



Case Study: Introduction of the Hormonal IUD in New and Emerging Markets

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What is the **Hormonal IUD**?

Sometimes referred to as the levonorgestrel-releasing intrauterine system (**LNG IUS**), the **hormonal IUS**, or the **LNG IUD**

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

Two QA'd Products:

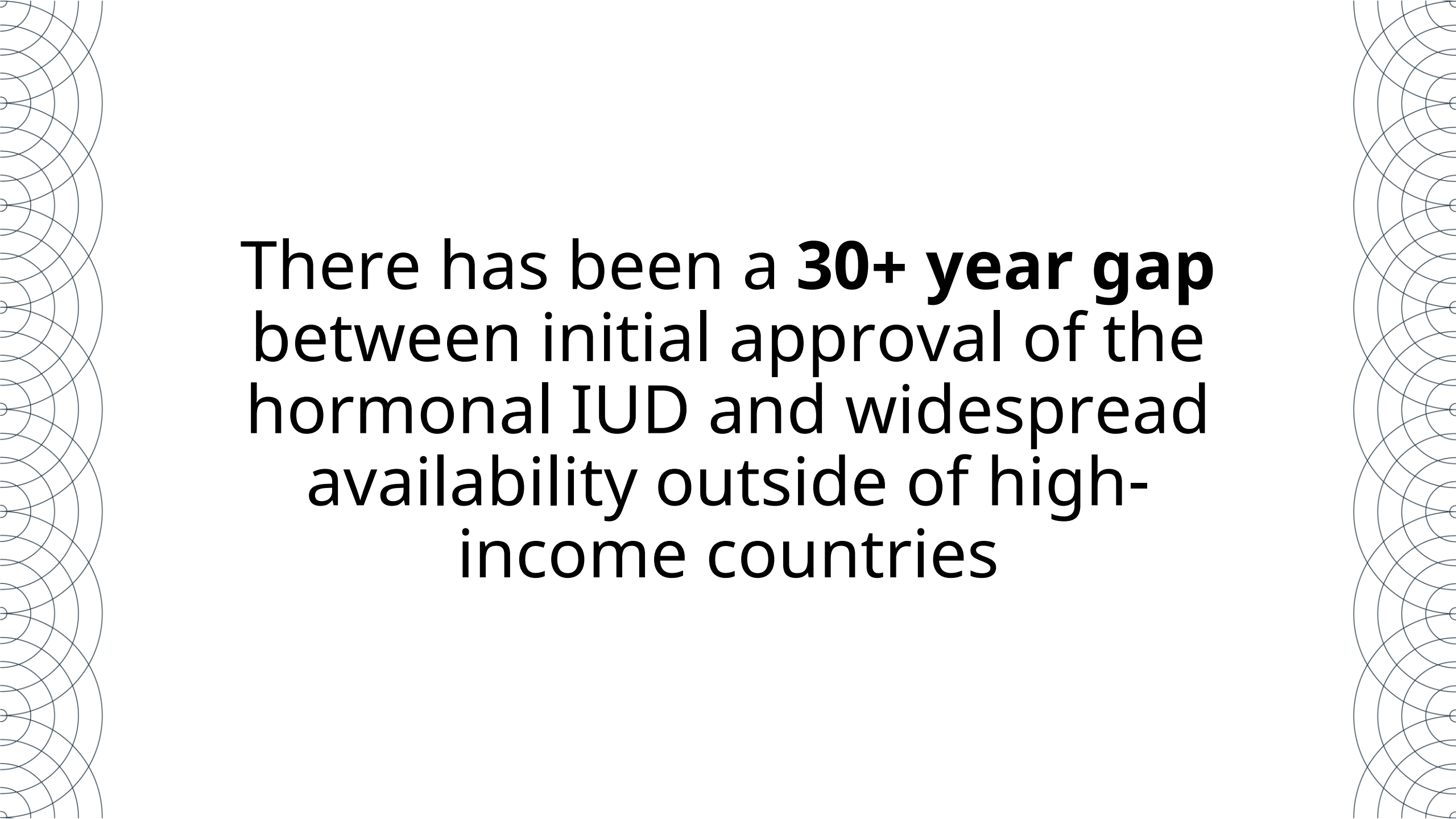


Looks Like:	Works By:	Provides:
 <p>Plastic T-frame with 52 mg of levonorgestrel</p>	<ul style="list-style-type: none"> • Thickening cervical mucus • Inhibiting sperm movement & survival 	<ul style="list-style-type: none"> • 99% contraceptive efficacy for up to 8 years • Potential treatment for heavy menstrual bleeding
Benefits		Challenges
<ul style="list-style-type: none"> • Decreases menstrual pain, bleeding, inflammation & symptoms of anemia • Rapid return to fertility • No partner participation 		<ul style="list-style-type: none"> • Vaginal insertion & removal by medical provider • Insertion pain & no universal pain management guidelines • Side effect profile may be undesirable



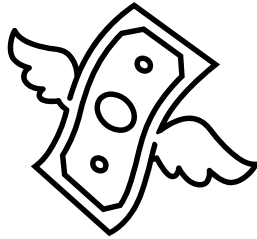
