

November 2021











03 04 Approach & TABLE OF Overview Results **Appendix Model Inputs CONTENTS** Background Model design Nigeria Overview of Summary of Markov results hormonal Approach model **IUD** products Zambia structure Summary of ■ Project Team results results Model inputs



01 - Overview

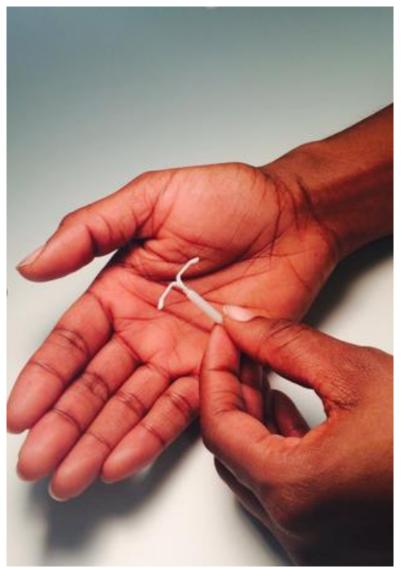


Photo credit: Medicines360



Background

- Existing evidence demonstrates that long-acting reversible contraception (LARCs) are more costeffective over time compared to short-acting contraceptive methods.¹
- In low- and middle-income countries (LMICs) two categories of LARCs copper IUDs and implants are widely available.
- However, a third LARC, the levonorgestrel-releasing intrauterine device (IUD) also known as the hormonal IUD—has historically not been widely available in LMICs. The landscape is now changing. In 2021, the hormonal IUD was added to the USAID and UNFPA catalogues for the first time.² As of November 2021, initial orders have been placed in several countries including Madagascar, Nigeria, Rwanda, and Zambia.
- The Hormonal IUD Access Group is a global consortium of governments, donors, researchers, manufacturers, procurement agencies, and service delivery groups that are collaborating to expand access to the method in the context of volunteerism and full method choice. As part of this, a learning agenda was developed which includes questions about cost-effectiveness of the method.³
- Research has been conducted through the LEAP Initiative in Nigeria and Zambia to understand users' and providers' perspectives of the method and to document continuation rates.⁴ The governments in both countries are now planning broader scale-up of the method.

^{1 –} Trussell J, Lalla AM, Doan QV, Reyes E, Pinto L, Gricar J. Cost effectiveness of contraceptives in the United States. Contraception. 2009 Jan;79(1):5-14. Epub 2008 Sep 25. Erratum in: Contraception. 2009 Aug;80(2):229-30.

²⁻https://familyplanning2020.org/news/introduction-long-acting-family-planning-method-usaid-and-unfpa-product-catalogs

^{3 -} Rademacher KH, Sripipatana T, Pfitzer A, Mackay A, Thurston S, Jackson A, Menotti E, Traeger H. A Global Learning Agenda for the Levonorgestrel Intrauterine System: Addressing Challenges and Opportunities to Increase Access. Glob Health Sci Pract. 2018;6(4):635-643.

^{4 -} Brunie A, Stankevitz K, Nwala AA, Nqumayo M, Chen M, Danna K, Afolabi K, Rademacher KH. Expanding long-acting contraceptive options: a prospective cohort study of the hormonal intrauterine device, copper intrauterine device, and implants in Nigeria and Zambia. Lancet Glob Health. 2021 Oct;9(10):e1431-e1441



Summary of approach to cost-effectiveness analysis

Objectives

Our aim was to estimate the incremental cost-effectiveness of the hormonal IUD compared to other contraceptive methods available in Nigeria and Zambia over a 5-year and 10-year period. Separate models were built for Nigeria and Zambia reflecting the different service delivery contexts, contraceptive prevalence, and current method mix. Costs were estimated from the perspective of the health system as well as from the societal perspective.

Key questions addressed

- Q1 What are the costs associated with method use, discontinuation/switching, and method failure of the hormonal IUD and other commonly available methods in Nigeria and Zambia over a 5-year and 10-year period from a health system and a societal perspective?
- Q2 What is the incremental cost-effectiveness (primary measure: unintended pregnancies averted) of the hormonal IUD and other methods in both countries?

Significance of the analysis for decision-making

The results of this modeling exercise can provide additional information to help decision-makers
weigh the trade-offs of scaling up the hormonal IUD within the context of a full contraceptive
method mix, taking into account both the additional costs and the relative effectiveness
associated with method provision.



Summary of Results

- Results of the cost-effectiveness analysis showed that over a 10-year period, the hormonal IUD was more cost-effective (i.e., lower incremental cost per unintended pregnancy avoided) compared to implants from both the health systems and societal perspectives in both Nigeria and Zambia, with the copper IUD remaining the most costeffective LARC option over the 10-year period.
- With similar (Nigeria) or slightly higher (Zambia) continuation rates as the Copper-T and implants and lower failure rates than Copper-T, the hormonal IUD is able to avert more unintended pregnancies over a 10-year period compared to other LARCs.



