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Post-placental IUD insertion: A mixed methods assessment of women's experiences

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ABSTRACT

Background: Post-placental intrauterine device (IUD) insertion has the potential to reduce rapid repeat pregnancies. As the procedure becomes more widely adopted in the US, it is important to understand women's perceptions about the procedure. Studies examining patient-centered outcomes are currently lacking.

Objectives: The objectives of this study include: 1) To describe women's experiences with post-placental IUD insertion through postpartum semistructured interviews. 2) To establish a mean pain score for the procedure using a 100mm visual analogue scale (VAS). 3) To assess procedural pain using a 4-point Likert verbal rating scale (VRS).

Methods: This concurrent mixed methods pilot study was conducted at the University of New Mexico Hospital. Women with and without an epidural were enrolled. Procedural pain was assessed using the VAS and VRS immediately after IUD placement and at the time of the interviews. Interviews were conducted prior to hospital discharge. The interviews explored participants' decision

pathways, procedure experience, decisional regret, and contraception knowledge. Interview data were coded and analyzed iteratively to identify emergent themes. Participants rated their overall satisfaction on a 5-point Likert scale at the end of the interview.

Results: In the no epidural group 30 women underwent pain assessment and nine participated in an interview. In the epidural group 36 women underwent pain assessment and 12 participated in an interview. The VAS scores did not demonstrate a normal distribution in both the no epidural and epidural groups. The median VAS scores were 40.5mm and 2.8mm in the no epidural and epidural groups, respectively. In the no epidural group, 53.3% of women reported none-mild pain. Most women (88.9%) in the epidural group reported none-mild pain. The interview data did not reveal substantial differences between the no epidural and epidural groups. Women's satisfaction with the procedure was high in both groups. Convenience was the dominant decision-driver to undergo the procedure. Actual procedural pain and duration were less than expected among the majority of interviewees.

Conclusions: Women who undergo post-placental IUD insertion report high satisfaction and no regrets about the procedure. Our study offers valuable counseling points to offer women if they are considering post-placental IUD placement.

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Introduction

Two thirds of women have an unmet need for family planning within a year of giving birth [1]. This is particularly the case among minorities and poor women. Many women do not seek postpartum care because of substantial socioeconomic and logistical barriers [2-4] and the postpartum period is a time at which contraception is often initiated. The availability of long-acting reversible contraception (LARC) following delivery has been shown to decrease rates of rapid repeat pregnancy and its well-established risks [5-7]. Post-placental intrauterine device (IUD) insertion is a pragmatic strategy to eliminate barriers to LARC access. During the immediate postpartum period women are motivated to initiate contraception, they are not pregnant, access to medical care is readily available and the procedure itself required little extra time or equipment.

Post-placental IUD insertion is as safe and effective in preventing pregnancy as interval insertion (IUD insertion at a time outside of the postpartum period) [8-11]. In general, LARC devices have been shown to be more cost-effective than other methods of contraception [12]. Furthermore, a recent cost-effectiveness analysis suggested that post-placental IUD placement may be superior to interval placement [13]. There has been an increase in IUD utilization in the US [14] and to date, eleven states have approved Medicaid reimbursement for post-delivery placement [15]. Despite ample evidence supporting the safety, effectiveness and public health benefits of post-placental IUD insertion, the practice is relatively uncommon among US providers and many women remain unaware of this option. Reasons for underutilization in the US include lack of

reimbursement, insufficient provider knowledge and training, and limited patient awareness.

Current research regarding post-placental IUD insertion has primarily focused on clinical outcomes including expulsion, perforation, infection, continuation, and pregnancy rates [10, 11, 16]. Few studies have examined the procedure using a patient-centered approach, including little information regarding pain with IUD insertion or patient satisfaction with post-placental placement. A recent study in India reported aggregate categorical pain scores and satisfaction scores with post-placental IUD insertion among over 2700 women who delivered both vaginally and via cesarean section. None of the women in the study who had a vaginal delivery had regional anesthesia (personal communication with primary author). In addition, the authors recorded data on women who also received the IUD within 48 hours of delivery. The majority of women in this study reported “no pain at all” or “little discomfort”, and satisfaction scores were high [17]. Another small study assessing IUD continuation rates at six months as a primary outcome recorded VAS scores after post-placental IUD placement among 15 women who had an epidural. They reported a mean VAS score of 1.07mm without reporting a standard deviation [18]. Thus, the current body of literature is lacking with regard to the patient perspective about post- placental IUD insertion. The objective of our mixed methods pilot study was to explore women’s perspectives on postplacental IUD insertion following vaginal delivery with a standardized ring forceps insertion technique. In order to meet this objective we had the following specific aims:

1. To describe women's experiences with post-placental IUD insertion through postpartum semi-structured interviews.

2. To establish the mean pain score and standard deviation using a 100mm visual analog scale (VAS).

3. To assess insertional pain using a 4-point Likert verbal rating scale (VRS) as a secondary pain assessment.

4. To assess patient satisfaction with the IUD insertion experience using a 5-point Likert scale.

5. To assess provider ease of IUD insertion with a 4-point Likert scale.

Methods

Study design and setting

We conducted a concurrent mixed methods pilot study using quantitative and quantitative approaches at the University of New Mexico Hospital (UNMH), Albuquerque, New Mexico from December 2013 to March 2015. UNMH performs approximately 3000 deliveries per year with epidural and cesarean section rates of approximately 45% and 22%, respectively. The majority of women are Hispanic (60%), and non-Hispanic Whites and Native Americans comprise about 17% and 11% of parturients, respectively. Approximately 80% of women have Medicaid or are uninsured [19]. The IUDs used for the study were a covered benefit for women with Medicaid insurance or were acquired from a grant to the UNM Family Planning Center for uninsured women. As a result of our sourcing of IUDs, the vast majority of participants were women with Medicaid or who were uninsured. The UNMH Health Science Center Human Research Review Committee approved the study. The study was registered at ClinicalTrials.gov, registration number NCT02312726.

Recruitment

We enrolled English and Spanish-speaking only (SSO) women ≥ 18 years of age who anticipated a vaginal birth. We recruited patients at UNMH affiliated antenatal clinics and the UNMH Labor & Delivery (L&D) unit, provided women were not in active labor; the majority of women enrolled on labor and delivery were being admitted for induction. Women were approached about participation

in the study if after antenatal contraceptive counseling they elected to undergo IUD placement in the immediate postpartum period.

Women were excluded from enrollment for the following reasons: contraindications to using the copper T380A IUD (Cu-IUD) or the levonorgestrel intrauterine system (LNG-IUS); current use of controlled substances for chronic pain management; current substance use disorder/ addiction diagnosis. Post-enrollment exclusion criteria included: unanticipated cesarean delivery; postpartum hemorrhage (defined as an estimated blood loss requiring intervention beyond standard therapy and not resolved within approximately 10 minutes); chorioamnionitis; manual placental extraction; manual placement of the IUD; unsuccessful IUD placement; third or fourth degree laceration; untreated gonorrhea, chlamydia and/or trichomoniasis; known or suspected distorted uterine cavity; desire to withdraw from the study; non-notification of a research team member in time to attend delivery/precipitous delivery.

At enrollment all women gave written research consent. Women provided demographic data including pregnancy and sexually transmitted infection (STI) history. Participants recruited during antenatal care were contacted by phone at 36-37 weeks gestation in order to confirm ongoing understanding of and willingness to participate in the study, and to update contact information. We continued recruitment until we collected pain scale data on at least 30 women who did not have epidural analgesia in labor and 30 women who had epidural analgesia. Participants were given a $20 gift card to a local retailer for

completing the pain scales, and an additional $30 gift card for taking part in an interview.

