Is this going to hurt?

An investigation into managing pain for the insertion of intrauterine contraceptives for women in the UK

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1. Abstract

The insertion of intrauterine contraceptives (IUCs) can be an invasive and painful procedure for women, and current guidelines by the Faculty of Sexual and Reproductive Health (FSRH), and National Institute of Clinical Excellence (NICE) do not provide recommendations for analgesia as standard. This survey and review demonstrate evidence for the pain experienced by women during insertion of IUCs and summarises literature on pain modulation methods. IUCs are devices which alter the environment of the uterus and cervical mucus to be inhospitable to a fertilised egg, thus avoiding unwanted pregnancy. Some are also licensed for use in treating dysmenorrhea, or painful periods. Primary data was sourced through an online survey on SurveyMonkey.com and shared via social media to 75 anonymous women who had had an IUC inserted. The survey results show the most common pain score on a scale of 0-10 was 8, and 46% participants felt the pain experienced was higher than anticipated. Women who had not had children prior to the procedure (nulliparous) had higher mean pain scores than women with children (multiparous). These findings confirm previous research proving nulliparous women find the procedure more painful than multiparous women. Current literature demonstrates evidence of the efficacy of paracervical lidocaine blocks as pain relief for IUC insertion (IUC-I). The findings from this study provide evidence for a more comprehensive review of protocols for IUC-I in the UK, as currently no analgesia is licensed or recommended, and it can be an unnecessarily painful experience for women.

2. Introduction

2.1 Intrauterine contraceptives

IUCs are T-shaped devices implanted in the uterus, also known as intrauterine devices (IUDs) or intrauterine systems (IUSs). They are implanted by opening the vaginal canal using a speculum and a 'sound' to dilate the cervix and provide space for the IUD/IUS inserter (Fig.1). The cervix is stabilised in position by using single or multi-toothed forceps, called a tenaculum (Fig.2). The inserter is then introduced to the cervix, and once the healthcare professional feels the fundus of the uterus with the inserter, it can be retracted and the arms of the IUC opened, to leave the threads hanging into the vagina. This procedure is undertaken in GP surgeries, sexual health clinics, and hospitals, by specifically trained professionals. There is no specified protocol for use of analgesia or anaesthetic for this procedure (FSRH, 2015).

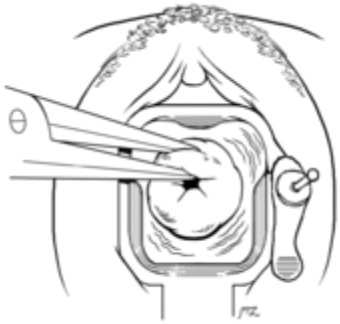

Figure 1. Drawing of speculum in vagina to visualise cervix, and tenaculum in place to stabilise it.

(Image reproduced from *A Book for Midwives,* Klein, Miller and Thomson 2020 with permission)

Figure 2. Schematic diagram demonstrating insertion steps for Mirena IUS, after speculum and tenaculum placement. This process is the same for other forms of IUC.

(Image reproduced from *www.drugwatch.com/mirena/insertion* , Llamas, 2020)

There are several forms of IUCs, some of which contain and secrete different amounts of levonorgestrel, a progestogen hormone, named by brand name: Kyleena, Mirena, Levosert and Jaydess, and are licensed for between three and five years of use as contraceptives. The Mirena IUS is also licensed for management of menorrhagia, and in menopause or perimenopause as the progesterone component for combined hormone replacement therapy. The Levosert IUS is licensed for use for management of menorrhagia as well as for contraception.

The IUD contains copper which alters the chemical environment of the uterine cavity and the cervical mucus. There are several preparations, with copper on the stem and arms of the device which can be used for between five and ten years. These are only licensed for contraception.

IUCs are a form of long-acting reversible contraception (LARC), and are some of the most effective forms of avoiding unintended pregnancy since they are a 'fit-and-forget' method, which remain effective for several years, unlike daily pills or regular injections (FSRH, 2015). For this reason, LARCs are encouraged for younger women who are not ready or are not interested in starting a family in the near future.

2.2 Rationale

Current guidelines by the FSRH recognise that the insertion of an IUC can be painful, with predictive factors for painful experience: nulliparity, anxiety, length of time since previous pregnancy or previous period. Therefore, several modes of pain relief have been investigated in research for this procedure, although none are mandatory to provide (FSRH, 2015). The NICE guideline for IUCs does not include specification for the use of analgesia at insertion, but recognise that the procedure can be painful, and some healthcare professionals use analgesia at their own discretion (NICE, 2018). Considering the breadth of research regarding pain relief options for this procedure, a survey was curated to collect information about women's experiences of insertion of IUCs. This then provided rationale for a short review of current evidence for modulation of pain during IUC-I.

2.3 Research questions

In order to address the objectives and rationale two research questions (RQs) were formed:

RQ1. Is IUC-I painful?

RQ2. Are women provided with adequate analgesia for this procedure?

3. Methodology

3.1 Ethical approval

A statement (Appendix 9.3) prior to questions stated the aims of the survey, detailed information regarding anonymity of answers, and included a statement regarding consent if continuing with the survey after reading the statement. It stated that any questions can be skipped, and the survey can be terminated at any point whilst taking it and the participant's answers be destroyed. Patient withdrawal after submission was not possible, however my contact details were included for any questions regarding the survey or the project.

I submitted my survey through Bournemouth University Online Ethics Checklist (Appendix 9.1). This was approved with minor changes to the opening statement, as it suggested patients could withdraw their answers after submission, although this was impossible as answers were anonymous.

I also checked my survey with the NHS Health Research Authority and Medical Research Council ethical review site which advised I would not need to submit it for their approval, since it did not meet their requirements (Appendix 9.2).

3.2 Survey design

A 10-question survey was collated using the website SurveyMonkey to provide information on patient experiences of IUC-I, addressing both RQs and collecting relevant background information about the participant which may impact the validity of answers (Appendix 9.3).

I chose to use an online survey as the information collected is potentially sensitive, so preserving the participant anonymity was vital. Most data collected was quantitative, for scientific analysis and to quantify subjective information such as pain.

The draft survey was reviewed by an independent Survey Methodologist, who advised using a readability checker to reduce medical jargon and improve accessibility to participants. Statements were also reworded to reduce leading questions and yield more unbiased responses.

Questions 1, 2, 3 and 4 provided information on variables which may influence pain scores, such which IUC was implanted, when it was implanted, and if their cervix had dilated to give birth before.

Questions 5, 8, 9 and 10 aim to address RQ1. Q5 was the assessment of the insertion pain experienced. For this question, I included the Universal Pain Assessment Tool (UPAT) which is often used in primary and secondary care to rate pain experience (Fig.3). The use of facial expressions, alongside a 0-10 number scale and verbal descriptions of how much the pain is affecting you aims to standardise perceptions of pain. In experimental research, a visual analogue scale (VAS) is often used for patients to rate pain on a line from zero to 100 millimetres. I did not feel this method was appropriate in my study as the pain was historical, so the visual and verbal cues on the UPAT may assist in quantifying pain from memory.

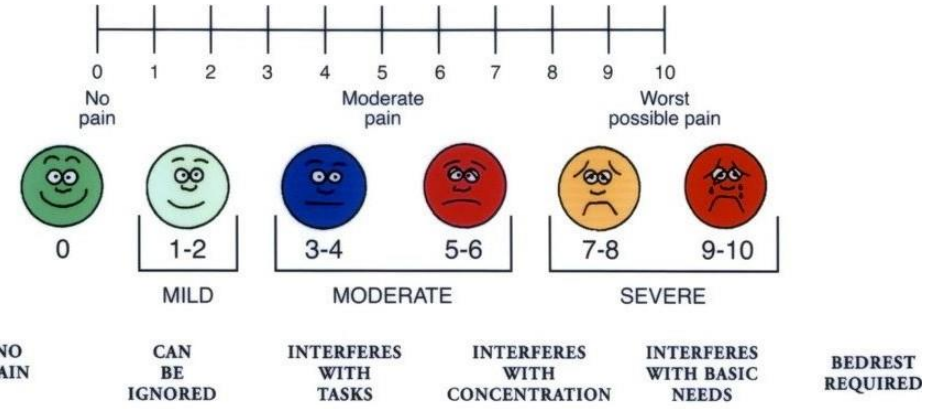

Figure 3. Universal Pain Assessment Tool from Q5 of patient survey

Copyright free, (Dugashavili *et al.*, 2016)

Q8 asks about pain when leaving the appointment and is therefore relevant to RQ1 and 2. Q9 asks about pain expectations and whether the participant felt accurately informed of any pain to expect during IUC-I. The FSRH guidance states a preliminary appointment is required to obtain informed consent and provide necessary information to the patient, as well as ensuring the IUC is appropriate and safe for this patient. Q9 assess whether these expectations from the preliminary appointment were accurate.

Q10 explores additional symptoms the participant may have experienced as a result of the insertion, and an 'Other' option for free text. These results provide information regarding other physical factors confounding their pain experience.

I considered adding a question regarding whether or not they would have the IUC inserted in future due to previous insertion experience, however I did not feel this would be specific enough to provide information regarding IUC-I pain. Some IUC devices are implanted for 5 years, so it would be challenging to weigh up all the benefits and risks of the IUC, alongside future planning for children or different contraceptive choices. For this reason, this question was not included and instead will be addressed in the Discussion section.

Q6 addresses RQ2 and aims to explore variation of what pain relief options women in the UK were being offered. Prior to writing this question, research was conducted of the FSRH, NICE and local NHS guidelines on IUC-I, of which options may be available to patients, to provide as multiple choice answers.