02 – Approach& Model Inputs

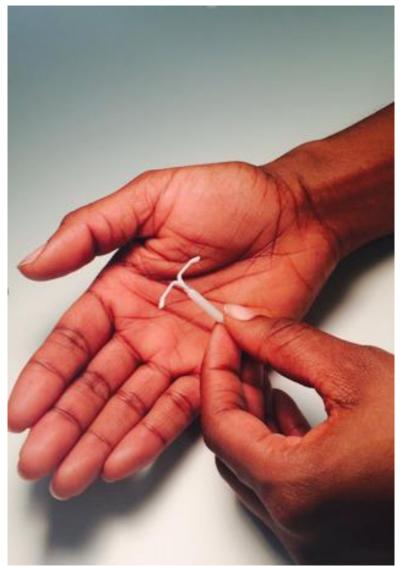


Photo credit: Medicines360



Overview of Approach

Objective	Approach
Estimate the costs and effectiveness of the hormonal IUD (hormonal IUD) compared to five other FP methods: copper IUD, 3-year implant, 5-year implant, 3-month injectable and monthly oral contraceptive pills (OCPs).* Approach assumed facility-based provision for a cohort of women of reproductive age over a 5-year and 10-year period.	Monte Carlo simulation (n=1,000) of a Markov model for cohorts of 100,000 women from the health system and societal perspectives in Nigeria and Zambia.



Note: Given that LARCs (hormonal IUD, copper IUD, and implants) require insertion and removal by a trained provider, this model was designed to compare **facility-based** provision of all methods (including 3-month injectables and OCPs).

^{*} Assuming advanced provision of OCPs where client receives 3 months of supply per visit.

Model Design



Design

Recursive Excel-based Monte Carlo simulation (n=1,000 runs) of a Markov model for cohorts of 100,000 women using each of the six methods at time 0 in each of 2 countries (Nigeria and Zambia). The models repeat on a 6-monthly basis to reflect transitions of: method continuation, method switching/discontinuation, and method failure (unintended pregnancy). Results were summarized for a **5-year and 10-year period**. For each cycle, costs associated with method uptake, continuation, switching, discontinuation and failure were accumulated as appropriate based upon the probability of events. Continuers whose method expires, incur removal and reinsertion costs at time of method expiration. Monte Carlo simulation used to generate 1,000 estimates for each cohort. Results are based upon average result across 1,000 runs.

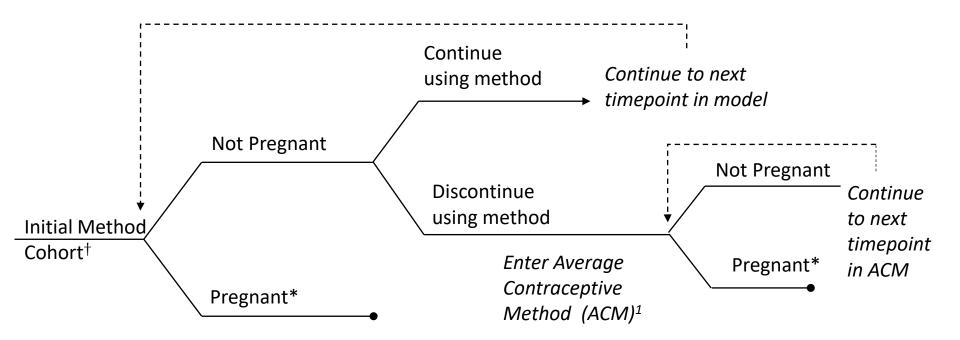


Note: Other costing analyses conducted under LEAP documented some of the costs required for demand creation and training¹. Costed roadmaps for method introduction were developed in both countries in partnership with government that estimate costs associated with scale-up including demand creation and training. However, for the purposes of this model, upfront training and demand creation costs for hormonal IUD introduction have not been included.

^{1 –} Brunie A, Rademacher KH, Nwala AA, Danna K, Saleh M, Afolabi K. Provision of the levonorgestrel intrauterine system in Nigeria: Provider perspectives and service delivery costs. Gates Open Res. 2020 Aug 6;4:119. doi: 10.12688/gatesopenres.13135.1.

Markov Model Structure





¹ ACM is based on current contraceptive use rates and contraceptive method mix in Nigeria and Zambia, according to data from the most recent DHS surveys. Methodology for calculating ACM as described in Mavranezouli I. The cost-effectiveness of long-acting reversible contraceptive methods in the UK: analysis based on a decision-analytic model developed for a National Institute for Health and Clinical Excellence (NICE) clinical practice guideline. Hum Reprod. 2008 Jun;23(6):1338-45.

