MAYO CLINIC

ORIGINAL ARTICLE

Pregnancy Reasonably Excluded Guide (PREG) Evaluation of Pregnancy Status Before Contraceptive Procedures: Improved Availability of Same-Day Insertion

Danielle J. O'Laughlin, PA-C, MS; Petra M. Casey, MD; Claire E. Jensen, MD; and Margaret E. Long, MD

Abstract

Objective: To determine whether implementation of the Pregnancy Reasonably Excluded Guide (PREG) in a primary care gynecology clinic improves access to contraceptive procedures and affects the number of urine human chorionic gonadotropin (hCG) tests.

Patients and Methods: PREG was administered to 981 women aged 18 to 50 years (1012 visits) who were seen in a primary care gynecology clinic for contraceptive procedures from September 30, 2015, through April 30, 2018. Contraceptive procedures included insertion of an intrauterine contraceptive (IUC) or subdermal contraceptive implant. After PREG review and patient discussion, health care professional decided to perform the procedure with or without hCG measurement or to reschedule if the patient's pregnancy status was uncertain. We collected data on the rate of same-day contraceptive procedures and the rate of hCG testing. Data from the PREG implementation period were compared with historical data from 185 women undergoing contraceptive procedures before PREG implementation.

Results: Measurement of hCG was performed in 53% of women before and 24.1% (224 of 1,012 visits) after PREG implementation in the primary care setting. After PREG implementation, 974 0f 1012 patients (96.2%) were eligible for a same-day contraceptive procedure. If traditional criteria, current menses, or a preexisting IUC or implant in place were required for IUC or implant insertion, only 594 patients (58.7%) would have qualified for a same-day procedure. No contraceptive procedures occurred in pregnant women.

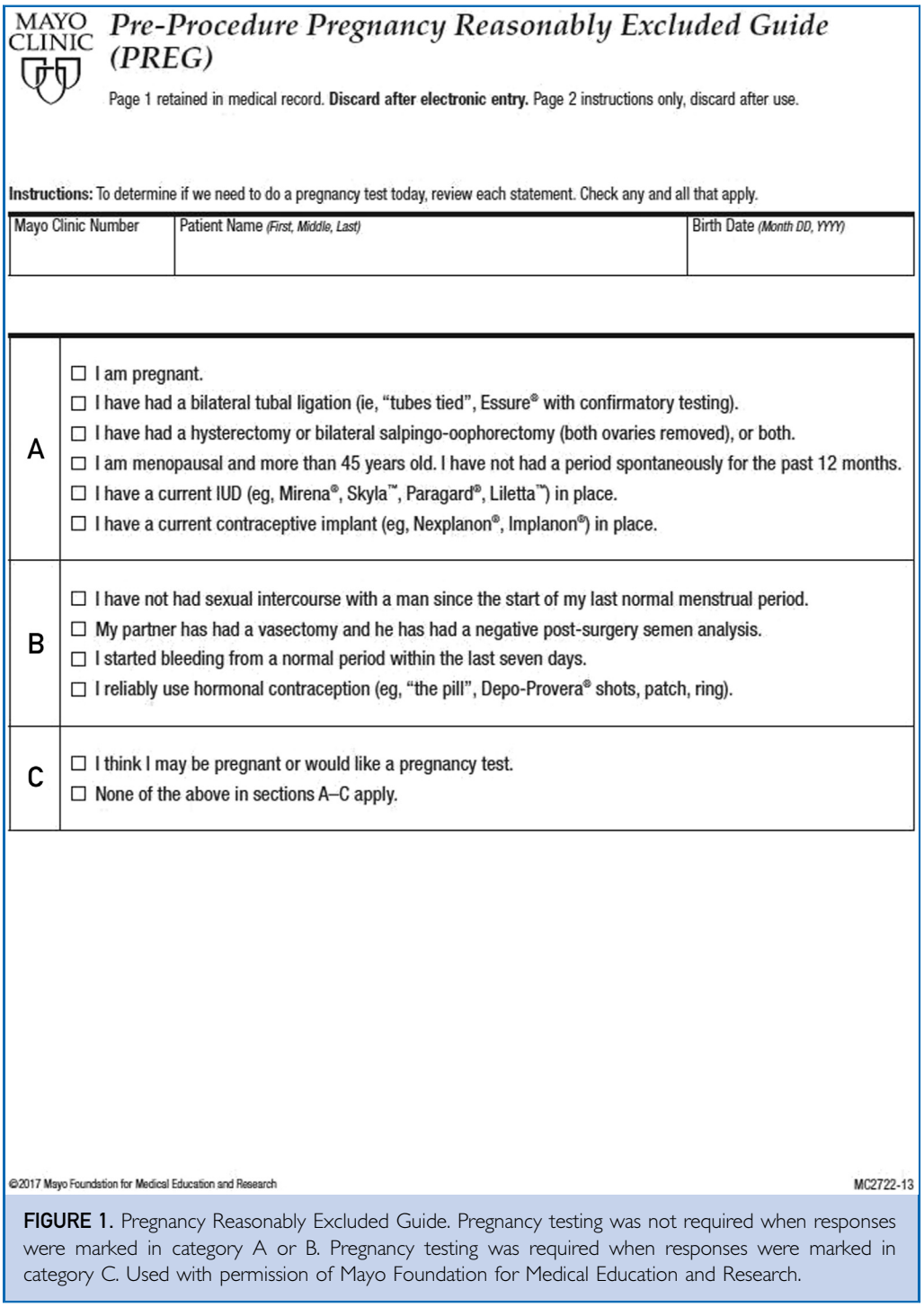
Conclusion: PREG implementation allowed for same-day IUC or implant insertion in 974 women (96.2%) seen for a contraceptive procedure. Most of the women (75.9%) did not require preprocedure hCG measurement.

