Published in final edited form as:

Contraception. 2018 July ; 98(1): 63–68. doi:10.1016/j.contraception.2018.03.029.

Changes in uptake and cost of long-acting reversible contraceptive devices following the introduction of a new low-cost levonorgestrel IUD in Utah's Title X clinics: a retrospective review

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Abstract

Objective: The objective was to assess changes in long-acting reversible contraceptive (LARC) method uptake at Utah's Title X clinics before and after introduction of a new, low-cost levonorgestrel (LNG) 52 mg IUD (Liletta®). Study design: We conducted a retrospective medical record review of LARC visits occurring at seven Title-X family planning clinics in Utah before the introduction of the low-cost LNG IUD (preintroduction period: 01/01/2014–04/30/2015) and after (postintroduction period: 05/01/2015–03/31/2016). We ran segmented, interrupted time series ordinary least squares regression models using Newey–West standard errors to assess both the change in numbers of women initiating any LARC method and the average payment amount per LARC method. We evaluated both the low-cost LNG IUD and all LARC methods.

Results: At the outset of preintroduction period, there were 29.2 [95% confidence interval (CI): 20.1–38.4] monthly LNG IUD insertions. Immediately postintroduction, there was a significant level of increase of 14.4 LNG IUD insertions the first month (95% CI: 2.0–26.8) followed by a significant trend increase each month of 2.4 additional LNG IUD insertions (95% CI: 0.32–4.47). Postintroduction, there was a significant level of remitted-payment decrease from all sources of –\$240.43 per LNG IUD (95% CI: –311.02 to 168.87) followed by a significant monthly trend decrease of –\$23.01 per LNG IUD (95% CI: –32.02 to –13.98). There were minimal changes in uptake and payment of other LARC methods following the introduction of the low-cost LNG IUD.

Conclusions: Following introduction of a low-cost LNG IUD at Title X clinics, LNG IUD initiation increased and average payment for the method decreased.

Implications: Reducing the cost of LARC methods, both to clinics and to patients, is essential to expanding access. Additional efforts to develop and provide access to low-cost copper IUDs and subdermal implants as well as novel LARC methods should be continued.

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Conflict of interest:

The Department of Obstetrics and Gynecology, University of Utah, receives contraceptive clinical trials research funding from Bayer, Bioceptive, Contracept, Medicines 360, Merck and Teva.

Keywords

Contraception; Cost; IUD; Intrauterine device; Liletta®; LNG IUD

1. Introduction

The use of intrauterine devices (IUDs) and subdermal implants continues to rise in the United States (US). The proportion of women using these methods increased from 3% to 12% between 2002 and 2012 [1]. Many women who are now choosing highly effective, long-acting reversible contraceptives (LARCs) previously relied on shorter-acting methods [2]. This shift in method mix corresponds to a decline in unintended pregnancies documented from 2008 to 2011 [3]. Additionally, there is increasing positive regard for LARC among both users and providers due to high rates of patient satisfaction and updated recommendations, such as removing barriers based on age and nulliparity [2,4–8].

Even with these noted changes in user and provider preferences, considerable barriers to accessing LARC remain. Obstacles to obtaining LARC include user awareness [9], medical provider knowledge and skill [10], and financial burdens [2]. Individuals with limited financial resources are particularly sensitive to out-of-pocket costs. Previous research demonstrated significant decreases in LARC uptake with each US \$100 incremental increase in out-of-pocket costs. Among women interested in a LARC method, 87% selected and received a LARC device when out-of-pocket expenditure were below \$200, compared to only 28% when costs exceeded \$200 [2]. In addition, several large community initiatives have shown increased LARC uptake following the complete removal of out-of-pocket costs [11–14].

Additionally, cost barriers can also affect clinic and provider recommendations. In a survey of more than 400 federally qualified health centers, the most commonly cited barrier to offering LARC methods included the initial stocking costs of the devices, as well as insufficient staffing and training to provide them [15]. Under the US Department of Health and Human Services 340B drug-pricing program, safety net providers and other eligible entities are able to purchase outpatient medications at significantly reduced price [16]. The 340b program mandates that 340B pricing be at least 23% lower for a name-brand product, but that can still be in excess of \$300 with baseline pricing between \$500 and \$2000 [17].