**If it's so great, what's the
problem?**



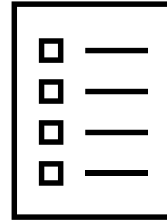


There has been a **30+ year gap** between initial approval of the hormonal IUD and widespread availability outside of high-income countries

Key Barriers to Global Public Sector Access



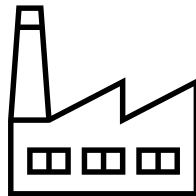
**Per Unit
Cost**



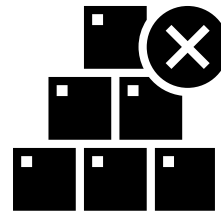
**Procurement
Policy**



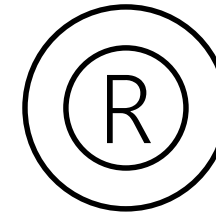
**Service Delivery
Constraints**



**No Local
Manufacturing**



**Limited QA'd
Products**



**Complex
Registration**

Early Movers: ICA Foundation, 2003-Present



Image Courtesy of ICA Foundation

215,925
Units*
in
41
Countries
to
Governments, Local
Nonprofits, Hospitals,
Service Delivery Partners

* As of March 2023



But the global product
introduction community **wasn't**
satisfied with inequitable access
to hormonal IUD



Major Movement: Supplier Commitment to Cost

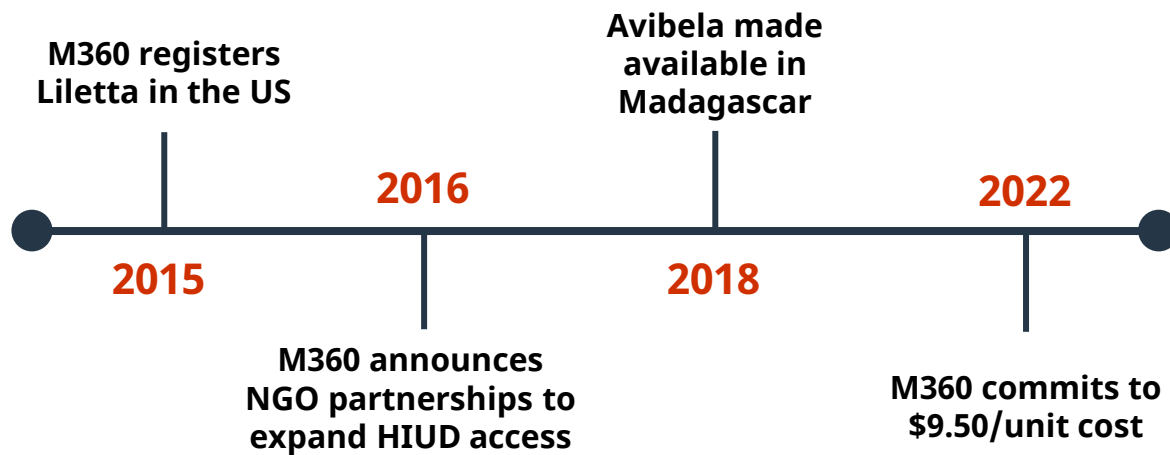


Image Courtesy of Evelyn Hockstein/Medicines360

Formation of the Hormonal IUD Access Group

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.