 ■ Mayo Clin Proc Inn Qual Out 2020;4(3):295-304

The unintended pregnancy rate in the United States, although decreasing, is still unacceptably high despite numerous contraceptive options and increasing use of long-acting reversible contraception (LARC).[1] Approximately 3 million pregnancies each year (approximately half of all pregnancies) are unintended.[1]

Contraception initiation including LARC (intrauterine contraceptive [IUC] or subdermal contraceptive implant) requires exclusion of pregnancy. Pregnancy assessment varies across and within organizations. To exclude pregnancy, practices have included (1) screening with point-of-care human chorionic gonadotropin (hCG) measurement, (2) relying on referring physicians to order hCG testing, or (3) requiring women to be menstruating at the time of the contraceptive procedure. In the luteal phase, hCG testing may miss an early pregnancy.[2] In settings with low pregnancy rates, many women with a low likelihood of pregnancy will have a negative test result, with an increase in the percentage of false-positive hCG results.[3] Inconsistent ordering may delay contraceptive procedures

From the Division of Community Internal Medicine (D.J.O.) and Department of Obstetrics and Gynecology (P.M.C., C.E.J., M.E.L.), Mayo Clinic, Rochester, MN.



MAYO CLINIC

Pre-Procedure Pregnancy Reasonably Excluded Guide (PREG)

Page 1 retained in medical record. **Discard after electronic entry.** Page 2 instructions only, discard after use.

Instructions: To determine if we need to do a pregnancy test today, review each statement. Check any and all that apply.

Mayo Clinic Number	Patient Name *(First, Middle, Last)*	Birth Date *(Month DD, YYYY)*

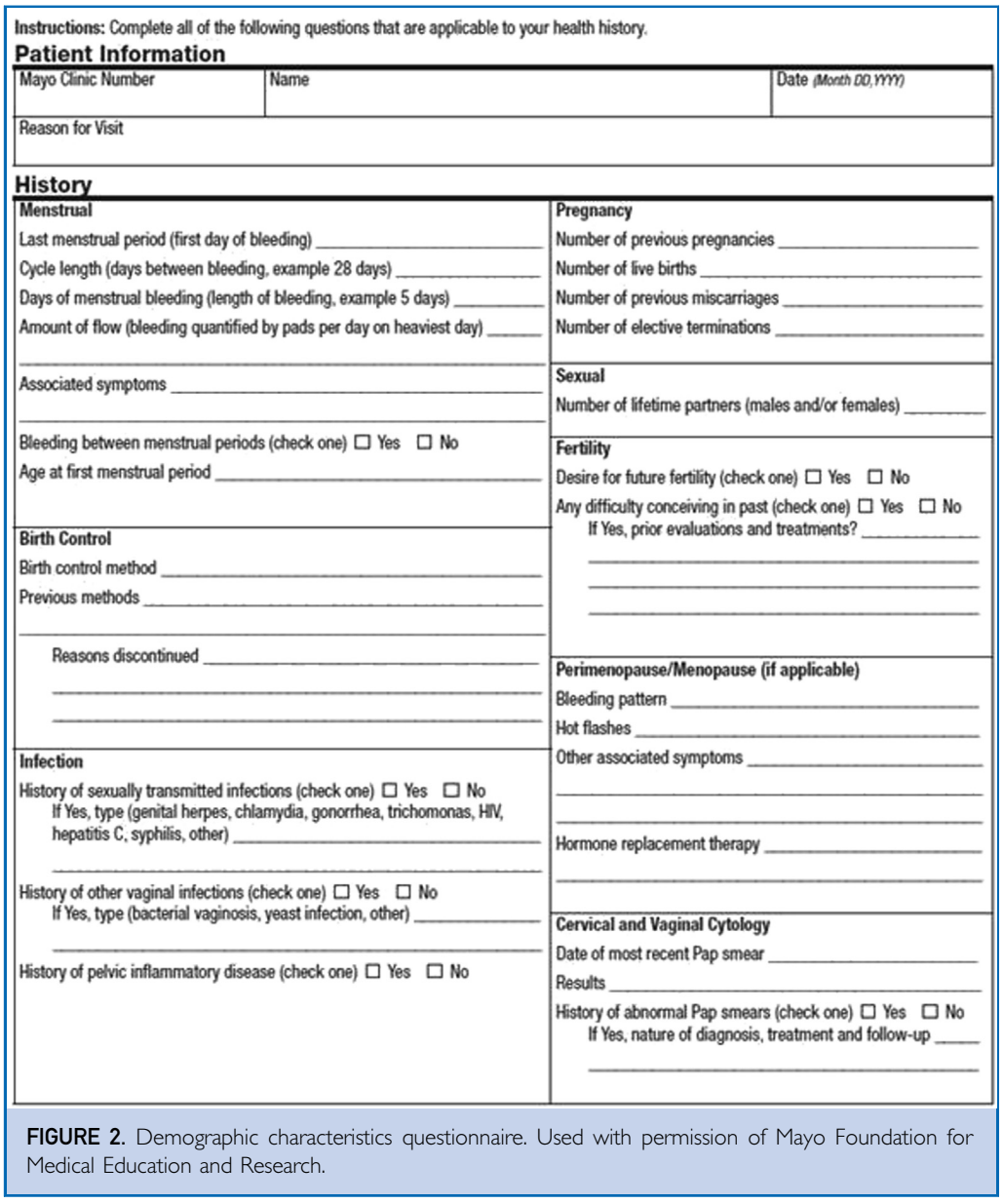
A	☐ I am pregnant. ☐ I have had a bilateral tubal ligation (ie, "tubes tied", Essure® with confirmatory testing). ☐ I have had a hysterectomy or bilateral salpingo-oophorectomy (both ovaries removed), or both. ☐ I am menopausal and more than 45 years old. I have not had a period spontaneously for the past 12 months. ☐ I have a current IUD (eg, Mirena®, Skyla™, Paragard®, Liletta™) in place. ☐ I have a current contraceptive implant (eg, Nexplanon®, Implanon®) in place.
B	☐ I have not had sexual intercourse with a man since the start of my last normal menstrual period. ☐ My partner has had a vasectomy and he has had a negative post-surgery semen analysis. ☐ I started bleeding from a normal period within the last seven days. ☐ I reliably use hormonal contraception (eg, "the pill", Depo-Provera® shots, patch, ring).
C	☐ I think I may be pregnant or would like a pregnancy test. ☐ None of the above in sections A–C apply.

