

LEAP Initiative: A mixed-method, longitudinal study of the user population in Zambia



DRAFT for
review





Research objectives

The goal of this research was to generate evidence on the user population of the LNG-IUS through an improved understanding of their profiles and experiences

1

To describe LNG-IUS acceptors compared to women choosing other LARCs or injectables

2

To describe factors affecting uptake of the LNG-IUS from clients' perspectives

3

To estimate method-specific 6- and 12-month LARC continuation rates and assess women's satisfaction using these methods



Summary: Key Take-Aways



Demographics: LNG-IUS and copper IUD users had closer socio-demographic characteristics when compared to each other than relative to implant and injectable users.

Previous method use: 91-99% of LARC acceptors had ever used a modern method; 61% of LNG-IUS acceptors were using a short-acting method as their last method prior to the LNG-IUS.

Reasons for method choice: The most common reason for choosing a method across LARCs was long-acting, followed by right for my body and convenient. Over 20% of LNG-IUS users also mentioned effective, discreet, and few/manageable side effects. A smaller but sizable proportion of LNG-IUS acceptors cited treatment of heavy or painful period.

Method preference if the LNG-IUS had not been available: 59-65% of copper IUD and LNG-IUS users and 40% of implant users would have chosen another LARC if the method they received had not been available. 22% of copper IUD and 11% of implant users would have opted for the LNG-IUS.

Continuation rates: Over the course of the study 7 LNG-IUS, 14 Copper IUD, and 12 implant users reported that they stopped using their methods. Continuation rates for the LNG-IUS were 96% at six months and 95% at 12 months.

Satisfaction with method use: Satisfaction with the method and with the bleeding pattern are higher overall for the LNG-IUS compared to implants. Differences between results for the copper IUD and the LNG-IUS are less clear.

Perceptions of bleeding changes: 78-81% of LNG-IUS users who said they had experienced reduced bleeding reported that reduced bleeding had had a positive impact on their lives overall. However, acceptability of amenorrhea was mixed.

Menstrual hygiene management: More LNG-IUS users reported a reduction in the amount of menstrual products used compared to before they received their method relative to users of other LARCs.



Research design



Mixed-method study across 20 public facilities in Copperbelt and Muchinga



Quantitative component

Prospective, longitudinal survey with clients at public facilities

In-person interviews

- Baseline survey with 710 women choosing the LNG-IUS, copper IUD, implant or three-month injectable - within 100 days of method uptake (July - December 2018)
- Follow-up surveys with a subset of 367 LARC users* - 6 and 12 months after baseline

*103 injectable users were not followed up over time or included in the qualitative sample because the primary focus of the study is on comparing client experiences with the LNG-IUS to experiences with other LARCs. In addition, the sample size for follow-up surveys was based on estimating method-specific continuation rates. 13 LNG-IUS, 19 copper IUD and 208 implant users were not re-contacted due to oversampling at baseline.



Qualitative component

Follow-up in-depth interview (IDI) with 30 survey participants

In-person IDIs with subset of survey participants who chose the LNG-IUS, copper IUD or implants*

- Selected from 9 facilities
- IDI within 21 weeks of baseline survey



Inclusion criteria and sampling for the phone survey



Research assistants screened and recruited women who received services at facilities, and scheduled an in-person interview at a convenient time. Inclusion criteria were:

- **Age:** 16-49 years old
- **Location of service:** One of 20 public health facilities in Copperbelt and Muchinga provinces with providers who participated in the first SFH clinical trainings on LNG-IUS service provision in July-November 2017
- **Method received:** LNG-IUS, copper IUD, implant or three-month injectable. Only LARC users were eligible for follow-up interviews



The dates at which women received their method were extracted from clinic records. Only women who had **received their method 0-100 days prior to the baseline interview** were retained for the final analyses.

Profile of study participants



IN-PERSON SURVEY WITH CLIENTS* (n=710)

Baseline method**					
LNG-IUS		153	Implant		286
Copper IUD		168	Injectable		103

Age (mean = 29)		
16-24 years	25-34 years	35-49 years
30%	48%	22%

Marital Status		Parity (mean = 3.6)	
Single	15%	0	5%
Married	77%	1-2	44%
Other	7%	3-4	36%
		5+	15%

Highest Education Completed (14% no education or < primary)		Urban Wealth Index	
	Primary 44%	Lowest	11%
	Secondary 34%	Second	13%
	> Secondary 8%	Middle	24%
		Fourth	25%
		Highest	27%

FOLLOW-UP In-depth interviews (IDIs)



- 16 women who chose the LNG-IUS
- 12 women who chose an implant
- 2 women who chose the copper IUD

*Note: Numbers may not add to 100 due to rounding.
 **Injectable users were not followed up over time. Only a subset of 367 LARC users were followed-up over time due to oversampling at baseline.



Baseline survey results



Socio-demographic characteristics



<i>Baseline method</i>	LNG-IUS 	Copper IUD 	Implant 	Injectable 
Mean age	30	32	27	28
Married	75%	87%	74%	75%
Mean parity	3	3	2	2
Want to limit	29%	33%	15%	17%
Completed secondary or higher	50%	49%	37%	36%
Full-time or self-employed	41%	28%	20%	26%
Urban wealth index upper quintile	34%	41%	18%	17%

 n=710

Compared to women who chose the implant or the injectable, LNG-IUS and copper IUD users were older, had more children and were more educated; more were in the upper wealth quintile and more wanted to avoid having any more children. More LNG-IUS reported full-time or self-employment relative to women using other methods.

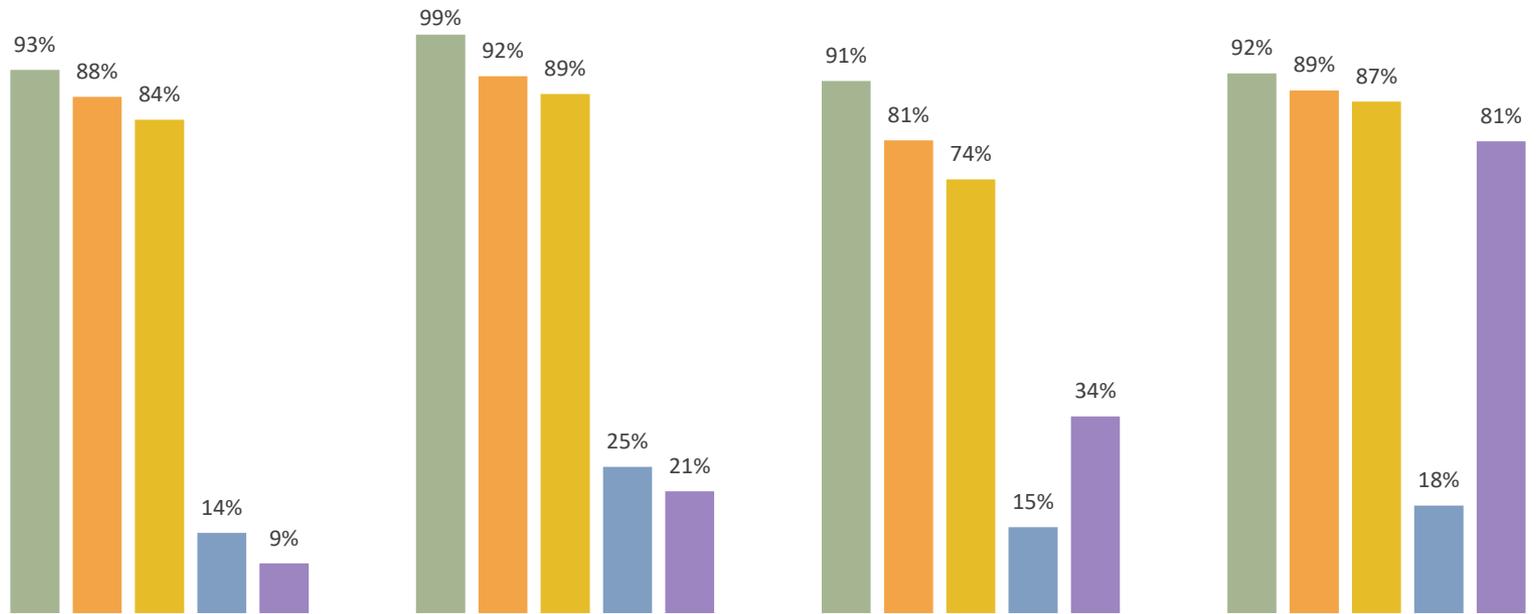


Contraceptive use history



Prior use of contraception

■ Modern method*
 ■ Hormonal method
 ■ LARC
 ■ IUD
 ■ Current method



Baseline method



n=710

* Modern methods include LNG-IUS, copper IUD, implant, injectables, pills, EC and condoms