When the participant presented for delivery, written informed consent was obtained for the post-placental IUD insertion procedure by a resident physician who was not a member of the research team. We allowed up to 30 minutes from placenta delivery for IUD placement, with a goal to place the IUD within ten minutes.

Quantitative Data Collection and Analysis

The primary objective of the quantitative component of our study was to describe the distribution of and establish a mean visual analog scale (VAS) procedural pain score for women at the time of post placental IUD placement among women with and without epidural analgesia in labor. We recruited with the intent to collect at least 30 VAS scores in each group as this number is generally sufficient to satisfy the central limit theorem and thus describe a particular aspect of a sample population. The central limit theorem states that the distribution of sample means will approach normality provided that the number of observations is sufficiently large enough. A sample size of 30 is often considered sufficient [20].

Following delivery of the placenta and immediately prior to IUD insertion, the participant was asked to rate her current pain level on two pain scales: 1) 100-mm VAS with anchors at 0mm=*no pain*, 100mm=*pain as bad as it can be*; 2) 4-point Likert visual rating scale (VRS); 0=*no pain*, 1=*mild pain*, 3=*moderate*

pain, 4=*severe pain*. Participants were shown the pain scales and instructed in how they would be administered at the time of recruitment. We used the VRS as a secondary assessment of pain because there has not yet been a robust study of pain with post-placental IUD insertion using a VAS. We did not know how the VAS scores would perform for this procedure, and there was a concern a VAS floor effect among women who had a labor epidural. The IUD was placed under trans-abdominal ultrasound guidance to the level of the uterine fundus using a standardized ring forceps insertion technique [21] by a physician who had demonstrated proficiency in the procedure. Competency in post-placental IUD placement was determined after physicians participated in standardized training with competency evaluation. The VAS and VRS were again used to assess procedural pain within five minutes of IUD insertion. We collected data regarding labor, epidural status, time from placental delivery to IUD placement, type of IUD, IUD insertion procedure, and pre-procedure pain medications if administered. The physician who placed the IUD rated ease of insertion on a 4-point Likert scale: 1=*easy*, 2=*somewhat easy*, 3=*somewhat difficult*, 4=*difficult*. Participants were scheduled for an appointment with their primary obstetric provider within two weeks of delivery for an IUD check.

We calculated measures of central tendency for the VAS data and frequency data for the VRS data. We used frequency data to describe provider ease of insertion and participant satisfaction (see section 2.2). Descriptive statistics were performed to describe participant characteristics and aspects of the IUD insertion procedures. We used STATA 12.1 for analysis of our

quantitative data (Stata Statistical Software: Release 12, 2011. College Station, TX).

Qualitative Data Collection and Analysis

We developed a semi-structured interview guide in order to explore areas of interest around immediate post-placental IUD placement (Appendix A). Our objective was to characterize a full range of participant responses within four domains of potentially relevant areas of exploration within the context of the procedure: 1) decisional influences, 2) experience of procedure, 3) decisional regret, 4) contraceptive knowledge. At the end of each interview, women were asked to rate their overall satisfaction on a 5-point Likert scale: 1=*very dissatisfied*, 2=*satisfied*, 3=*neutral*, 4=*satisfied*, 5=*very dissatisfied*. English interviews were performed by the primary investigator. Spanish interviews were carried out by a native Spanish speaker who was a member of the research team, and who was versed in qualitative research methodology. Interviewers did not provide participant prenatal care, perform informed consent for the IUD insertion procedure, or place the IUDs immediately postpartum. The interviews were audio recorded, transcribed and de-identified. The Spanish interviews were transcribed into both Spanish and translated into English by a transcriptionist with these skills. Interviewees were a convenience sample of enrollees and were selected based on availability of the interviewers during the participants' postpartum admission. We conducted interviews with women both with and

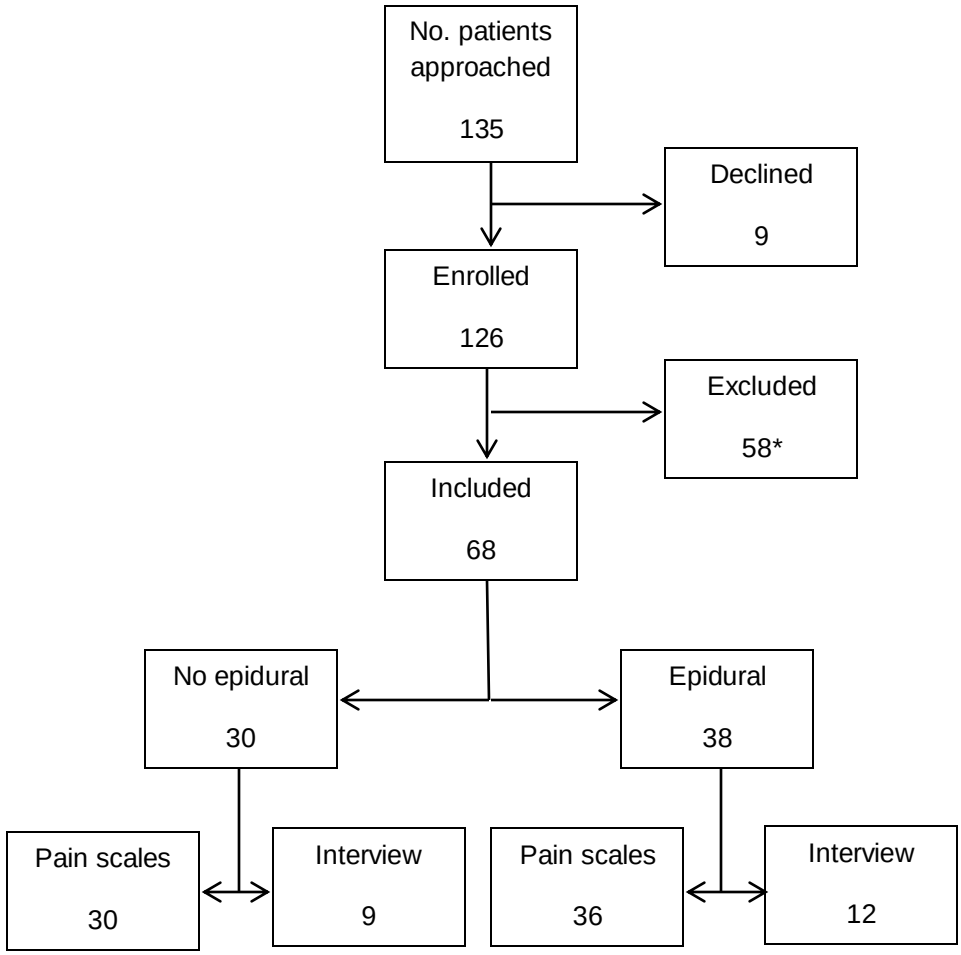
without epidural analgesia. Interviews were conducted within 24 hours of delivery in the participant's postpartum recovery room.