 MC2722-13

FIGURE 1. Pregnancy Reasonably Excluded Guide. Pregnancy testing was not required when responses were marked in category A or B. Pregnancy testing was required when responses were marked in category C. Used with permission of Mayo Foundation for Medical Education and Research.

and consequently may increase the risk of unintended pregnancy, in addition to overusing health care resources.

The Pregnancy Reasonably Excluded Guide (PREG), a 12-statement checklist, was developed and effectively implemented in the Department of Obstetrics and Gynecology at Mayo Clinic in 2013.[4,5] After revision to support its use in more diverse patient populations, PREG implementation has expanded to



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 _____

FIGURE 2. Demographic characteristics questionnaire. Used with permission of Mayo Foundation for Medical Education and Research.

the preoperative setting and has the potential to be used in additional health care areas.[6]

PREG uses traditional criteria to identify cases in which hCG measurement is not indicated, plus items modified from a checklist by Stanback et al[7] for ruling out pregnancy among family-planning clients. The checklist by Stanback et al,[7] supported by the World Health Organization and Centers for Disease Control and Prevention, has a greater than 99% negative predictive value for pregnancy.[4,8] Criteria from the Stanback et al[7] list incorporated into PREG were being within 7 days before the onset of normal menses, having had no intercourse since normal menses, and correct and consistent use of contraception.[6] Being limited to hormonal contraception, the contraceptive use criteria in PREG are more conservative than those used by Stanback et al.[7] Traditional criteria that indicate a negative result on screening for pregnancy without hCG

measurement include hysterectomy, bilateral salpingo-oophorectomy, tubal ligation, and menopause. A known pregnancy also does not require hCG testing. When screening hCG testing is performed, especially in the absence of historical exclusion criteria, negative results must be interpreted in the context of the woman's menstrual, coital, and contraceptive history. Additionally, in settings such as evaluation of abdominal pain or vaginal bleeding in which diagnostic certainty regarding pregnancy status is needed, a pregnancy test is indicated, not a screening tool like the Stanback et al checklist[7] or PREG.

Previously, no formal process had been used at our institution to exclude pregnancy in the primary care setting. When a primary care gynecology (PCG) clinic opened at Mayo Clinic in Rochester, Minnesota, in September 2015, PREG use was implemented as a decision aid and standardized approach to exclude pregnancy. The aim of the current study was to determine whether the implementation of PREG in our PCG clinic improved access to same-day contraceptive procedures, without unnecessary hCG testing.

PATIENTS AND METHODS

Study Setting

The study was approved by the Mayo Clinic Institutional Review Board. The staff from the PCG clinic involved in the study included desk attendants who administer PREG, nurses who confirm PREG completion, and advanced practice providers (APPs; physician assistants, nurse practitioners) who review and discuss the PREG with the patient. The APPs from the PCG clinic have a special interest in women's health and have additional training in gynecologic consultations and procedures. At the time of appointment scheduling, women were encouraged to continue efforts to prevent pregnancy until their appointment. Nursing counseling was available on request.