[†] Note: There are separate models for each method-specific cohort of 100,000 women. Results based upon 1,000 runs of each model with beta distribution of method-specific estimates of method failure and method discontinuation at each time point.

^{*}Note: Model includes costs associated with outcomes of unintended pregnancies (delivery, miscarriage or abortion) after which point, they leave the model

LEAP LNG-IUS INITIATIVE

Analytical Methods

Overview

The key analysis was the **incremental cost-effectiveness ratio** comparing the results across the six FP methods. The **incremental cost per unintended pregnancy averted was the key result.** From this we also estimated the incremental cost per unplanned births averted, abortions averted, and maternal deaths averted.

This model comparison was intended to be consistent with standard estimates of impact used by other mathematical models of contraceptive use (e.g., see Askew et al., 2017). Results are reported both from the health system perspective as well as the broader societal perspective.

Note: We are able to conduct additional sensitivity analyses around cost estimates assigned to key inputs including commodity prices, continuation rates, and pregnancy-related events, as desired.

Askew I, Weinberger M, Dasgupta A, et al. Harmonizing methods for estimating the impact of contraceptive use on unintended pregnancy, unsafe abortion, and maternal health. Glob Health Sci Pract. 2017;5(4):658-667.



Variables & Operational Definitions

Dependent variables	Independent variables
<u>Health system perspective</u>	 Method-specific continuation and failure
• Service delivery costs – cost of method initiation visits by method,	ratesUnit costs associated with
cost of any follow-up visits (LARCs), cost of method resupply (DMPA and OCPs), cost of method discontinuation by method*	 Unit costs associated with commodities and events (encounters with health
• Unintended pregnancies due to method failure – Cost of pregnancy	system)
(including antenatal care, delivery, and complications) from failure of initial method or from subsequent FP use, if any, by discontinuers	
Societal perspective (includes health system costs above) 1	
 Cost to clients – Travel and time costs associated with clinic visits, out-of-pocket costs associated with pregnancy (including antenatal care, delivery, and complications) 	

1 – Results reported in next section reflect both health system perspective and societal perspective. Costs to clients included in calculation of societal perspective costs only.

^{*}Note: Costs for possible adverse clinical outcomes (e.g., uterine perforation) not included in model

Model inputs & sources



Data element	Hormonal IUD	Other FP methods	Average Contraceptive Method (ACM)
Contraceptive failure rates	Trussell et al.	Trussell et al.	Trussell et al.
Contraceptive continuation rates	LEAP studies — 6 mo and 12 mo	 Implants and copper IUD: LEAP studies Other methods: DHS StatCompiler 	DHS StatCompiler
Cost of Pregnancy (weighted for all outcomes)	Guttmacher (Adding it Up)	Guttmacher (Adding it Up)	Guttmacher (Adding it Up)
Cost of method initiation, follow-up and/or removal (method dependent)	LEAP costing exercise + global inputs	LEAP costing exercise + global inputs	LEAP costing exercise + global inputs

Sources:

- Darroch JE, Singh S and Weissman E, (2016) Adding It Up: The Costs and Benefits of Investing in Family Planning and Maternal and Newborn Health 2014—Estimation Methodology, New York: Guttmacher Institute. Available here.
- DHS StatCompiler http://statcompiler.com.en
- Trussell J, et al. "Chapter 26 Contraceptive Efficacy" in Contraceptive Technology, 21st edition Managing Contraception, LLC. 2018.

Model inputs continued



Unit procurement prices assumed in model

Method	Unit procurement price of commodity in USD	Source
Copper IUD (T380A)	\$0.44	UNFPA Product Catalogue
Hormonal IUD (7 year duration)	\$10.90	UNFPA Product Catalogue
Oral contraceptive pills (OCPs)	\$0.78	UNFPA Product Catalogue
Implant (3 year duration)*	\$6.70	Press release, DKT and Dahua**
Implant (5 year duration)	\$8.50	UNFPA Product Catalogue
Injectable (3 month duration)**	\$0.85	UNFPA Product Catalogue

^{*} For the 3-year implant, the price of Levoplant, a 2-rod contraceptive implant, was used (\$6.70/unit)

^{**} For 3-month injectable, price of DMPA-SC used for model.