We used a grounded theory approach in the development of our interview guide, and during data collection and analysis. Grounded theory methodology is a hypothesis generating approach and can assist in creating a theoretical framework on a topic through iterative empirical data collection [22]. Four pilot interviews were conducted, two in English and two in Spanish, in order to refine the interview guide before proceeding with our formal qualitative data collection. The four domains referenced above were used as the basis for the initial interview template. Using an iterative approach, we expanded the components of the domains refined the interview guide as analysis of the transcript data progressed. We continued conducting the interviews until emergent themes were identified and data saturation was reached in both the no-epidural and epidural samples. The primary author reviewed all transcripts and identified thematic areas of interest as a means to develop a preliminary coding structure. The Spanish-speaking interviewer confirmed findings for the Spanish interview data. A preliminary coding template was vetted against two interviews prior to reviewing and coding all transcripts. The transcripts were imported in NVivo10 to organize and analyze the data (QSR International Pty Ltd.; 2012). New coding elements were added to the original coding structure as necessary to capture relevant concepts (Appendix B). Queries were generated in NVivo in order to examine the range of responses in both groups and to finalize the selection of the primary thematic findings.

Results

Approximately 300 women had post-placental IUDs placed following vaginal delivery at UNMH during our active recruitment period; 68 women, with a median age of 27 (18-43 years), participated in our study. The majority was multiparous (80.9%), and self-identified as being of Hispanic ethnicity (89.7%). The majority of women (71.6%) reached a high school level of education or did not complete high school, and reported annual household income of $20,000 or less (59.1%). Twenty-nine (43.4%) participants were SSO and 38 (57.6%) were English speaking. The median gestational age at delivery was 278 days (Table 1). As per our study design, 30 enrollees did not have an epidural in labor and 38 had an epidural. We collected pain scale data on 30 women in the no-epidural group and 36 women in the epidural group. We conducted interviews with nine women in the no-epidural group and 12 women in the epidural group (Figure 1). All IUDs were inserted within 1-20 minutes of placental delivery and the majority (72%) were placed within 10 minutes. Figure 1 and Table 1 display participant recruitment flow and participant characteristics, respectively.

Figure 1. Participant recruitment flow



*Excluded

15 C-section
5 Postpartum hemorrhage
6 Chorioamnionitis
1 Manual placenta extraction
3 Failed IUD placement
7 Manual IUD placement
21 Other (e.g., precipitous delivery)

Table 1. Participant characteristics

	Total (*n* = 68)	**Interviewee (*n* = 21)**
Age (yrs, median)	27	27
Gestational age at delivery (days, median)	278	275
Parity		
Multiparous	55 (80.9)	13 (61.9)
Ethnicity		
Hispanic	61 (89.7)	18 (85.7)
African American	1 (1.5)	1 (4.8)
American Indian/ Alaska	4 (5.8)	2 (9.5)
Asian American	1 (1.5)	--
White	1 (1.5)	--
Language of preference		
English	38 (55.9)	15 (71.4)
Spanish	30 (44.1)	6 (28.6)
Education		
Did not complete high school	21 (31.3)	4 (19.1)
Completed high school/ GED	27 (40.3)	7 (33.3)
In college/completed some college	16 (23.9)	8 (38.1)
Completed college	3 (4.5)	2 (9.5)
Employment		
Employed part time	8 (11.8)	2 (9.5)
Employed full time	8 (11.8)	4 (19.1)
Student	7 (10.3)	3 (14.3)
Homemaker	31 (45.6)	7 (33.3)
Temporary work leave	2 (2.9)	1 (4.8)
Unemployed	12 (17.6)	4 (19.0)
Income (*missing data)	**n*=66	**n*=20
Less than $20,000	39 (59.1)	10 (50.0)
$20,000 - 40,000	23 (34.9)	8 (40.0)
$40,000 - 60,000	3 (4.5)	2 (10.0)
$60,000 - 80,000	1 (1.5)	--
Insurance		
None	39 (57.4)	9 (42.9)
Medicaid	26 (38.2)	10 (47.6)
Commercial	3 (4.4)	2 (9.5)

n (%) unless otherwise indicated

Quantitative Results

Procedural VAS scores did not exhibit a normal distribution at the three assessment time points in both the no-epidural and epidural groups. Figures 2 and 3 show the distribution of VAS scores for both groups.

Figure 2. No epidural: Procedure VAS scores

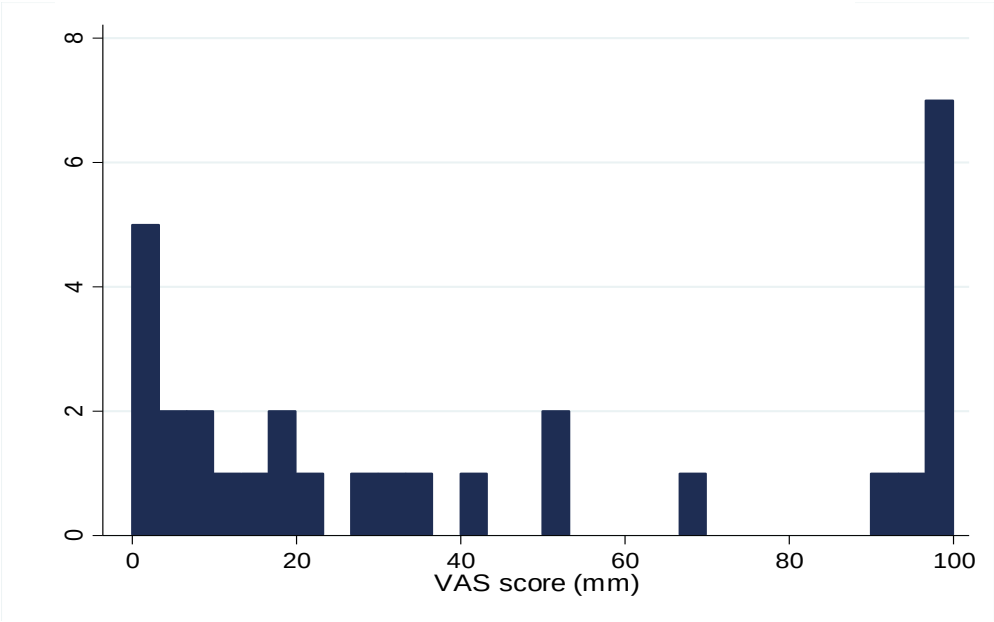
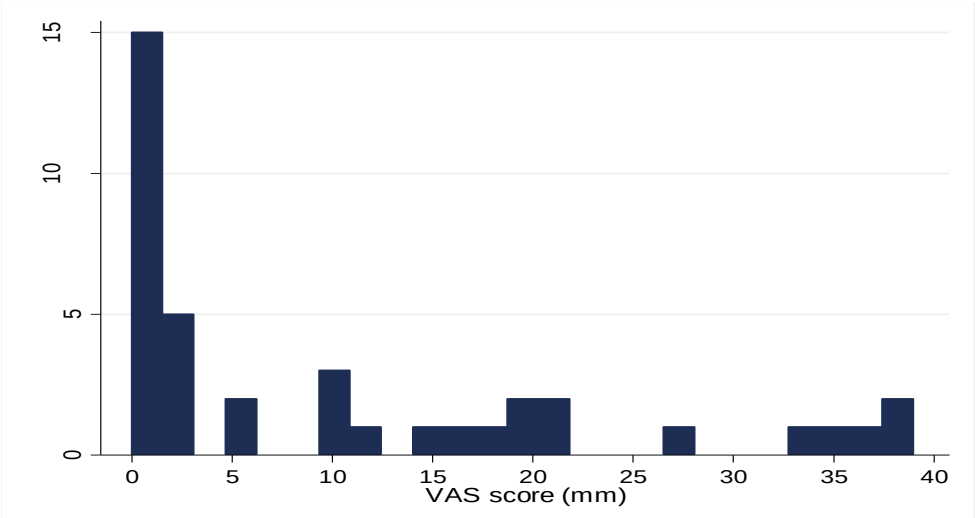


Figure 3. Epidural: Procedure VAS scores



The median procedural VAS scores for the no-epidural and epidural groups were 40.5mm and 2.8mm, respectively. Median pre-insertion VAS scores for the no-epidural and epidural groups were 31.8mm and 2.8mm, respectively. Median VAS scores for women who underwent postpartum interviews were 20.0mm and 3.0mm for the no-epidural and epidural groups, respectively (Table 2; Figure 4 and Table 3).

