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Successful Provision of Long-Acting Reversible Contraception in a Sexual Health Clinic

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Abstract

Background: Women who attend sexual health clinics are at high risk for sexually transmitted infections and unintended pregnancy. Long-acting reversible contraceptives (LARC) are very effective contraceptive methods, but the provision of LARC in such clinics is not well described in the literature.

Methods: We conducted a retrospective chart review of women who presented to Denver Sexual Health Clinic for any reason and received family planning services between April 1, 2016, and October 31, 2018. We assessed demographic and clinical factors associated with contraceptive method received and conducted a subanalysis of those with intrauterine device (IUD) insertions on the same-day versus delayed insertion. Among those who received an IUD, we assessed rates of pelvic inflammatory disease (PID) 30 days after insertion.

Results: Of the 5064 women who received family planning services in our clinic, 1167 (23%) were using a LARC method at the time of their visit. Of the 3897 who were not using a LARC, fewer women, 12.6%, chose LARC (IUD and progestin implant), compared with 33.3% who chose new short-acting reversible contraceptives. Further analysis of the 270 IUD initiators revealed 202 (74.8%) received the IUD on the same day, whereas 68 (25.2%) had delayed IUD insertion. There were 9 incident cases of gonorrhea or chlamydia in those who received same-day IUD and 1 incident case among those who had delayed IUD insertion. There were no cases of PID at 30 days after insertion in either group.

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Conclusions: Study findings support IUD provision in a sexual health clinic on the day of initial visit without increased risk of PID.

Long-acting reversible contraceptives (LARC) such as intrauterine devices (IUDs) and contraceptive implants are highly effective in preventing pregnancy with failure rates of less than 1% per year of use.¹ The ability to provide LARC methods to women, especially adolescents, has been shown to dramatically decrease the rate of unintended pregnancy.² Current Centers for Disease Control and Prevention (CDC) guidance for health care providers on contraception highlights medical eligibility criteria for contraceptive use including IUD insertion.³ Insertion of IUD is contraindicated for women who have current pelvic inflammatory disease (PID) or a symptomatic sexually transmitted infection (STI).³ Women including those at risk for STI can receive IUD insertion and STI screening on the same day.³ Furthermore, CDC contraceptive guidance and previous research has shown that same-day IUD insertions are safe in women without signs of cervicitis, in high-risk settings.^{1,3–5} Unfortunately, misconceptions about IUD use persist despite these studies, especially among women at increased risk for STI acquisition and subsequent PID in the setting of IUD placement.⁶ Although there have been publications describing provision of LARC in many high-risk settings,^{2,4} there is little information on the provision of LARC in a sexual health clinic with a high volume of patients seeking STI care.

The Denver Sexual Health Clinic (DSHC) is the largest integrated family planning and sexual health clinic in Colorado. This clinic is part of a local public health agency, Public Health Institute at Denver Health, and is embedded in a safety net hospital system, Denver Health (DH). The DSHC provides confidential, comprehensive, low-cost services for diagnosis, treatment, management, and prevention of STIs. Since 2001, the DSHC has offered family planning services (FPS) to patients presenting for STI evaluation through Federal Title X funding. Family planning services provided at DSHC includes contraceptive methods counseling and education, provision of contraceptive method of choice, and management of an existing birth control method. A comprehensive description of these services is provided elsewhere.⁷ Condoms and a broad range of Food and Drug Administration-approved contraceptive methods are available either free of charge or at a reduced rate based on a sliding scale. The clinic began a LARC insertion program in 2009 that was slowly expanded and regularly offered by 2011. By mid-2014, the clinic began offering LARC to patients presenting without symptoms of STIs who desired LARC on the same day as their routine STI testing or family planning visit in alignment with CDC guidance on LARC insertion.³ Before this, patients often had to return within 45 days of negative chlamydia and gonorrhea test results for IUD placement.

The purpose of this study is to describe the clinical characteristics of women who choose LARC compared with short-acting reversible contraceptives (SARC; oral contraceptive pills, vaginal ring, injectable contraception, and hormonal patch) in a sexual health clinic among those without an existing LARC method. We also compared the demographic and clinical characteristics of women with same-day versus delayed insertion and the association between IUDs and subsequent STI and PID in this population by examining rates of incident STI and PID within 30 days of insertion.

