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Implementation of a Survey to Reduce Urine Pregnancy Tests Prior to Gynecology Procedures in Primary Care

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Implementation of a Survey to Reduce Urine Pregnancy Tests Prior

to Gynecology Procedures in Primary Care

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Abstract

Excluding pregnancy in individuals prior to initiating contraception is important. The Pregnancy Reasonably Excluded Guide (PREG) uses twelve questions related to a patient's reproductive history to effectively rule out pregnancy without administering a urine pregnancy screen, saving the patient both time and money. The PREG survey was given at Mayo Clinic in Rochester, MN, from 2015 to 2018 to all patients receiving an Intrauterine Device or Subdermal Implant.

This study examined data from the 2018 collection year to determine if urine screening requests by providers were reduced from the pre-PREG data. It also determined whether urine tests were requested disproportionally for patients by their age range or type of contraceptive procedure. One-hundred sixty-eight women between the ages of 18 and 50 were included, with the majority identifying as white (84%) between the ages of 18 and 31 (54%).

Using a Chi-square analysis, it was found that neither urine test by age ($p=0.69$) nor urine test by procedure ($p=0.98$) were significant. Urine tests were not requested more often for certain procedures or by patient age. However, the number of urine screens requested pre-PREG compared to the number requested post-PREG for the year 2018 was significant ($P<0.01$).

Through implementation of the PREG survey, urine pregnancy testing was drastically reduced and in turn, there were reduced costs to patients and the clinics.

Introduction

Unplanned pregnancy is defined by the CDC as a pregnancy that is unwanted or

mistimed (2015), and in the United States, approximately 50% of pregnancies are unplanned

(Winner, et al., 2012). According to Gibson, Koenig, & Hindin (2008), there are a handful of ill

effects that stem from an unplanned pregnancy for both the child and the parents. These

include higher risk behaviors in mothers like continuing to smoke, drink alcohol, or use illegal

drugs after a pregnancy is confirmed. In one study, women with unintended pregnancies were

26% less likely to quit smoking, more likely to postpone prenatal care, and less likely to

breastfeed or breastfeed for less than the recommended time (Gibson, et al., 2012). Effects to

mothers include an increase in depression, unsafe abortion, and maternal death (Gibson, et al.,

2012).

Some of the most effective contraceptive methods to prevent these negative outcomes

are Long-Active Reversible Contraceptives or LARC methods. The category includes intrauterine

devices like Mirena and Paragard, and subdermal implants like Nexplanon. While these

methods are extremely effective, failing less than 1% of the time, only 6% of women on

hormonal contraception were using these methods in 2012 (Winner, et al., 2012).

There are a few possible barriers to choosing LARC methods. The first is a lack of

comfort inserting the devices among primary care providers, who are often the main providers

of women's health care. One study found that 87% of respondents were not trained to place

subdermal implants and 41% were not trained to place IUDs (Lunde, et al., 2014). Having

providers who are trained in LARC method insertion is the strongest predictor of their patients'

use of the method, as those who lack training are less likely to recommend the method.

Greenberg, et al., 2012).

Once patients have decided that a LARC method is right for them, there are a few

barriers that stand between them and the actual procedure. One is that providers should be

"reasonably certain" that patients are not already pregnant before beginning a new

contraceptive method, due in part to the redundancy of starting the method and the belief of

some providers that contraceptives can cause harm to an early pregnancy (Morroni, Findley,

Westhoff, 2017). Two accepted ways to determine pregnancy status are by administering a

pregnancy test, or by having the patient complete the procedure during their menses. These

requirements can prove difficult to women who have difficulty traveling to appointments, need

time off work, or need to be on a birth control method as soon as possible. In addition, luteal

phase pregnancies may not be detected by a urine test or indicated by a lack of active bleeding.

A common problem, however, is that women experience delays when waiting for urine

pregnancy test results, or may not be able to accurately take a urine pregnancy test. Morroni et

al. found that women were less likely to return for a second appointment and women who did

return were 60% more likely to have gotten pregnant in the meantime (2017).