Q7 is regarding pre-procedural analgesia to explore any disparity between practices. Since Q7 addressed the offer of analgesia, rather than the actual acceptance and administration of pain relief, it cannot be determined whether these methods improve pain scores from this survey. This type of data is better analysed experimentally by randomised control trials (RCTs), and subsequent reviews and meta-analyses than in a survey format, due to the presence of confounding variables.

3.3 Sampling and data collection

This survey was shared on my personal social media accounts and then re-shared by 'friends'. I chose to use this method of sampling as it was quick and safe during April 2020, and many of my friends and followers are women of reproductive age who may have had an IUC. I used Facebook, Twitter, Instagram and LinkedIn to share links to the survey, although once clicked the user remained anonymous. I would have liked to have sampled women in reproductive clinics, GP surgeries and gynaecology departments at hospital, to gain a more random cohort, however once COVID-19 was at epidemic levels in the UK, it was not appropriate to be in healthcare settings for research. Additionally, many 'non-essential' procedures such as IUC-I were postponed to expand capacity for potential COVID-19 patients.

The survey link was shared on 6/4/2020 with an aim to receive 50 responses. The survey was live for eight days and yielded 75 responses. 3 participants in my survey had their IUC implanted whilst under a general anaesthetic for another procedure. For this reason, I excluded their answers and pain scores from the results as this would not be representative of the pain experience, though I am grateful for their time spent completing the survey. This sampling method was timely and efficient, and I had a higher response rate than expected in and it was shared nationally, so different participants from across the UK were able to share their data, providing information about varying practices. Undesirably, this method was not random, as I relied on the fact that I had friends or connections who had undergone IUC-I. I could not guarantee that these were all 'true' participants, as everyone had access to the link and there was no proof of IUC required to participate in the survey. Most of my friends and connections are similar to me in age and background, so although I did not collect any personal information, it is likely that the sample was not representative of age, race, and socioeconomic status. Sharing the survey via social media and online also assumed that all the participants are internet literate and able to fill in an online survey.

3.4 Data analysis

Survey answers were presented in charts by SurveyMonkey for visual interpretation of raw data. Results were extracted from the SurveyMonkey website and transcribed into Microsoft Excel for data analysis and presentation.

Two-tailed t-tests were used to compare mean pain scores between two groups of participants e.g. nulliparous vs. multiparous (Appendix 9.8). This test was used as it compares means between groups which are independent of one another, such as different groups of participants who have different experiences. The results of this test provide a p-value, which at 0.05 or below is determined statistically significant. Results above 0.05 show a likelihood that results are random, and down to chance or if equal to or below 0.05, there is a significant correlation.

The analysis of variance (ANOVA) test compares independent means from more than 3 data sets to determine the significance of difference between means. This test was used to compare mean pain scores from Q5 between 5 groups separated by time since IUC-I, as answered in Q2 (Appendix 9.10). ANOVA scores compare means with different n values in each data set where the variance is very different, affecting the mean.

Systematic literature searches were conducted on Embase and Pubmed to retrieve papers for review. Abstracts of relevant studies were read and summarised into a database for personal use and comparison in compilation of the Discussion section.

4. Results

Only results relevant to the RQs are presented, all raw data, statistical tests and graphs are included in the appendix.

4.1 RQ1. Is IUC-I painful?

The modal answer to Q5 on a scale of 0-10 for pain experienced during IUC-I was 8 (severe on the UPAT), the median answer was 6 (Fig.4). The mean average pain score is indicated by the dashed line (5.64).

59% patients surveyed left their appointment in pain, whilst for 37% the pain had resolved (Fig.5).

Alongside pain, Q10 showed 34% participants who answered experienced nausea/ vomiting during their IUC-I appointment, and 34% experienced dizziness/fainting (Fig.7).

47% patients in Q9 felt the level of pain experienced during the IUC-I appointment was higher than expected (Fig.6). 42% felt the level of pain experienced was as described by healthcare professionals, and 10% felt the level of pain experienced was lower than described by healthcare professionals.

