is an Cu-IUD, because of the local release of progesterone. Placement of Mirena in the cervical canal did not increase risk of pregnancy relative to placement in the uterine cavity.  

Training Resources: Virtual Training Module

Provision of licences to access the online training platform

1. Task description
2. Task list with next and back buttons to skip the steps
3. Change view of the uterus or device
4. Show or hide the interior of the uterus
5. End the simulation and get feedback report
6. Action buttons for the current task
7. Change the language

Increase understanding of key steps, including applying traction

View the procedure from different perspectives

Compare techniques for anteverted and retroverted uteri
Mirena® has a favorable bleeding profile

Menstrual blood loss progressively declines with Mirena® use, resulting in lighter periods.

Medicines360 and Avibela™

Jill Keesbury, Sr. Director, Global Access, Medicines360
MDAWG and Manufacturers Group
Medicines360 is a nonprofit pharmaceutical organization with a mission to catalyze equitable access to medicines and devices through product development, policy advocacy, and collaboration with global and U.S. partners.
AVIBELA is a hormonal IUD indicated for contraception and treatment of heavy menstrual bleeding

- **Duration of use:** 6 years (extension to 8 years in process)
- **Shelf-life:** 5 years

- Our IUD is approved by the U.S. FDA and 25+ other stringent regulatory authorities
- AVIBELA was one of 2 hormonal IUDs added to the global procurement catalogs in 2021
- AVIBELA can be made available in 88 countries in Africa, Central America and the Caribbean, and South and Southeast Asia
- AVIBELA is registered in 7 countries in Africa with 9 more registrations pending approval
Medicines360’s goal is to build sustainable markets for the hormonal IUD

- AVIBELA’s arrival on the global market in 2015 at an affordable price made the hormonal IUD a viable contraceptive option for women in LMICs

- We supply AVIBELA using a total market approach
  - Access pricing for the public sector
  - Affordable and competitive prices for the social marketing and private sectors
Medicines360 helps strengthen global and country capacity to provide hormonal IUDs

In-country research
- Introduction pilots in Madagascar, Zambia, and Tanzania (ongoing)
- FHI 360’s anemia study in Kenya

Regulatory capacity-building
- Registered AVIBELA via EAC-MRH and published experience
- Developed harmonized labeling strategy; shared via RHSC webinar

Awareness generation
- Presented at HIUD Access Group webinars
- Provided informational webinars in Spanish for RHSC’s ForoLAC

Training resources
- Training deck and video (EN, FR, SP)
- Nigeria-based expert clinical trainer

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What’s next for Medicines360 and AVIBELA?

**Expanding equitable access**
- New AVIBELA registrations
- Extending AVIBELA’s duration of use from 6 to 8 years

**Keeping AVIBELA affordable**
- Enabling affordable access through the global procurement catalogs
- Reducing the cost of manufacturing to keep prices low

**Prioritizing partnerships**
- Continued participation in HIUD Access Group to support country introduction and scale-up
- Forming new global partnerships to expand AVIBELA’s reach

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Ashley Smith
Senior Public Health Advisor with USAID in the Office of Population and Reproductive Health, Commodity Security and Logistics Division
USAID’s support for product introduction

- Availability is part of choice
- Global supply coordination
- Technical support locally
Procurement support to countries

- Countries and missions indicate interest
- Local introduction plan developed
- Mission places order in catalog
- GHSC-PSM procures with supplier and ships to country
- Shipment information shared in VAN
- Introduction efforts supported by technical assistance and USAID partners
- Coordination with Hormonal IUD Access Group
Addressing introduction challenges

- Demand creation
- Quantification for new products
- Ensuring global supply during scale up
- Provider training and system readiness
- Ensuring supply chain integrity
- Integration into data systems
- Tracking changes in method mix and new users
Lawrence Anyanwu, Director - Reproductive Health
Nigeria Federal Ministry of Health