METHODS

We examined the electronic health record (EHR) for women who presented to our clinic for any reason and received FPS between April 1, 2016, and October 31, 2018. Women eligible for FPS were identified based on their sex assigned at birth listed as female and no surgical history of tubal ligation or hysterectomy noted in the EHR. Women were included in the analyses if they were eligible for and received FPS. For each visit in the DSHC, detailed medical/sexual history, baseline/current contraceptive use, family planning education, and choice of contraceptive method after counseling (if one was not previously in use) were recorded. In addition, STI screening tests and subsequent results, and/or treatment were also recorded for each FPS visit. All data were recorded in the EHR (Epic Systems Corporation, Verona, WI). The EHR is used by all clinical programs within DH including DSHC, thus providing access to clinical information for patients seen throughout the health system including the 525-bed hospital, 2 urgent and emergency care facilities, the network of 9 federally qualified health centers, and 17 school-based clinics. The 21/2-year period chosen for this retrospective study was influenced by when the EHR was first implemented in April 2016 and before changes were made to family planning program in November 2019 to further facilitate same-day LARC placement. The long study period allowed for a large sample size to evaluate for diagnosis of PID after LARC placement.

Incident STIs were determined based on positive laboratory test results for gonorrhea and/or chlamydia infection documented within the shared EHR for the entire DH system: (1) 90 days preceding the initial visit in DSHC or (2) on the date of visit. Diagnoses of PID were determined by review of electronic record throughout the DH system and based on clinical diagnosis within 30 days after the IUD placement visit.

We conducted several analyses. First, we examined demographic and clinical characteristics of all women receiving FPS between April 1, 2016, and October 31, 2018; demographic and some clinical characteristics were obtained from the last clinical visit within the study period. A subgroup analysis was performed for women, stratified by type of contraceptive use: LARC methods or SARC as previously defined. If, during a single visit, the patient reported using multiple birth control methods, she was placed into the most effective category of birth control. If the patient had multiple visits within the study period, we only included the birth control method chosen in the last visit within the study period. Demographic and clinical characteristics were examined between LARC and SARC users. Individuals who chose an IUD method were then followed to examine STI and PID diagnoses within 30 days of insertion. Finally, among women who initiated an IUD, we compared those who received it the same day versus delayed IUD insertion. An algorithm that combines providers' notes and screening filters was used to determine IUDs inserted on the same day versus delayed with a final chart review for confirmation. We used χ^2 tests of association, Satterthwaite t test, or Fisher exact tests to identify any significant differences of patient characteristics between groups. Statistical analyses were performed using SAS 9.3 (SAS Institute, Cary, NC). Given a wide range of missing values, we retained these values as missing/unknown for all analyses. This project was reviewed by the Quality Improvement Committee of Denver Health, which is authorized by the Colorado Multiple Institutional

Review Board at the University of Colorado, Denver, and was determined not to be human subjects' research. As such, this project did not require institutional review board approval.

RESULTS

From April 2016 to October 2018, 6519 women were seen in the clinic, of those, 5814 (89.2%) were eligible for FPS. Of these, 5064 women received FPS, and the demographic and clinical characteristics of these women are shown in Table 1. The mean age was 26.9 \pm 7.1 years; most identified as Hispanic (41.8%), whereas 36% identified as White, non-Hispanic, and 15.8% as Black, non-Hispanic. With regard to socioeconomic status, most were at or less than 150% of the federal poverty level (85.3%), and either uninsured (49.1) or had public health insurance (19.9%). Approximately one-fourth of patients reported 2 sexual partners in the 3 months before their visit, and most had no prior pregnancy (74.6%). Most patients (74%) presented to the clinic for STI testing and without a symptomatic complaint. A small proportion of patients (11%) had a positive chlamydia or gonorrhea test result on the day of visit.

Of the 5064 women who received FPS, 1167 (23%) had an existing LARC at the time of their visit. Of those without an existing LARC (3897), a new LARC or SARC method was initiated by 53.4% (2083 of 3897). Overall, fewer women chose LARC (IUD and progestin insert), 492 of 3897 (12.6%) compared with 1298 of 3897 (33.3%) who chose a new SARC (oral contraceptive pills, vaginal ring, or contraceptive patch). The demographic and clinical characteristics of those who chose a new LARC or SARC method are compared in Table 2. The groups were similar in mean age (25.9 \pm 6.6 vs. 25.6 \pm 6.2 years). Women who chose LARC over SARC were more likely to identify as Hispanic (55.2% vs. 42.9%, *P*<0.001), less likely to identify as Black (9.1% vs. 14.9%, *P*<0.001), and more likely to be uninsured (50.7 vs. 46.8, *P*<0.01). There was no difference between the groups with respect to positive GC/CT test result on the same day of the visit.