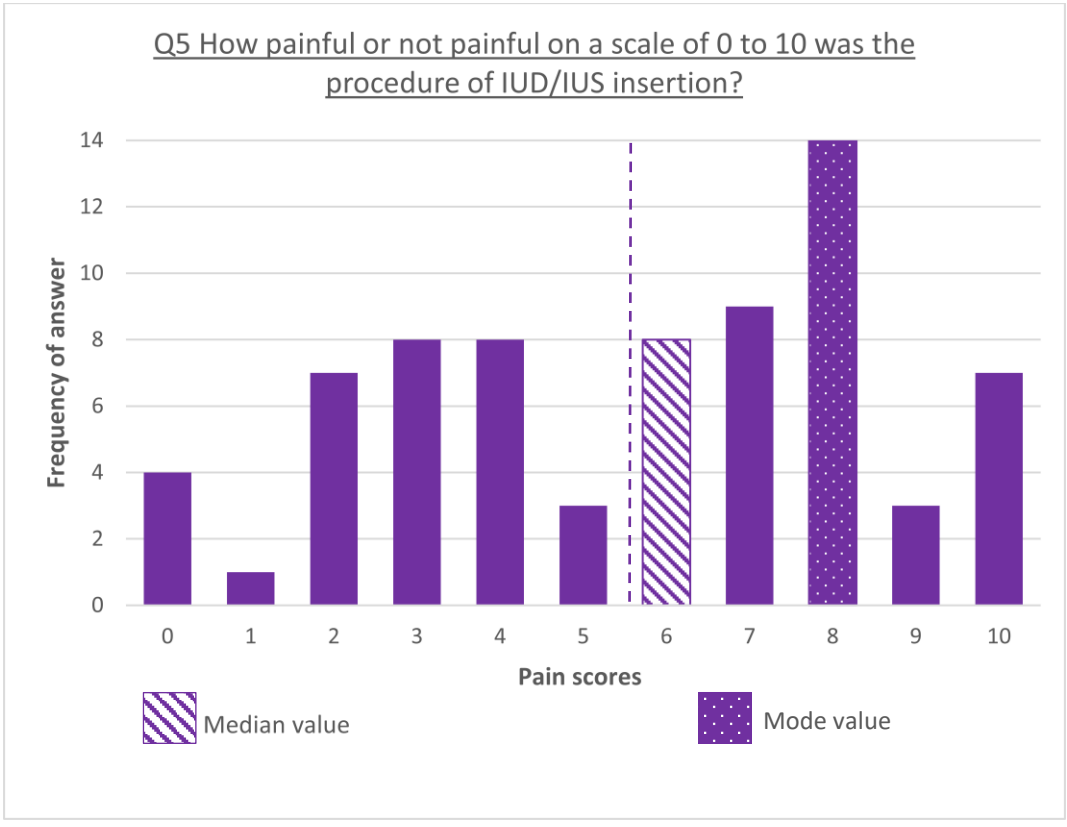

Figure 4. Graphical representation of the responses to Q5

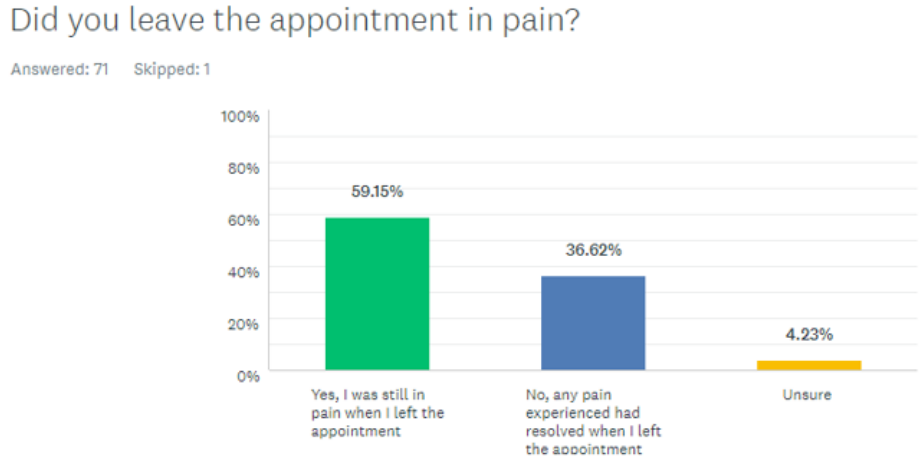

Figure 5. Graphical representation of the responses to Q8

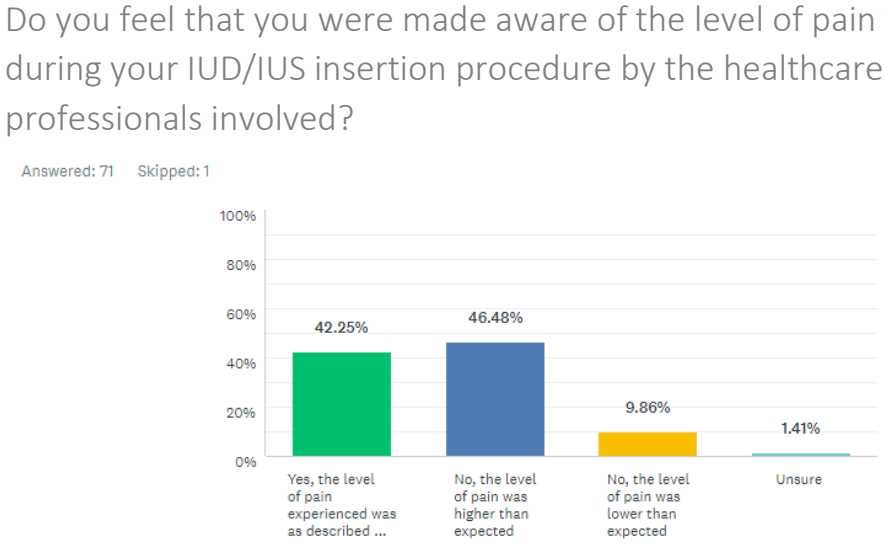

Figure 6. Graphical representation of the responses to Q9

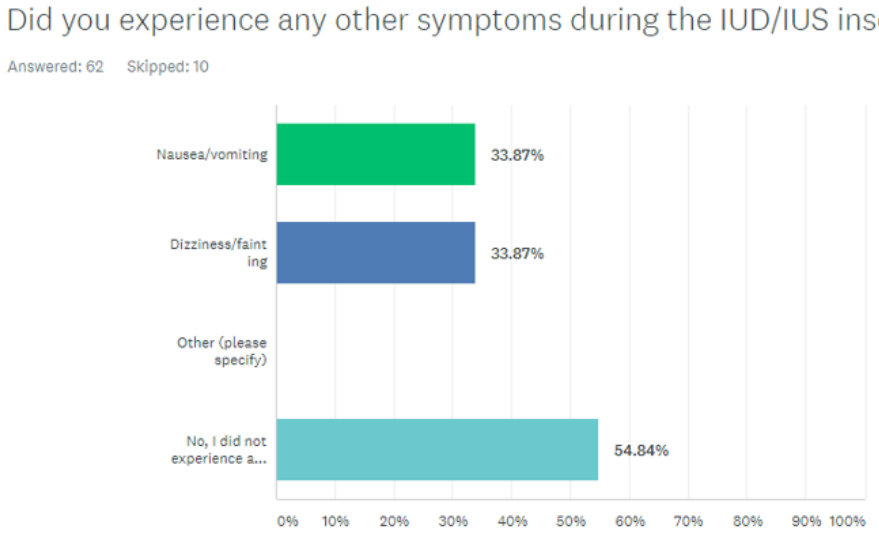

Figure 7. Graphical representation of the responses to Q10

4.1a. RQ1: Confounding variables to pain experience: parity

Figure 8 demonstrates the distribution of pain scores from Q5, separated by whether participants report having given birth vaginally prior to IUC-I (multiparous) or had not given birth vaginally prior to IUC-I/had never given birth vaginally (nulliparous) as reported in Q4. Mean pain scores for each group are indicated by dashed line, 4.29 for multiparous women and 5.97 for nulliparous women. The median pain score for nulliparous participants was 6.5, whilst for multiparous participants the median was 3.5.

The mean pain scores of nulliparous (n=58) and multiparous (n=14) women were compared using a two-tailed t-test (Appendix 9.8), to provide a p value of 0.048 demonstrating that mean pain scores for nulliparous women were statistically significantly higher than multiparous women. This is displayed in Figure 9 with error bars represent the standard error of mean.

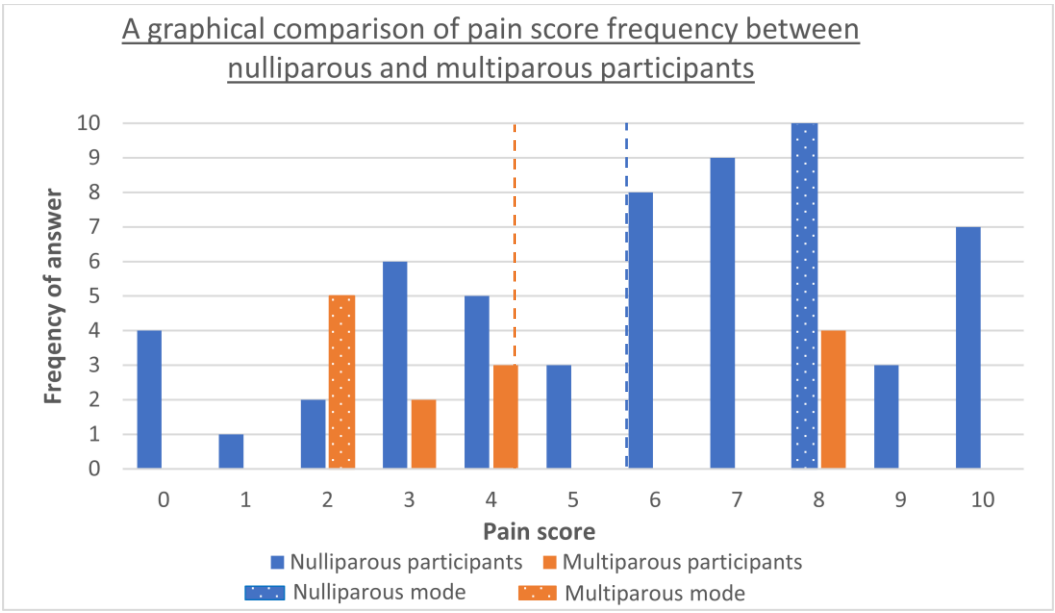

Figure 8. Graphical representation of pain score comparison between nulliparous and multiparous participants

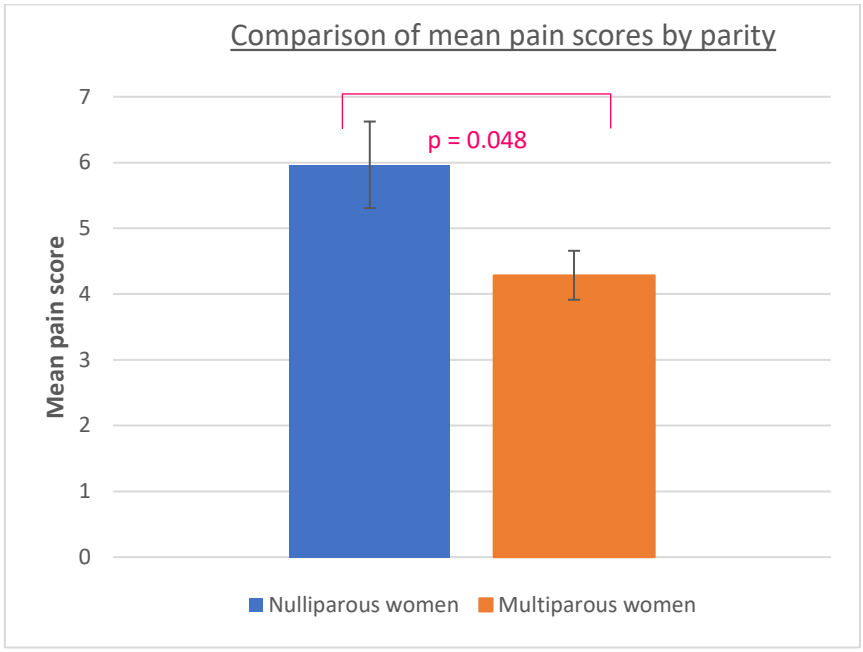

Figure 9. Graphical representation of comparison of mean pain scores (Q5) between nulliparous and multiparous participants

4.1b. RQ1: Confounding variables to pain experience: type of IUC

A two-tailed t-test demonstrated that type of IUC from Q3 responses (Mirena or Copper) did not have a statistically significant influence on pain scores (Q5) (Appendix 9.9)(p=0.42). Figure 10 demonstrates means compared by type of IUC with error bars representing the standard error of mean pain scores.

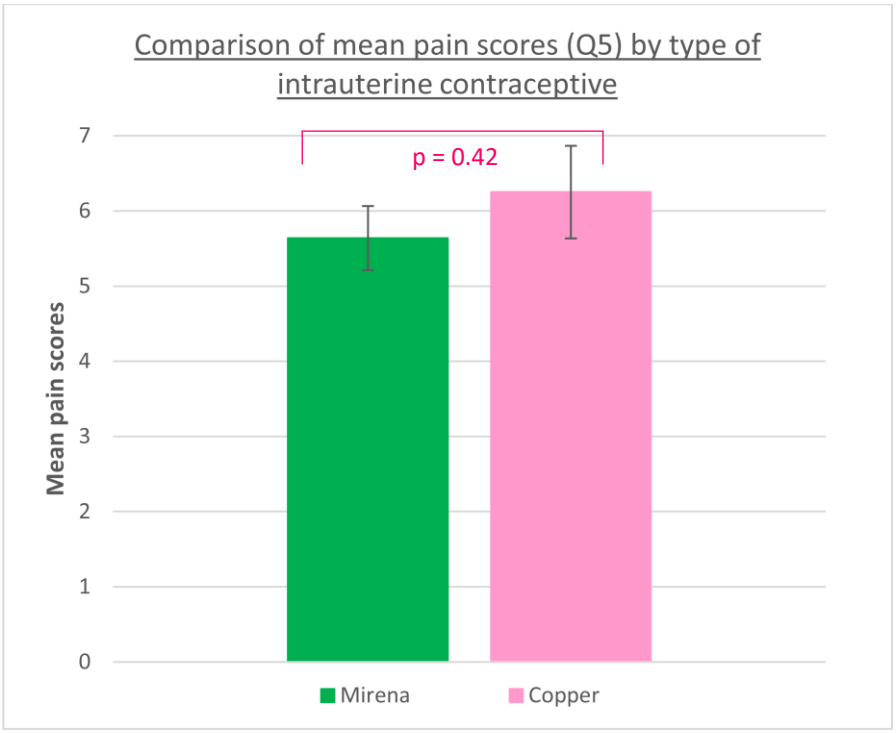

Figure 10. Graphical representation of comparison of mean pain scores (Q5) by type of IUC

4.1c. RQ1: Confounding variables to pain experience: time since insertion

ANOVA statistical test compared time since insertion (Q2) and found no significant difference in pain scores (Appendix 9.10) ($p = 0.39$). Time since IUC-I is therefore not a variable influencing recollection and reporting of pain scores. Figure 11 demonstrates a comparison of the Q5 mean pain scores split by women who had IUC-I <1 year ago (n=25), 1-2 years ago (n=12), 2-3 years ago (n=7), 3-4 years ago (n=5), and 4+ years ago (n=21). Error bars represent the standard error of mean.