Model inputs continued



Method Continuation Rates assumed in model (Nigeria)*

Method	Year 1	Year 2	Year 3	Year 4	Year 5	Year 6	Year 7	Year 8	Year 9	Year 10
Copper IUD (T380A)	.869	.739	.689	.653	.628	.603	.579	.554	.530	.505
Hormonal IUD (7 year duration)	.868	.754	.654	.568	.493	.428	.372	n/a	n/a	n/a
Oral contraceptive pills (OCPs)	.791	.626	.495	.391	.310	.245	.194	.153	.121	.096
Implant (3 year duration)	.850	.800	.550	n/a						
Implant (5 year duration)	.850	.800	.550	.402	.337	n/a	n/a	n/a	n/a	n/a
Injectable (3 month duration)	.820	.620	.480	.418	.395	.372	.348	.325	.302	.279

Method Continuation Rates assumed in model (Zambia)*

Method	Year 1	Year 2	Year 3	Year 4	Year 5	Year 6	Year 7	Year 8	Year 9	Year 10
Copper IUD (T380A)	.891	.781	.671	.593	.544	.494	.445	.395	.346	.297
Hormonal IUD (7 year duration)	.947	.897	.849	.804	.762	.721	.683	n/a	n/a	n/a
Oral contraceptive pills (OCPs)	.713	.508	.362	.258	.184	.131	.094	.067	.021	.007
Implant (3 year duration)	.831	.741	.591	n/a						
Implant (5 year duration)	.831	.741	.591	.483	.417	n/a	n/a	n/a	n/a	n/a
Injectable (3 month duration)	.790	.510	.320	.267	.255	.243	.231	.219	.206	.194

^{*} Based upon the one year continuation rates observed for hormonal IUD, Copper-T, and implants in the LEAP studies in Nigeria and Zambia, we projected these rates forward assuming the same annual rates. For injectables and OCPs, the reported rates from the DHS StatCompiler were projected in a similar manner for both countries.

Model inputs continued



Estimates of provider time spent on different tasks and monthly salaries for nurse-midwives

	Time, min	
Counseling a new FP client (mean)	23	
Provision and removal (mean)	Time inserting, min	Time removing, min ^a
Hormonal IUD	9	4
Copper IUD	10	4
One-rod implant	7	14
Two-rod implant	11	21
Monthly salaries	USD	
Average monthly salary for nurse- midwife in SFH network in Nigeria	\$273	
Average monthly salary for nurse- midwife in public sector in Zambia	\$304	

Sources:

- Insertion and removal times: LEAP survey administered with providers in Nigeria
- Salary Nigeria: LEAP survey administered with providers
- Salary Zambia: Government circular, obtained through personal communication with FHI 360 staff, 2020



03 - Results

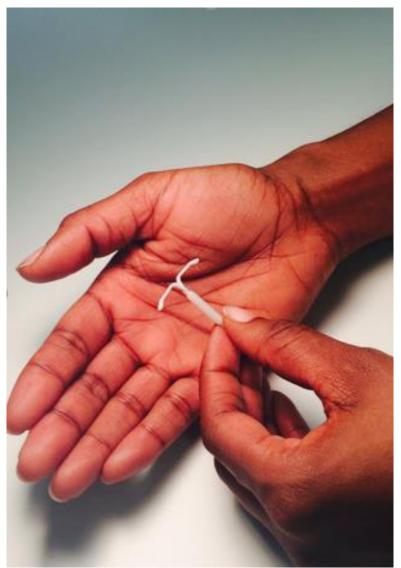
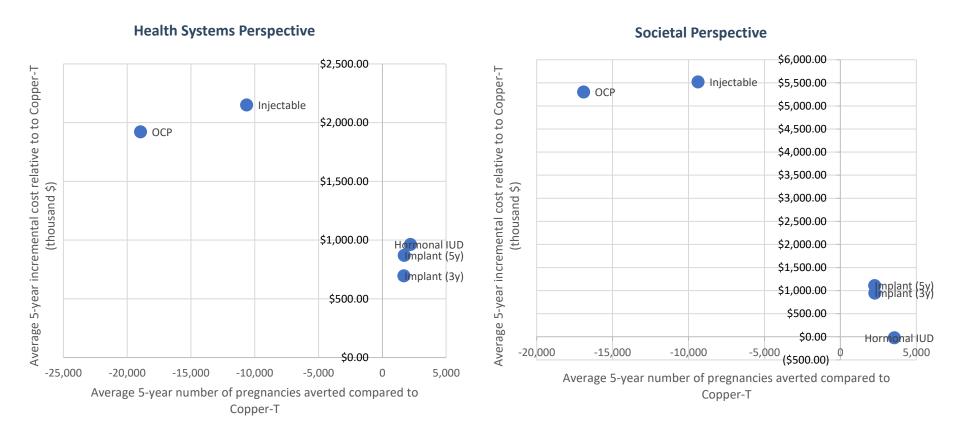