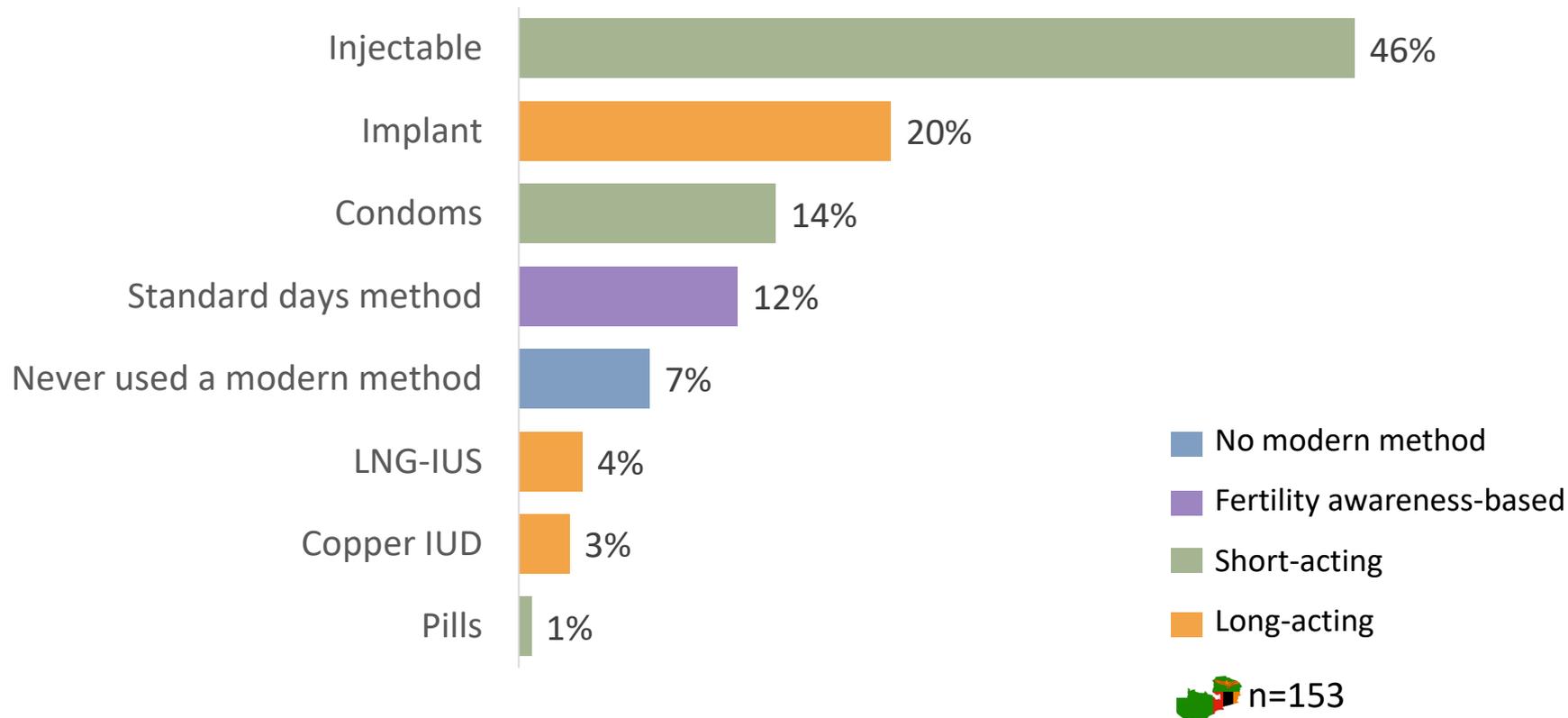
91-99% of LARC acceptors had ever used a modern method and 74-89% had ever used a LARC. Prior IUD use was highest among copper IUD acceptors. 34% of implant users, 21% of copper IUD users and 9% of LNG-IUS users had ever used the same method before compared to 81% of injectable users.



Last method used by LNG-IUS acceptors



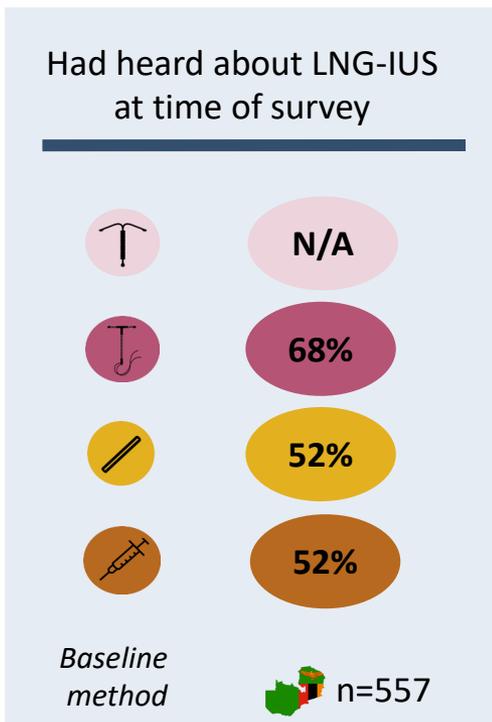
Baseline method



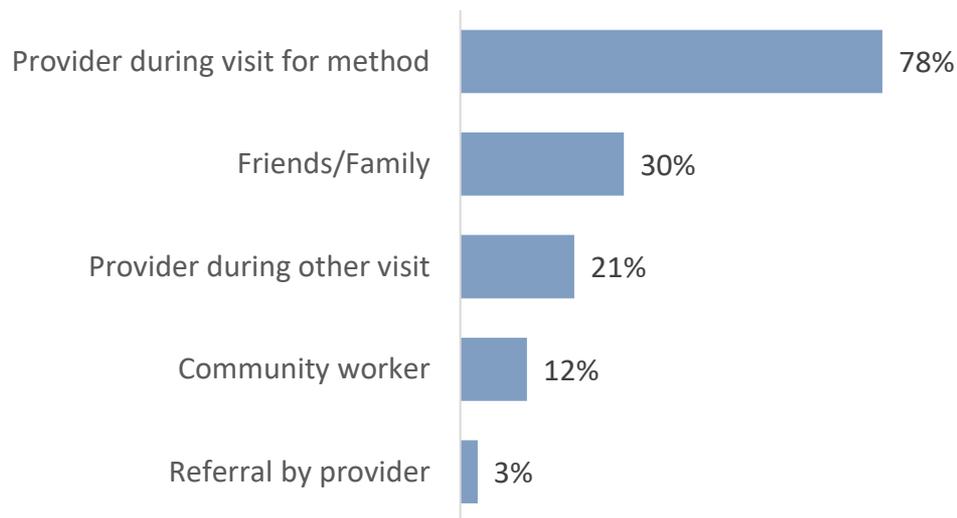
61% of LNG-IUS acceptors were using a short-acting method as their last method prior to the LNG-IUS and 7% of LNG-IUS acceptors were new users. The most common method LNG-IUS acceptors reported last using were injectables and implants. 12% of LNG-IUS reported the SDM as their last method.



Awareness of and demand for the LNG-IUS



Sources of information about the LNG-IUS among women who had heard about the method, including LNG-IUS users*



* Multiple responses possible

n=471



More than half of women who chose other methods had heard of the LNG-IUS. Providers were the main source of information about the LNG-IUS.