A method that deserves exploration is the use of a pregnancy exclusion checklist.

Implementing a checklist would allow providers to forgo a urine screen by reasonably excluding

pregnancy based on a survey with questions related to menstrual cycle, sexual history, and

prior contraceptive use. Min, Buckel, Secura, Peipert, and Madden (2014) found that their six-

question exclusion guide had an accuracy of ruling out luteal pregnancy in 99% of women who

also had a negative urine pregnancy test and ruled out typical pregnancy in 69% of women who

had a negative pregnancy test. Another study looked at using a pregnancy exclusion checklist in teenagers and younger women. Whiteman, et al. looked at a group of black females ages 14-19 and found their guide had a sensitivity range of 55%-100% and a specificity range of 39% to 89% (2014). The range of results could be due to the irregularity that is typical of younger women's menstrual cycles.

Mayo Clinic in Rochester, Minnesota has developed their own version of a survey titled "Pregnancy Reasonably Excluded Guide" or "PREG". They implemented the 12-question patient survey in 2015 and, when appropriate, have been using it in place of traditional pregnancy tests prior to gynecological procedures. Additional urine testing could still be requested at the provider's discretion after discussing the survey results with the patient and if concerns for pregnancy were still present. This study aimed to examine whether the PREG survey effectively reduced the number of urine tests performed from the pre-PREG data of 2015 to the post-PREG data of 2018. It also looked at whether when additional urine testing was requested, if it was done so more often for certain age groups or certain procedure types (intrauterine device vs subdermal implant).

Methods

The PREG survey was given to all patients when they checked in as part of their pre-gynecology procedure appointment paperwork and health histories. (See appendix A for survey questions and B for the scoring guide.) Only the surveys of those who had consented to research at Mayo Clinic were included in the study with an original sample of 1,012 female patients ages eighteen to fifty. The survey answers were entered into an excel sheet, with additional chart review completed if necessary to clarify patients' answers.