Table 2. VAS scores (mm): No epidural and Epidural groups at 3 time points

No epidural *n* = 30	Range	Mean	Standard deviation	Median	Interquartile range
Pre-insertion	0.0 – 96.0	35.3	29.3	31.8	40.0
Procedure	0.0 – 100.0	41.4	34.1	40.5	56.0
Recall[‡]	0.0 – 93.0	28.6	33.2	20.0	54.5
Epidural *n* = 36					
Pre-insertion	0.0 – 69.0	10.6	15.9	2.8	18.0
Procedure	0.0 – 100.0	10.9	19.5	2.8	14.5
Recall[‡]	0.0 – 26.0	5.4	7.4	3.0	7.8

[‡] No epidural: *n* = 9; Epidural: *n* = 12

Figure 4. VAS scores: No epidural and Epidural groups at 3 time points

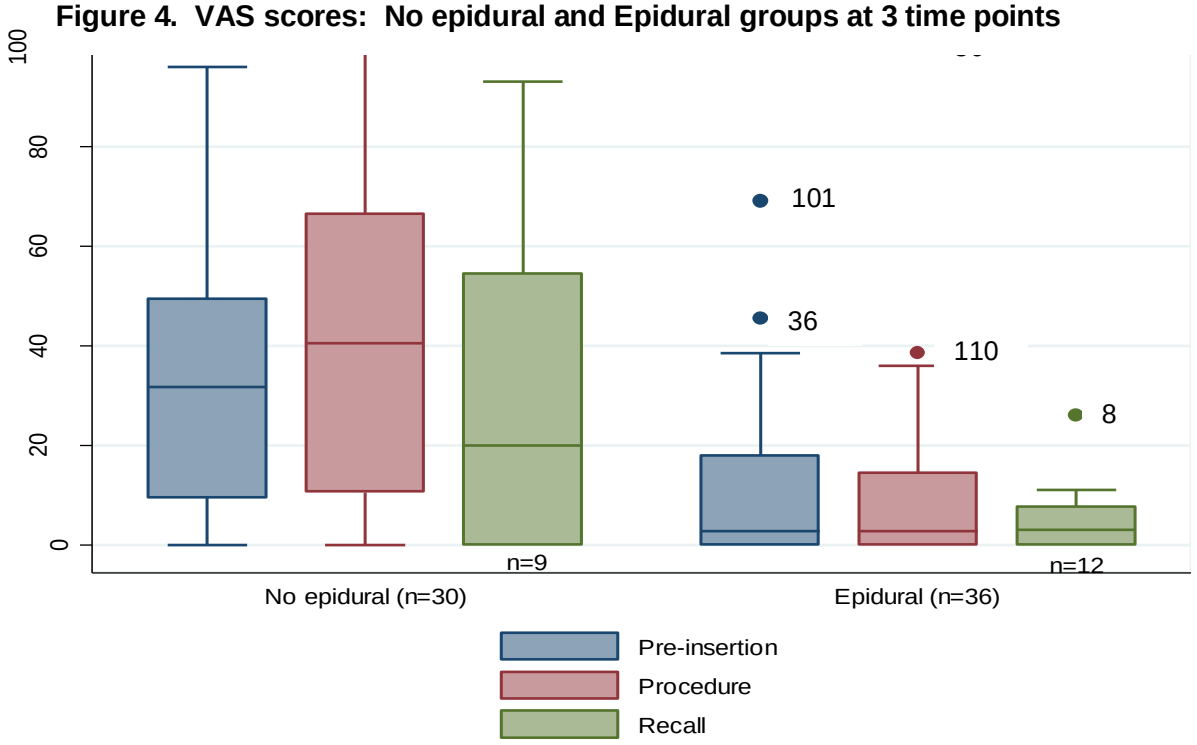


Table 3. VAS score outliers

Patient ID	Pre-insertion	Procedure	Recall
36	*45.5	*100.0	---
101	*69.0	31.5	---
110	30.0	*38.5	---
8	28.5	36.0	*26.0

* = outliers

VRS scores are shown in Table 4. Pre-insertion pain was rated as none/mild in 50% and 94.4% of the no-epidural and epidural groups, respectively. Procedural pain was rated as none/mild in 53.3% and 88.9% of the no-epidural and epidural groups, respectively. Two-thirds (66.7%) and 100% in the no-epidural and epidural of the participants rated their pain as none/mild, respectively, upon recall during their interviews. The pre-insertion pain was rated

as moderate/severe in 50% and 5.6% of the no-epidural and epidural groups, respectively. The procedural pain was rated as moderate/severe in 46.7% and 11.1% of the no-epidural and epidural groups, respectively. Upon recall 33.3% and 0.0% in the no-epidural and epidural groups rated their pain as moderate/severe, respectively.

Table 4. VRS scores *n*(%): No epidural and Epidural groups at 3 time points

	No epidural (*n* = 30)	**Epidural** (*n* = 36)
No pain / Mild pain		
Before IUD placement	15 (50.0)	34 (94.4)
IUD placement	16 (53.3)	32 (88.9)
Recall[‡]	6 (66.7)	12 (100.0)
Moderate pain/ Severe pain		
Before IUD placement	15 (50.0)	2 (5.6)
IUD placement	14 (46.7)	4 (11.1)
Recall[‡]	3 (33.3)	0 (0.0)

[‡]Recall: No epidural *n* = 9, Epidural *n* = 12

Of the nine interviewees who did not have an epidural, two (22.2%) stated they were “satisfied”, and seven (77.8%) stated they were “very satisfied” with the overall IUD insertion procedure. All 12 (100%) of the interviewees who had an epidural in labor rated their overall satisfaction with the experience as “very satisfied” (Table 5).

Table 5. Participant satisfaction scores, *n* (%)

Satisfaction	**No epidural** *n* = 9	**Epidural** *n* = 12	**Overall** *n* = 21
Very satisfied	7 (77.8)	12 (100.0)	19 (90.5)
Satisfied	2 (22.2)	0 (0.0)	2 (9.5)
Neutral	0 (0.0)	0 (0.0)	0 (0.0)
Dissatisfied	0 (0.0)	0 (0.0)	0 (0.0)
Very dissatisfied	0 (0.0)	0 (0.0)	0 (0.0)

Ratings for provider ease-of-insertion were similar between the two groups. Of the 30 no-epidural IUD placements, 26 (86.7%) were rated as "easy" or "somewhat easy". Thirty-two of 35 (91.4%) placements were rated as "easy" or "somewhat easy" in the epidural group (one procedure was not rated by the provider). In each group, three IUD insertions were rated as "somewhat difficult" and none were rated as "difficult" (Table 6).