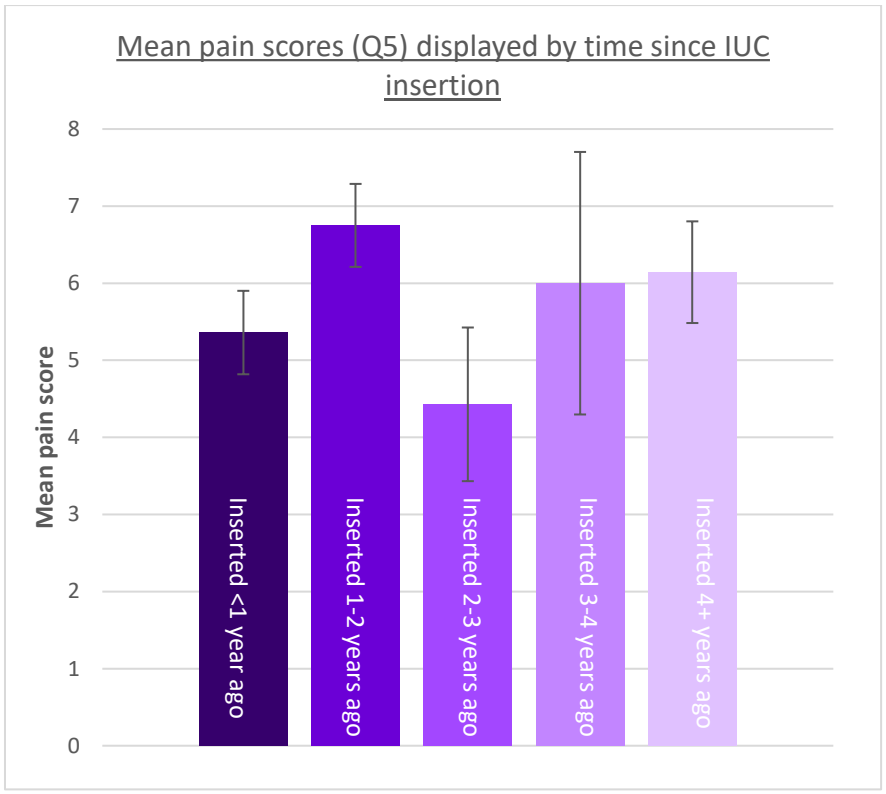

Figure 11. Graphical representation of comparison of mean pain scores (Q5) by time since insertion

4.2 RQ2 results

This survey demonstrated that 62% of participants were not offered pain relief in their appointment, whilst 15% were offered a form of local anaesthetic (Fig.12). 60% were encouraged to take prophylaxis prior to insertion (Fig.13). Q8 responses also are relevant to RQ2 and demonstrated that 59% surveyed women left their appointment in pain (Fig.5).

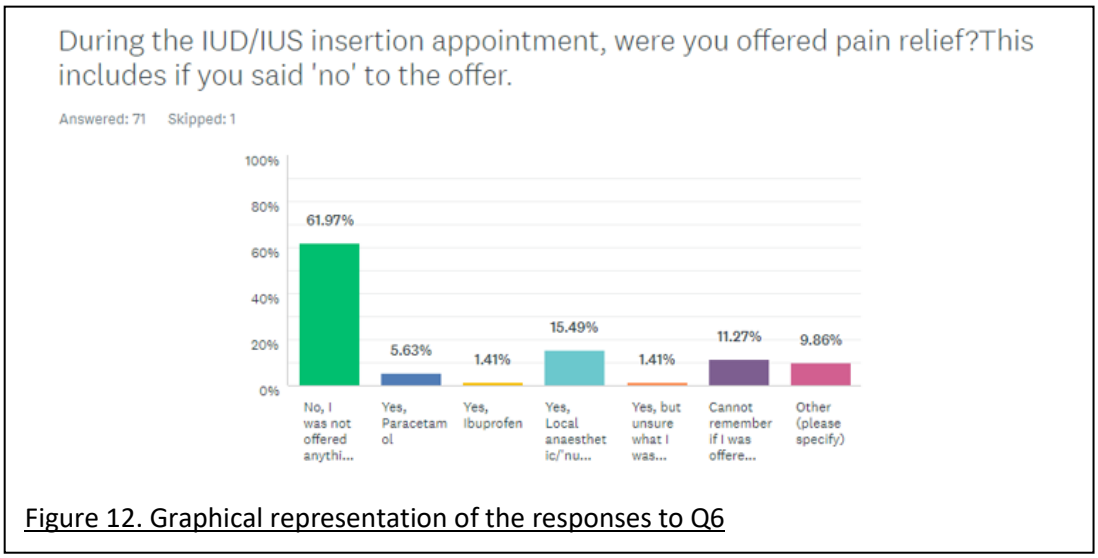

Figure 12. Graphical representation of the responses to Q6

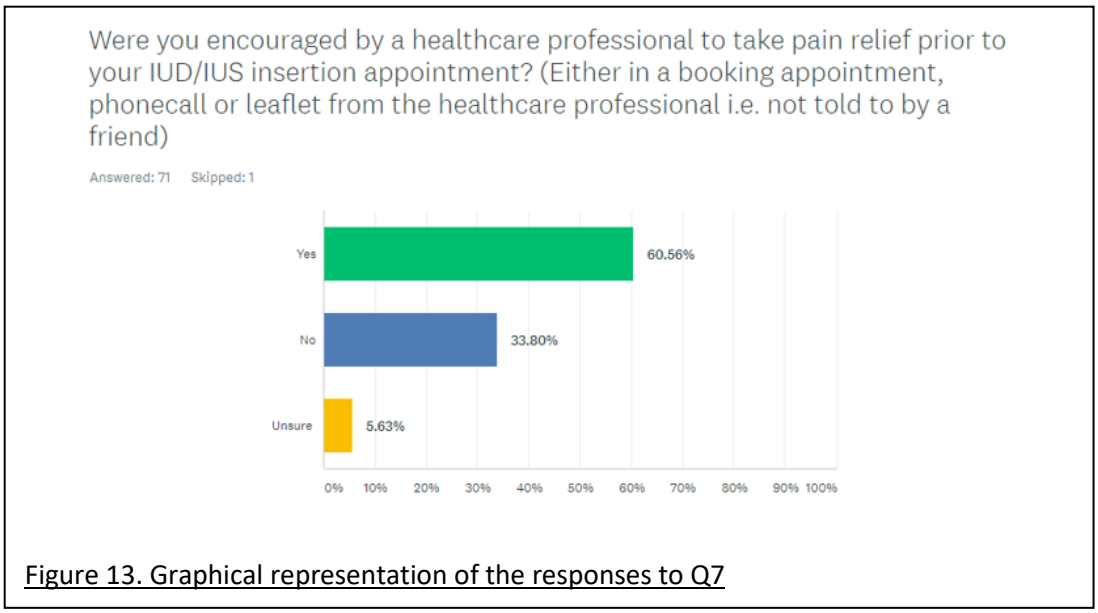

Figure 13. Graphical representation of the responses to Q7

5. Discussion

5.1. RQ1 discussion: Is IUC-I painful?

Evidence from Q5 (Fig.4) suggests IUC-I is severely painful for some patients. The most common pain score was 8, the mean was 5.64 and the median value was 6. These results alone demonstrate that the procedure causes severe pain on the UPAT. This suggests stronger pain relief is required, and provides evidence for consideration of changes to the guidelines for sexual health clinics, general practices and gynaecology centres for IUC-I. Conversely, 7% women surveyed rated the pain as 0 or 1, displaying a wide distribution in IUC-I pain experience. Women were not stratified by those who had pain relief and those who did not in this survey, so it is impossible to determine whether these participants reported lower scores.

The current guidance from the FSRH recognises that anxiety, dysmenorrhea and nulliparity are predictors of more painful insertion, however recommendations are not made for analgesia in these patients. It is not mentioned in the FSRH or NICE guidance for IUC-I that the potential for a more painful insertion should be discussed with nulliparous women, anxious women, or women who experience dysmenorrhea, highlighting issues regarding informed consent for the procedure.

Q9 responses indicated 47% surveyed participants experienced pain higher than anticipated during IUC-I. This suggests the pre-procedural consultation may not be comprehensive in managing patient expectations for IUC-I, and that adequate analgesia is not provided to some women. Research indicates professionals can underestimate pain, as demonstrated by comparisons of VAS pain scores between patients and inserters, with patients scores higher than estimated by inserter (Maguire *et al.*, 2014). This research suggests that IUC-I briefings may not accurately estimate the pain level, since inserters do not recognise the pain as being as high as is experienced by patients.

Findings from Q10 showed approximately one third (34%) of surveyed participants experienced nausea or vomiting and one third (34%) experienced dizziness and fainting (Fig.7). Whilst this is not necessarily due to pain and may be related vasovagal responses which are not uncommon with IUC-I, it exacerbates the unpleasant experience for women. Vasovagal syncope occurs during IUC-I due to parasympathetic innervation by the vagus nerve in the cervix, which is slightly dilated for the procedure. This can provoke symptomatic bradycardia, causing lightheadedness or dizziness, nausea, and diaphoresis.