For this post-PREG study, the number of requested urine screens from the 2018 collection period (January through April) was compared with the pre-PREG sample from the 2015 collection period (January through September). There were a total of 185 patients ages eighteen to fifty in the pre-PREG group and 168 patients ages eighteen to fifty in the post-PREG group. Figure A below shows the age breakdown of the 168 patients and figure B shows the racial representation present, both from post-PREG in 2018. Other demographic data from the pre-PREG group was not available for comparison.
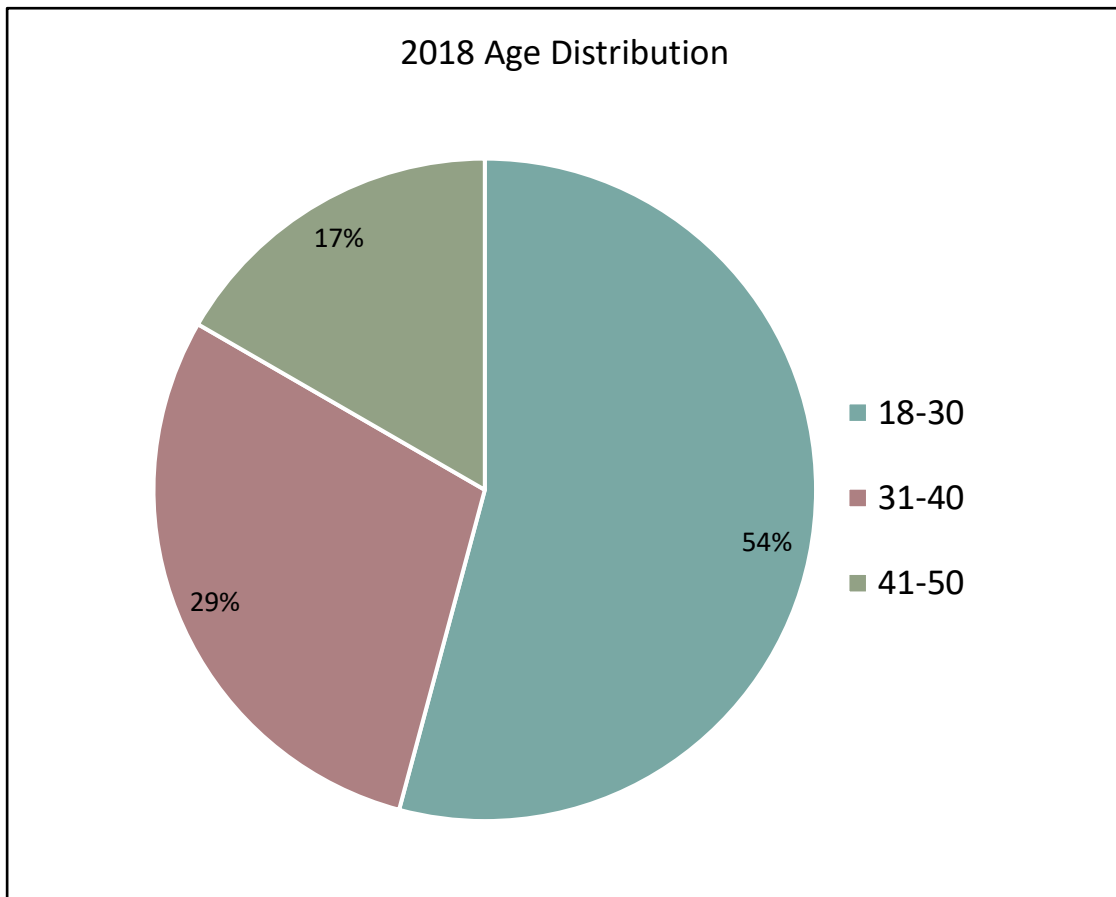
Figure A: Age distribution of patients who took PREG in 2018
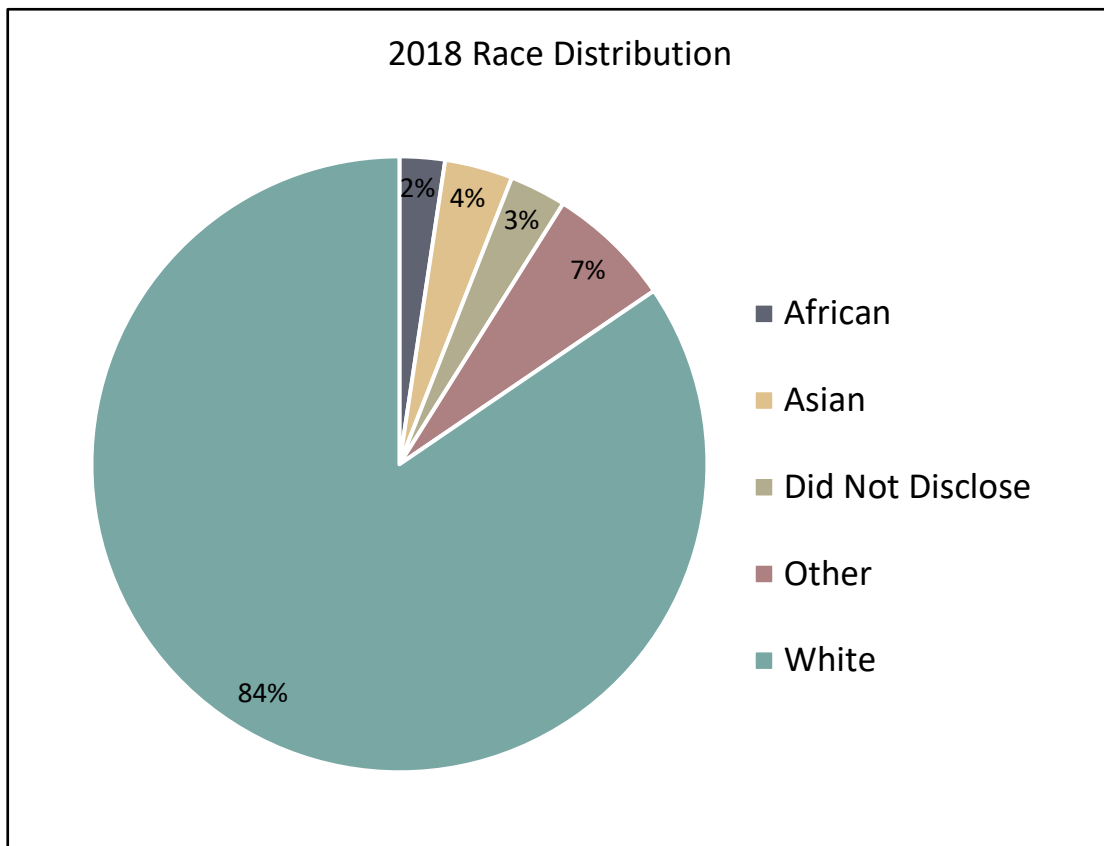
Figure B: Race distribution of patients who took PREG in 2018