Photo credit: Medicines360

Implant (3-year duration) is most cost-effective alternative to Copper-T for the health system but from a societal perspective Hormonal IUD is cost saving



Average annual incremental costs and benefits of all evaluated contraceptive methods relative to Copper-T IUD at 5 years (results per 100,000 women)

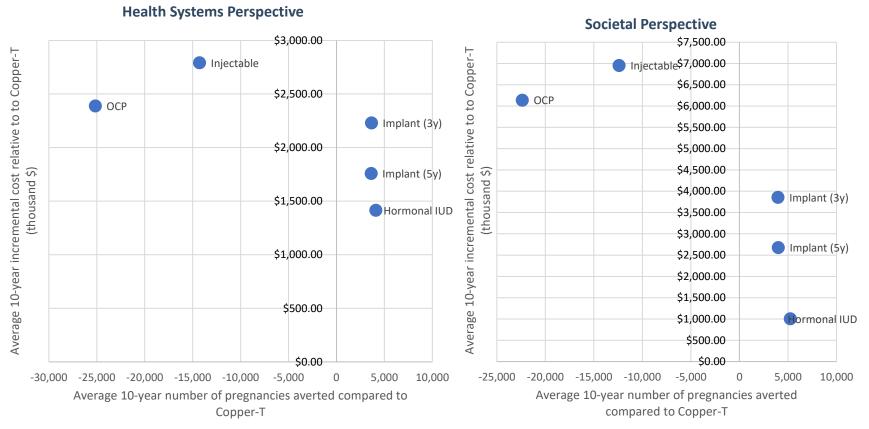


^{*} As the least costly option, the copper IUD serves as our reference from which the Incremental Cost-Effectiveness Ratios (ICERs) are computed for the more expensive options

Hormonal IUD is most cost-effective alternative to Copper-T IUD under either a health system or societal perspective



Average annual incremental costs and benefits of all evaluated contraceptive methods relative to Copper-T IUD at 10 years (results per 100,000 women)



^{*} As the least costly option, the copper IUD serves as our reference from which the Incremental Cost-Effectiveness Ratios (ICERs) are computed for the more expensive options



CEA model results in Nigeria – over 5 years for 100,000 women

N			
Baseline FP Method	Costs	Number of pregnancies	Incremental cost to avert one pregnancy
Copper-T*	\$757,866	4,867	Reference*
Implant (3y)	\$1,450,561	3,151	\$403.64
Implant (5y)	\$1,625,465	3,137	\$501.75
Hormonal IUD	\$1,722,222	2,662	\$437.49
ОСР	\$2,668,344	23,608	Fewer pregnancies averted
Injectable	\$2,893,260	15,327	Fewer pregnancies averted

	Nigeria: Societal Pers	pective	
Baseline FP Method	Costs	Number of pregnancies	Incremental cost to avert one pregnancy
Copper-T*	\$2,974,021	5,128	Reference*
Hormonal-IUD	\$2,947,156	1,651	- \$7.53
Implant (3y)	\$3,893,437	2,926	\$401.10
Implant (5y)	\$4,061,238	2,860	\$461.01
OCP	\$8,267,444	22,017	Fewer pregnancies averted
Injectable	\$8,496,898	14,738	Fewer pregnancies averted

^{*} As the least costly option, the copper IUD serves as our reference from which the Incremental Cost-Effectiveness Ratios (ICERs) are computed for the more expensive options



CEA model results in Nigeria – over 10 years for 100,000 women

Ni			
Baseline FP Method	Costs	Number of pregnancies	Incremental cost to avert one pregnancy
Copper-T*	\$1,260,133	7,715	Reference*
Hormonal IUD	\$2,680,857	3,663	\$350.62
Implant (5y)	\$3,033,658	4,154	\$498.04
Implant (3y)	\$3,478,528	3,167	\$487.77
OCP	\$3,656,373	33,115	Fewer pregnancies averted
Injectable	\$4,038,673	21,964	Fewer pregnancies averted