Table 6. Provider ease of IUD insertion, *n*(%)

Provider ease of insertion	**No epidural** *n* = 29*	**Epidural** *n* = 38	**Overall** *n* = 67
Easy	15 (51.7)	19 (50)	34 (50.7)
Somewhat easy	11(37.9)	16 (42.1)	27 (40.3)
Somewhat difficult	3 (10.4)	3 (7.9)	6 (9.0)
Difficult	0 (0.0)	0 (0.0)	0 (0.0)

*one missing data point

One of the interviewees who did not have an epidural was given 50mcg of fentanyl three minutes prior to IUD placement. More than one attempt was required to place the IUD in this case and placenta delivery to IUD placement time was 12 minutes. She rated her pain as "severe" at all three time points and rated her satisfaction as "satisfied". Another interviewee who had more than one insertion attempt and no epidural did not receive fentanyl. She rated her pain as "moderate" at all three time points and was "very satisfied" with the insertion procedure.

Qualitative Results

We explored four primary domains with our interviewees; decisional influences, experience of procedure, decisional regret, and knowledge and use of contraceptive methods. During the process of conducting the interviews and transcript analysis, we observed that the participants' report of the informed consent process was an additional area worth exploring.

We conducted 21 interviews; nine with women who did not have an epidural and 12 with women who had an epidural. Fifteen of the 21 interviewees were consented for the procedure during antenatal care and six were consented at the time of admission to our labor and delivery ward. Interviews lasted between 25-40 minutes. There were minimal interruptions by hospital staff during the course of all interviews. If other people (e.g. family, partner) were in the room at the time of the interview, they were invited to contribute per the interviewees' consent. One interviewee received 50 mcg of fentanyl three minutes prior to IUD placement. Two of the interviewees who had an epidural did not undergo pain scale assessment at the time of IUD placement.

Table 1 depicts demographics for the interviewees. All but three of the interviewees identified as being Hispanic and six women were SSO. Comparative analyses of the qualitative data of the Spanish-speaking vs. the English-speaking women did not reveal significantly different responses. It is worth noting, however, that three SSO women were the only participants with prior knowledge of immediate post-placental IUD insertion. In addition, three

uninsured SSO women would have elected to have a postpartum tubal sterilization but could not afford it.

Notably, analysis of the responses between women who did not have an epidural and those who had an epidural did not yield major demonstrable differences regarding their procedure experiences (with the exception of the recall pain assessments) or report of decisional regret. Eleven women were identified as having difficult or stressful labor or IUD placement experiences for the following reasons: 1) vacuum-assisted delivery or modified Ritgen maneuver performed (n=3), 2) newborn was immediately transferred to pediatric assessment for meconium or congenital anomaly (n=3), 3) more than one IUD insertion attempt (n=2), 4) self-identified "difficult" labor (n=3). There were no significant differences between the narratives of these women and the other interviewees. Appendix C is a list of illustrative participant quotes by domain.

Decisional influences

The overwhelmingly dominant theme of why women elected to have an IUD placed immediately following delivery was the convenience of doing so. They reported that they anticipated it would be far easier to undergo the procedure as a continuation of giving birth, rather than having a separate, potentially painful, interval insertion ("already here I might as well… knock it out, you know, two birds with one stone."). They recognized the logistical and financial challenges of returning for a postpartum visit as well as the risk of getting pregnant during that interval ("…he works and sometimes I have no car to

come here."). In addition, interviewees acknowledged the forget-ability of the IUD, ("Not having to worry about it on a daily basis or forgetting and having to make up for it. It's already there, it's not having to be worried about… the scariness of missing it and then maybe possibly having another child."). When prompted women reported that effectiveness was very important when choosing a contraceptive method, however few women specified that IUDs are superior to other methods at preventing pregnancy.

The majority of women discussed their decision with at least one other person; i.e. their partner, a family member, and/or a friend. Some women recognized that it's important for women to make an individualized choice regarding birth control, ("I think the thing you have to think about the most when you choose your birth control is that is it something that's gonna work for you.").

Women reported that past experiences with birth control methods, including IUDs, were a determining factor in their decision to have an IUD placed after delivery. Issues that were raised included, but were not limited to, forgetting oral contraceptive pills, unintended pregnancy, and various unfavorable side effects caused by other methods. Eight women had used IUDs previously and expressed that they had an overall favorable experience with it, with the exception of one woman who had it removed after a month secondary to cramping. Three women wanted to have a post-partum tubal ligation but were uninsured and therefore couldn't afford it. They expressed relief to have the option of immediate post-placental IUD placement at no extra cost.

Experience of procedure

None of the interviewees were able to recall detailed aspects of the IUD placement procedure. In addition, none of the women perceived an imposition on their delivery experience because of having an additional procedure and possibly extra people in the room ("…to me it wasn't that big of a deal…. to have one more procedure. It was kind of I'm already in this position… might as well just get it done now instead of later."). Two participants noted that the insertion took more than one attempt; neither woman had an epidural and the ease-of-insertion was rated as "somewhat easy" for both. In general, interviewees noted that necessary equipment and the IUD was immediately available for the procedure, thus expediting the procedure. Two interviewees recalled that the IUD or equipment was not immediately available in the room. Most women reported that they weren't paying close attention to the IUD insertion process, but rather were distracted by their newborn and they remarked that this was a positive aspect of the procedure experience (17/21 interviewees), ("…they gave me the baby right away and I was just focused on the baby"). This was the case whether the baby was placed directly on the woman's chest after delivery, or if the baby went to the warmer for assessment. Not all women knew beforehand that an ultrasound was going to be used to guide the IUD insertion process. Some interviewees noted that they felt discomfort with the application of the abdominal transducer pressure.

When asked, none of the interviewees had any negative feedback in terms of what could have been done differently, with the exception of the two

women who had more than one placement attempt, ("I imagine they were like students that were trying to place it, because then the last time, when they did place it a doctor came who had more experience."; "…because I was like do they know how they're putting it… you know like it kind of threw me off, like I thought it was just go in and be done.").

All of the women reported that they considered beforehand the pain they might experience during IUD placement. Many interviewees expressed that it was preferable to undergo a potentially painful procedure immediately after giving birth, rather than have an additional painful procedure remote from delivery ("…like I'm gonna be hurting at that time so I prefer to be hurt the same day that I'm hurting, than come back six weeks later"). Eighteen of 21 interviewees reported that they experienced less pain with IUD insertion than they had expected (no epidural = 6/9, epidural = 12/12), ("…it's not really that it hurts a lot when the[y] place the IUD but it's just that it's very, very close to the birth, right?"). Two women in the no-epidural group had more pain than expected, and one woman without an epidural expected it to hurt as an extension of delivery and had no expectations otherwise ("like I said, everything's so tender, so raw, so… so anything that touches down there would have hurt anyway").

Of the 15 women who were asked to compare labor pain with IUD insertion pain, 12 reported that their labor was more painful (no epidural = 6, epidural = 6), ("…you're not associating the pain with the IUD but the pain you kind of just all over went through."). Two women who did not have an epidural

said that labor pain was equal to IUD placement pain, and one woman who did not have an epidural "forgot everything". The majority of women expressed surprise that the procedure was brief, ("you're done? Like really? That was it? "). They also noted that the transition between placental delivery and IUD placement was relatively seamless, ("…the placenta came out and um, they just put it in right away. I didn't feel anything."). When asked about anticipated procedure duration, most women thought it would take longer than it did. Three women reported that they expected the procedure to last from 15 to 40 minutes, ("I thought maybe like 30 or 40 minutes or something.").