The PREG survey (Appendix A) includes twelve questions including the following:

1. I am pregnant.

2. I've had a bilateral tubal ligation ("tubes tied," Essure with confirmatory testing).

3. I've had a hysterectomy and/or bilateral salpingo-oophorectomy (both ovaries removed).

4. I am menopausal and greater than 45 years old- no period spontaneously for the past 12 months.

5. I have a current IUD (Mirena, Skyla, ParaGard, Liletta) in place.

6. I have a current contraceptive implant (Nexplanon, Implanon) in place.

7. I have not had sexual intercourse with a man since the start of my last normal period

8. My partner has had a vasectomy and he has had a negative post-surgery semen analysis.

9. I started bleeding from a normal period within the last seven days.

10. I reliably use hormonal contraception ("the pill," Depo Provera shots, patch, ring).

11. I think I may be pregnant or would like a pregnancy test.

12. None of these apply

To score the survey (see Appendix B for full scoring guide), the questions are divided into three groups: A (Questions 1-6), B (Questions 7-10), and C (Questions 11 and 12). Women who answered questions in Category A were deemed unlikely to be pregnant today or become pregnant soon. They are physically unable to become pregnant or use a contraceptive method that is free of human error and therefore more effective. Category B women were unlikely to be pregnant today but would need additional evaluation if they were to need to come back in the future. These women are less likely to be pregnant, but the questions rely more on the patient's report and the accuracy of their recall. The questions can also not rule out a luteal pregnancy with question #9. Women answering from Category C could not rule out pregnancy today and would need some type of pregnancy testing prior to their procedure and if it was determined a pregnancy test would not be accurate due to recent sexual activity and menstrual cycle, they would be asked to rescheduled and come back when they could complete the pregnancy test and the results would be more accurate.

Data is summarized using counts and percentages. A chi square analysis was performed to determine whether urine tests were requested more often pre-PREG compared to post-PREG.

A Chi-square analysis was also used to determine if urine tests were requested (a) more often for either the subdermal implant or IUD or (b) more often for a certain age range or type of contraceptive procedure. A p-value < 0.05 was considered statistically significant.

Results

Below, Table A shows the breakdown of answers given on the PREG survey in 2018.

PREG items	Calendar Year 2018 (N=168)
Item #2: I've had a negative pregnancy test today	1 (0.6%)
Section A items	
#1: I am pregnant	0 (0.0%)
#8: I've had a bilateral tubal ligation	0 (0.0%)
#11: I've had a hysterectomy or BSO	0 (0.0%)
#12: I am menopausal and >45 years old	0 (0.0%)
#10: I have a current IUD in place	37 (22%)
#16: I have a current contraceptive implant in place	17 (10.8%)
Section B items	
#6: I have not had sexual intercourse with a man since the start of my last normal period	67 (39.9%
#9: My partner had had a vasectomy and he has had a negative post-surgery semen analysis	8 (4.8%)
#3: I started bleeding from a normal period within the last 7 days	57 (33.9%)
#7 I reliably use hormonal contraception	46 (26.4%)
Section C items	
#17: I think I may be pregnancy or would like a pregnancy test	4 (2.5%)
#13: None of the above apply	10 (6.0%)
Mutually exclusive categorization based on the hierarchy listed below (top to bottom)	
I think I may be pregnant or would like a pregnancy test	4 (2.5%)
I had a negative pregnancy test today	1 (0.6%)
Marked an X in Section A only	25 (14.9%)
Marked an X in Section B only	94 (56.0%)
Marked an X in both Sections A & B	34 (20.2%)
None of the above apply	10 (6.0%)