Contraceptive decision-making



Baseline method	Knew method they wanted before visit	Chose method on their own*	Partner knows they are using method
	50%	86%	72%
	76%	83%	84%
	83%	80%	80%
	86%	87%	85%

* Primary source of influence among women who reported being influenced by others (n=77)

- Husband/partner (33%)
- Providers (26%)
- Friends/colleagues (25%)
- Other family members (15%)

n=710

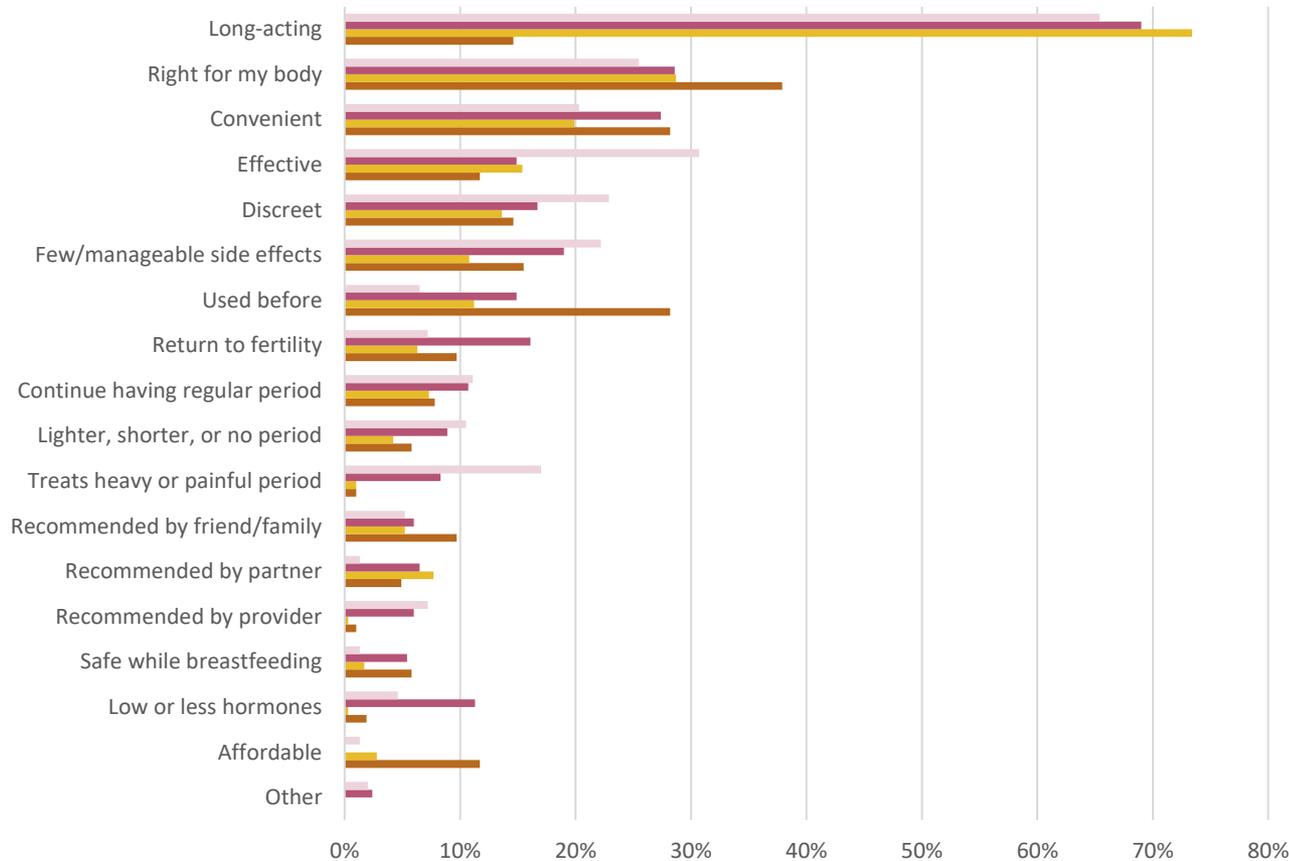


Half of LNG-IUS acceptors already knew the method they wanted before their visit, which is less than for other methods. Most women reported choosing the method on their own. Partner awareness of method use was lower among LNG-IUS users compared to women using other methods.



Reasons for method choice*

Baseline method



n=710

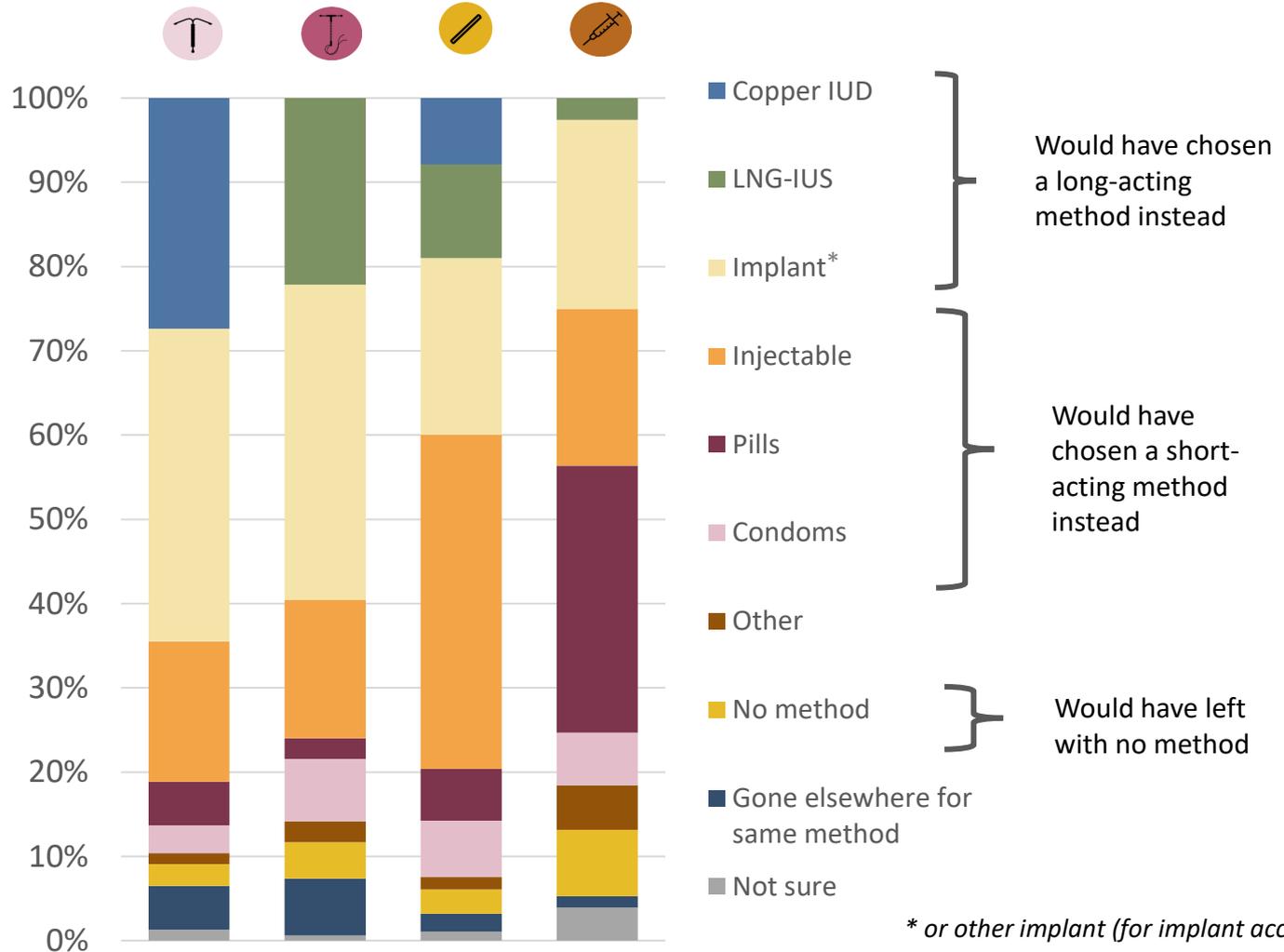
* Multiple responses possible

The most common reason for choosing a method across LARCs was long-acting, followed by right for my body and convenient. Over 20% of LNG-IUS users also mentioned effective, discreet, and few/manageable side effects. A smaller but sizable proportion of LNG-IUS acceptors cited treatment of heavy or painful period.