Decisional regret

None of the interviewees expressed regret about having an IUD placed post-delivery, despite their epidural status. Women reported feeling "relief", "secure", "happy" and "reassured" to have their birth control in place prior to discharge from the hospital. All of the participants stated they would consider undergoing post-placental IUD insertion again, and would endorse this approach to postpartum birth control to family members and friends (one participant was not specifically asked about method endorsement).

Contraceptive knowledge

Women reported a history of use of a variety of contraceptive methods, and some had used several methods; contraceptive pills/patch (n=13), depot-medroxyprogesterone acetate (DMPA) (n=10), IUD (n=8), condoms (n=4).

Interviewees offered mixed responses, both favorable and unfavorable, when asked about prior knowledge of IUDs.

Informed consent

All women except one reported that the counseling process around post-placental IUD placement was adequate and provided "just enough" information for them to make an informed decision. Regardless of the counseling setting (prenatal visit vs L&D), few interviewees were able to cite more than one risk of the procedure without prompting. Thirteen women verbalized the risk of expulsion unprompted, five needed to be prompted, and two did not recall expulsion as a risk. When asked about the greatest risk of having an IUD placed after delivery, many women cited infection or the IUD becoming "embedded" or "ingrown". One woman thought that the biggest risk was that her "uterus would tear" and that she would subsequently be infertile. Most of the interviewees reported that they were not provided with a detailed explanation of how the procedure is performed, e.g., that an ultrasound would be used to guide insertion, ("...you see the ultrasound you'd be like, wait...are they looking for another kid?"), nor were they informed about what to anticipate in terms of procedural pain or duration. One woman talked at length about how she felt very well counseled on the on the risks, benefits, alternatives and procedural elements. She reported that she had undergone extensive counseling during more than one prenatal visit. She stated that because she had comprehensive counseling with her provider, this had a positive impact on her experience.

Participants were asked to role play counseling a friend or family member about immediate post-placental IUD insertion. When doing so, the women overwhelmingly focused once again on the convenience of having the IUD placed after birth, and the forget-ability of IUDs ("Something that's just in there, it's with you, and it goes with you wherever you need it."). During this exercise, none of the participants discussed the risks or offered an explanation of the procedure unless prompted. Although some interviewees recognized that a given individual's pain perception is a unique experience, they thought that counseling about pain expectation would be helpful for women considering post-placental IUD placement.

Discussion

This mixed method pilot study of post-placental IUD placement quantified women's procedural pain, and also characterized structural drivers in women's decision-making processes, explored their subjective experiences in the context of labor, and identified areas of improvement for the informed consent process.

The primary aim of our quantitative data collection was to establish mean pain scores, on a VAS, among women who did and did not elect epidural analgesia during labor. Neither groups' scores demonstrated a normal distribution and standard deviations were large; we therefore also reported median scores with inter quartile ranges. The VAS scores of the no-epidural group demonstrated the maximum range, and those of the epidural group exhibited a floor effect. It is possible, although unlikely, that more observations would have revealed a distribution of scores with a demonstrable mean, particularly in the no-epidural group; even in that case, the standard deviation would likely remain large. Categorical measures of pain in this case were more informative in quantifying the pain component of women's experiences.

Interview data further enhanced our understanding of women's perceptions of the procedure. With the exception of recall pain scores, epidural groups did not differ significantly in their perceptions. Satisfaction scores were high and women were pleased with their decision for IUD insertion prior to hospital discharge. Overwhelmingly, interviewees reported that the convenience of immediate post-placental IUD insertion and the forget-a-bility of IUDs were key

determinants in their decision. Furthermore, many women stated that they perceived IUD placement as a continuation of labor (i.e., already in pain from labor and "in the position"). They reported immediate insertion was far more acceptable than overcoming barriers to get to a postpartum visit and endure another painful procedure. Several interviewees recognized that leaving the hospital without contraception initiation increased the risk of rapid repeat pregnancy.

The majority of women reported that labor pain was greater than or equal to that of IUD placement, regardless of epidural status. In addition, most interviewees indicated that the pain of IUD placement was less than expected. Fear of pain may limit the uptake and/or willingness to recommend post-placental IUD insertion. Our pain data may be helpful to women considering this option, as well as to clinicians inserting postpartum IUDs. These qualitative findings as well as our quantitative pain data should be key elements in counseling for the post-placental IUD insertion procedure.

Another prominent theme in our interviews was the distracting influence of the newborn; women's attention was focused on the newborn, thus rendering the IUD insertion procedure less intrusive and painful. Women disclosed no regrets about their decision, would make same decision again, and would endorse immediate post-delivery IUD placement to others. All interviewees were "very satisfied" or "satisfied" with the overall IUD insertion experience, consistent with findings of Kumar et al. [17].

We identified gaps in patient comprehension and/or recall of important elements of the informed consent process for the procedure. This is a common occurrence and is certainly not limited to IUD insertion [23-26]. While the majority of women stated they had adequate counseling, none could cite more than one risk of the procedure without prompting. Some women did not recognize that the most critical risk is that of expulsion. Participants did not have a grasp on specifically how and when the IUD would be inserted, and that the procedure involved abdominal ultrasound-guided placement. Although patients' ability to differentiate between procedural and research consent was not an objective of the study, we noted that several participants' responses were indicative of misperception around this issue, particularly when women were enrolled at the time of their admission to labor and delivery. This occurred despite our concerted efforts to avoid such confusion, and we took the necessary time to redirect participants as necessary. This phenomenon remains an ongoing challenge for clinical researchers and we must recognize the issues around enrolling vulnerable populations and avoiding "therapeutic misconception". Therapeutic misconception is a concept that describes a condition whereby a research subject falsely assumes personal benefit by virtue of participating in a research study, rather than taking into account actual clinical risks and benefits [27].

Our study had several limitations. Most women in our study were Hispanic and of low socioeconomic status, reflective of our general obstetric population. We did not interview enough women to determine differences in

perceptions across socioeconomic strata, if they exist. However, because our participants were primarily of low socioeconomic status, we captured the experiences of women who may be at risk of poor access to care and therefore our findings are relevant to reaching this population. Additionally, our study took place in an academic teaching institution and all but one of the IUDs was placed by a resident physician. While these factors limit the generalizability of our findings, our participant demographic represents the very women who have multiple barriers to access highly effective contraception. Poor women and women of color are disproportionately affected by logistic and financial obstacles to family planning services [28, 29] and more widespread availability of post-placental IUD placement has the potential to significantly reduce these health disparities.

All but one of the IUD placements in this study were performed by ob-gyn resident physicians who had undergone competency training in the procedure (one procedure was performed by an attending physician). However, as the study progressed and systems were more firmly established, residents' proficiency likely improved. It is possible that improved mastery resulted in different perceptions among women at the start of the study compared with the end. Providers incorporating post-placental IUD insertion into their practice, should appreciate this learning curve and understand that patient-centered outcomes, as well as lower expulsion rates, are likely to improve with experience [30-32]. Having the necessary materials and personnel immediately available to

place the IUD results in expedited placement, potentially decreasing the risk of expulsion [8-10], and providing a more satisfactory experience for the patient.

We recognized from the outset that measurement of pain with IUD insertion so close to the labor and delivery experience is a confounded assessment. However, this phenomenon may have a positive impact on a woman's IUD placement experience as suggested by our qualitative findings.

All IUDs were sourced by our LARC grant supply or provided by Medicaid. Some participants may not have had access to contraception had it not been for our study, potentially contributing to social desirability bias, particularly in the interview setting.