Table A: Breakdown of 2018 PREG survey patient responses

Only a small percentage (0.6%) had been requested to complete a urine test prior to their appointment. Additional urine screens could have been requested after reviewing a patient's survey. The majority (56%) chose an option in Category B, which indicated they were unlikely to be pregnant today, but would need additional evaluation in the future.

Of the 185 patients from pre-PREG in 2015, 98 (53%) were requested to have urine screens. Figure E shows there was a statistically significant difference in the percentage of urine screens ordered in 2015 compared to 2018 as shown in Figure C (53% vs. 16%. P<0.01).

Comparison of Urine Screens Pre- and Post PREG		
	Pre-PREG (2015)	**Post-PREG (2018)**
Urine	98 (53%)	27 (16%)
No Urine	87 (47%)	141 (84%)
Total	185	168

Figure C: Comparison of requested urine screens requested pre- and post- PREG survey

Out of the 168 patients in 2018, the majority were white (84.52%) and between the ages of 18 and 30 (54.17%). The mean age was to undergo a contraceptive procedure was 30 and most patients (55.35%) had never given birth. Demographic information for the pre-PREG patients was not available for comparison. See Table B below for additional demographic information.

Age	Mean Age= 30.18	
	Count (N=168)	Percent
18-31	91	54.17%
31-40	49	29.17%
41-50	28	16.67%
Race	Count (N=168)	Percent
African	4	2.38%
Asian	6	3.57%
Did Not Disclose	5	2.98%
Other	11	6.55%
White	142	84.52%
Parity	Mean # Children= 0.85	
	Count (N=168)	Percent
0	93	55.35%
1	23	13.70%
2	38	22.62%
3+	14	8.33%

Table B: Demographic information for patients who took PREG in 2018

16% of patients (21 out of 131) who received an IUD had a urine test and 16% of patients (6 out of 37) who received a subdermal had a urine test. There was no association between type of protection and provider decision for a urine screening (p>0.05).

Figure D below shows a breakdown of the urine test requests by IUD insertion or subdermal