Intervention

An interprofessional team approach was used in the implementation of PREG. PREG (Figure 1) was provided at the time of PCG clinic appointment check-in to women aged 18 to 50 years seen for contraceptive procedures (IUC and implant placement) from September 30, 2015, through April 30, 2018. Exclusion criteria were the inability to independently read English and complete PREG and denial of access to their medical records for research purposes.

We also developed a demographic characteristics questionnaire (Figure 2) to support clinic quality and flow, which was administered along with PREG. This questionnaire gathered patient characteristics including desired contraceptive procedure, menstrual history, prior contraception, history of gynecologic infection, gravidity and parity, fertility history, perimenopausal symptoms, and cervical cytological history.

Nursing staff confirmed PREG completion and relayed the information to the APP. The PREG and demographic characteristics questionnaire were then reviewed and discussed in private with the patient. If hCG testing was indicated per APP order, nursing staff performed point-of-care urine pregnancy testing with the ICON 20 hCG (HemoCueAmerica), which has a threshold of 20 mIU/L in urine. Institutional quality control processes for this testing were continued. The contraceptive procedure was performed if appropriate. If the patient's pregnancy status was uncertain, the visit was rescheduled.

PREG contains 3 groups of statements that help determine whether pregnancy testing is required. Group A statements determine whether women are either pregnant or reasonably *not* pregnant that day and unlikely to become pregnant in the near future. Women who met criteria for group A did not require pregnancy testing. Group B statements determine whether women are reasonably not pregnant that day but could become pregnant in the near future. Women who met these conditions did not require pregnancy testing that day but could require pregnancy testing in the future. Group C statements identify women who state they might be pregnant, want a pregnancy test, or do not meet criteria in group A or B. Women in this category required preprocedure pregnancy testing. Women with a negative pregnancy test result and criteria from group A (except previously diagnosed pregnancy), group B, or both are reasonably not pregnant and can proceed with the scheduled procedure. Pregnancy testing could proceed or be added if either the patient or physician desires it during

Mayo Clin Proc Inn Qual Out ■ June 2020;4(3):295-304 ■ https://doi.org/10.1016/j.mayocpiqo.2020.01.008
www.mcpiqojournal.org

TABLE 1. Demographic Characteristics, Pregnancy History, and Outcomes for Primary Care Gynecology Clinic Visits[a,b]

Variable	Value (N=1012 visits)
Patient age at visit (y)	30.6 (8.6)
Race	
White	878 (86.8)
Black/African American	33 (3.3)
American Indian/Alaskan Native	2 (0.2)
Asian/Pacific Islander	47 (4.6)
Other	42 (4.1)
Not disclosed/unknown	10 (1.0)
Hispanic or Latina	
Yes	36 (3.6)
No	944 (93.3)
Not disclosed/unknown	32 (3.2)
Gravidity	0 (0-2)
Parity	0 (0-2)
Type of contraception	
Etonogestrel implant, 68 mg	200 (19.8)
IUC	812 (80.2)
Levonorgestrel-releasing intrauterine system, 52 mg	711 (70.3)
Intrauterine copper contraceptive	49 (4.8)
Levonorgestrel-releasing intrauterine system, 13.5 mg	51 (5.0)
Levonorgestrel-releasing intrauterine system, 19.5 mg	1 (0.1)
Point-of-care pregnancy test	244 (24.1)
hCG positive	1 (0.4) (0.1% of cohort)
Rescheduled	
No	974 (96.2)
Not recorded	2 (0.2)
Yes	36 (3.6)

[a]hCG = human chorionic gonadotropin; IUC = intrauterine contraceptive.
[b]Data are presented as mean ± SD, No. (percentage) of visits, or median (interquartile range).

or after review of PREG criteria. Review and discussion of PREG criteria are absolute requirements for this process. For women in group C with a negative hCG result and no criteria in group A or B, pregnancy may be excluded or conception may have occurred in the preceding 12 to 13 days, depending on menstrual and coital history.[9] For example, consistent condom use or an interval of 17 days since unprotected coitus, along with a negative urine hCG result, were sufficient to reasonably exclude pregnancy and can be especially helpful criteria in women with irregular or long cycles. For women seeking removal and replacement of LARC after the US Food and Drug Administration–approved interval of use, the time since insertion was also considered. This determination was made by the APP during review and discussion of PREG and hCG results with the patient.