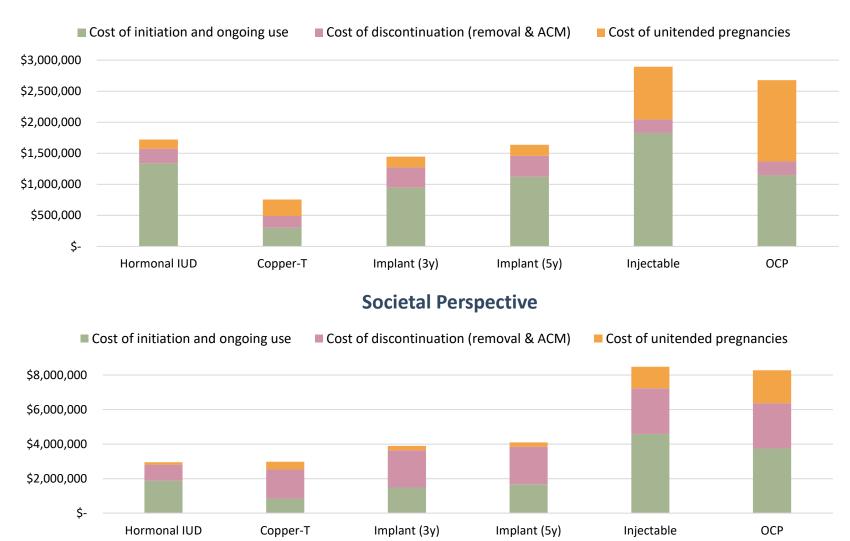
	_		
Baseline FP Method	Costs	Number of pregnancies	Incremental cost to avert one pregnancy
Copper-T*	\$4,490,091	8,028	Reference*
Hormonal-IUD	\$5,520,567	2,755	\$195.42
Implant (5y)	\$7,199,558	4,003	\$673.15
Implant (3y)	\$8,379,024	4,010	\$1,057,475
OCP	\$10,694,569	30,669	Fewer pregnancies averted
Injectable	\$11,441,656	20,034	Fewer pregnancies averted

^{*} As the least costly option, the copper IUD serves as our reference from which the Incremental Cost-Effectiveness Ratios (ICERs) are computed for the more expensive options

Distributions of cost across models and methods – Nigeria (5 year)



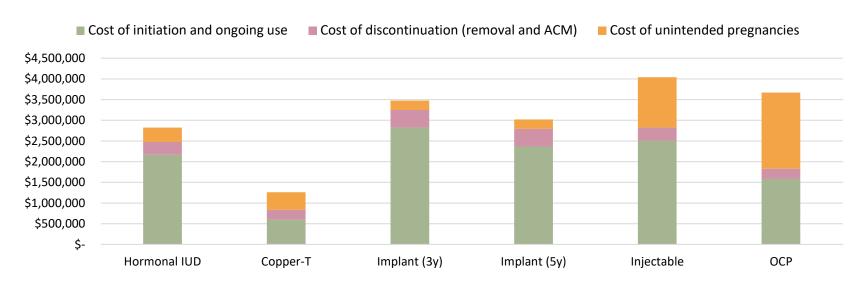
Health System Perspective



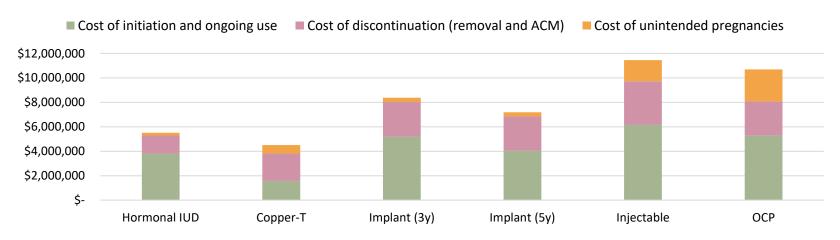
Distributions of cost across models and methods – Nigeria (10 year)



Health System Perspective



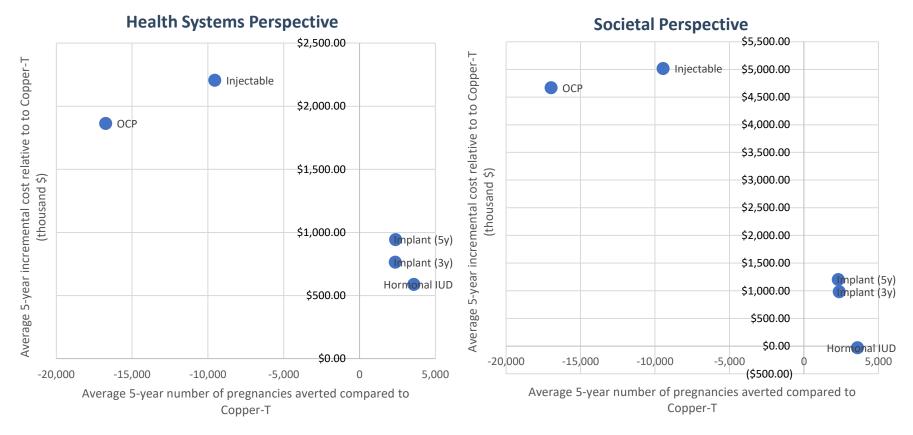
Societal Perspective



Hormonal IUD would be viewed as cost-effective alternative under a health syst perspective and slightly cost-saving under a societal perspective



Average annual incremental costs and benefits of all evaluated contraceptive methods relative to the copper IUD* at 5 years (results per 100,000 women)