Of the women initiating IUD for contraception at any point during the study period, 202 of 270 (74.8%) received it the same day. Table 3 compares characteristics of women who chose an IUD and received it on the same day versus those who had delayed IUD insertion. There were no significant differences in demographic factors—age, race, ethnicity, poverty level, or insurance status—between the 2 groups. However, more women in the delayed IUD placement group self-reported a positive GC/CT result within the preceding 12 months (32.2% vs. 16.8%, P < 0.01).

Finally, to assess whether the patients who received a same-day IUD insert had a higher rate of diagnosis of PID after insertion, we reviewed future follow-up visits of patients (anywhere in the DH health system) with same-day versus delayed IUD for diagnosis of PID within 30 days of insertion. Of the 270 patients who received an IUD, 27 of 202 same-day IUD patients (13.4%) and 20 of 68 with delayed IUDs (29.4%) returned for follow-up care within 30 days of their IUD placement visit (Table 4); patients were either seen in the sexual health clinic or elsewhere in the DH system. There were 9 incident cases of GC/CT in those who received a same-day IUD and 1 incident case among those who had a delayed IUD insertion. All patients diagnosed with GC or CT in our clinic were notified quickly (within

2 business days) and treatment was provided within 7 days. On average, during the study period, approximately 81% of all women were treated for chlamydia and gonorrhea within 7 days of their positive test result. There were no cases of PID in either group during the follow-up period.

DISCUSSION

Long-acting reversible contraceptives are a highly effective method of birth control, which have been shown to be safely and effectively provided in other high-risk settings.^{2,4} This report supports the acceptance of LARCs, in particular same day IUD insertion among women who attend a sexual health clinic. Our study also shows very low rates of gonorrhea and chlamydia and no cases of PID 30 days after IUD insertion.

From a population perspective, LARC is the most effective method available at low cost in our clinic; however, only 12.6% of women who chose a new birth control method at their sexual health clinic visit, opted for a new LARC. According to the National Survey of Family Growth conducted in 2017 to 2019, among women aged 15 to 19 years in the United States, approximately 65% of women use some form of contraception, whereas 34.7% do not. In the same population, 10.4% of women were using LARC. This population is similar to our study population in terms of racial and ethnic diversity; in addition, the percent of women using LARC in the slice of the US population completing the National Survey of Family Growth mirrors the proportion of women who chose LARC in our clinic population.⁸

With respect to the safety of LARC provision in our sexual health clinic, we found no cases of PID among the small percentage of IUD users who returned for follow-up care after placement. Rates of PID are very low in general and among IUD users. A systematic review study showed that PID risk is also quite low in women with (0%-5%) and without (0%-2%)STIs at the time of insertion.⁹ In a study of nearly 58,000 California women receiving IUDs in a managed care setting, the rates of PID among women who were screened or not screened for chlamydia and gonorrhea were very low at 0.54%.⁵ Although this study was primarily among insured persons, the managed care population was diverse in terms of race and ethnicity, which is similar to our study population. The managed care population was slightly older than our clinic population with an average age of 32 years. However, a subgroup analysis of women 26 years and younger, the rates of PID remained the same. A retrospective chart review study from a university clinic in Chicago located in an area with high rates of chlamydia and gonorrhea described low rates of PID (0.7%) among 384 IUD recipients.¹⁰ Although this study had a higher rate of self-reported STIs (47%) at the time of IUD insertion, the incident rate of laboratory-confirmed GC was 0.8%, and that of CT was 2.3%, which is lower than the DSHC rates. In contrast to our study, the follow-up period was much longer (1 year), and patients in the Chicago clinic were more likely to follow up after IUD placement, with 73% having a follow-up visit within the 1-year period. Lastly, results from the large contraceptive choice project in St. Louis, another urban area with high incident rates of chlamydia and gonorrhea, also showed similarly low rates of PID (<1%) among IUD users at high risk for STIs.¹¹ Our findings provide additional support for the delivery of wide-ranging contraceptive services including same-day IUDs insertions in a sexual health clinic.