PREG and demographic characteristics questionnaire results were stored in a database. Reviews of the electronic health record were used to gather information on age, race, date of procedure, whether hCG testing was completed along with the result, and whether the visit was rescheduled. These data were summarized for the study interval and subdivided by calendar year. These data were then compared with data collected for 185 women who underwent contraceptive procedures in the primary care setting in 2015 before PREG implementation. SQUIRE 2.0 guidelines were used as a framework for reporting findings.[10]

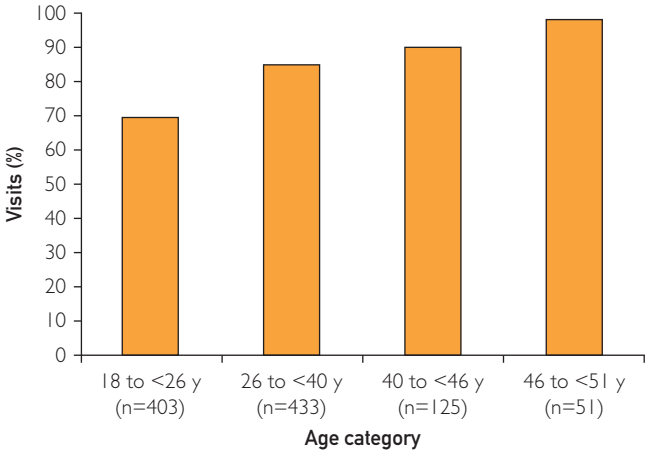


FIGURE 3. Percentage of intrauterine contraceptive users by age.

RESULTS

We collected data from 1012 visits among 981 women scheduled for IUC or implant placement during the study period. Overall, the mean age of women screened with PREG was 30.6 years; at 1012 visits, 880 patients (87.0%) identified as white, 533 (52.7%) reported gravidity of 0, and 557 (55.0%) reported parity of 0 (Table 1). Most of the contraceptive procedures (812 of 1012 [80.2%]) were IUC placement; the other 19.8% of procedures (200) were placement of the contraceptive implant etonogestrel, 68 mg (Table 1). Twenty women (1.9%) had contraceptive procedures after bilateral tubal ligation or menopause for off-label use.[11]

At 1012 visits after PREG implementation, 974 women (96.2%) were eligible for their scheduled contraceptive procedure (Table 1). Only 36 women (3.6%) had their appointment rescheduled because of uncertain pregnancy status, and 2 women (0.2%) did not have this information recorded in the medical record. If traditional criteria, current menses, or presence of a current IUC or implant had been used to exclude pregnancy, only 594 (58.7%) would have qualified for a same-day procedure. No contraceptive procedures occurred in pregnant women. No failures to detect pregnancy were identified after the procedures based on the absence of reports to the PCG clinic, obstetric health care professionals, and quality offices.

Before PREG implementation, 98 of 185 women (53.0%) in a historical cohort had hCG measurement. Use of PREG decreased the rate of hCG testing to 24.1% (244 tests per 1012 visits) with point-of-care urine testing and an additional 3.5% (35 tests per 1012 visits) with laboratory testing ordered in advance. Of the 244 point-of-care hCG tests, 1 was positive in the context of a group C response, and the contraceptive procedure was postponed. Measurement of hCG after PREG implementation was grouped by age and procedure type. Women aged 18 to less than 26 years had the highest rate of office hCG tests (114 of 403 [28.3%]) compared with age 26 to less than 40 years (101 of 433 [23.3%]), age 40 to less than 46 years (17 of 125 [13.6%]), and age 46 to less than 51 years (12 of 51 [23.5%]). Women scheduled for implant placement had a higher rate of hCG tests (55 of 200 [27.5%]) than those scheduled for IUC placement (189 of 812 [23.3%]). The rate of intended IUC placement increased with increasing age (Figure 3).

PREG responses by category are summarized in Table 2. Among the 1012 visits, 538 patients (57.6%) had group B responses only, 145 (14.3%) had group A only, 144 (14.2%) had responses in both groups A and B, and 105 (10.4%) had group C responses. "I think I may be pregnant" or "I would like a pregnancy test" (a subset of group C) was the response for 4 women (0.4%). On the basis of PREG responses alone without APP review, 121 women (12.0%) would have required pregnancy testing. Provider review and discussion of the PREG led to a 24.1% rate of urine hCG testing in the clinic (244 of 1012 visits), with an additional 3.5% (35 patients) having laboratory pregnancy testing ordered before the procedure visit by the referring physician. Indications for testing after provider review of PREG included identification of an expired LARC, recollection of intercourse, clarification of abnormal menses, inconsistent contraception use, and provider or patient request. The rate of hCG testing decreased each year, from 42.9% (15 of 35) in 2015 to 29.0% (95 of 328) in 2016, 22.0% (108 of 491) in 2017, and 16.5% (26 of 158) in 2018 (Table 2). Rates of laboratory pregnancy testing ordered before the procedure visit similarly decreased.