Method client would have chosen if method received not available

Baseline method



n=710

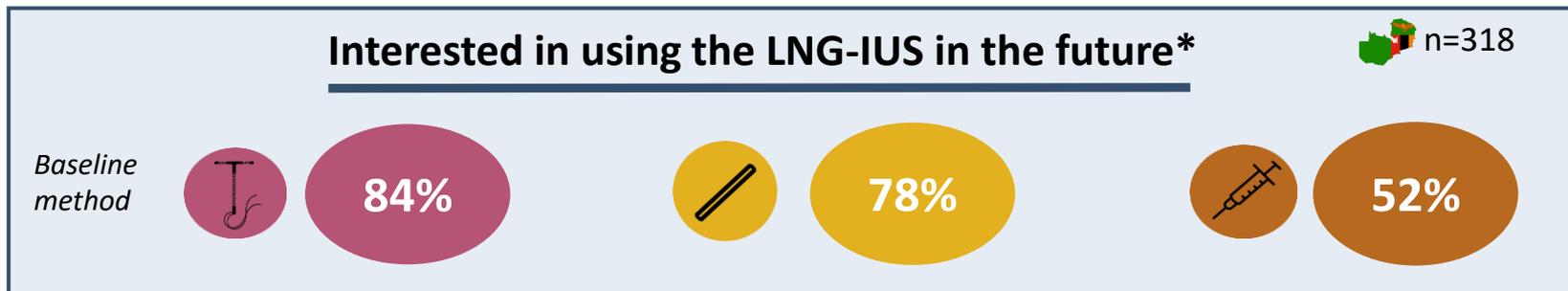
* or other implant (for implant acceptors)



59-65% of copper IUD and LNG-IUS users and 40% of implant users would have chosen another LARC if the method they received had not been available. 22% of copper IUD and 11% of implant users would have opted for the LNG-IUS. Injectable users would have mostly favored short-acting methods.



Interest in LNG-IUS among women who chose other methods



Reasons not interested in using the LNG-IUS in the future among women who were not sure or not interested in using the LNG-IUS (top reasons)**  n=77

-  **56%** Fear of insertion procedure
-  **16%** Afraid will travel in body
-  **15%** Fear partner will feel strings
-  **11%** Fear becoming infertile
-  **9%** Concerned about side effects
-  **9%** Pain/discomfort after insertion

* Among those who had heard about the method

** Multiple responses possible



About ½ of injectable acceptors and over ¾ of copper IUD and implant acceptors said they may be interested in using the LNG-IUS at some point in the future. The main reason for not being interested in using the LNG-IUS in the future was fear of the insertion procedure.



Service delivery experiences



Baseline method	LNG-IUS 	Copper IUD 	Implant 	Injectable 
Told about other methods	93%	96%	93%	92%
Told about bleeding changes and/or side effects	95%	90%	88%	83%
Correctly reported duration of protection*	95%	94%	92%	98%
Told can remove at any time	97%	98%	91%	NA
Felt privacy sufficient	99%	99%	98%	86%
Had problem when received method	20%	17%	15%	9%
Median price paid for method	0	0	0	0

n=710

*n=705; 5 implant clients did not know the type of implant they had and were excluded from this calculation



Many but not all women recalled being counseled on other methods, bleeding changes and/or side effects, and, for LARCs, on when to get a removal. 15-20% of LARC acceptors reported problems with method insertion.

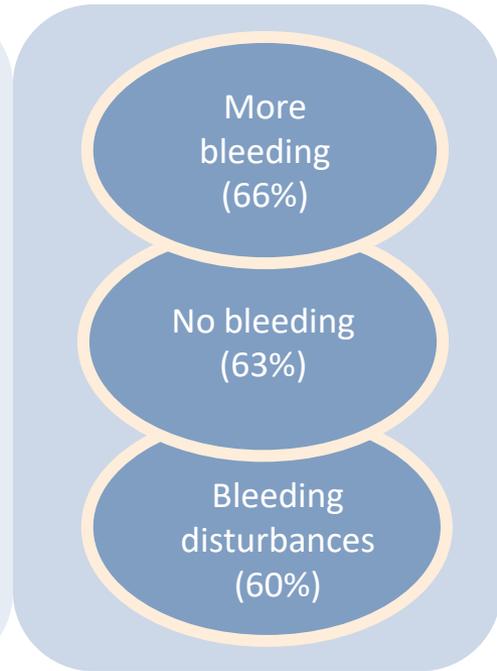
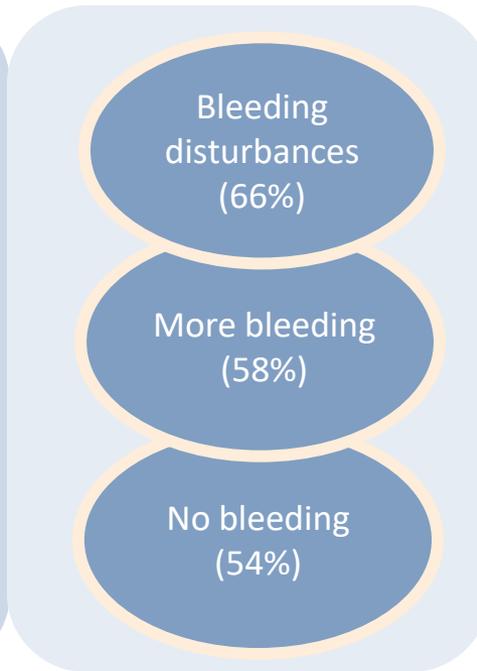
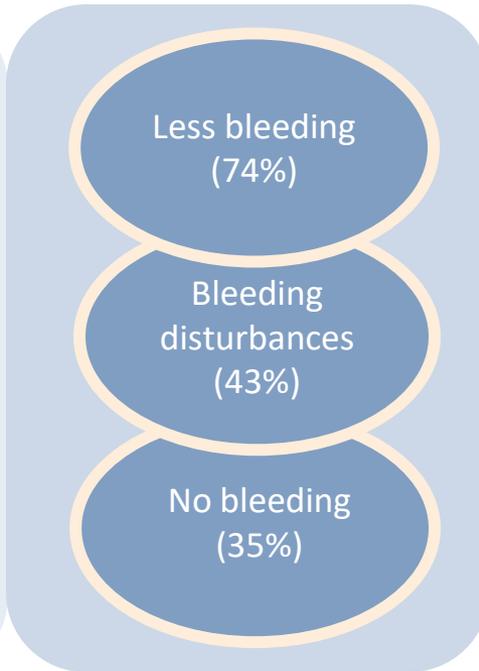
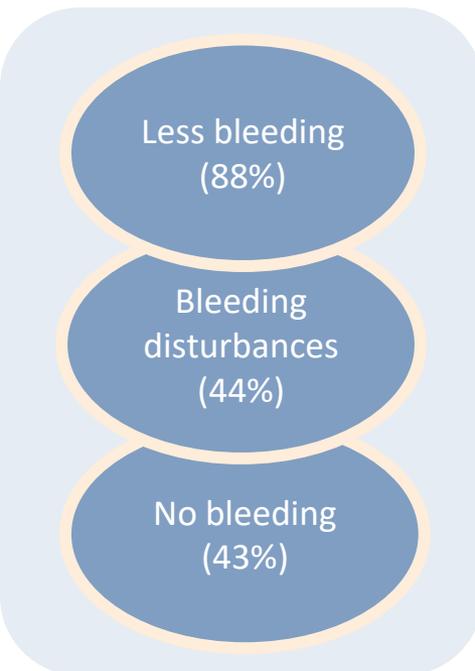


Counseling on bleeding changes and side effects for method received (top 3)



Among women counseled*

Baseline method



 n=636

* Multiple responses possible



The most commonly reported counseling messages were around bleeding changes. Many LNG-IUS users reported being told about the potential for reduced bleeding but fewer recalled being told about amenorrhea. Based on women’s reports, there may be some gaps in the amount and quality of counseling on both bleeding changes and side effects.