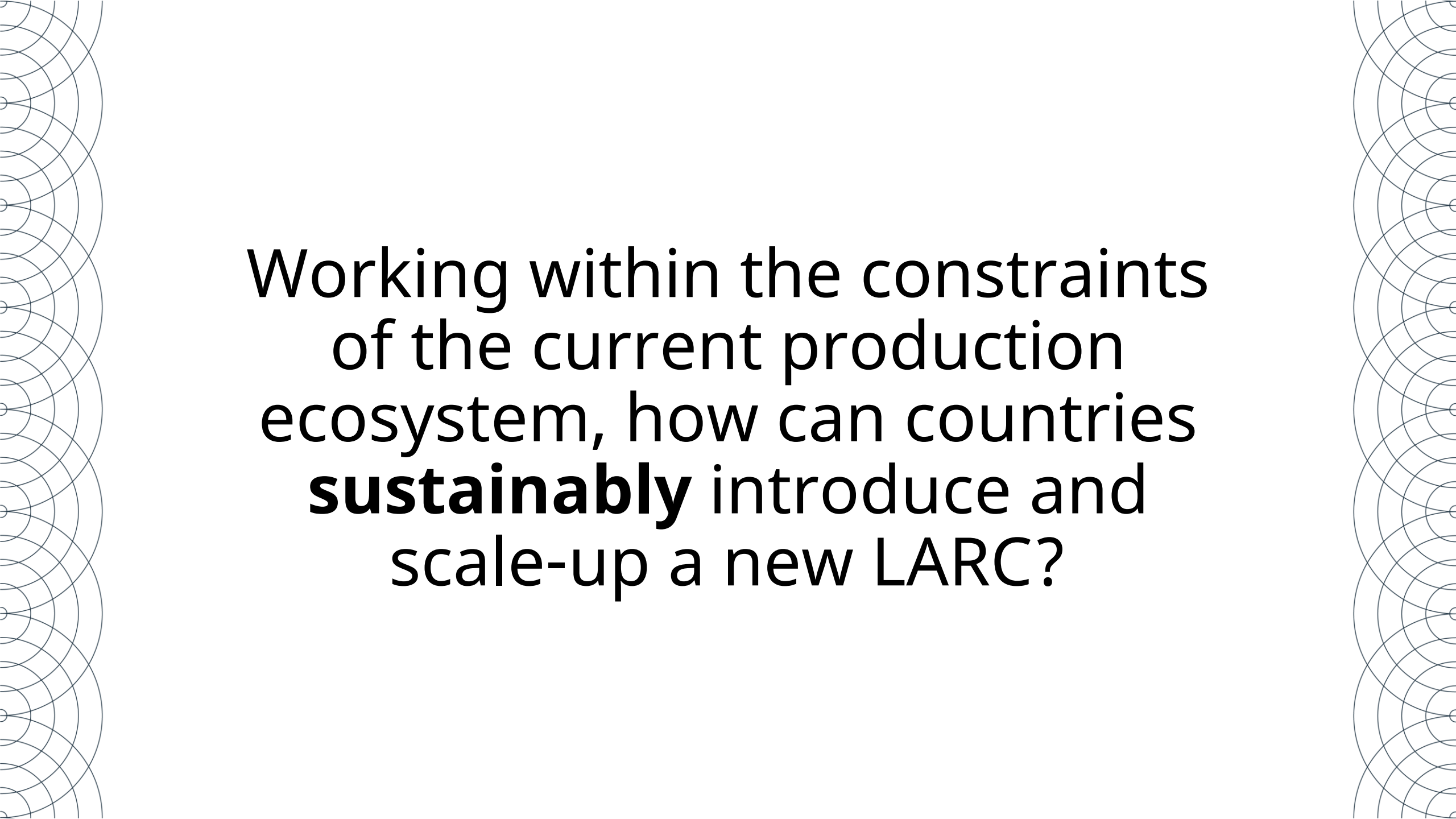
Operations Group

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.