implant
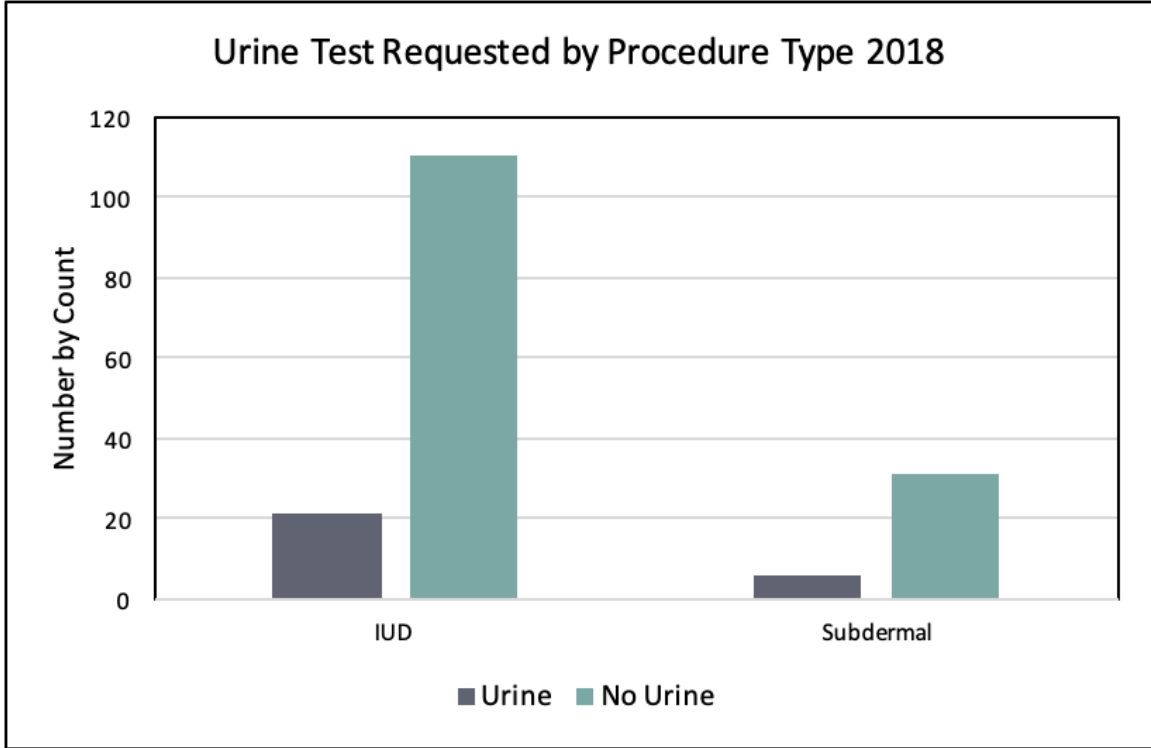
Urine Test by Procedure Post-PREG (2018)			
Procedure Type	Urine	No Urine	Total
IUD	21 (16%)	110 (84%)	131 (78%)
Subdermal	6 (16%)	31 (84%)	37 (22%)
Total	27 (16%)	141 (84%)	168

Figure D: Breakdown of urine screens requested by procedure type

A second question to be determined by the data was whether urine tests were requested more often for one age group compared to another. The distribution of urine tests completed among the three age groups (18-30, 31-40, and 41-50) were similar to each other ($p > 0.05$) suggesting that a provider was no more likely to request patients of certain ages to complete urine tests more often than patients in other age groups. Figure E shows a breakdown of the age groups and requested urine tests and illustrates a similar distribution among them.
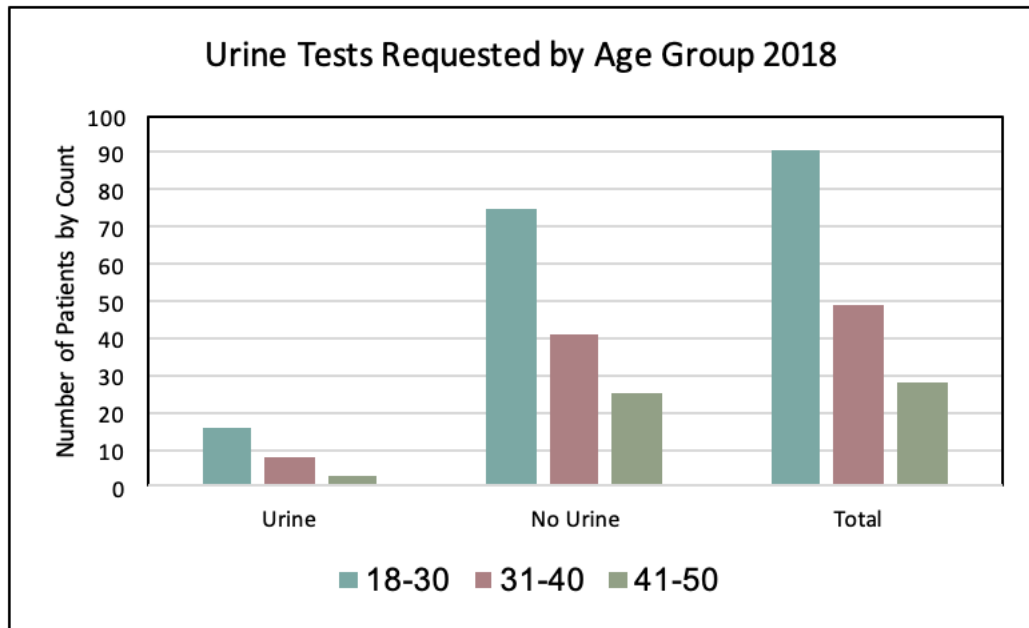
Urine Test by Age Post-PREG (2018)			
Age Range	Urine	No Urine	Total
18-30	16 (17%)	75 (82%)	91
31-40	8 (16%)	41 (84%)	49
41-50	3 (10%)	25 (89%)	28
Total	27 (16%)	141 (84%)	168