Title X providers are eligible for 340B pricing, and Planned Parenthood Association of Utah (PPAU) is the only Title X grantee for the State of Utah. Utah is one of only seven states that did not expand Medicaid through the Affordable Care Act and does not have a Medicaid family planning waiver. As such, there is a substantial health insurance coverage gap, with more than 200,000 Utah women estimated to be in need of publicly supported family planning services [18]. Utah's Title X clinics are a primary source of contraceptive support for low-income women.

In 2012, two-thirds of LARC users nationwide selected a levonorgestrel (LNG) IUD, making it the most commonly used LARC method in the US [1]. Prior to 2015, the Mirena® (52 mg LNG IUD) and Skyla® (13.5 mg LNG IUD) (both distributed by Bayer Women's

Healthcare, Whippany, NJ, USA) were the only available hormonal IUDs in the US. The Liletta®, a 52-mg LNG IUD (distributed by Allergan/Medicines360), was approved in February 2015 by the FDA and became the third hormonal IUD option in the US [19]. Under the 340b pricing scheme, the total cost of the Liletta device is \$50 [17].

PPAU clinics began exclusively offering the new low-cost IUD for clients seeking LNG IUD beginning May 2015. Additionally, while PPAU purchases these devices at reduced cost, they also offer further cost subsidies to low-income and uninsured women by using a sliding scale to determine maximum payment amount at the time of service based on reported income. The sliding scale fee structure can be applied to the device cost, as well as the clinical fees related to insertion. We hypothesized that the clinics' initial cost-savings for LNG IUDs would increase LNG IUD uptake. In addition, we considered that these reduced costs could increase the ability to purchase all LARC methods, thereby increasing uptake of all LARC devices. This study assesses the impact of the low-cost LNG IUD on LARC uptake at Title X clinics in Utah.

2. Materials and methods

2.1. Study design and population

We conducted a retrospective review of electronic health records (EHR) from seven Title X PPAU clinics in Utah. Eligible records for review included any new or established female patient between the ages 12 and 45 who presented to the clinic during the study period for a new method of contraception. We excluded patient records where the visit was to purchase over-the-counter contraceptive methods (condoms or emergency contraception pills), if the EHR noted reliance on vasectomy/female sterilization for pregnancy prevention or if the contraceptive visit included research project participation providing free contraception.

As the introduction of the low-cost LNG IUD to the participating clinics occurred in May 2015, we divided our study into a preintroduction period (January 1, 2014–April 30, 2015) and a postintroduction period (May 1, 2015–March 30, 2016). We selected the latter date as the cutoff due to the beginning the HER Salt Lake Contraceptive Initiative, a community-wide public health intervention the following month, occurring in the same Title X clinics assessed here [20]. We included both new and established patient data for the method selected at the first visit during the study period, while we excluded subsequent visits from analysis. Data extracted from the EHR included demographic information, method selection and insurance/payment information.

2.2. Statistical analyses

We conducted interrupted time series ordinary least squares analyses (ITSA) to (1) compare trends in LNG-IUD and non-LNG LARC methods and (2) assess changes in average payment per visit after the introduction of the low-cost LNG-IUD. The ITSA design is a robust method of assessing population change over time in quasi-experimental design that is increasingly used and recommended to assess public health interventions [21–24]. ITSA has been widely used in drug utilization research, particularly to assess drug policy changes [23].

For our analyses, we defined the primary outcomes as change in contraceptive method uptake; specifically, as is common with ITSA, we assessed changes in level (immediately postintroduction) and slope (trend over time) of both LNG IUD insertions and other non-LNG LARC insertions after the introduction of the low-cost LNG IUD. We also looked at level and slope changes in the average payment per visit in the subset of patients whose medical records indicate that payment was remitted for the contraceptive visit; information from the payment record did not specify whether the amount paid came from the patient, insurer or a combination of both.

To assess both level and slope change of the different outcome variables, we conducted single-group interrupted time series ordinary least squares regression analyses, accounting for autocorrelation for each variable. The interrupted time series regression model equation is as follows:

$$Y_t = \beta_0 + \beta_1 T_t + \beta_2 X_t + \beta_3 X_t + T_t + \epsilon_t$$

where β_0 represented the initial number of a device selected or average payment made, β_1 estimated the average monthly change in the number over the preintroduction period, T_t represented the time since the beginning of the study period, β_2 represented the change in the level of the outcome that occurred in the period immediately following the introduction of the low-cost LNG IUD, X_t was an indicator variable representing the pre/postintroduction period, β_3 represented the difference between pre/postintroduction trends for each outcome and ϵ_t was the term accounting for random error and autocorrelation. After examining Cumby–Huizinga general tests for time series autocorrelation, we accommodated up to five lags within our models [25]. We determined statistically significant differences at pb.05. All analyses were conducted using STATA 14.0 statistical software (College Station, TX, USA). The University of Utah Institutional Review Board approved this study.