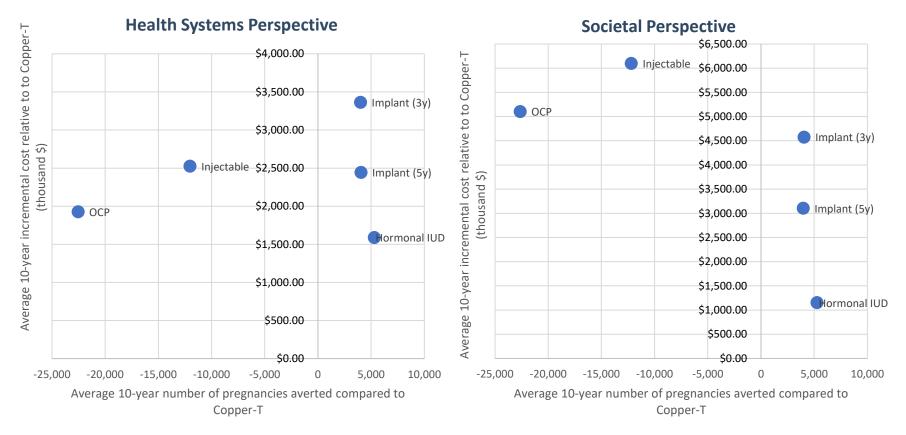


^{*} As the least costly option, the copper IUD serves as our reference from which the Incremental Cost-Effectiveness Ratios (ICERs) are computed for the more expensive options

Hormonal IUD is most cost-effective alternative to Copper-T IUD under either a health system or societal perspective



Average annual incremental costs and benefits of all evaluated contraceptive methods relative to the copper IUD* at 10 years (results per 100,000 women)



^{*} As the least costly option, the copper IUD serves as our reference from which the Incremental Cost-Effectiveness Ratios (ICERs) are computed for the more expensive options

Preliminary: CEA model results in Zambia – over 5 years for 100,000 women



Z			
Baseline FP Method	Costs	Number of pregnancies	Incremental cost to avert one pregnancy
Copper-T*	\$1,423,461	5,213	Reference
Hormonal IUD	\$2,013,210	1,630	\$164.59
Implant (3yr)	\$2,194,881	2,906	\$334.38
Implant (5y)	\$2,369,513	2,837	\$398.17
ОСР	\$3,288,889	22,082	Fewer pregnancies averted
Injectable	\$3,625,837	14,768	Fewer pregnancies averted

Za			
Baseline FP Method	Costs	Number of pregnancies	Incremental cost to avert one pregnancy
Copper-T*	\$3,140,286	5,165	Reference
Hormonal IUD	\$3,103,019	1,654	- \$10.61
Implant (3y)	\$4,154,572	2,882	\$444.28
Implant (5y)	\$4,335,520	2,877	\$522.39
OCP	\$7,840,390	22,033	Fewer pregnancies averted
Injectable	\$8,176,143	14,791	Fewer pregnancies averted

^{*} As the least costly option, the Copper IUD serves as our reference from which the Incremental Cost-Effectiveness Ratios (ICERs) are computed for the more expensive options

Preliminary: CEA model results in Zambia – over 10 years for 100,000 women



7	_		
Baseline FP Method	Costs	Number of pregnancies	Incremental cost to avert one pregnancy
Copper-T*	\$2,290,180	8,085	Reference
Hormonal IUD	\$3,872,778	2,717	\$294.82
Implant (5y)	\$4,729,714	3,949	\$589.83
Implant (3yr)	\$5,654,247	3,996	\$822.71
ОСР	\$4,214,564	30,530	Fewer pregnancies averted
Injectable	\$4,811,085	20,233	Fewer pregnancies averted

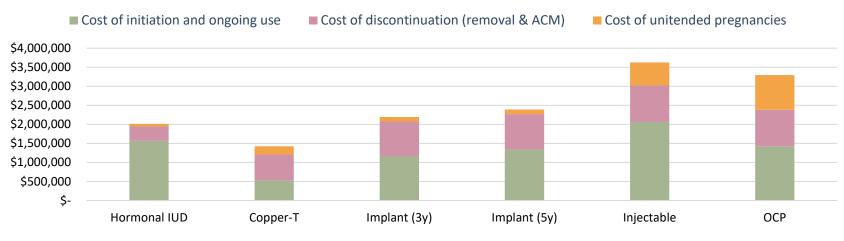
Z			
Baseline FP Method	Costs	Number of pregnancies	Incremental cost to avert one pregnancy
Copper-T*	\$4,841,291	8,019	Reference
Hormonal IUD	\$5,991,458	2,738	\$217.79
Implant (5y)	\$7,958,142	3,981	\$771.88
Implant (3y)	\$9,435,077	3,979	\$1,137.08
OCP	\$9,923,504	30,268	Fewer pregnancies averted
Injectable	\$10,968,406	20,215	Fewer pregnancies averted