The procedure for IUC-I has several steps which can cause pain. The stabilisation of the cervix using a tenaculum which grasps the mucosa, can puncture the tissue and causing uterine cramping (Doty and MacIsaac, 2015). The FSRH guidance recommends the tenaculum is applied slowly to minimise this pain. The cervix is dilated, either using a sound device or the IUC inserter, which can be a painful process. The IUC is then inserted and the arms opened in the uterine cavity, which can cause further cramping. Cramping pain is also a post-procedural symptom which can carry on for hours following IUC-I, confirmed in Q8 as 59% participants left the appointment in pain. Patients are encourage to continue analgesia at home, and whilst this is an normal expectation of the procedure, it has implications on her occupation, such as needing the day off work or not being able to care for any dependents.

5.1a RQ1: Confounding variables to pain experience: parity

Nulliparity is identified in the FSRH guidance as a risk factor for more painful insertion (FSRH, 2015). It has been suggested in research that dilation of the cervix in nulliparous women, whose cervixes have not dilated before to deliver a child causes a more painful IUC-I experience (Anthoulakis *et al.,* 2018). Figures 8 and 9 demonstrate my survey results corresponding with this, and t-tests showed nulliparous women found insertion 39% more painful than multiparous women (Appendix 9.8).

Severe pain at IUC-I could have consequent effects on reluctance to repeated IUC use for nulliparous women. Fear of pain is a proven barrier to trial of IUCs in adolescents and young women, suggesting better analgesia could improve uptake rates (Bharadwaj et al., 2012). IUCs are a LARC, encouraged for use for nulliparous women as they are more reliable than contraceptive pills or Depot injections in terms of minimising unintended pregnancy and are most cost-effective for the NHS (FSRH, 2010). Anxiety or pain regarding the fitting of LARCs should not be a barrier to nulliparous women, since they are a suitable and effective method of contraception, so pain relief options should be addressed, and the guidelines should reflect this.

5.1b RQ1: Confounding variables to pain experience: type of IUC

To ensure high numbers of participants, I included women with any form of IUC in my research. To confound this, participants were asked which form of IUC they had in Q3, to compare pain scores. A two-tailed t-test determined no significant difference between pain scores in the two most popular forms of IUC in the participants surveyed: Mirena and Copper (Fig.10, Appendix 9.9). Data was not analysed for the other types of IUC such as Jaydess (n=2), Kyleena (n=2) or Levosert (n=1) as the sample sizes were very small which would affect the analysis.

5.1c RQ1: Confounding variables to pain experience: time since insertion

Q2 was included to accommodate for the confounding variable of time since IUC-I and whether this would impact recollection of any pain experienced. This variable was addressed to exclude memory bias in analysis of pain scores and to eliminate any influence of the counter-effects of the IUC itself. The Mirena IUS is licensed as a therapy for menorrhagia, which can accompany dysmenorrhea, therefore in theory the modulation of any cyclical-related pain since IUC-I could impact on recollection of pain at insertion. The mean pain scores per participant in each time frame were not statistically significantly different depending on time since insertion as calculated by an ANOVA test with no discernible trend in scores (Fig.11, Appendix 9.10). This would suggest there was no memory bias related to IUC-I experience and therefore this is not a confounding variable in the reporting of pain in this survey.

5.2 RQ2 discussion: Are women provided with adequate analgesia for IUC-I?

Results from Q6 demonstrated 62% of women surveyed were not offered any pain relief during their IUC-I appointment. These results could be confounded by memory bias, but suggest that most clinics do not offer pain relief during the procedure, however, results of Q7 suggest 61% women surveyed were advised to take pre-procedural analgesia. This allows time for onset of action of the analgesic effects of ibuprofen and/or paracetamol, therefore should be taken 45-60 minutes prior to the appointment.

The mean pain scores of women who had pain relief versus those who did not were not compared in this study, as the question was phrased about the offer of pain relief from healthcare professionals, and included women who refused it. Therefore, I do not have accurate pain scores for women who took certain modes of pain relief, and this data is better evaluated in experimental studies.

Review literature into IUC-I pain relief notes that there is a significant difference between pain perception with use of oral or local analgesia compared with placebo but suggests that it is not appropriate for routine use. Any additional interventions involve additional risks such as infection or allergic reaction, therefore analgesia could be offered in instances with predictive factors to increased pain i.e. nulliparity and anxiety (Gemzell-Danielsson et al., 2019).

For other minor operative procedures carried out in primary care such as skin lesion excisions, patients are provided with adequate local anaesthetic to ensure the procedure is painless, and the numbness continues for several hours after the appointment, enabling patients to perform their normal daily duties. Tooth extraction at the dentist involves mandatory local anaesthetic. It seems an omission of fairness to women, undergoing a pro-active procedure to prevent unwanted pregnancy that adequate pain relief is not standard procedure.

The 'gender-pain gap' or 'pain bias' is an observation that pain experienced by women is not taken as seriously or treated as radically as it is in men. This could be an outdated unconscious bias of "brave men and emotional women", meaning men are less likely to express pain and therefore when they do, it is interpreted as worse than in women, who are stereotypically more emotional (Samulowitz *et al.,* 2018). This has profound epidemiological effects. On average, women in the UK wait longer from first presentation to be diagnosed with cancer than men, and in Emergency Departments receive less analgesia than male counterparts when presenting with acute abdominal pain, demonstrating the presence of a bias against female patients in healthcare (Din et al., 2015, Chen et al., 2008). In the context of IUC-I, a procedure which only affects people with uteruses – mostly cisgender women – is gender bias neglecting women of necessary pain relief?

5.2a RQ2: Evidence for lidocaine

15% women surveyed in Q6 responded that they were offered a form of local anaesthetic for the procedure. Evidence is conflicting for lidocaine use, particularly for the paracervical block technique which involves 3-4 points of injection on the cervix but carries a risk, of infection and bleeding (Zapata *et al.,* 2016, Brown and Trouton, 2013). Nonetheless, meta-analyses have demonstrated reduction of VAS pain scores for paracervical lidocaine during IUC-I and tenaculum placement when compared with placebo (Pergialiotis *et al.*, 2014, Anthoulakis *et al.,* 2018).

Topical lidocaine gel on the cervix has poor supportive evidence in RCTs compared to the effect of placebo gel in terms of VAS score reduction (Zapata *et al.,* 2016, Gemzell-Danielsson et al.,

2013). Contradictory to this, lidocaine-prilocaine cream has been proven in other meta-analyses to effectively reduce pain at tenaculum placement during IUC-I, with paracervical lidocaine injection next most effective (Samy et al., 2019). Topical 4% preparations of lidocaine gel preparations show more benefit in reducing pain scores for nulliparous women during IUC-I, when compared with 1% paracervical injection and 2% gels (Lopez et al., 2015). The FSRH guideline references evidence that paracervical 1% lidocaine blocks do reduce VAS scores compared with placebo for IUC-I, however it only recommends use for insertions which are anticipated to be difficult.

Disparities in use of local anaesthetic are noted within the FSRH guidance, indicating that 25% surveyed healthcare professionals routinely use local anaesthetic for IUC-I, whilst a further 25% rarely or never use it, suggesting it is not adapted to the patient and their predisposing factors to pain, but to the inserters preference (Akintomide, Sewell and Stephenson, 2013). Further research could investigate reluctance in IUC inserters to use analgesia and their justification.

This evidence supports the concept that a decision on a suitable pain management plan should be discussed between the healthcare practitioner and the patient, either at the pre-procedural consultation or at the insertion appointment, considering the patients' ideas and concerns, alongside their predisposing factors to pain experience.

5.2b RQ2: Evidence for non-steroidal anti-inflammatory drugs

Evidence for use of non-steroidal anti-inflammatory drugs (NSAIDs) to reduce pain scores at IUC-I is poor, despite it being widely recommended as pre-procedural analgesia. Meta-analyses have evaluated the use of five NSAIDs and found only tramadol and naproxen show reduction in VAS scores (Zapata *et al.,* 2016, Lopez et al., 2015). This evidence has also been tested for high-dose ibuprofen (800mg), and no reduction in pain at IUC-I, in either nulliparous or multiparous women (Bednarek *et al.,* 2015).

There is not sufficient trial evidence to prove the effectiveness of prophylactic ibuprofen in reducing pain of IUC-I, however, it is suggested to reduce post-procedural pain and cramping, so is recommended in guidance (Hubacher et al., 2006).

5.2c RQ2: Evidence for cervical priming agents

Misoprostol is used as a cervical priming agent, inserted vaginally or taken orally to soften and dilate the cervix slightly, which can be used for IUC-I, alongside other procedures such as termination of pregnancy or induction of labour. Misoprostol is a synthetic prostaglandin analogue which binds receptors in the cervical myometrium and reduces cervical tone to slightly dilate it. This in theory makes IUC-I easier, by improving access to the uterus.

Evidence for the effectiveness of misoprostol does not show reduction in pain scores, and can increase pain at IUC-I due to forced cervical dilation making it a poor option for women as pain relief (Zapata *et al.,* 2016, Samy et al., 2019, Lopez et al., 2015).

Nitroprusside or nitroglycerin gels have also been evaluated for their effectiveness in softening the cervix. Whilst its efficacy as a cervical primer to aid ease of insertion is proven, this was not reflected by a decrease in pain scores (Bednarek et al., 2013, Samy et al., 2019).