3. Results

There were 125,965 patient visits in the preintroduction period and 84,333 in the postintroduction period. After removing ineligible visits, there were 23,196 initial contraceptive visits preintroduction (16 months) and 9604 initial contraceptive visits postintroduction (11 months) (Fig. 1). Table 1 presents the demographic profiles and contraceptive device distribution of the patients involved in this study and differences between periods. Demographics were generally stable between the two groups, though there was an increase in the proportion of the population who were ≥ 18 years old in the postintroduction period. Overall, LARC insertion visits increased as a proportion of the method mix, from 1407/23,196 (6.1%) to 1803/9604 (18.8%) in the pre- and postperiods. Of patients who selected a LARC device, 43% ($n=607$) selected an LNG IUD in the preintroduction period and 48% ($n=859$) selected an LNG IUD in the postintroduction period. The proportion of patients selecting an LNG IUD device who paid nothing out of pocket increased from 51.5% ($n=313$) in the preintroduction period to 59.9% ($n=515$) in the postintroduction period.

Table 2 provides overall trend output for all indicators. Fig. 2 graphically represents primary outcome trends. At the outset of the study, there were 29.2 [95% confidence interval (CI): 20.1–38.4] monthly LNG IUD insertions. During the preintroduction period, there was a nonsignificant, increasing trend of 1.02 insertions per month (95% CI: 0.001–2.0). Immediately following the introduction of the low-cost LNG IUD, at the onset of the postintroduction period, the number of monthly LNG IUD insertions increased significantly by 14.4 LNG IUD insertions per month (95% CI: 2.0–26.8). This was followed by a significant trend increase during the postintroduction period where, each month, 2.4 additional LNG IUD insertions (95% CI: 0.3–4.5) occurred. Similarly, at the outset of the study, there were 42.9 non-LNG LARC insertions (95% CI: 37.0–48.7). During the preintroduction period, there was a nonsignificant increasing trend of 0.84 additional LARCs per month (95% CI: 0.2–1.5). Immediately following the introduction of the low-cost LNG IUD, there was a nonsignificant decrease in the use of other LARC methods (–3.5; 95% CI: –17.1 to 10.1), but a subsequent significant increase of 5.6 non-LNG LARCs per month (95% CI: 2.6–8.6) during the preintroduction period.

For payment data, the average payment of an LNG IUD at the outset of the study period was \$176.97 (95% CI: 146.14–206.14). There was an increasing monthly average payment of \$17.97 (95% CI: 14.60–21.34) during the preintroduction period. Following the introduction of the low-cost LNG IUD, there was an immediate, significant drop of –\$240.43 (95% CI: –311.98 to 168.87), followed by a significant decreasing cost trend per month during the postinsertion period (–\$23.00; 95% CI: –32.02 to –13.98). For other LARC devices, the average payment at the outset of the study period was \$240.50 (95% CI: 186.95–294.06). There was a nonsignificant increasing monthly average payment of \$4.26 (–1.23 to 9.76) during the preintroduction period. After the introduction of the low-cost LNG IUD, there was a nonsignificant increase in payment of other LARC devices (\$7.70; 95% CI: –65.28 to 80.68), followed by a nonsignificant decreasing payment trend of –\$2.07 (95% CI: –10.2 to 6.04) per month during the preintroduction period.

4. Discussion

Following the introduction of the low-cost LNG IUD, we reported both a significant intervention (level) effect and a significant increased trend associated with the use of LNG IUDs at Title X clinics in Utah. Together, the level increase of 14.4 LNG IUD insertions together with the trend increase of 2.4 LNG IUDs per month over the 11 months of the postintroduction period provides a combined increase of 38.4 additional LNG IUD insertions in the final month of the study and approximately 290 total additional LNG-IUD insertions above expected projections had the low-cost device not been introduced. These findings account for the varying length in time periods and number of patients served in the two groups. It is probable that a contributing factor to this surge in LNG IUD uptake is related to the significant cost reduction, which may have affected clinic purchasing and stocking, and subsequent provider recommendation and insertions. Other studies that explored reducing cost barriers to LARC access have also demonstrated increases in LARC uptake [2,11–14]. However, these evaluations explored increasing insurance coverage of family planning services or provision of free contraceptives. Our study differs in that it demonstrates that decreasing the cost of LARC devices through the development of new,

lower-cost methods also impacts uptake, potentially through different mechanisms. Future studies should assess the impact that contraceptive device cost has not only on patient decision making but also on clinic purchasing, stocking, and subsequent counseling and provision of all LARC methods. Additionally, Title X clinics are more likely to offer LARC devices than federally qualified community health centers [15], creating the potential for even greater impact with the introduction of low-cost devices in these clinics.