Mayo Clin Proc Inn Qual Out ■ June 2020;4(3):295-304 ■ https://doi.org/10.1016/j.mayocpiqo.2020.01.008
www.mcpiqojournal.org

TABLE 2. PREG Results

PREG items	Calendar year				Total (N=1012)
	2015 (N=35)	2016 (N=328)	2017 (N=491)	2018 (N=158)	
I've had a negative pregnancy test today	1 (2.9%)	15 (4.6%)	18 (3.7%)	1 (0.6%)	35 (3.5%)
Category A items					
I am pregnant	0	0	0	0	0
I've had a bilateral tubal ligation	3 (8.6%)	5 (1.5%)	10 (2.0%)	0 (0.0%)	18 (1.8%)
I've had a hysterectomy or BSO	0	0	0	0	0
I am menopausal and >45 years old	1 (2.9%)	0 (0.0%)	1 (0.2%)	0 (0.0%)	2 (0.2%)
I have a current IUD in place	5 (14.3%)	56 (17.1%)	99 (20.2%)	40 (25.3%)	200 (19.8%)
I have a current contraceptive implant in place	0 (0.0%)	32 (9.8%)	27 (5.5%)	17 (10.8%)	76 (7.5%)
Category B items					
I have not had sexual intercourse with a man since the start of my last normal menstrual period	10 (28.6%)	103 (31.4%)	177 (36.0%)	59 (37.3%)	349 (34.5%)
My partner has had a vasectomy and he has had a negative post-surgery semen analysis	3 (8.6%)	18 (5.5%)	20 (4.1%)	7 (4.4%)	48 (4.7%)
I started bleeding from a normal period within the last 7 days	9 (25.7%)	105 (32.0%)	170 (34.6%)	53 (33.5%)	337 (33.3%)
I reliably use hormonal contraception	11 (31.4%)	118 (36.0%)	152 (31.0%)	44 (27.8%)	325 (32.1%)
Category C items					
I think I may be pregnant or would like a pregnancy test	0 (0.0%)	0 (0.0%)	0 (0.0%)	4 (2.5%)	4 (0.4%)
None of the above apply	6 (17.1%)	40 (12.2%)	46 (9.4%)	9 (5.7%)	101 (10.0%)
Mutually exclusive categorization based on the hierarchy listed below (top to bottom)					
I think I may be pregnant or would like a pregnancy test	0 (0.0%)	0 (0.0%)	0 (0.0%)	4 (2.5%)	4 (0.4%)
I had a negative pregnancy test today	1 (2.9%)	15 (4.6%)	18 (3.7%)	1 (0.6%)	35 (3.5%)
Marked an X in Category A only	5 (14.3%)	41 (12.5%)	73 (14.9%)	26 (16.5%)	145 (14.3%)
Marked an X in Category B only	21 (60.0%)	182 (55.5%)	292 (59.5%)	88 (55.7%)	583 (57.6%)
Marked an X in both Categories A & B	2 (5.7%)	50 (15.2%)	62 (12.6%)	30 (19.0%)	144 (14.2%)
None of the above apply	6 (17.1%)	40 (12.2%)	46 (9.4%)	9 (5.7%)	101 (10.0%)

Of women with a negative pregnancy test result, 158 (56.6% of all 279 pregnancy tests) had at least 1 group A or group B criterion to exclude pregnancy, including 51 who identified a current normal menses. Additionally, some women who identified their IUC or implant as expired were within the manufacturer's guidelines for duration of use so actually had group A criteria in addition to their negative pregnancy test result. Other women with negative results had LARC that had been in place beyond the manufacturer's guidelines so did not meet group A criteria but were within a duration of documented efficacy (eg, use of the levonorgestrel-releasing intrauterine system for less than 6 years or implant use just slightly longer than 36 months) for pregnancy exclusion.[12,13]

DISCUSSION

Before the implementation of PREG, no formal process existed for pregnancy assessment, and hCG testing was based on physician discretion and practice style. PREG use in this primary care contraceptive procedure clinic setting allowed more women to undergo same-day contraceptive procedures. Reduced delay in initiating contraception/LARC placement is associated with lower unplanned pregnancy rates.[14] With PREG, pregnancy status was more consistently and objectively documented in this screening population, and no failure of pregnancy detection on procedure day was identified.

PREG focuses pregnancy testing on women who have a higher likelihood of

pregnancy. By identifying women with a very low likelihood of pregnancy using historical criteria, more women were able to forgo unnecessary pregnancy testing, thus decreasing delay in access to contraceptive procedures, rates of false-positive pregnancy test results, and personal and health care costs. PREG presents a structured opportunity for shared decision making regarding preprocedural pregnancy testing and had no unintended negative consequences related to use or cost in our setting. Rates of pregnancy testing, in fact, decreased.