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Our study has a few limitations. One major limitation was our measure of PID in this population. Although the risk of PID is increased in the first 3 weeks after insertion, PID is a rare outcome and can occur any time after IUD placement, and diagnosis is largely based on clinical findings.⁶ We relied on diagnosis codes and chart review to identify cases of PID in our population, which may not have adequately identified all cases of PID even though our search spanned the entire DH system. In addition, only looking 30 days after IUD placement, although this includes the time of increased risk, likely resulted in missing cases of PID in the months to years after IUD placement. Furthermore, follow-up data were only available for patients seen within our health system (a sexual health clinic, community health centers, and a hospital); therefore, diagnosis of PID was based on diagnosis codes from our health system only. In addition, our clinical practice does not mandate a follow-up visit after IUD placement, rather patients are told to follow up if new concerns arise. This reliance on passive follow-up rather than actively assessing for PID in all patients who received an IUD may have also led to missed cases of PID. It is also possible that some cases of PID were missed because some of our patients were seen at an outside health care facility. However, in view of our high rate of patients who are uninsured and the free services offered in our clinic, we suspect that most patients would have returned to us or our safety net hospital system for future visits if new concerns arose within 30 days of their IUD placement.

Additional limitations of our study include that, although patients in the delayed-insertion IUD group were more likely to return for a follow-up visit, given that we pulled data from any visits across the system, we do not know if these follow-up visits were related to the IUD placement. Another limitation is that women were included in the analysis based on the time period and not the primary reason for visit; all were counseled on family planning options, but their primary aim for visiting our clinic may not have been for family planning reasons. Also, given that the data were abstracted from our electronic records, unfortunately, not all the demographics were available for every patient. For example, condom use was only available for 18% of the study population; therefore, it was excluded from the analyses.

Injectable contraception use was documented in the EHR as well; however, we were unable to separate previous versus new use of injectable contraception in the analysis because of how this is recorded in the EHR. This likely did not affect our study findings because this was a small proportion (~5%) of the study population. Lastly, another limitation was the decision to get an IUD on the same day versus returning for an IUD at a future visit, which was not always dictated by the patient, and the reasons are not well documented. Some examples include inadequate time in the visit to address another chief complaint and insert LARC, delayed starts to appointments, and the presence of a clinical concern such as cervicitis that precluded IUD placement or patient preference.

Despite the limitations of our study, our results may be useful for the implementation of current clinical guidance and provision of LARC and IUD insertions in sexual health clinics that see women with high rates of STIs. A recent review of trends in sexual and reproductive health services among women in the United States showed an overall shift in women obtaining services from private providers; however, publicly funded and Title X clinics like the DSHC remain an important access point for certain women—young, identify as persons

of color, low income, and uninsured—who have limited access to care.¹² Our findings also add to the literature that supports the importance of offering contraception in a sexual health clinic including same-day IUD insertion in women who are at high risk for both pregnancy and STI.

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TABLE 1.

Demographic and Clinical Characteristics of Women Receiving Family Planning Services at Denver Sexual Health Clinic (April 1, 2016– October 31, 2018)

	n	%
Total family planning users [*] (deduplicated)	5064	100
Age. y		
Mean/Median/SD, y	26.9/26.0/7.1	
<19	616	12.2
20–24	1546	30.5
25–29	1460	28.8
30–39	1113	22.0
40	329	6.5
Poverty level		
150%	4320	85.3
>150%	744	14.7
Marital status		
Single	4500	88.9
Married	367	7.3
Divorced or separated	152	3.0
Unknown/Other \dot{f}	45	0.8
Insurance type		
Public	1008	19.9
Private	401	7.9
Uninsured	2487	49.1
Missing/Unknown	1168	23.1
Self-report GC/CT positive in the past 12 mo		
Yes	669	13.2
No	4395	86.8
Laboratory-confirmed GC/CT positive in last	90 d	
Yes	106	2.1
No	4958	97.9
GC/CT positive on the day of visit		
Yes	557	11.0
No	4507	89.0
Birth control methods, last visit \ddagger		
Existing LARC (IUD, implant)	1167	23.0
Injectable contraception (new or existing)	266	5.3
New contraceptive implant	226	4.5
New IUD insertion	293	5.8
New oral contraceptive pills	1162	22.9
New vaginal ring	128	2.5

	n	%
New contraceptive patch	8	0.2
Condoms (male or female)	1946	38.4
None	373	7.4
Other [§]	467	9.2
Prior pregnancy		
Yes	1287	25.4
No	3777	74.6
No. sex partners in past 3 mo		
0	235	4.6
1	1908	37.7
2	1248	24.7
Missing/Unknown	1673	33.0
STI symptom status		
Symptomatic	1315	26.0
Asymptomatic	3749	74.0