Figure E: Breakdown of urine screens requested by age group

Discussion

The main goal of the study was to determine if adding the survey helped to reduce the number of urine screens requested by providers prior to procedures, indicated by few ordered urine screens. Additional goals were to confirm if there were any biases towards a certain procedure or age range in terms of requesting a urine screen. The percentage of urine screens requested dropped significantly from the pre-PREG collection period (January to August 2015) to the post-PREG collection period. It is possible that the percentage of urine screens dropped more dramatically in this study because it compared only the most recent post-PREG data from 2018 to 2015 pre-PREG data. For example, comparing pre-PREG 2015 urine screen data to post-PREG 2016 data likely shows a more modest drop in urine screen orders as providers were still learning to use the survey and trust its recommendations.

The results of the analysis done on pre- and post- PREG survey answers support the continued use of the survey in the primary care gynecology clinic. It provides a convenient way for patients to reasonably exclude pregnancy without the extra cost of completing a urine test or the inconvenience of scheduling an appointment during menses. No patients in the sample had any complications such as device expulsion and no patients were actually pregnant when the PREG survey indicated it was unlikely up through the end of data collection in late 2018.

In addition, being able to do same-day procedures opened provider accessibility because patients did not need to use two appointment slots on different days. Because patients are less likely to return for a second appointment (Morroni et al, 2017), patients should be set up as soon as possible with their preferred method, preferably same-day to reduce chances of pregnancy while waiting for a second appointment.

The PREG survey has potential to be useful in areas other than gynecology and primary care. Pregnancy testing is also done prior to surgeries and other kinds of procedures (Kahn, et al., 2008) and it could be a useful tool to rule out pregnancy in those patients as well. Additional research would need to be done to determine if there was a difference in how providers not specialized in gynecology or primary care would evaluate the survey results, particularly for the women in Category B, who are not pregnant today but may in the future. It's possible these providers would not be as confident in the survey and therefore still request urine tests. It would be necessary to look at whether safety for patients was affected based on who is reading the results.

Another area for additional study would be to look at the use of the PREG survey in younger patients. Unintended pregnancy among teenagers is a current public health issue and teenagers are more likely to stick with a contraceptive method that does not require extra thought or effort the way oral contraceptives and condoms do. (Fleming, Sokoloff, & Raine, 2010). It would be important to look at the efficacy of the survey to exclude pregnancy and how issues commonly affecting teenagers like menstrual irregularity would affect the results.

Limitations

Limitations of this study include having a small sample size to analyze. It's also possible that different providers were more (or less) conservative in their decisions to use the PREG survey as the deciding factor for requesting urine screens. Another limitation was only using data from patients aged 18-50. Data from patients older than 50 and younger than 18 were included in the original data, but removed for this study. It is possible a bias in requesting urine tests could exist for older or younger patients.

Conclusion

LARC methods are the most effective types of birth control, removing the possibility of human error. When pregnancies are unplanned, they can come with an array of negative effects and behaviors that can affect a child for years to come. When a woman is ready to initiate a contraceptive method, it's important to be able to get it to her in a timely manner to further reduce her chance of unplanned pregnancy. The PREG survey has been shown to have a positive effect on patients by accurately and safely allowing them to have the procedures they need without delay.

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Appendix

Appendix A: PREG Patient Survey

Gynecology Clinic Questionnaire
Employee and Community Health

MAYO CLINIC

This form collects information that is part of the medical record. **Discard after use.**

Instructions: Complete all of the following questions that are applicable to your health history.