In-depth interviews



Facilitators to LNG-IUS uptake emerging from IDIs with women



Like other LARCs, **the LNG-IUS offers:**

- Freedom for economic pursuits and better care for children
- Convenience of fewer clinic visits and reduced user involvement



Reduced bleeding and treatment of menorrhagia are attractive, especially for prior copper IUD users, because of reduced use of pads and lifestyle benefits



Women want methods with **minimal or tolerable side effects**



Method presentation by provider is influential



Facilitators to LNG-IUS uptake emerging from IDIs with women



Right now I am happy, my period has completely stopped...I am not buying pads anymore, so I am happy, I am resting, it is a breather [participant smiles]

- LNG-IUS user



[LNG-IUS] has a longer duration period so I can have time to work other than having children all the time

- LNG-IUS user



I initially was using the pill. Now the pill was not compatible with my body, I used to have stomach aches. So that is how I decided to try out this new method.

- LNG-IUS user



Barriers to LNG-IUS uptake emerging from IDIs with women



Some women have **concerns about intrauterine placement**, although **among those, some choose the LNG-IUS anyway**



Acceptability of amenorrhea is mixed due to a perception that periods are important to cleanse the body



The **relative “newness”** of the LNG-IUS constrains the ability to get information on the method from other women



Barriers to LNG-IUS uptake emerging from IDIs with women



...every woman needs to menstruate and be cleaned... sometimes it can cause stomach problems if she is not menstruating, that's why sometimes you find that women get stomach complications
- LNG-IUS user



I was scared...because it's new. Since it's new we thought maybe it can bring problems but we asked a lot of questions
-LNG-IUS user



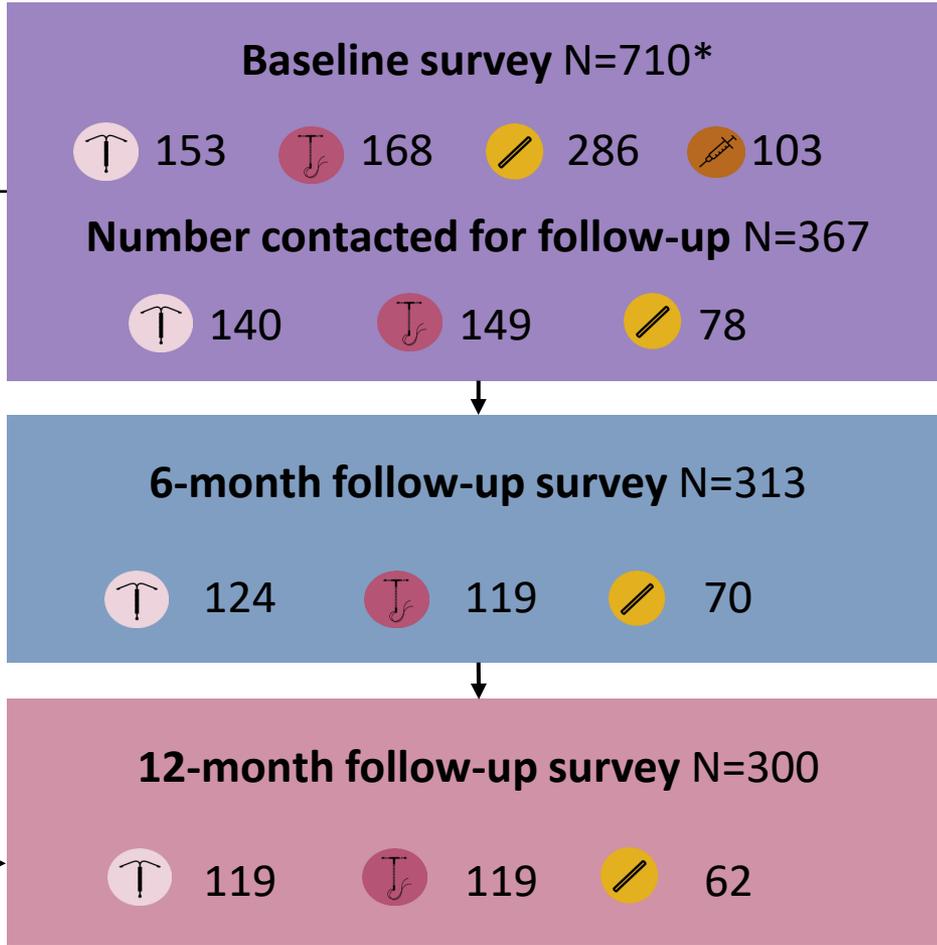
[The provider said] that this might be uncomfortable or scary for you since this is your first time getting an insertion in the uterus and I did get scared actually during the procedure... Having something inserted in your uterus it's not easy, thoughts come like what of if something went wrong while inserting, or what if it moves but later all my fears went because am used to it now
-LNG-IUS user



Continuation results



Longitudinal design



* Of the initial sample of 710 women, injectable users were not contacted further due to study design. 13 LNG-IUS, 19 Copper IUD, and 208 Implant users were not contacted further due to oversampling

26 clients lost-to-follow-up (LTF) after baseline

18 clients reported removing method at 6mo and were not recontacted at 12mo

23 women who completed the interview at 6mo were then LTF

Women not reached at 6mo were recontacted at 12mo

28 clients completed endline and not midline



Direct comparisons between 6 month and 12 month outcomes (such as concluding that a certain factor increased or decreased over time) **should be avoided** because of the differences in the two samples.



Continuation rates

6 month continuation rates n= 323

Estimate (95% CI)



LNG-IUS



Copper IUD



Implant

96.3% (91.3%-98.4%)

94.0% (88.4%-97.0%)

90.4% (80.9%-95.3%)

12 month continuation rates n=285

Estimate (95% CI)



LNG-IUS



Copper IUD



Implant

94.7% (89.2%-97.4%)

89.1% (82.3%-93.4%)

83.1% (72.2%-90.1%)



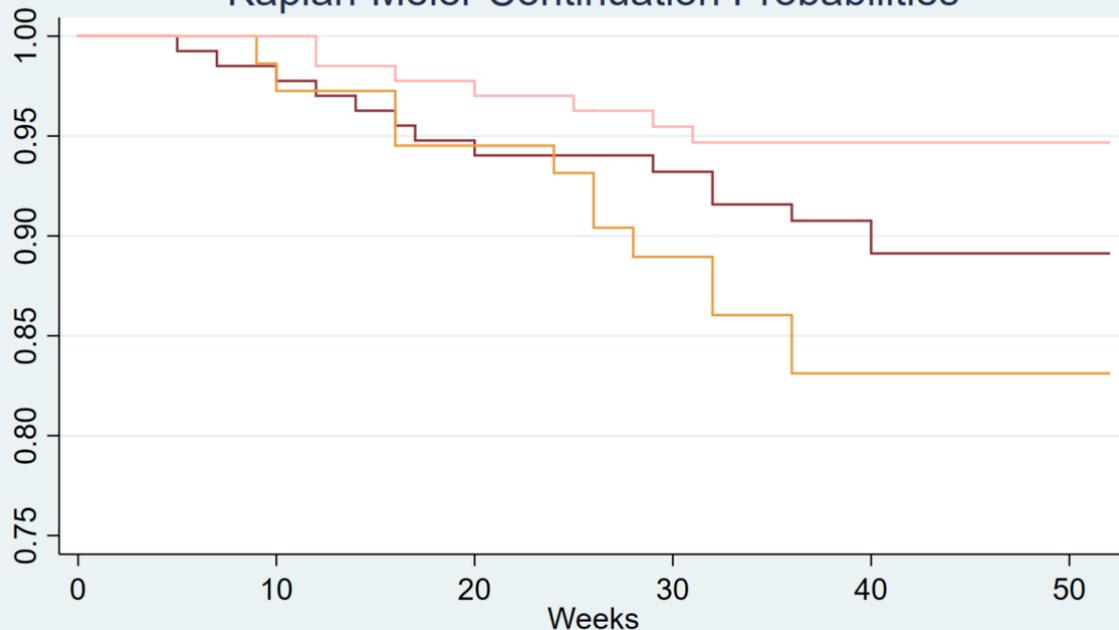
Over the course of the study 7 LNG-IUS, 14 Copper IUD, and 12 implant users reported that they stopped using their methods. Continuation rates for the LNG-IUS were 96% at six months and 95% at 12 months.