Our study lays the groundwork for future patient-centered research on post-placental IUD insertion. Our study examined women's perceptions in the context of a standardized ring forceps insertion technique. Other insertion techniques, including manual insertion and IUD inserter placement, are used and were not evaluated in this study. Further research comparing insertion techniques may yield results that would suggest superiority of one technique over another from a patient perspective. Additional qualitative research may reveal important differences in acceptability, uptake and procedure experience across the socioeconomic spectrum. Given the cognitive, physical, and emotional burden of the labor experience, measuring pain immediately after delivery may be a problematic undertaking. However, as pain is an integral part of any procedure, we recommend that this component of the patient experience

continue to be evaluated, perhaps with a categorical measure instead of a VAS. Finally, it would be informative to conduct follow-up assessments to determine how women's perceptions may change over time, as well as to ascertain IUD continuation and expulsion rates.

Implications

Our pilot study fills a critical gap in our understanding of women's experiences of post-placental IUD insertion. We were successful in quantifying women's perceptions of pain using a single insertion technique. We also initiated meaningful dialog with women about the determinants of their subjective experiences and thoughts from the point of decision-making through post-insertion reflections. As the practice of post-placental IUD insertion becomes more widespread among clinicians, and as public and private reimbursement for the procedure and device increases [15, 33, 34], it is imperative that we appreciate how patients experience the procedure. Our findings are instrumental to appropriate counseling of women and for improving the informed consent process. As our understanding of patient's perspectives on post-placental IUD placement develops, we may be able to effect an increase in uptake, with a subsequent decrease in the incidence of rapid repeat pregnancy and its many known risks [7], as well as increase overall utilization of IUDs.

Recommendations

1. Clinicians should offer eligible women post-placental IUD placement in the context of a comprehensive overview of the available methods. Women should

be informed of the details of the insertion procedure as well as expectations for procedural pain and duration.

2. Regional anesthesia is not necessary specifically for pain alleviation relative to the IUD insertion procedure. A rapid-onset, short-acting analgesic (e.g., fentanyl) may be used pre-IUD insertion, with attention to onset of action and peak effect to achieve an optimal result.

3. Place the newborn on the mother's chest immediately after delivery and during the IUD insertion process, if possible.4. L&D staff should have the IUD, necessary instruments and ultrasound immediately available to expedite IUD insertion after placental delivery.

APPENDIX A.

Semi-structured interview guide

Thanks for taking the time to share your thoughts with us today. We're doing these interviews to find out from women how they feel about having an IUD put in right after having their baby. We plan to use the results of these interviews to make the procedure as acceptable and satisfactory to women as we can. We also value your opinions about IUDs and birth control in general. As a reminder, we'll be recording this interview and we will keep your answers confidential. Your name and other identifying information about you will not be associated with the interview in any way. This interview should only take 30-40 minutes of your time. You will be receiving the gift card from one of our research team members before discharge form the hospital.

I want to confirm that you have signed the research consent form and that you understand this interview will be recorded and transcribed for analysis. (Patient verbalizes consent)

Do you have any questions before we get started?

(Identify who is in the room, i.e. if family member, partner/FOB, etc.)

(Interviewer: Ask how she's doing, how the birth went, how is the baby doing AND Are you planning to breastfeed?

I. Decisional influence

The first section of the interview has to do with exploring your decision to have an IUD placed right after giving birth

IA. I would like to start off by having you think back to when you first made the decision about having an IUD put in right after having your baby. Can you please share with me what kinds of things led you to make that decision?

Prompts: Cost, insurance, convenience, friend or family told you about it.

(If applicable) What birth control have you used after having your other babies?

IB. What's your ideal family size? Who makes these decisions in your family?

Prompts: You? Partner?

How did you come to these decisions?

IC. Did you speak to your partner, or friends/ family about your decision to have an IUD placed right after giving birth?

Prompts: (If yes) What kinds of things did you talk about with them and what were their opinions about it?

Do you have friends or family who had an IUD placed right after giving birth?

Do you know if they were happy with their choice?

ID. What do you recall your provider telling you about having an IUD placed after giving birth?

Prompts: Were you given enough information?

Was it too much information?

Were you told about the risks? benefits? (flush out her understanding of each risk and benefit – what does she recall?

What did you feel like was the <u>biggest risk</u> of having the IUD inserted?

What did you feel like was the <u>best thing</u> about having the IUD inserted?

IE. Women have different options about when to get an IUD after they've had a baby. Some decide to wait, for example, until a postpartum visit or sometime after that. Please tell me about your decision to do this right after having the baby; what made this appealing to you?

IF. Did you have specific concerns before having the IUD placed?

Prompt: What concerns did you have?

Did you talk about these concerns during your prenatal visits?

Did your provider adequately answer your questions/ address your concerns?

IG. Why did you select the (Mirena/ Copper) IUD over the (Mirena / Copper)?

IH. Have you used an IUD in the past? Tell me about how that was for you.

Prompts: When did you have it placed?

What kind of IUD was it; hormone IUD (Mirena) or non-hormone IUD (Copper/ Paragard)?

Were you satisfied with the IUD? Why or why not?

That's the end of the section on your decision to have the IUD inserted right after giving birth. Do you have anything else to say about your decision?

II. Experience of procedure

In this next section, I'd like to ask you a few questions about your experience of having the IUD inserted right after you had your baby.

IIA. I'd be interested to hear how the procedure went from your perspective. Can you walk me through what you remember about having the IUD put in?

Where was the baby when you had the IUD placed? Was this OK? (Explore if she thought the baby was a distraction during the procedure, if she was bothered by not having the baby at the chest if this was the case, etc.)

IIB. If you could change anything about how the procedure went, what would that be?

Prompts: Too many people in the room? Not being with the baby right away? Too much "busyness" after the baby was born?

Was it too long of a procedure?

Is there anything that could have been done that would have made the procedure better for you?

IICa. You rated your pain with the procedure on two pain scales for us. Think back to having the IUD placed…. I'm now going to ask you to rate the pain you had with the procedure on the same two pain scales. (Re-educate about the pain scales then administer the interview VAS and VRS).

IICb. Can you separate the pain with the birth and the pain with the IUD placement? (Explore: Were they the same? Which was worse? What kind of pain (if any) did she feel with the procedure?

IID. Tell me about the expectations you had about procedure.

Prompts: Was the pain you experienced more or less than you expected to have?

How long did you think the procedure was going to take?

Was everything ready to go to put the IUD in? Did you have to wait?

That's the end of the section on your experience with the IUD placement procedure. Do you have anything else to share about your experience?

III. Decisional regret

This is a new section of the interview. Now that you've had the IUD put in, I have a few questions to find out more about how you feel about this decision.

IIIA. Thinking back to the procedure, would you have made a different decision about when to have the IUD inserted (for example, like waiting until your postpartum visit to have the IUD inserted (after 6 weeks from now)?

Prompt: Why or why not?

IIIB. I'm also interested in any feelings you might have about having the IUD inserted right after giving birth?

Prompts: Relieved to have your birth control taken care of?

Too much of a "big deal" to have placed right after giving birth?

IIIC. Would the amount of pain you had with the IUD insertion affect your willingness to have an IUD placed again after having a baby?

Prompt: How about willingness to recommend this kind of birth control to other women?

IIID. In general, would you be likely to recommend to family members or friends having an IUD placed right after giving birth?

Prompt: Why or why not?