*Categories do not all sum to total because of missing data for individual variables.

 † Other marital status includes significant other or widowed.

 \ddagger If multiple birth control methods were noted in a visit, then the patient was placed in the category with the most effective birth control method. Existing methods were reported by patient during visit. New methods were those chosen by the patient during the visit.

\$ Other birth control method: coitus interruptus, abstinence, fertility awareness methods, no method, desires pregnancy, method unknown, relies on male birth control method (vasectomy or male condoms), refused to disclose.

CT indicates chlamydia; BC, birth control; GC, gonorrhea; IUD, intrauterine device; OCP, oral contraceptive pills; STI, sexually transmitted infection.

TABLE 2.

Demographic and Clinical Characteristics of Women Who Chose Long-Acting Reversible Contraceptives (LARC) Compared With Women Who Chose Short-Acting Reversible Contraceptives (SARC; April 1, 2016–October 31, 2018)

	LARC Method ^{*†}		SARC [†] ‡		
	n	%	n	%	P [§]
Total	616	100	1554	100	
IUD	270	43.8			
Same-day IUD insertion	202	74.8			
Delayed IUD insertion	68	25.2			
Age, y					
Mean/Median/SD	25.9/25	.0/6.6	25.6/25.0/6.2		0.22
<19	98	15.9	224	14.4	0.38
20–24	183	29.7	545	35.1	0.61
25–29	181	29.4	444	28.6	0.02
30–39	125	20.3	285	18.3	0.71
40	29	4.7	56	3.6	0.23
Race/Ethnicity					
Hispanic	340	55.2	667	42.9	< 0.01
White, non-Hispanic	188	30.5	560	36.1	0.01
Black, non-Hispanic	56	9.1	232	14.9	< 0.01
Other/Unknown	32	5.2	95	6.1	0.41
Poverty					
<150%	544	88.3	1328	85.5	0.08
>150%	72	11.7	226	14.5	
Marital status					
Single	527	85.6	1424	91.6	< 0.01
Married	68	11.0	79	5.1	< 0.01
Divorced or separated	16	2.6	42	2.7	0.51
Unknown/Other	5	0.8	9	0.6	0.54
Insurance type					
Public	90	14.6	306	19.7	0.02
Private	37	6.0	140	9.0	0.04
Uninsured	312	50.7	727	46.8	< 0.01
Missing/Unknown	177	28.7	381	24.5	
Self-report GC/CT positiv	ve in past 12	mo			
Yes	109	17.7	264	17.0	0.69
No	507	82.3	1290	83.0	
Laboratory-confirmed GC	C/CT positive	e in the pa	st 90 d		
Yes	13	2.1	40	2.6	0.53
No	603	97.9	1514	97.4	

	LARC Method ^{*†}		SARC [†] ‡			
	n	%	n	%	P §	
Laboratory-confirmed GC/CT positive on the day of visit						
Yes	46	7.5	161	10.4	0.04	
No	570	92.5	1393	89.6		
Prior pregnancy						
Yes	203	32.9	372	23.9	< 0.01	
No	413	67.1	1182	76.1		
No. sexual partners in past	3 mo					
0	39	6.3	58	3.7	< 0.01	
1	243	39.5	657	42.3	< 0.01	
>2	77	12.5	404	26.0	< 0.01	
Missing/Unknown	257	41.7	435	28.0	< 0.01	
STI symptom status						
Symptomatic	69	11.2	416	26.8	< 0.01	
Asymptomatic	547	88.8	1138	73.2		

 * Categories do not all sum to total due to missing data for individual variables.

 † LARC: contraceptive implants and intrauterine devices.

 \ddagger SARC: pills, ring, patches and progesterone injection.