Continuation rate curves



Kaplan-Meier Continuation Probabilities



Number at risk

Method	Baseline	6 months	12 months
Copper IUD	134	126	109
LNG-IUS	134	129	119
Implant	73	68	57

Log-rank test for equality*

method	events observed	events expected
Copper IUD	14	12.82
LNG-IUS	7	13.27
Implant	12	6.91

chi2 = 6.85
p-value 0.0326

Pairwise log-rank tests*

Method vs. method	chi2	P-value
Copper IUD vs. Implant	1.43	0.23
Copper IUD vs. LNG-IUS	2.58	0.11
Implant vs. LNG-IUS	7.04	0.008



*These tests have **low power** (large type II error) because sample sizes were calculated to estimate method-specific continuation rates rather than comparisons.



The survival curves for implant and LNG-IUS users were statistically different, with continuation higher among LNG-IUS users compared to implant users.



Satisfaction with methods

At 6 months n=313

At 12 months n=300

Baseline method



Satisfied with method

87%	94%	87%
-----	-----	-----

96%	92%	85%
-----	-----	-----



Happy with bleeding pattern

85%	92%	77%
-----	-----	-----

88%	88%	76%
-----	-----	-----



Recommended method to someone else

89%	81%	81%
-----	-----	-----

83%	81%	91%
-----	-----	-----



Advised someone else not to use method

2%	4%	2%
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1%	2%	0%
----	----	----



Satisfaction with the method and with the bleeding pattern are higher overall for the LNG-IUS compared to implants. Differences between results for the copper IUD and the LNG-IUS are less clear.

Self-reported positive aspects of method use

6 months n=313 12 months n=300

Baseline
method



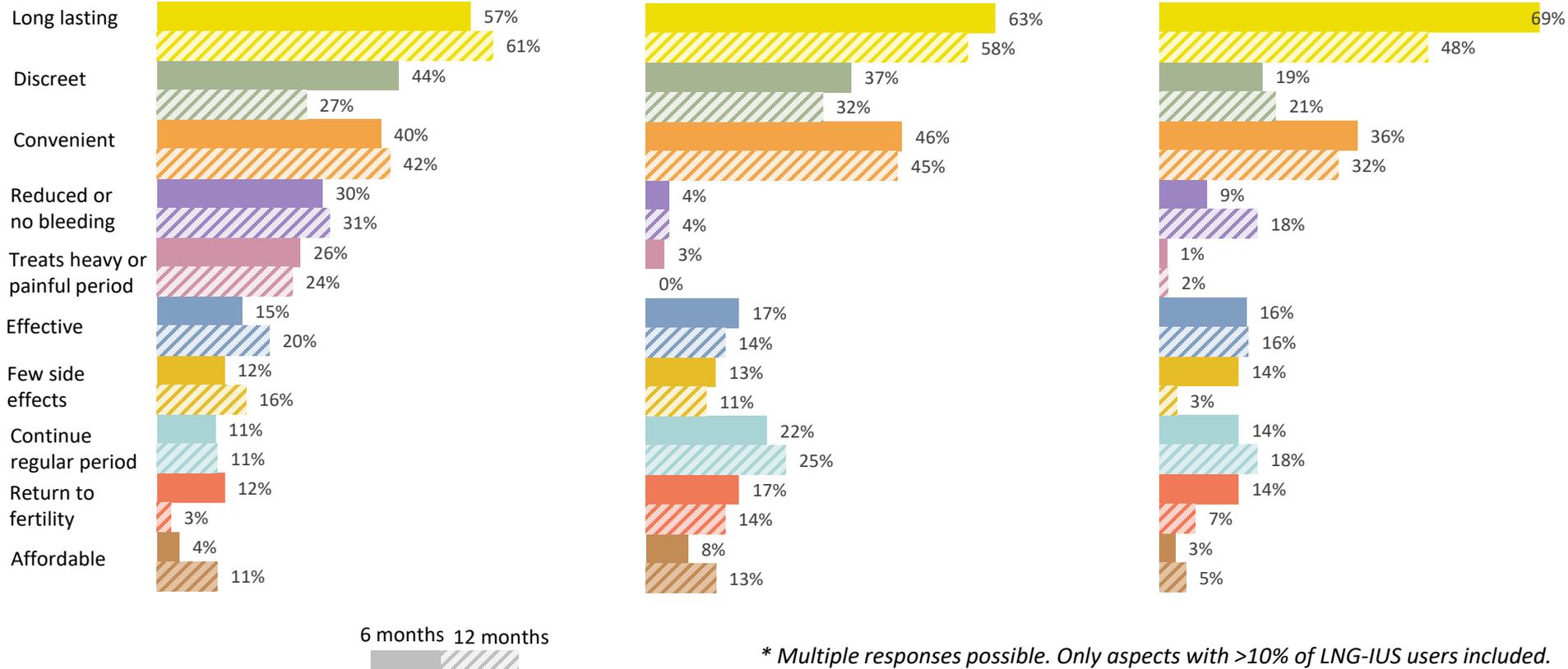
■ n=124
▨ n=119



■ n=119
▨ n=119



■ n=70
▨ n=62



* Multiple responses possible. Only aspects with >10% of LNG-IUS users included.

Perceived positive aspects of the LNG-IUS were similar to other methods and similar in the 6 and 12 month samples. They included duration of protection, convenience, and discreet use. A sizable proportion of LNG-IUS also reported reduced bleeding as a benefit.

Self-reported negative aspects of method use

6 months n=313 12 months n=300

Baseline method



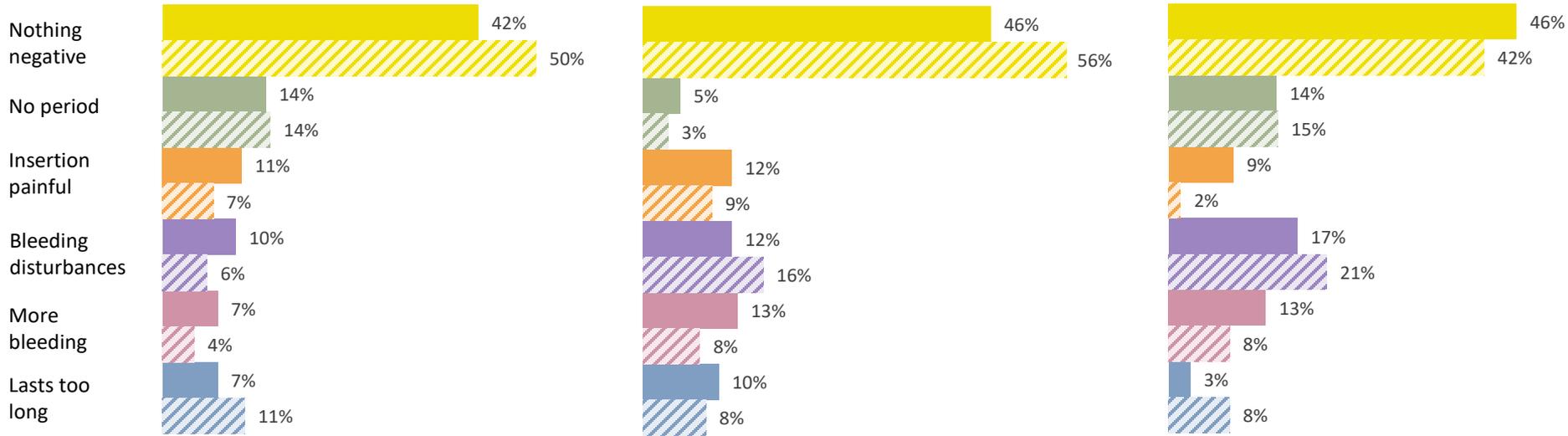
■ n=124
▨ n=119



■ n=119
▨ n=119



■ n=70
▨ n=62



6 months 12 months

* Multiple responses possible. Only aspects with >10% of responses included.