5.2d RQ2: Evidence for verbal anaesthesia

Anxiety regarding the procedure is a predisposing factor to pain experience at IUC-I as documented in FSRH guideline, however additional pain management measures are not addressed. 'Verbal anaesthesia' is a pain modulation technique recommended in literature for this procedure, involving an assistant to distract the woman, make conversation throughout and comfort her (McCarthy, 2017). These strategies reduce anxiety and therefore perceived pain without pharmacological side effects or risks (Gemzell-Danielsson et al., 2013). It does require the time and cost of a qualified individual alongside the inserter for the appointment, although it is already an FSRH recommendation to have a trained colleague present to assist in the procedure and with any potential complications.

6. Implications and conclusion

The findings of this survey provide evidence of a problem in contraceptive care, for which further research is required to solve. Based upon the survey findings, alongside published research there is evidence that in some women, the procedure of IUC-I causes severe pain, which may be predicted by predisposing factors such as parity and anxiety regarding the procedure. These factors, already identified within national guidelines, could form the basis of a pre-procedural assessment for suitability of analgesia for IUC-I. Since IUC-I pain can be a barrier to trying or replacing IUCs it is important that this is accurately disclosed, and pain relief options are discussed.

Suitable pain relief options such as paracervical lidocaine blocks should be discussed between professional and patient, alongside information on realistic expectations of pain for the patient during and after the procedure. Considering these factors, future amendments to guidelines for this procedure could be more definitive in their recommendations for when to use analgesia for IUC-I and in which patient groups. Disregarding the use of analgesia in a proactive procedure to prevent unwanted pregnancy is an unjust penalty to women and undermines the experiences of those who find the procedure painful.

7. Acknowledgments

- Massive thanks to my dissertation supervisor and tutor, Professor Chantal Simon for assisting me in writing this work and being at my beck and call over email!
- Thank you to my oldest friend and research guru Alex Buckley for your support and advice.
- Most of all, thanks to each of the 75 women who responded to my survey and disclosed their honest experiences so I could write this.

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9. Appendix

9.1: BU Research ethics approval

Bournemouth University

Research Ethics Checklist

About Your Checklist	
Ethics ID	32193
Date Created	20/04/2020 11:34:35
Status	Approved
Date Approved	03/06/2020 14:09:14
Date Submitted	31/05/2020 10:07:33
Risk	High

Researcher Details	
Name	Chloe Balderstone
Faculty	Faculty of Health & Social Sciences
Status	Postgraduate Taught (Masters, MA, MSc, MBA, LLM)
Course	MSc Physician Associate Studies
Have you received funding to support this research project?	

Project Details	
Title	The use of analgesia in insertion of intrauterine contraceptive devices (IUCDs)
Start Date of Project	10/01/2020
End Date of Project	31/01/2021
Proposed Start Date of Data Collection	06/04/2020
Original Supervisor	Chantal Simon
Approver	Ethics Programme Team
Summary - no more than 500 words (including detail on background methodology, sample, outcomes, etc.)	
I am conducting a survey from the patient's perspective of their experience of pain during insertion of IUCDs; small devices which are inserted into the vagina, through the cervix to sit in the womb of a woman for contraception. This experience has been reported as painful, though there are no guidelines from any association for what pain relief should be recommended or used for this procedure. I decided to conduct a small survey of women's experiences, and use existing literature on different modes of pain relief to discuss current protocols and whether they should be reviewed to include better pain relief.	

Filter Question: Does your study involve Human Participants?

Participants
Describe the number of participants and specify any inclusion/exclusion criteria to be used

75Women who have had an IUCD fitted before	
Do your participants include minors (under 16)?	No
Are your participants considered adults who are competent to give consent but considered vulnerable?	No
Is a Disclosure and Barring Service (DBS) check required for the research activity?	No

Recruitment	
Please provide details on intended recruitment methods, include copies of any advertisements.	
Using social media	
Do you need a Gatekeeper to access your participants?	No

Data Collection Activity	
Will the research involve questionnaire/online survey? If yes, don't forget to attach a copy of the questionnaire/survey or sample of questions.	Yes
How do you intend to distribute the questionnaire?	
online	
If online, do you intend to use a survey company to host and collect responses?	Yes
If yes, please provide details of survey company.	
Survey monkey	
Will the research involve interviews? If Yes, don't forget to attach a copy of the interview questions or sample of questions	No
Will the research involve a focus group? If yes, don't forget to attach a copy of the focus group questions or sample of questions.	No
Will the research involve the collection of audio materials?	No
Will your research involve the collection of photographic materials?	No
Will your research involve the collection of video materials/film?	No
Will the study involve discussions of sensitive topics (e.g. sexual activity, drug use, criminal activity)?	Yes
Please provide details and measures taken to minimise risks	
Whether or not the patients have given birth vaginally - included an option for 'Prefer not to answer'.	
Will any drugs, placebos or other substances (e.g. food substances, vitamins) be administered to the participants?	No
Will the study involve invasive, intrusive or potential harmful procedures of any kind?	No
Could your research induce psychological stress or anxiety, cause harm or have negative consequences for the participants or researchers (beyond the risks encountered in normal life)?	No
Will your research involve prolonged or repetitive testing?	No

Consent	
Describe the process that you will be using to obtain valid consent for participation in the research activities. If consent is not to be obtained explain why.	
The text before my survey:"Please only fill in this survey if you have had an intrauterine device/system (IUD/IUS) inserted before. This survey is to collect information on experiences of the insertion of IUD/IUS or 'the coil'.This data will contribute to a literature review for my Masters project on my Physician Associate MSc course.This data is anonymous, you are not required to include any personal data, or provide any information on the individual or facility where you underwent the procedure.There are no questions regarding why you chose this method of contraception.If you consent to the above, and would like to participate in this anonymous survey, please continue.You are able to withdraw from the survey throughout, skip questions you would prefer not to answer and request withdrawal of your information afterwards, via email.My email is s5128669@bournemouth.ac.uk if you have any questions regarding the survey, or your answers. "	
Do your participants include adults who lack/may lack capacity to give consent (at any point in the study)?	No
Will it be necessary for participants to take part in your study without their knowledge and consent?	No

Participant Withdrawal	
At what point and how will it be possible for participants to exercise their rights to withdraw from the study?	Before the study, I stated participants can discontinue the survey whilst taking, or skip questions they would prefer not to answer
If a participant withdraws from the study, what will be done with their data?	Their answers will be deleted, and therefore not included in the analysis.

Participant Compensation	
Will participants receive financial compensation (or course credits) for their participation?	No
Will financial or other inducements (other than reasonable expenses) be offered to participants?	No

Research Data	
Will identifiable personal information be collected, i.e. at an individualised level in a form that identifies or could enable identification of the participant?	No
Will research outputs include any identifiable personal information i.e. data at an individualised level in a form which identifies or could enable identification of the individual?	No

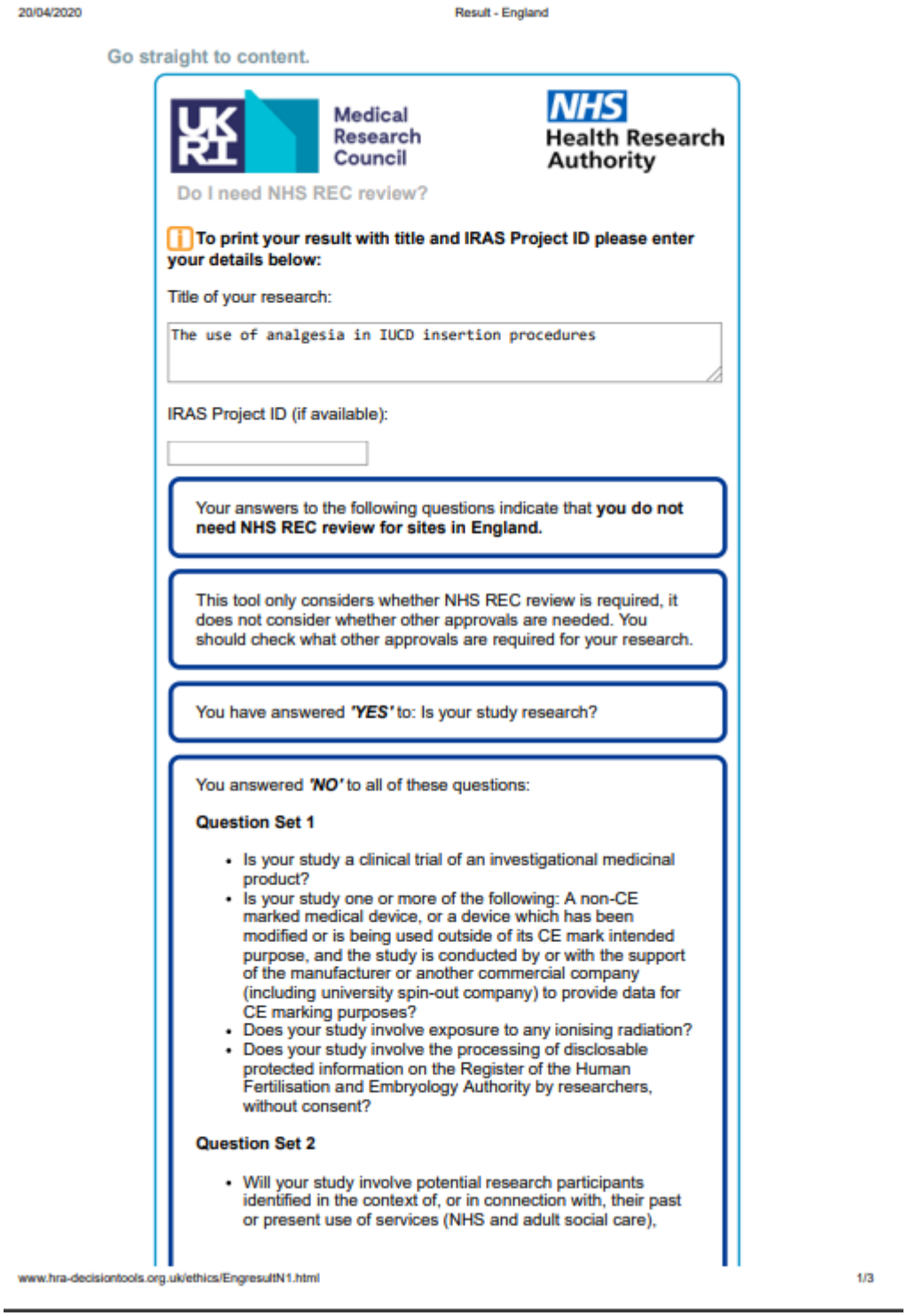
Storage, Access and Disposal of Research Data	
Where will your research data be stored and who will have access during and after the study has finished.	
It is currently stored on the SurveyMonkey site, but will be deleted once the project is finished.It will be included in my project, so anyone reading or marking it will see the final analysis.	
Once your project completes, will any anonymised research data be stored on BU's Online Research Data Repository "BORDaR"?	No
Please explain why you do not intend to deposit your research data on BORDaR? E.g. do you intend to deposit your research data in another data repository (discipline or funder specific)? If so, please provide details.	
I did not state this in my survey so cannot share it to BORDaR	