Patient Information

Mayo Clinic Number	Name	Date *(Month DD, YYYY)*

Reason for Visit

History

Menstrual

Last menstrual period (first day of bleeding) _____

Cycle length (days between bleeding, example 28 days) _____

Days of menstrual bleeding (length of bleeding, example 5 days) _____

Amount of flow (bleeding quantified by pads per day on heaviest day) _____

Associated symptoms _____
_____

Bleeding between menstrual periods (check one) ☐ Yes ☐ No

Age at first menstrual period _____

Birth Control

Birth control method _____

Previous methods _____
_____

    Reasons discontinued _____
_____
_____

Infection

History of sexually transmitted infections (check one) ☐ Yes ☐ No
    If Yes, type (genital herpes, chlamydia, gonorrhea, trichomonas, HIV,
    hepatitis C, syphilis, other) _____
_____

History of other vaginal infections (check one) ☐ Yes ☐ No
    If Yes, type (bacterial vaginosis, yeast infection, other) _____
_____

History of pelvic inflammatory disease (check one) ☐ Yes ☐ No

Pregnancy

Number of previous pregnancies _____

Number of live births _____

Number of previous miscarriages _____

Number of elective terminations _____

Sexual

Number of lifetime partners (males and/or females) _____

Fertility

Desire for future fertility (check one) ☐ Yes ☐ No

Any difficulty conceiving in past (check one) ☐ Yes ☐ No
    If Yes, prior evaluations and treatments? _____
_____
_____
_____

Perimenopause/Menopause (if applicable)

Bleeding pattern _____

Hot flashes _____

Other associated symptoms _____
_____
_____

Hormone replacement therapy _____
_____

Cervical and Vaginal Cytology

Date of most recent Pap smear _____

Results _____

History of abnormal Pap smears (check one) ☐ Yes ☐ No
    If Yes, nature of diagnosis, treatment and follow-up _____
_____

Appendix B: PREG Scoring Guide

For Office Use Only

Candidates for PREG Screening

1. Women age 18 to 50.
   a. Not undergoing a pregnancy related procedure.
   b. Not having emergency surgery requiring start time in less than 1 hour.
   c. Women age 14 to 18 should have pregnancy testing.
2. To be used for pre-procedure screening only. Not a substitute for diagnostic testing.
3. Process altered if patient is unable to read, understand, and accurately answer questions. In these instances the group A questions can generally be used, especially if collaborating history is available in the medical record. Examples include, but are not specifically limited to:
   a. Non-English speaking
   b. Unable to read the form
   c. Unable to provide own medical consent
       i. Intellectual impairment
       ii. Active psychiatric disease impairing judgment
   d. Incarcerated women
   e. Experiencing severe pain
   f. Administration of medication or substance that might impact memory or judgment
   g. Women with any learning barriers identified

Note: Inquiry about specific pregnancy symptoms did not improve the sensitivity of pregnancy screening by history.

Hierarchy of Reasons: C > A > B

A. Women in this category are either known to be pregnant or reasonably not pregnant and are unlikely to become pregnant soon.
   Action: No pregnancy test needed today unless she requests one.
   The surgical listing should already acknowledge that she is pregnant. If not, notify the service.

B. Women in this category are reasonably not pregnant **today**, but will require evaluation **again** prior to future exposures of concern.
   Action: No pregnancy test needed today unless she requests one.

C. Women in this category require pregnancy testing today prior to her procedure, unless hCG (pregnancy test) lab report from the last 36 hours.
   1. Positive pregnancy test — notify the service now. Depending on the exposure of concern:
       a. She is not a candidate for the procedure.
       b. She is a candidate with modifications.
       c. She is a candidate with no modifications required.
           Service will arrange for evaluation for pregnancy or other reasons for elevated hCG.
   2. Negative pregnancy test.
       a. Urine pregnancy test is negative **and** any Group A (other than pregnancy) or Group B statement: She is reasonably not pregnant.
       b. Urine pregnancy test is negative **and** no Group A (other than pregnancy) or Group B statement:
           i. She is reasonably not pregnant, but depending on menstrual and coital history, she may have conceived up to 14 days ago.