Many women reported experiencing nothing negative about their method. The most commonly reported negative aspect associated with the LNG-IUS was amenorrhea, whereas for copper IUD and implant users, it was bleeding disturbances.

Most commonly reported side effects (other than bleeding changes)*

6 months n=313 12 months n=293

Baseline method



n=124
n=117

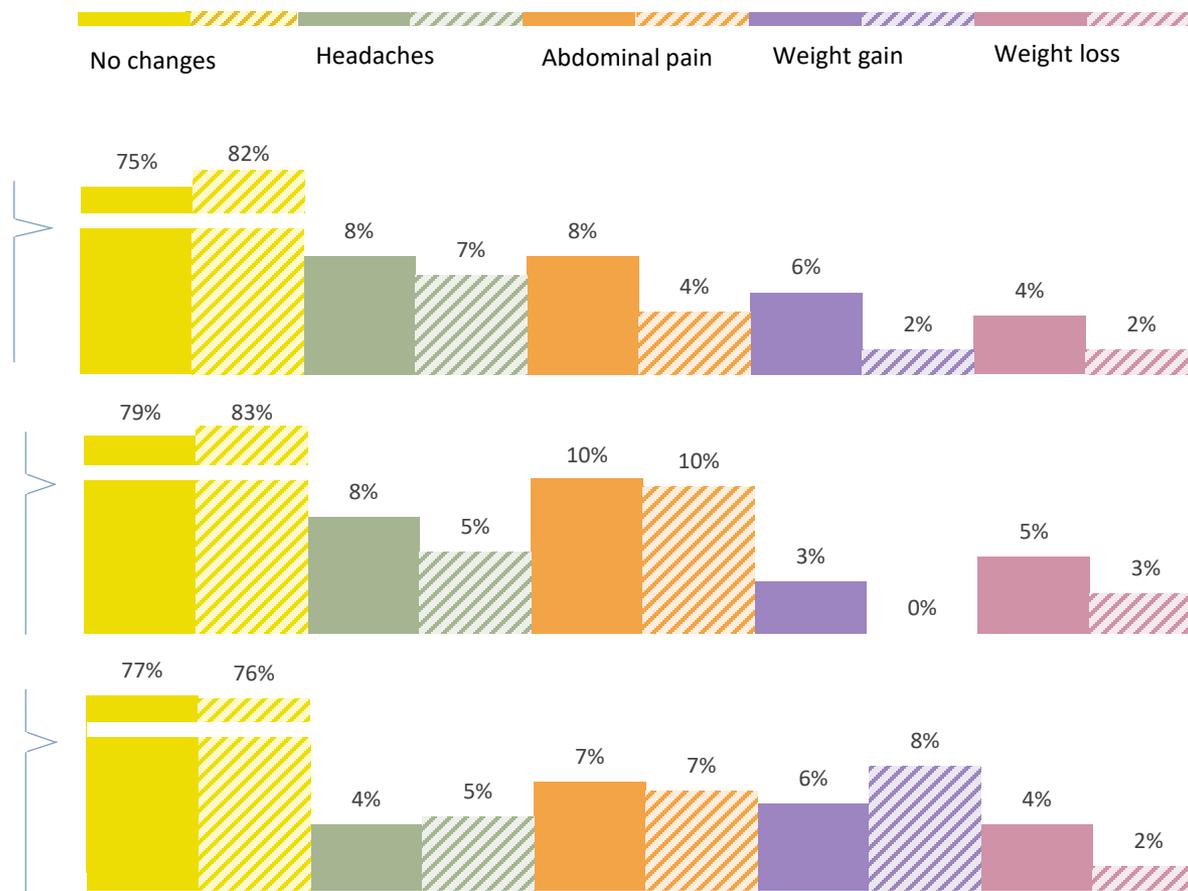


n=119
n=114



n=70
n=62

6 months 12 months



* Multiple responses possible



Across methods and time points, the majority of women reported not having experienced side effects. Each type of side effect was reported by 10% or less of women.

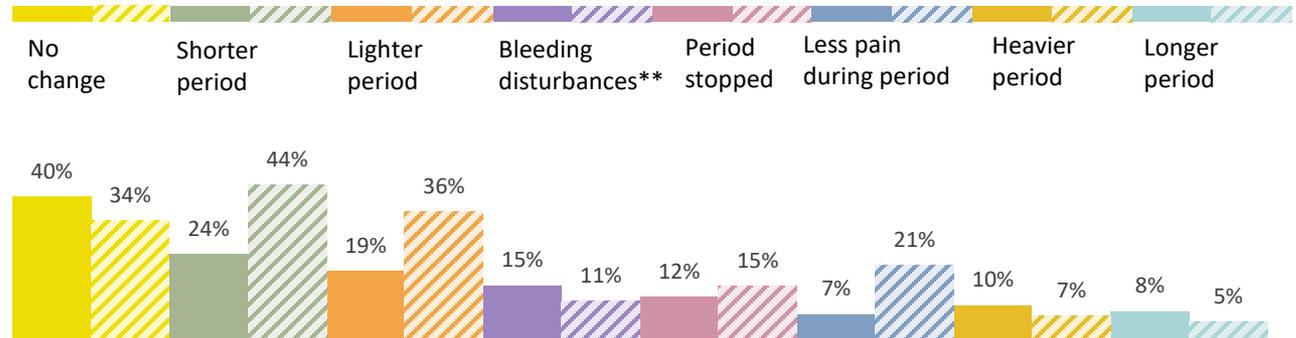
Most commonly reported bleeding changes*

6 months n=313 12 months n=298

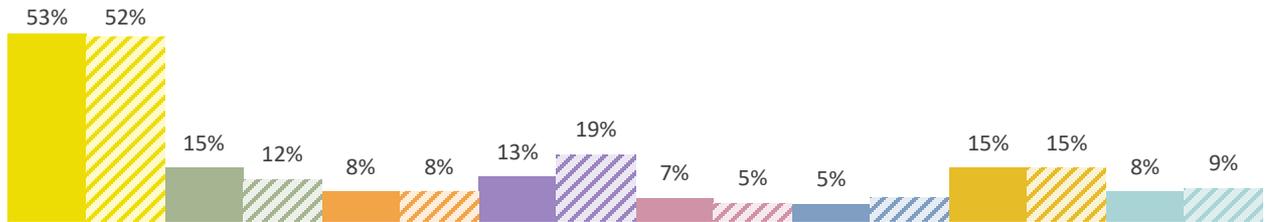
Baseline method



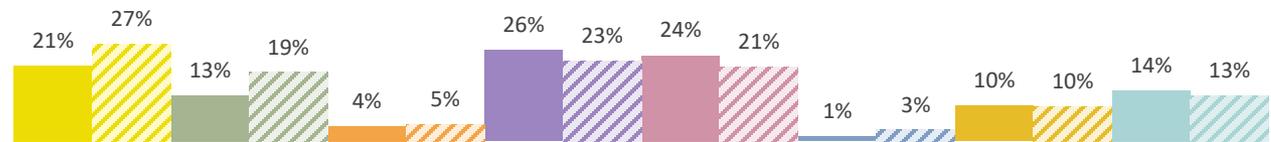
n=124
n=119



n=119
n=117



n=70
n=62



6 months 12 months

* Multiple responses possible ** Irregular period, spotting



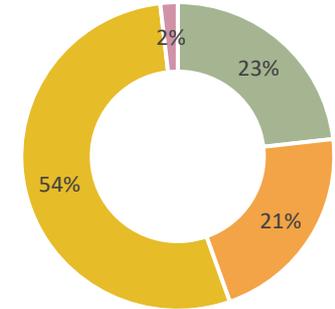
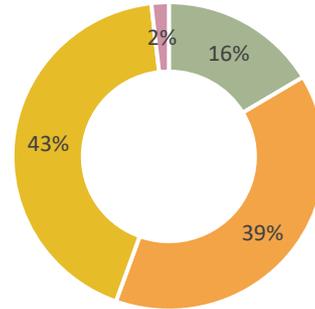
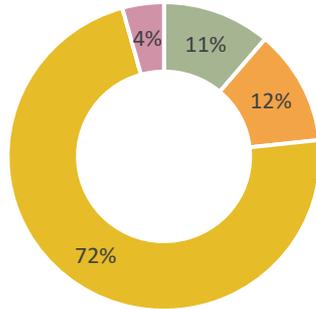
The most commonly reported bleeding changes with the LNG-IUS were shorter and/or lighter period and many women also reported no changes to their period. More implant users reported amenorrhea and bleeding disturbances compared to LNG-IUS and copper IUD users.