IIIE. Is there anything that you wish your provider had told you about the procedure before the IUD was placed? (really tease this one out – this a big reason why this study is being done; good counseling = better uptake.)

Prompt: Did your provider to talk with you about the amount of pain you might have with the procedure? (If no): Would this have been useful information for you? (If yes): Was this information useful to you?

That's the end of this section. Do you have anything else to share about how you feel about your decision to have the IUD placed after giving birth not that it's done?

IV. Knowledge/ awareness

This is the last big section of the interview. I have just a few more questions about your previous experiences with birth control.

IVA. Can you tell me what other forms of birth control have you used? (Explore with her)

Prompts: Did you consider using any other methods after having your baby?

Which ones?

Why did you choose an IUD this time over the other methods?

IVB. **What did you know or hear about IUDs prior to this experience?**

Prompt: What were your opinions about IUDs?

IVC. Tell me about how you knew about being able to have an IUD inserted right after giving birth?

Prompts: From your prenatal provider? Hearing about this study? Friends or family?

IVD. Thinking about all the things we've been talking about, what is most important to you as far as a birth control method goes?

Prompts: Effectiveness?
Ease of use?
Side effects ?
Reversibility?

Cost?

IVE. Now that you've had the IUD insertion experience after giving birth*, knowing what you know now*, how would you counsel a friend or relative on having the procedure done?

Prompts: Risks & benefits?
What to expect for pain with procedure and other aspects?

IVF. Who do you trust more when considering birth control? your Provider? / friend? / family? (Explore how she views the advice she gets from her provider vs others/ testimonials, etc).

That's the end of this section about birth control awareness. Is there anything else about IUDs or birth control in general that you want to share with us?

V. Standardized questions

We're almost done! I'd like you to rate your overall satisfaction with having an IUD placed right after giving birth. On a scale of 1 to 5 where 1 = lowest satisfaction and 5 = highest satisfaction (show and explain the scale).

VA. Please rate your overall satisfaction with the procedure:

1 = lowest satisfaction, 5 = highest satisfaction

1 = Very dissatisfied	1
2 = Dissatisfied	2
3 = Neutral	3
4 = Satisfied	4
5 = Very satisfied	5

Satisfaction can be kind of a complicated thing to measure and understand. What kinds of things do you think about when considering your satisfaction? What made this satisfying/ not satisfying.

Thank you for sharing your time with us. Is there anything else you'd like to let us know about so that we can help make IUD insertion, after giving birth, a positive experience for other women.

_____ _____ _____

Interviewer Date Time

APPENDIX B. CODING STRUTURE

DECISIONAL INFLUENCE

1) Counseling environment
- 1A. Prenatal visit
- 1B. L&D / admit

2) Influential network
- 2A. Female relative
- 2B. Partner
- 2C. Friends
- 2D. Medical provider

3) Informed consent
- 3A. Perceived adequacy
- 3B. Comprehension
- 3C. Perceived risks
- 3D. Perceived benefits

4) Key factors
- 4A. Reversibility
- 4B. Effectiveness
- 4C. Convenience
- 4D. Forget-a-bility
- 4E. Side effect profile
- 4F. Prior BC methods
- 4G. Hx IUD use
- 4H. Cost
- 4I. Media, other

5) Factors - Choice of IUD
- 5A. Duration of effectiveness
- 5B. Side effects profile
- 5C. Other

6) Prior knowledge of post-placental IUD

EXPERIENCE

6) Recall of procedure events

7) Factors influencing experience
- 7A. Prior knowledge of events
- 7B. Newborn as a distraction
- 7C. Instruments/US ready
- 7D. Pain - expectation
- 7E. Procedure duration expectation
- 7F. Other

8) Difference btw labor and IUD pain
- 8A. labor > IUD
- 8B. labor < IUD
- 8C. labor = IUD
- 8D. Don't know

DECISIONAL REGRET

9) Feelings about decision

10) Would recommend to others?
- 10A. Yes
- 10B. No

11) Revisit perception of counseling adequacy
- 11A. Adequate
- 11B. Inadequate

KNOWLEDGE /AWARENESS

12) Contraception - hx of use
- 12A.OCP/ring/patch
- 12B. DMPA
- 12C. IUD
- 12D. Implant
- 12E. Barrier

13) Experiences with other methods
- 13A. Reversibility
- 13B. Effectiveness
- 13C. Convenience
- 13D. Side effect profile
- 13E. Forget-ability

14) Prior knowledge of IUDs
- 14A. Favorable
- 14B. Unfavorable
- 14C. Mixed

15) Counseling/discussing a family member/ friend re: immediate post-placental placement

16) Interview Dynamics

17) Quotables

APPENDIX C

Participant quotes

Decisional influences	"…my biggest concern was having a newborn baby and not having like the time to remember to take the pill and all that, and I didn't want to risk, you know, getting pregnant right away." "…like a lot of people don't have the time to you know reschedule and… or forget, you know to… have to go back and a lot of people don't even go back to their six weeks checkup that I know of." "…for Mexicans sometimes we say, oh, I'll do it later. I'll do it probably in two weeks. I'll make an appointment. By the time you make the appointment you're pregnant already, so I was like, no, that's not gonna happen to me. I just want to do it right away." "I don't know…if I'm gonna be able to drive to the clinic with the baby so… it was better like do it right away." "I never went back for my six weeks…I was doing so much and then I'm like, oh, great, now I'm pregnant again." "Well, I wanted to have an operation so I would not have more babies. But it is very expensive…and the people in the clinic that I used to go told me that I had to have 5 babies so they could do a tubal ligation, so I decided to get the 10 year device."
Experience of procedure	"I thought it was gonna be, you know, difficult. But it wasn't. I think I didn't feel anything." [N] "…then they placed the IUD so there was no time for the pain to go down a little." [N] "I think you're thinking more about the pain of the delivery… in reality it was more the pain of the delivery than the IUD." [Y]

	"It was actually to me painless and quick. It was over before I even knew it was going in." [Y] "I was thinking like, oh, I wonder if that's gonna take away from, you know, like bonding with the baby and all that but it didn't at all because I was basically up here with my baby and you guys were doing your thing." [N] "…cause they had to get it [IUD] through another person or something like that. They have to order it or something like that so it took awhile" [N] "I was shocked that they had it [ultrasound] there...I think if you would go into it and you see the ultrasound you'd be like, wait. Are they looking for another kid?" [Y]
Decisional regret	I: "…with the amount of pain that you had with the placement procedure, would that change your willingness to do it again?" P: "No, like I said, everything was already hurting, instead of having to…possibly go back and have it hurt again, getting it inserted." [N] I: "…if you had another baby, uh, the pain that you felt, would that affect your decision to have or not have an IUD placed again or no?" P: "No, no, no. It wouldn't affect it." [N] I: "Would you do it again? Would you have another IUD placed?" P: "Oh, yeah." [Y] "Even if it did cause me a little more pain because honestly I think it's worth it." [Y]
Contraception knowledge/ experience	"with having an IUD in the past, I knew that worked best for me. I knew…of any risks of…like heavier bleeding and stuff like that with an IUD, but to me that was something that… I... that risk was better than the other" "Just that it like could fall out or move, but same thing as missing your pill and getting

	pregnant again, so..." "That if you lift…anything heavy, it will come out. Uh, what else? Oh, he was telling me that it was gonna be um, uncomfortable for him… when you have sex." "…like my mom she said back in the day they put her on one and it had like incarnated on her, you know like stuck inside."

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