Final Review	
Are there any other ethical considerations relating to your project which have not been covered above?	No

Risk Assessment	
Have you undertaken an appropriate Risk Assessment?	Yes

Attached documents
Patient survey v2.docx - attached on 31/05/2020 10:04:57

9.2: NHS/medical research council decision: does not need approval



20/04/2020 Result - England

Go straight to content.

UKRI Medical Research Council

NHS Health Research Authority

Do I need NHS REC review?

To print your result with title and IRAS Project ID please enter your details below:

Title of your research:

The use of analgesia in IUCD insertion procedures

IRAS Project ID (if available):

Your answers to the following questions indicate that **you do not need NHS REC review for sites in England.**

This tool only considers whether NHS REC review is required, it does not consider whether other approvals are needed. You should check what other approvals are required for your research.

You have answered ***'YES'*** to: Is your study research?

You answered ***'NO'*** to all of these questions:

Question Set 1

- Is your study a clinical trial of an investigational medicinal product?
- Is your study one or more of the following: A non-CE marked medical device, or a device which has been modified or is being used outside of its CE mark intended purpose, and the study is conducted by or with the support of the manufacturer or another commercial company (including university spin-out company) to provide data for CE marking purposes?
- Does your study involve exposure to any ionising radiation?
- Does your study involve the processing of disclosable protected information on the Register of the Human Fertilisation and Embryology Authority by researchers, without consent?

Question Set 2

- Will your study involve potential research participants identified in the context of, or in connection with, their past or present use of services (NHS and adult social care),

www.hra-decisiontools.org.uk/ethics/EngresultN1.html 1/3

including participants recruited through these services as healthy controls?
- Will your research involve prospective collection of tissue (i.e. any material consisting of or including human cells) from any past or present users of these services (NHS and adult social care)?
- Will your research involve prospective collection of information from any past or present users of these services (NHS and adult social care)?
- Will your research involve the use of previously collected tissue and/or information from which individual past or present users of these services (NHS and adult social care), are likely to be identified by the researchers either directly from that tissue or information, or from its combination with other tissue or information likely to come into their possession?
- Will your research involve potential research participants identified because of their status as relatives or carers of past or present users of these services (NHS and adult social care)?

Question Set 3

- Will your research involve the storage of relevant material from the living or the deceased on premises in England, Wales or Northern Ireland without a storage licence from the Human Tissue Authority (HTA)?
- Will your research involve storage or use of relevant material from the living, collected on or after 1st September 2006, and the research is not within the terms of consent for research from the donors?
- Will your research involve the analysis of human DNA in cellular material (relevant material), collected on or after 1st September 2006, and this analysis is not within the terms of consent for research from the donor? And/or: Will your research involve the analysis of human DNA from materials that do not contain cells (for example: serum or processed bodily fluids such as plasma and semen) and this analysis is not within the terms of consent for research from the donor?

Question Set 4

- Will your research involve at any stage procedures (including use of identifiable tissue samples or personal information) involving adults who lack capacity to consent for themselves, including participants retained in study following the loss of capacity?
- Is your research health-related and involving offenders?
- Does your research involve xenotransplantation?
- Is your research a social care project funded by the Department of Health and Social Care (England)?
- Will the research involve processing confidential information of patients or service users outside of the care team without consent? And/ or: Does your research have Section 251 Support or will you be making an application to the Confidentiality Advisory Committee (CAG) for Section 251 Support?

If your research extends beyond **England** find out if you need NHS REC review by selecting the *'OTHER UK COUNTRIES'* button below.

OTHER UK COUNTRIES


20/04/2020
Result - England
If, after visiting all relevant UK countries, this decision tool suggests that you do not require NHS REC review follow this link for final confirmation and further information.
Print This Page
NOTE: If using Internet Explorer please use browser print function.
About this tool
Feedback
Contact
Glossary
Algorithm

9.3: Patient survey of 'the coil' (IUD/IUS) insertion

Link to survey: https://www.surveymonkey.co.uk/r/PSHDDYQ

Please only fill in this survey if you have had an intrauterine device/system (IUD/IUS) inserted before.

This survey is to collect information on experiences of the insertion of IUD/IUS or ***'the coil'.***

This data will contribute to a literature review for my Masters project on my Physician Associate MSc course.

This data is anonymous, you are not required to include any personal data, or provide any information on the individual or facility where you underwent the procedure.

There are no questions regarding why you chose this method of contraception.

If you consent to the above, and would like to participate in this anonymous survey, please continue.

You are able to withdraw from the survey throughout, and skip questions you would prefer not to answer.

My email is s5128669@bournemouth.ac.uk if you have any questions regarding the survey, or your answers.

Please email me if you would like to read the final project.

1. Do you have an IUD/IUS in currently?

- Yes
- No

2. When was your IUD/IUS inserted?

- <1 year ago
- 1-2 years ago
- 2-3 years ago
- 3-4 years ago
- 4 + years ago

3. What form of IUD/IUS do you have?

- Mirena
- Kyleena

Chloe Balderstone

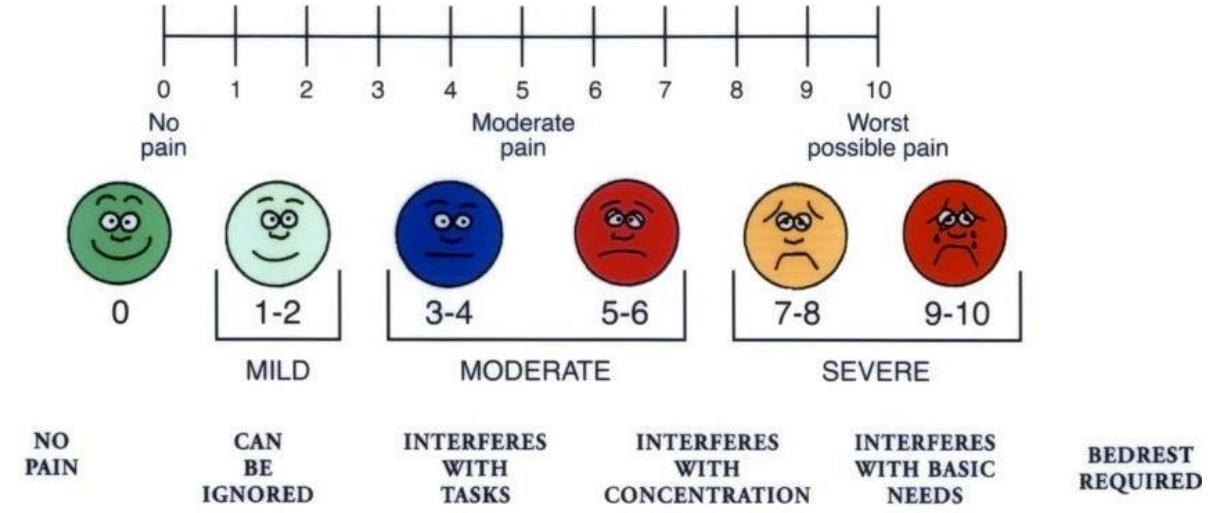
- Jaydess
- Levosert
- Copper coil
- Unsure
- Other (please specify)

4. Have you ever given birth vaginally?

- Yes, before I ever had an IUD/IUS inserted
- Yes, after I had an IUD/IUS inserted
- No, I have never given birth vaginally
- Prefer not to answer

5. How painful or not painful on a scale of 0 to 10 was the procedure of IUD/IUS insertion?

Use the Universal Pain Assessment Tool scale below to accurately remember the experience as it was inserted, not experiences since.



0 5 10

6. During the IUD/IUS insertion appointment, were you offered pain relief? This includes if you said 'no' to the offer.

- [ ] No, I was not offered anything to reduce pain during the insertion appointment
- [ ] Yes, Paracetamol
- [ ] Yes, Ibuprofen
- [ ] Yes, Local anaesthetic/'numbing gel'
- [ ] Yes, but unsure what I was offered
- [ ] Cannot remember if I was offered any pain relief
- [ ] Other (please specify)

7. Were you encouraged by a healthcare professional to take pain relief prior to your IUD/IUS insertion appointment?
(Either in a booking appointment, phonecall or leaflet from the healthcare professional i.e. not told to by a friend)

- ○ Yes
- ○ No
- ○ Unsure

8. Did you leave the appointment in pain?

- ○ Yes, I was still in pain when I left the appointment
- ○ No, any pain experienced had resolved when I left the appointment
- ○ Unsure

9. Do you feel that you were made aware of the level of pain to expect during your IUD/IUS insertion procedure by the healthcare professionals involved?