Governments
Donors
Researchers
Suppliers
Procurers
Implementers



Working within the constraints
of the current production
ecosystem, how can countries
sustainably introduce and
scale-up a new LARC?

Lessons from Past Global Introduction Efforts

What works?*

- Country-led planning and costing
 - Early & frequent implementing partner integration
- Phased introduction for effective stewardship of limited MOH resources
- Aligning orders with evidence-based demand estimates
- Ongoing “real world” research

What doesn't?*

- Developing country and implementing partner plans separately, rather than in parallel
- Reliance on a single product
- Prioritizing volume guarantees ahead of country need or interest
- Gaps between provider training and product availability

**Most of the time*

National Strategy for **Phased Hormonal IUD Introduction**

- 1 Establish rationale and objectives for introduction
- 2 Ensure quality-assured products are registered for use
- 3 Identify health care worker capacity building strategy
- 4 Quantify, procure, and integrate commodities into national supply chain processes
- 5 Update national monitoring systems
- 6 Align on demand generation strategy and materials
- 7 Monitor introduction progress
- 8 Maintain partner coordination mechanisms

Strategy for Phased Hormonal IUD Introduction

Just because it works in one place doesn't mean it works everywhere

- Why does it make sense to introduce the hormonal IUD here?
- Where should we target or begin introduction?
- What are our introduction priorities and timelines?

Procurement support will follow plan costing & quantification

- Can we support suppliers in registering Mirena or Avibela? Which product do we want to buy?
- How will each element of our introduction plan be paid for? Are there gaps in funding?
- Based on what we know about the hormonal IUD, how many units should we order?

Gradual introduction allows countries to use resources effectively

- Where will our introduction resources be used most effectively?
- How do we get clients interested in the hormonal IUD?
- How will we track and monitor introduction progress?



How can countries be sure that hormonal IUD is a **good fit** for their context?



Developing a **Global Learning Agenda**

1. Client Demand & User Profiles
2. Demand Generation
3. Service Delivery & Provider Perceptions
4. Noncontraceptive Attributes
5. Cost-Effectiveness



Stakeholders meet in Abuja, Nigeria in early 2020 to refresh the hormonal IUD learning agenda

Developing a **Global Learning Agenda**

1. Market Potential
2. User & Provider Experiences
3. Service Delivery
4. Non-Contraceptive Attributes
5. Cost-Effectiveness & Pricing
6. Equity
7. Country Capacity for Scale-Up



Stakeholders meet in Abuja, Nigeria in early 2020 to refresh the hormonal IUD learning agenda