Menstrual hygiene management

Menstrual product use at time of survey compared to before starting their method

More products
 Same amount
 Fewer products
 Different products

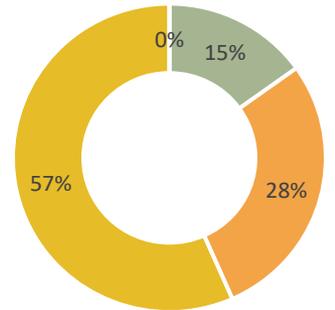
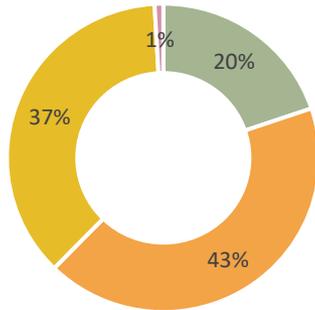
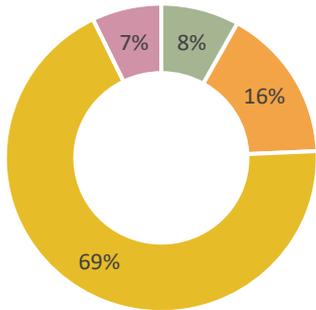
6 months



Baseline method



12 months



6 months n=272 12 months n=270; Only asked to continuers. 13 clients at ML and 15 clients and EL refused to answer this question.



About 60% of women reported primarily using disposable pads to manage their period across methods and time points. More LNG-IUS users reported a reduction in the amount of menstrual products used compared to before they received their method relative to users of other LARCs.

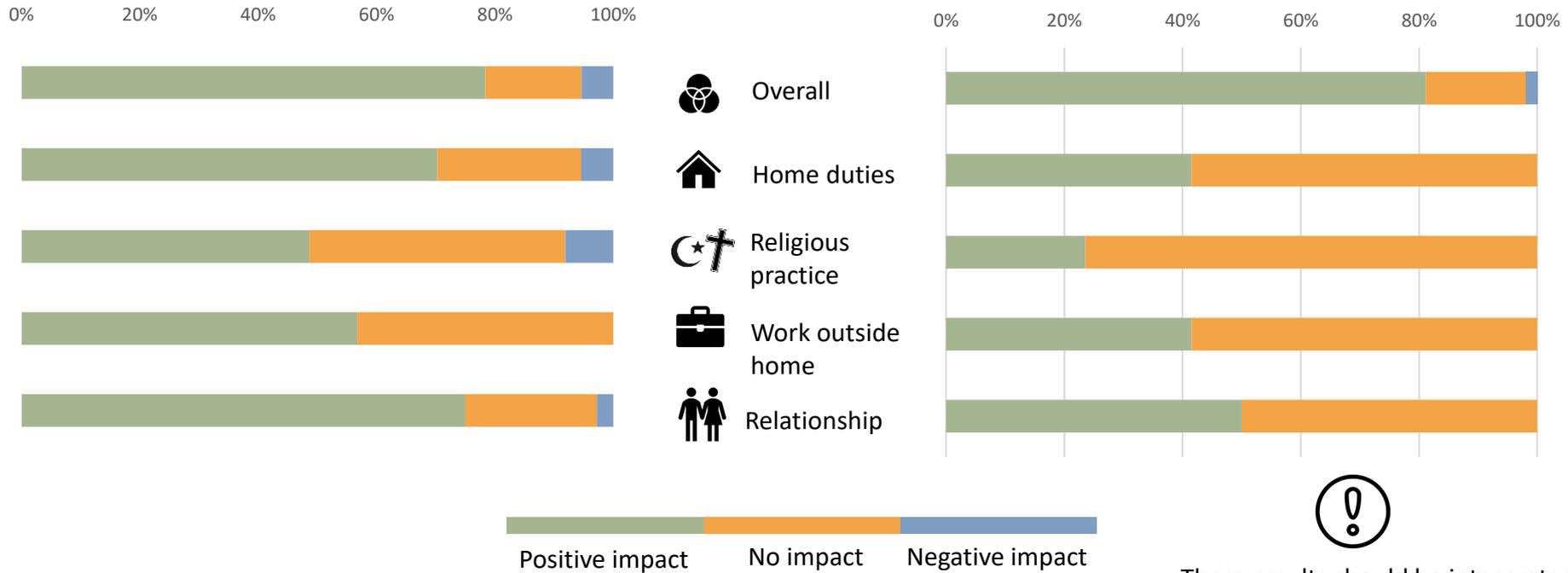
Perspectives on impact of reduced bleeding on aspects of women's lives

(among LNG-IUS users who experienced a lighter period, shorter period and/or no period)

6 months
n=37



12 months
n=53



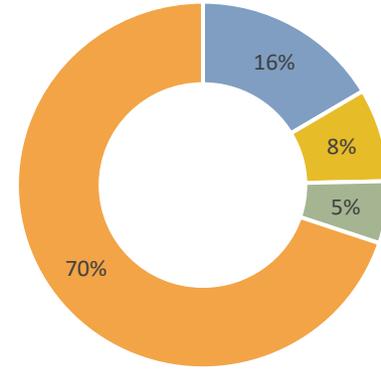
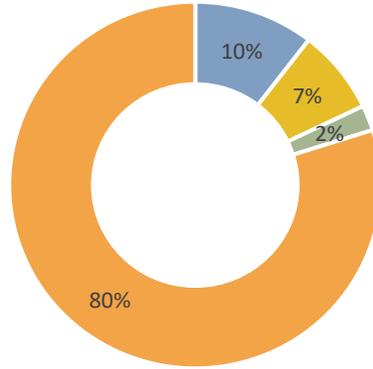
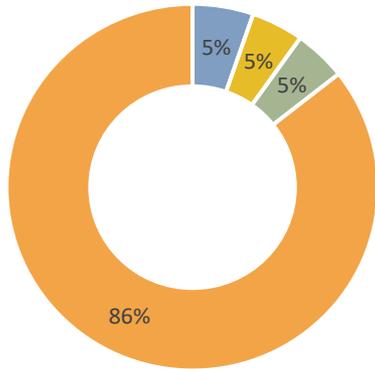
78-81% of LNG-IUS users who said they had experienced reduced bleeding reported that reduced bleeding had had a positive impact on their lives overall. When asked about specific aspects of their lives, the proportion of women reporting a positive impact was highest for relationship with partner.



Removal intention outcomes



Baseline method



N=339

- Never wanted removal
- Wanted removal but never tried
- Wanted removal, tried, still have method
- Removed

Main reasons never tried to get removal among those wanting removal (n=13)

LNG-IUS: changed their mind (n=4/6)

Copper IUD: changed their mind (n=3/4)

Implant: changed their mind (n=3/4)

Main reasons kept method among those wanting removal (n=22)

LNG-IUS: provider counselled to keep (n=4/6)

Copper IUD: provider counselled to keep (n=5/10)

Implant: provider counselled to keep (n=3/6)

Main reasons removed method (n=33)

LNG-IUS: bleeding disturbances (n=3/7)

Copper IUD: more bleeding (n=5/14)

Implant: more bleeding (n=6/12), bleeding disturbances (n=3/12)



Across methods, 70-86% of women never considered a removal and 2-5% thought about removing their method but never went to a provider to ask to get it removed. 5-16% got their method removed but 5-8% of women consulted a provider about a removal and kept their method.

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