It is important to note that there was also a significant increasing trend in the use of non-LNG LARC devices in the postintroduction period, although the proportion of Cu IUDs and implants did not increase to the extent of LNG IUDs. Potential future studies might also assess how increases in accessibility of a low-cost LARC method may subsequently affect uptake in other LARC methods as well, through attributes such as cost-shifting, provider awareness and/or counseling, etc. Despite an increase in uptake, the payment amount for other LARC methods stayed relatively high over the study period. For implant users in particular, payments remained high for both periods, and very few women obtained this device in either period. It is possible that developing and offering a low-cost implant would result in increased implant uptake in self-paying women.

Strengths of this study include its timeliness in assessing the impact of the increase in availability of low-cost LNG IUDs. Additionally, a strength of this analysis is that the regional Title X clinic patients allowed for an inclusion and assessment of insured and uninsured patients of a range of socioeconomic statuses, ages and race/ethnicity. The majority of these patients, however, represent underserved populations with limited financial resources. This study is also strengthened by standardized care across clinic locations, as we only included patients from PPAU Title X clinics with uniform staff training and protocol adherence. As such, our findings may be more generalizable to other Title X clinics nationwide.

This study had several limitations. First, we were unable to limit our research population only to new clinic patients. As a result, this increased our sample size and decreased the proportion of LARC users in the study population. Preference for and uptake of LARC during the study may have been influenced by external factors we could not account for including increased awareness of LARC methods in the community and desire for noncontraceptive benefits. Additionally, the payment amount reported here should be interpreted with caution, as we were unable to discern out-of-pocket versus billed amount for those with insurance; EHR review data are not specifically designed for research studies and thus are likely an imperfect indicator of payment. While we did not have sufficient study power to assess the effect of the low-cost LNG IUD in exclusively self-paying clients, we did conduct a sensitivity analysis on this subset of participants and found similar trends to our broader findings, suggesting decreasing out-of-pocket costs to self-paying patients. Future studies that can properly assess cost-effectiveness through the utilization of formal cost variables are an important step in further refining how low-cost methods affect both patients and clinics.

Another limitation is Utah's relatively unique contraceptive coverage gap (i.e., no ACA expansion or Medicaid family planning waiver) which results in very low utilization of

Medicaid in the population; this may limit external validity for populations with greater Medicaid coverage. Finally, though the study assessed uptake and payment, we wish to highlight that these are not the only important components of method uptake and use. Information around other outcomes, which was not possible from the medical records review, such as client satisfaction and discontinuation, is also important for future studies on the low-cost LNG IUD and other new methods.

LARC use is increasing among American women [1], especially with the removal of financial barriers via contraceptive coverage mandates and community initiatives. These data contribute to the hypothesis that by reducing the cost of the devices themselves, women have greater contraceptive access and ability to select a LARC device if desired. The introduction of a low-cost LNG IUD resulted in a surge of LNG IUD uptake. Unfortunately, there is only one low-cost LARC device currently in the US market. This study demonstrates an unmet need for further investment in and development of affordable, long-acting reversible contraception.

Acknowledgments

We would like to thank Penny Davies and Lesly Bailey at PPAU for assistance with project development and execution, as well as Corinne Davies for assistance with data acquisition and cleaning.

Initial findings were presented at the Society of Family Planning's annual North American Forum on Family Planning held in Denver, CO, November 2016.

The findings and conclusions in this article are those of the authors and do not necessarily represent the views of Planned Parenthood Federation of America, Inc.

Funding:

This research did not receive any specific grant from funding agencies in the public, commercial or not-for-profit sectors.

J.N.S. and D.K.T. receive support from the Eunice Kennedy Shriver National Institute of Child Health & Human Development and the Office of Research on Women's Health of the National Institute of Health under Awarded Number K12HD085852 and D.K.T. under K24HD087436.