False-positive hCG results are more common in perimenopausal and menopausal women because of increased secretion of pituitary hCG.[15] Many perimenopausal woman use LARC because levonorgestrel IUC is efficacious in managing abnormal uterine bleeding; thus, pregnancy assessment and avoidance of unnecessary testing is important to avoid contraceptive or therapeutic delay.[16] False-positive urine hCG results have also been reported with adenomyosis and interfering rheumatoid factor.[17,18]

Implementation of PREG for screening in the primary care setting creates a standardized approach to assess for pregnancy. PREG is also appropriate for use in noncontraceptive preprocedural settings. With continued use, physicians became more comfortable with its usefulness and validity. The rate of hCG testing performed decreased each year, from 42.9% in 2015 to 16.5% in 2018, which indicated an increased physician reliance on PREG. The testing rate of 42.9% in 2015 was higher than expected, but the downward trend through 2018 illustrated that practice change takes time. The latest hCG testing rate of 16.5% is similar to that seen with PREG use in the department of obstetrics and gynecology,[5] which supports that the decreased hCG testing was associated with PREG implementation. PREG has now been implemented successfully in several settings at Mayo Clinic.[5,6]

Patient-physician review and discussion of pregnancy exclusion criteria remained important to improve the validity of the assessment and further ensure that the woman was a candidate for screening alone (ie, asymptomatic) vs requiring a diagnostic evaluation (eg, abnormal menses or acute pelvic pain). Additionally, the criteria review strengthened the context of negative hCG results and facilitated interpretation. Physician involvement in screening also helped improve accuracy, decrease overreliance on hCG testing, and improve patient understanding and acceptance. PREG enhanced quality patient care components, including safe and efficient patient-centered care with testing when beneficial, avoidance of testing when potentially detrimental, and contextual interpretation of negative hCG results. These characteristics associated with PREG benefit the patient and the health care system.

This study reports on the generalizability and feasibility of PREG implementation in a primary care contraceptive procedure clinic setting. No ethical conflicts were apparent. PREG was administered to women who could read English and independently complete PREG. We did not perform PREG screening in women who could not read or independently complete the assessment to decrease the risk of misunderstanding or translation error. Further studies would need to be performed on the use of PREG in women who could not read or independently complete it.

Results mirrored successful implementation in the gynecology specialty clinic at Mayo Clinic, and a higher PREG acceptability in the primary care setting may be due to previous physician experience with PREG.[5] The multiyear study was done to control for this effect of previous experience and to ensure longevity of PREG use. The rate of positive pregnancy tests (0.1%) was lower than the 2.6% to 7.95% positive rates reported in some family planning settings.[2,19] The benefit of a screening tool such as PREG may be lower in populations with higher pregnancy rates. The sample size of 1012 visits over several years is a study strength and documented the success of PREG implementation. The interprofessional team approach was especially effective because it provided a time-efficient process and consistent messaging to patients while maintaining overall patient flow.

Women were not specifically evaluated for pregnancy after their procedure when a pregnancy present at the time of the procedure could be detected. However, women seen in this primary care clinic would have been unlikely to seek care for a pregnancy outside of

Mayo Clin Proc Inn Qual Out ■ June 2020;4(3):295-304 ■ https://doi.org/10.1016/j.mayocpiqo.2020.01.008
www.mcpiqojournal.org

the institution because of insurance coverage and care options. Additionally, a quality review would have been initiated for LARC placement during pregnancy.

Before the opening of the PCG clinic and use of PREG, contraceptive procedures were done across the primary care practice by multiple physicians, with no consistent documentation. For this reason, the comparison data did not accurately capture the same-day access or rescheduling rates. Thus, estimated historical same-day access and rescheduling rates had to be determined by analysis of same-day eligibility rates for contraceptive procedure based on the criteria of current menses and IUC or implant in place responses. This is a study limitation. Women in these procedure appointments had typically identified the desire for IUC or implant insertion in advance. They may have received information from their care team or community contacts on circumstances that exclude pregnancy (appointment during menses) and avoidance of pregnancy before the scheduled appointment (contraceptive use or abstinence). Other women had LARC that was incorrectly identified by them as being past the US Food and Drug Administration–approved duration of use. Other LARC was due to be replaced but was within a time frame during which continued efficacy had been documented.[12,13] These factors most likely affected the high rate of procedures completed on the scheduled day.

CONCLUSION

Implementation of PREG in primary care for scheduled IUC or implant insertion at Mayo Clinic was associated with eligibility for scheduled same-day insertion in 96.4% overall and in 75.9% without the need for hCG testing. Use of PREG creates a standardized approach to screen for pregnancy status. It facilitates the delivery of comprehensive care while minimizing unnecessary hCG testing, the risk of false-positive results, delayed care, and cost. Negative hCG results require interpretation in the context of menstrual and coital history. PREG use is sustainable over time and generalizable across the Mayo Clinic health care system and beyond. Continued implementation of PREG in other settings will aid in time- and cost-efficient health care for reproductive-aged women.

ACKNOWLEDGMENTS

We thank our advanced practice gynecology clinic colleagues at Mayo Clinic for their participation in this study. Editing, proofreading, and reference verification of the submitted manuscript were provided by Scientific Publications, Mayo Clinic.

Abbreviations and Acronyms: **APP** = advanced practice provider; **hCG** = human chorionic gonadotropin; **IUC** = intrauterine contraceptive; **LARC** = long-acting reversible contraception; **PCG** = primary care gynecology; **PREG** = Pregnancy Reasonably Excluded Guide

Potential Competing Interests: Drs Casey and Long have received research support from Merck & Co, Inc.

Publication dates: Received for publication October 2, 2019; revisions received January 3, 2020; accepted for publication January 27, 2020.