^{*} As the least costly option, the Copper IUD serves as our reference from which the Incremental Cost-Effectiveness Ratios (ICERs) are computed for the more expensive options

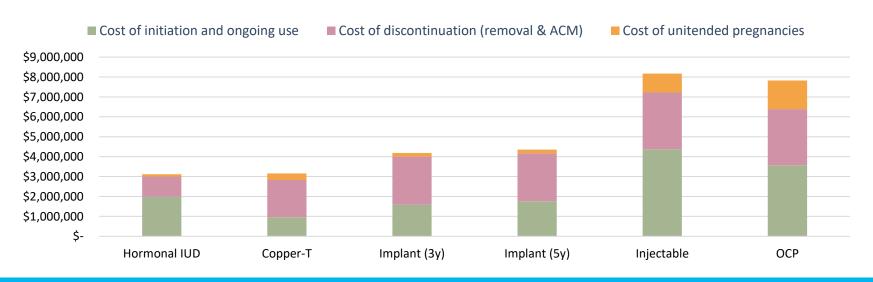
Distributions of cost across models and methods - Zambia



Health System Perspective



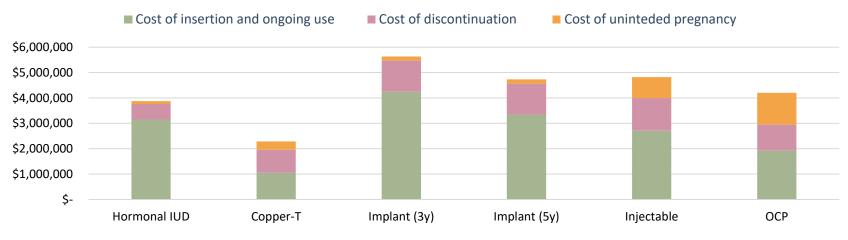
Societal Perspective



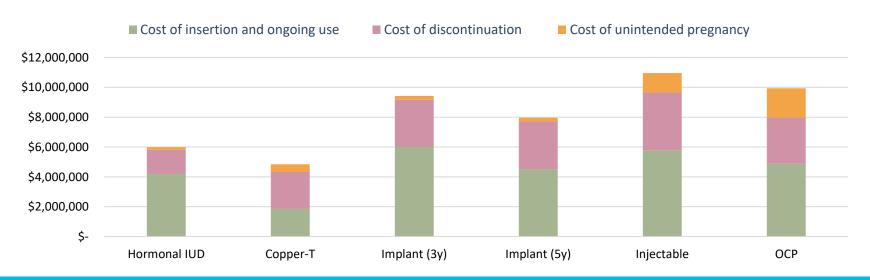
Distributions of cost across models and methods - Zambia



Health System Perspective



Societal Perspective





04 – Appendix

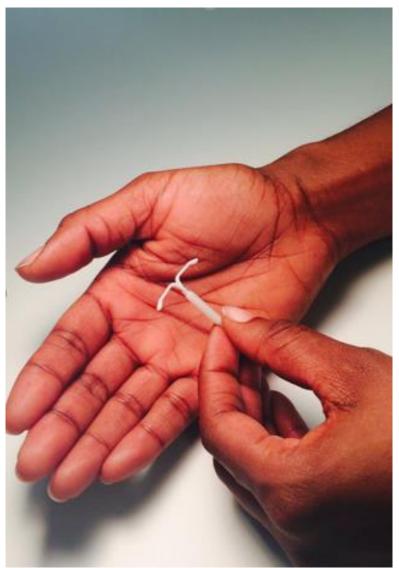


Photo credit: Medicines360



Overview of SRA-Approved Hormonal IUD Products

Supplier	Hormonal IUD product¹
Bayer AG	Mirena ²
International Contraceptive Access (ICA) Foundation	Unbranded LNG IUS product
Medicines ₃ 60	Avibela ³

- 1 In addition to the products listed in the table, there are several hormonal IUD products that are being introduced in a limited number of FP2020/FP2030 countries that are not currently approved by an SRA. As of 2021, no non-SRA approved hormonal IUD products have been prequalified by the World Health Organization.
- 2- Bayer AG also manufactures the hormonal IUD products Skyla and Kyleena. However, these products are not yet available in low-and middle-income countries, and therefore are not discussed
- 3 The Medicines 360 product is sold in the United States under trade name Liletta; the product sold in FP2020/FP2030 countries under the trade name Avibela.



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