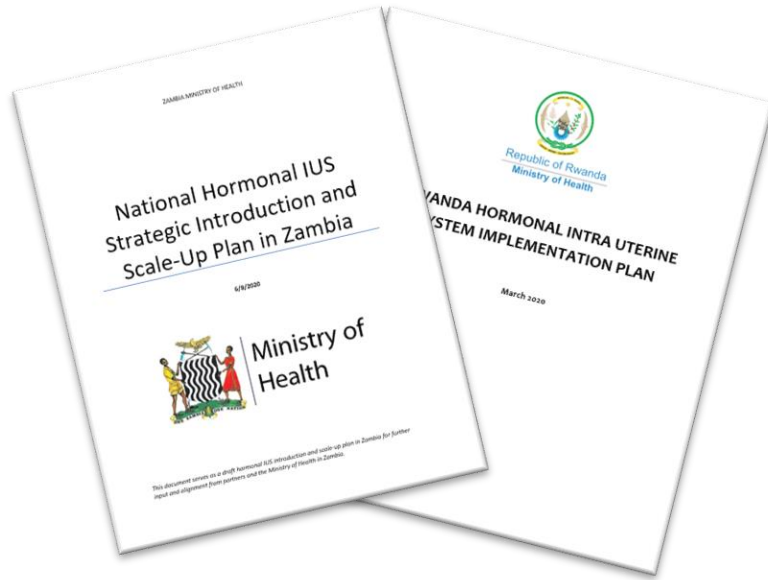
Piloting Hormonal IUD

Project	Research Timeframe	Country	Participants at Baseline	Study Design	Service Delivery Context/Channel(s)	Geographic Region
EECO	2018-2020	Madagascar	N=242	Longitudinal prospective survey within 12 months of insertion	19 social franchise clinics	Mahajanga, Toamasina, Antsiranana & Antananarivo
	2018-2019	Zambia	N = 166		30 public sector clinics	Copperbelt & Muchinga
SIFPO-2	2017-2019	Nigeria	N =205	Longitudinal prospective survey within 12 months of insertion	40 social franchise facilities	18 states
	2018-2020	Zimbabwe	N= 156		6 social franchise facilities	Harare, Manicaland, Midlands, Masvingo & Bulawayo
MCSP	2017-2019	Kenya	N = 432*	'Enhanced' M&E data, follow-up phone interviews, FGDs with providers	56 public health facilities	Kisumu & Migori
	2017-2019	Zambia	N=754*		41 public sector clinics	Eastern, Central, Southern, Luapula Province
LEAP	2018-2019	Nigeria	N = 888**	Mixed methods: Longitudinal prospective survey, IDIs, FGDs, costing	40 social franchise clinics	18 states
	2018-2019	Zambia	N = 710**		20 public sector clinics	Copperbelt & Muchinga

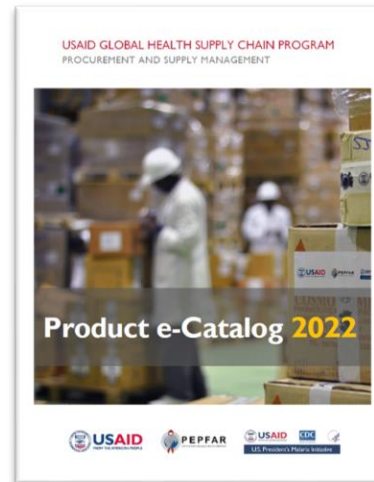


And then **COVID-19** hit.