 ${}^{\$}P$ value calculated using the χ^2 test.

 $\P_{\text{Satterthwaite } t \text{ test unequal variances (only means).}}$

 $/\!\!/_{P}$ value calculated using the Fisher exact test.

CT indicates chlamydia; GC, gonorrhea; IUD, intrauterine device; STI, sexually transmitted infection.

Demographic and Clinical Characteristics of Women Who Requested Intrauterine Device and Received It at First Initial Visit (Same Day) Versus Another Follow-Up Visit (Delayed Insertion), Denver Sexual Health Clinic (April 1, 2016–October 31, 2018)

	Same-Day IUD*		Delayed IUD*		
	n	%	n	%	P [†]
Total	202	74.8	68	25.2	
Age, y					
Mean/Median/SD	27.4/26	27.4/26.0/6.9		26.7/26.0/5.5	
19	20	9.9	4	5.9	0.31
20-24	56	27.7	20	29.4	0.78
25–29	62	30.7	26	38.3	0.25
30–39	49	24.3	16	23.5	0.90
40	15	7.4	2	2.9	0.19
Race/Ethnicity					
Hispanic	80	39.6	39	57.4	0.01
White, non-Hispanic	90	44.6	20	29.4	0.03
Black, non-Hispanic	16	7.9	7	10.3	0.54
Other/Unknown	16	7.9	2	2.9	0.26 [§]
Poverty					
150%	176	87.1	58	85.3	0.70
>150%	26	12.9	10	14.7	
Marital status					
Single	171	84.7	58	85.S	0.90
Married	23	11.4	7	10.3	0.80
Divorced	3	1.5	3	4.4	0.16
Unknown/Other	5	2.5	0	0	0.33 [§]
Insurance type					
Public	22	10.9	11	16.2	0.20
Private	16	7.9	7	10.3	0.49
Uninsured	106	52.5	29	42.7	0.12
Current drug use					
Yes	76	37.6	30	44.1	0.36
No	125	61.9	38	55.9	
Self-report GC/CT positi	ve in the pas	t 12 mo			
Yes	S4	16.8	22	32.3	< 0.01
No	168	83.2	46	67.7	
Laboratory-confirmed G	C/CT positiv	e in the p	ast 90 d		
Yes	3	1.5	2	2.9	0.60 [§]
No	199	98.5	66	97.1	2.00

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	Same-Day IUD*		Delayee				
	n	%	n	%	P^{\dagger}		
Laboratory-confirmed GC/CT positive on the day of visit							
Yes	16	7.9	2	2.9	0.26 [§]		
No	186	92.1	66	97.1			
Prior pregnancy							
Yes	69	34.2	30	44.1	0.14		
No	133	65.8	38	55.9			
No. sexual partners in p	oast S mo						
0	9	4.5	1	1.5	0.45 [§]		
1	75	37.1	28	41.2	0.44		
>2	28	1S.9	9	13.3	0.87		
STI symptom status							
Symptomatic	20	9.9	13	19.1	0.04		
Asymptomatic	182	90.1	55	80.9			

* Categories do not all sum to total because of missing data for individual variables.

 $^{\dagger}\!P$ value calculated using the χ^2 test.

^{\ddagger}Satterthwaite *t* test unequal variances (only means).

 $^{\$}P$ -value calculated Fisher's exact test.

CT indicates chlamydia; GC, gonorrhea; IUD, intrauterine device; STI, sexually transmitted infection.

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TABLE 4.

Comparing Same-Day IUD Versus Delayed IUDs 30 Days After IUD Insertion at the Denver Sexual Health Clinic (April 1, 2016–October 31, 2018)

	30 d After IUD Placement						
	Same-Day IUD Delayed IUD						
	n	%	n	%	Total	%	Р
Total IUDs	202	74.8	68	25.2	270	100	
Total returned *	27	13.4	20	29.4	47	17.4	< 0.01
GC/CT positive	9	4.5	1	1.5	10	3.7	0.03 [†]
PID diagnoses	0		0	0	0	0	

* Based on patients who returned for care to clinic or anywhere in the Denver Health system.

 ${}^{\dagger}P$ value calculated using the Fisher exact test.

CT indicates chlamydia; GC, gonorrhea; IUD, intrauterine device; PID, pelvic inflammatory disease.