- ○ Yes, the level of pain experienced was as described by the healthcare professionals
- ○ No, the level of pain was higher than expected
- ○ No, the level of pain was lower than expected
- ○ Unsure

10. Did you experience any other symptoms during the IUD/IUS insertion?

- [ ] Nausea/vomiting
- [ ] Dizziness/fainting
- [ ] No, I did not experience any other symptoms during the insertion appointment

Other (please specify)

Done

9.4: Q1 data

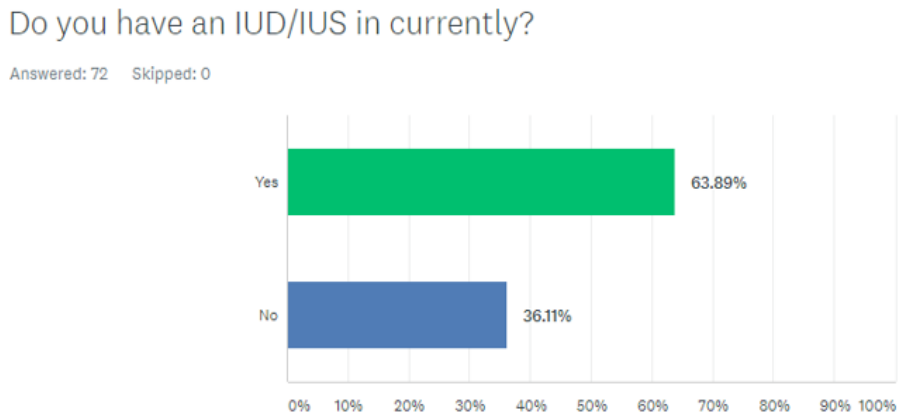


Figure 14. Graphical representation of the responses to Q1

The results of this question demonstrate that at the time of surveying (April 2020), 64% surveyed women currently had an IUC inserted, and 36% no longer had one.

9.5: Q2 data

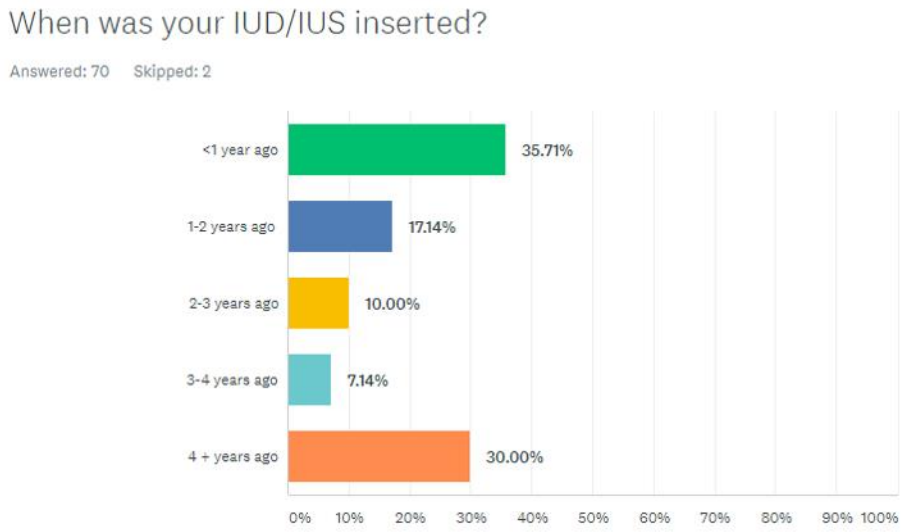


Figure 15. Graphical representation of the responses to Q2

The results of this question shows 36% surveyed participants had an IUC inserted within the past year of being surveyed, and 30% had had insertions over 5 years ago. 2 participants skipped this question.

9.6: Q3 data

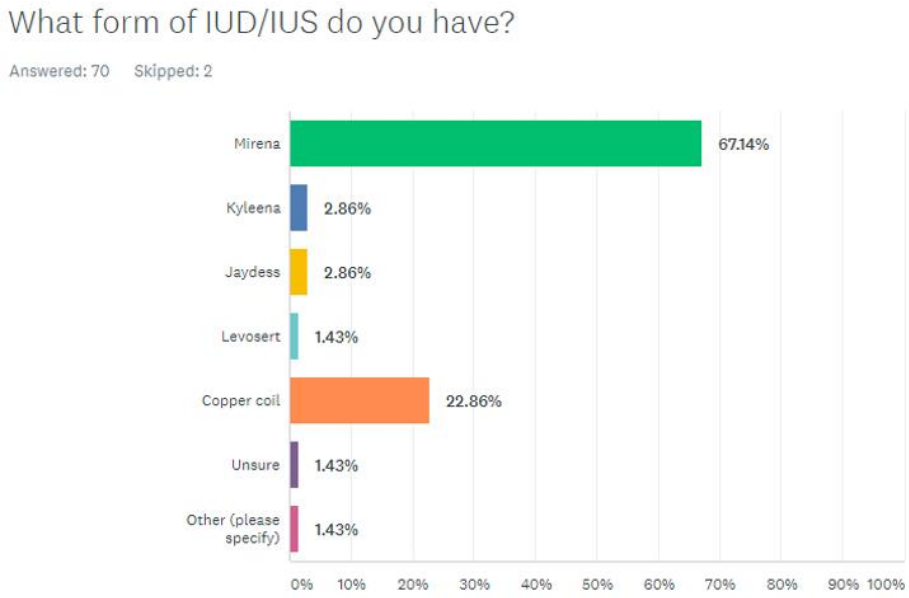


Figure 16. Graphical representation of the responses to Q3

67% women surveyed had had a Mirena IUS inserted, followed by 23% participants who had a copper coil, or IUD. The remaining 10% were spread throughout the other, less popular options. 2 women skipped this question.

9.7: Q4 raw data

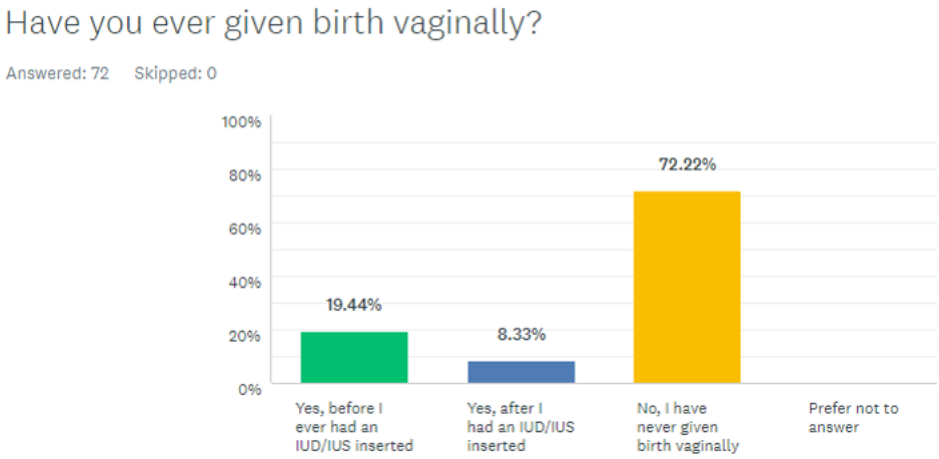


Figure 17. Graphical representation of the responses to Q4

The responses to this question demonstrate that 72% participants had not given birth vaginally prior to IUC-I, and 8% had given birth vaginally since IUC-I and are referred to as nulliparous in this study. 19% had delivered vaginally prior to insertion and are referred to as multiparous.

9.8 Q5 t-test: mean pain score compared by parity (Q4)

	Nulliparous participants	*Multiparous participants*
Mean pain score	5.97	4.29
Variance	8.17	6.53
Observations	58	14
Standard error	0.37	0.66
t Stat	2.01	
P(T<=t) two-tail	**0.048**	

Figure 18. Two-tailed t-test comparing mean pain scores (Q5) from nulliparous and multiparous women

9.9 Q5 t-test: mean pain scores compared by type of IUC (Q3)

	Mirena pain score	*Copper coil pain score*
Mean	5.638297872	6.25
Variance	8.540240518	6.066666667
Observations	47	16
df	31	
t Stat	-0.816784281	
P(T<=t) two-tail	**0.420284586**	
t Critical two-tail	2.039513446	

Figure 19. Two-tailed t-test comparing mean pain scores (Q5) from women who had Mirena IUS vs. Copper IUDs

9.10 Q5 ANOVA test: mean pain scores compared by time since insertion (Q2)

Anova: Single Factor

SUMMARY

Groups	*n*	*Average*	*Variance*
Inserted <1 year ago	25	5.36	7.323333
Inserted 1-2 years ago	12	6.75	3.477273
Inserted 2-3 years ago	7	4.428571	6.952381
Inserted 3-4 years ago	5	6	14.5
Inserted 4+ years ago	21	6.142857	9.128571

ANOVA

Source of Variation	*SS*	*MS*	*F*	*P-value*	*F crit*
Between Groups	31.49	7.8725	1.031064	**0.398022**	2.51304
Within Groups	496.2957	7.635319			
Total	527.7857				

Figure 20. Table demonstrating comparison of mean pain scores in groups determined by time since IUC-I