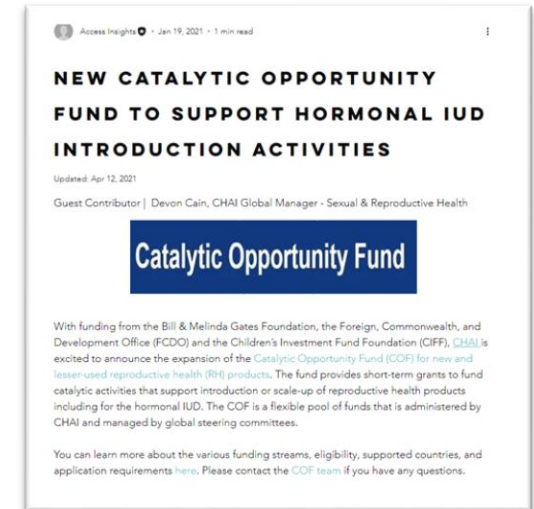
Removing Barriers to Access



Rwanda and Zambia finalize **costed introduction plans**

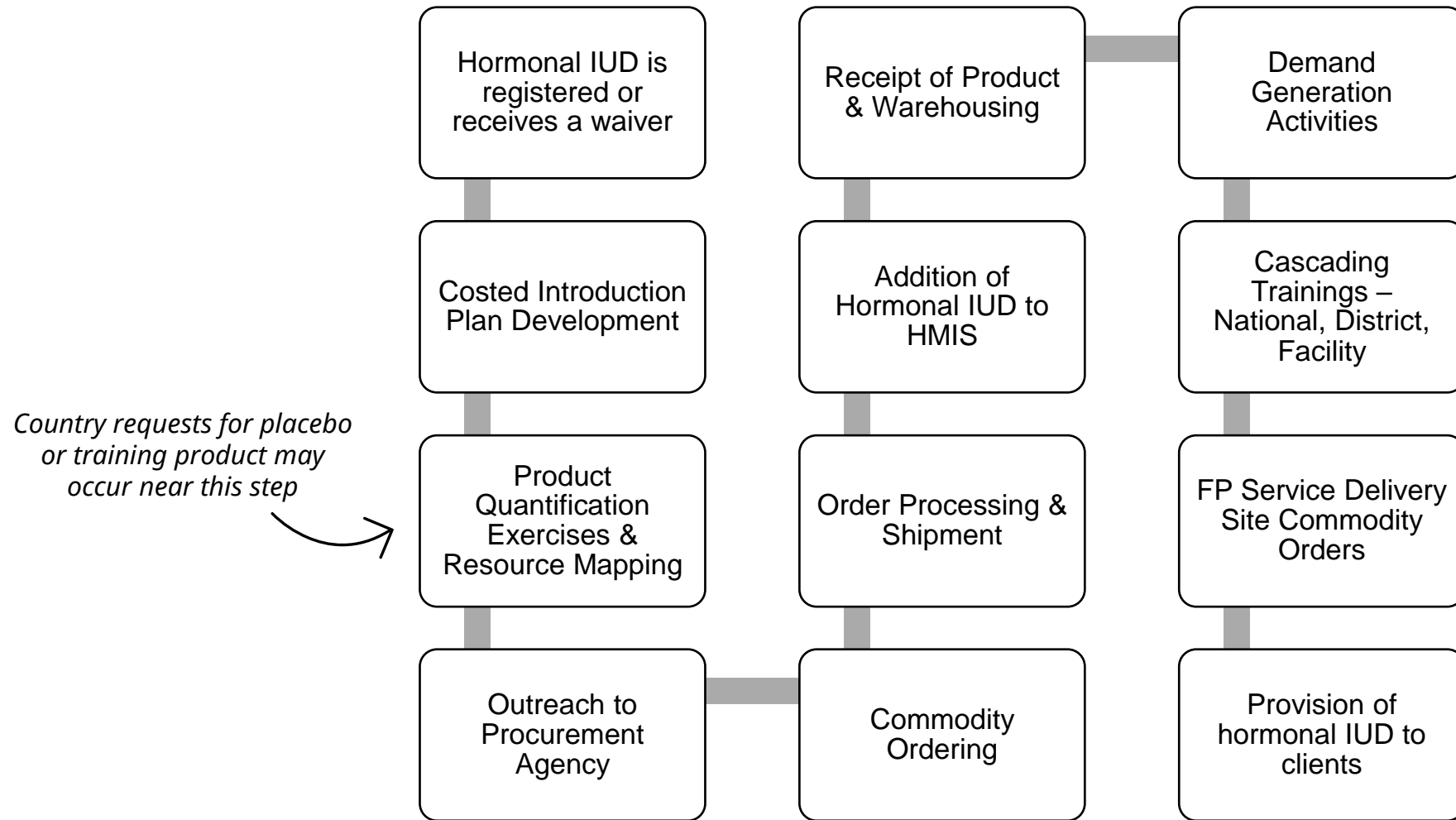


USAID and UNFPA add Mirena and Avibela to their **procurement catalogues**

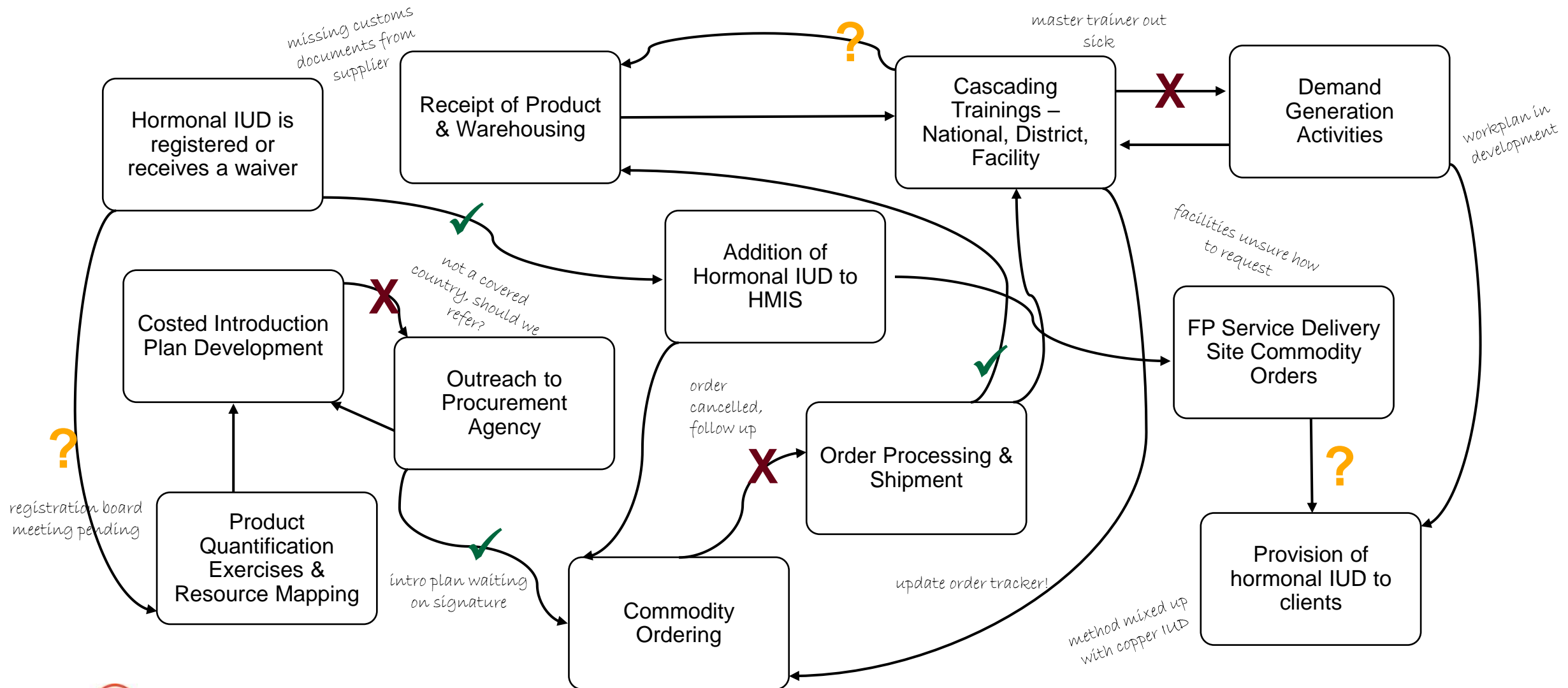


Hormonal IUD Catalytic Opportunity Fund opens to support introduction activities

Hormonal IUD Introduction Process Overview



Hormonal IUD Introduction Process Overview



Current Introduction Status

8*

Actively Introducing Countries

{ *DRC, Kenya, Madagascar, Malawi, Nigeria,
Rwanda, Uganda, Zambia* }

~215,000

Units of Hormonal IUD Received

5

Pre-Introduction Countries

{ *Bangladesh, Guinea, Honduras, Tanzania,
Yemen* }

~250,000

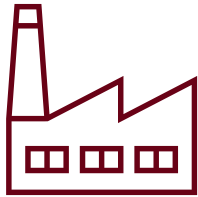
Units in Order Pipeline

43,269

Adopters in Q1 & Q2 2023

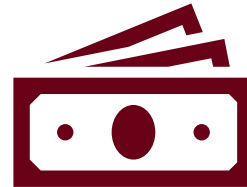
Nigeria, Zambia, Rwanda, Malawi

Lingering Challenges to Global Public Sector Access



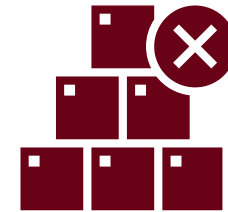
No Local Manufacturing

Potential Solution:
Tech Transfers to Local Manufacturers



Implementation Funding

Potential Solution:
Greater investment – global & national – in introduction activities



Limited QA'd Products

Potential Solution:
International Support of Existing Manufacturers to Receive WHO Pre-Qualification

And there's **more to learn** about hormonal IUD introduction

Why bother?

1. The hormonal IUD is effective, cost-efficient, and – most importantly – desirable and satisfactory to users
2. It helps to reinvigorate interest in other forms of intrauterine contraception and reignites national conversations about long-acting family planning
3. The hormonal IUD is a viable treatment option for heavy menstrual bleeding, pain, symptoms of endometriosis, and iron-deficient anemia

If it's an option **anywhere**, it must be an option **everywhere**



Thank You

To learn more about global hormonal IUD introduction:

www.hormonalIUD.org

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