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Fig. 1.

Analytic cohort flowchart of study participants in the Liletta surge study in Utah's Title X Clinics, January 2014–March 2016. *Reasons for exclusion included: emergency contraception or condom visit, reliance on vasectomy/female sterilization, participation in research project offering free LARC device, non-Title X clinic location.

Fig. 2. Outcome variables before and after the uptake of a low-cost LNG-IUD in Utah's Title X Clinics, January 2014–March 2016. LARC: long-acting reversible contraception; LNG IUD: levonorgestrel intrauterine device

Table 1

Demographic table of initial contraceptive visit patients in Utah's Title X clinics, before and after low-cost LNG-IUD availability

Variable	Preintroduction ^a (n=23,196)	Postintroduction ^a (n=9604)
Age category		
<18	1218 (8.6%)	1690 (17.6%)
18–24	6932 (49.2%)	4574 (47.7%)
25–29	2845 (20.2%)	1688 (17.6%)
30–34	1628 (11.6%)	862 (9.0%)
35–39	851 (6.0%)	493 (5.1%)
40–44	403 (2.9%)	192 (2.0%)
45+	221 (1.6%)	99 (1.0%)
Ethnicity		
Hispanic	5504 (23.7%)	2344 (24.4%)
Non-Hispanic	17,692 (76.3%)	7260 (75.6%)
Payer category		
Self-pay/none	10,788 (76.5%)	6949 (72.4%)
Public	816 (5.8%)	672 (7.0%)
Commercial	2494 (17.7%)	1977 (20.6%)
Cost of visit		
<\$50	22,039 (95.0%)	8602 (89.6%)
>\$50	1157 (5%)	1002 (10.4%)
Poverty Level		
<100% FPL	13,341 (57.5%)	9280 (96.6%)
>100% FPL	9855 (42.5%)	324 (3.4%)
Method type		
Short-acting	21,789 (93.9%)	7801 (81.3%)
ENG implant	260 (1.1%)	378 (3.9%)
LNG-IUD	607 (2.6%)	859 (8.9%)
Cu-IUD	540 (2.3%)	566 (5.9%)

Cu: copper; ENG: etonogestrel; FPL: Federal Poverty Level; IUD: intrauterine device; LNG: levonorgestrel.

^aPreintroduction: January 2014–April 2015; postintroduction: May 2015–March 2016.

Table 2

Parameter estimates^a for LARC insertions and payment amounts in Utah's Title X clinics, from January 2014 to March 2016

Parameter	Coefficient	Newey-West standard error	95% CI	p value
LNG-IUD				
Baseline trend β_1	1.02	0.47	0.34–2.00	.043
Level change after May 2015 Liletta introduction β_2	14.40	5.99	2.00–26.79	.025
Trend change after May 2015 Liletta introduction β_3	2.40	1.00	0.32–4.47	.026
Intercept β_0	29.27	4.43	20.10–38.44	<.001
Other LARC methods (copper IUD, implant)				
Baseline trend β_1	0.84	0.29	0.22–1.45	.010
Level change after May 2015 Liletta introduction β_2	–3.51	6.55	–17.08 to 10.05	.597
Trend change after May 2015 Liletta introduction β_3	5.59	1.43	2.62–8.56	.001
Intercept β_0	42.85	2.81	37.02–48.67	<.001
Average payment amount for an LNG-IUD				
Baseline trend β_1	17.97	2.89	11.98–23.95	<.001
Level change after May 2015 Liletta introduction β_2	–240.43	43.54	–330.50 to –150.35	<.001
Trend change after May 2015 Liletta introduction β_3	–23.00	5.92	–35.26 to –10.74	.001
Intercept β_0	176.14	21.97	130.68–221.60	<.001
Average payment amount for non-LNG LARC				
Baseline trend β_1	10.40	2.38	5.47–15.33	<.001
Level change after May 2015 Liletta introduction β_2	–106.87	30.54	–170.06 to 43.68	.002
Trend change after May 2015 Liletta introduction β_3	–11.00	3.42	–18.08 to –3.93	.004
Intercept β_0	210.24	18.8	171.35–249.13	<.001

LARC: long-acting, reversible contraception; LNG-IUD: levonorgestrel intrauterine device

^aParameter estimates derived from segmented, ordinary least squares regression model; p value tests the hypothesis that each of the coefficients is equal to zero, following the model specification included in the methods section of the accompanying paper.