Correspondence: Address to Margaret E. Long, MD, Department of Obstetrics and Gynecology, Mayo Clinic, 200 First St SW, Rochester, MN 55905 (long.margaret@mayo.edu).

ORCID

Margaret E. Long: https://orcid.org/0000-0002-8655-1764

REFERENCES

1. Secura GM, Allsworth JE, Madden T, Mullersman JL, Peipert JF. The Contraceptive CHOICE Project: reducing barriers to long-acting reversible contraception. *Am J Obstet Gynecol*. 2010; 203(2):115.e1-115.e7.
2. Min J, Buckel C, Secura GM, Peipert JF, Madden T. Performance of a checklist to exclude pregnancy at the time of contraceptive initiation among women with a negative urine pregnancy test. *Contraception*. 2015;91(1): 80-84.
3. Gong X, Poterack KA. Retrospective review of universal preoperative pregnancy testing: results and perspectives. *Anesth Analg*. 2018;127(2):e4-e5.
4. Division of Reproductive Health, National Center for Chronic Disease Prevention and Health Promotion, Centers for Disease Control and Prevention. U.S. Selected Practice Recommendations for Contraceptive Use, 2013: adapted from the World Health Organization Selected Practice Recommendations for Contraceptive Use, 2nd edition. *MMWR Recomm Rep*. 2013; 62(RR-05):1-60.
5. Long M, Ahlberg L, Beissel J, Cope A, Fosterling-Pearson G, Casey P. Efficient exclusion of pregnancy prior to initiation of long-acting reversible contraception or performance of an intrauterine procedure. *Eur J Contracept Reprod Health Care*. 2016;21(Suppl 1):95.
6. Wyatt MA, Ainsworth AJ, DeJong SR, Cope AG, Long ME. Implementation of the "Pregnancy Reasonably Excluded Guide" for pregnancy assessment: a quality initiative in outpatient gynecologic surgery. *Obstet Gynecol*. 2018;132(5):1222-1228.
7. Stanback J, Qureshi Z, Sekadde-Kigondu C, Gonzalez B, Nutley T. Checklist for ruling out pregnancy among family-planning clients in primary care. *Lancet*. 1999;354(9178):566.

8. Tepper NK, Marchbanks PA, Curtis KM. Use of a checklist to rule out pregnancy: a systematic review. *Contraception*. 2013; 87(5):661-665.
9. Gnoth C, Johnson S. Strips of hope: accuracy of home pregnancy tests and new developments. *Geburtshilfe Frauenheilkd*. 2014;74(7):661-669.
10. Ogrinc G, Davies L, Goodman D, Batalden P, Davidoff F, Stevens D. SQUIRE 2.0 (Standards for QUality Improvement Reporting Excellence): revised publication guidelines from a detailed consensus process [in Spanish]. *Medwave*. 2015; 15(10):e6318.
11. Allen RH, Cwiak CA. Contraception for midlife women. *Menopause*. 2016;23(1):111-113.
12. Rowe P, Farley T, Peregoudov A, et al; IUD Research Group of the UNDP/UNFPA/WHO/World Bank Special Programme of Research; Development and Research Training in Human Reproduction. Safety and efficacy in parous women of a 52-mg levonorgestrel-medicated intrauterine device: a 7-year randomized comparative study with the TCu380A [published correction appears in *Contraception*. 2016;94(3):288]. *Contraception*. 2016;93(6):498-506.
13. Ali M, Akin A, Bahamondes L, et al; WHO Study Group on Subdermal Contraceptive Implants for Women. Extended use up to 5 years of the etonogestrel-releasing subdermal contraceptive implant: comparison to levonorgestrel-releasing subdermal implant. *Hum Reprod*. 2016;31(11):2491-2498.
14. Curtis KM, Jatlaoui TC, Tepper NK, et al. U.S. Selected Practice Recommendations for Contraceptive Use, 2016. *MMWR Recomm Rep*. 2016;65(4):1-66.
15. Cole LA, Khanlian SA, Muller CY. Normal production of human chorionic gonadotropin in perimenopausal and menopausal women and after oophorectomy. *Int J Gynecol Cancer*. 2009; 19(9):1556-1559.
16. *Mirena [patient information]*. Whippany, NJ: Bayer HealthCare Pharmaceuticals Inc; 2000. Bayer HealthCare Pharmaceuticals Inc website, https://labeling.bayerhealthcare.com/html/products/pi/Mirena_PPI.pdf. Accessed August 16, 2019.
17. Er TK, Chiang CH, Cheng BH, Hong FJ, Lee CP, Ginés MA. False-positive urine pregnancy test in a woman with adenomyosis. *Am J Emerg Med*. 2009;27(8):1019.e5-1019.e7.
18. Marzinke MA, Jarrar P, Atkinson M, Humphrey RL, Detrick B, Sokoll LJ. Origin of a false positive urine pregnancy test in a patient with membranoproliferative glomerulonephritis type I. *Clin Chim Acta*. 2012;413(1-2):361-363.
19. Kasliwal A, Farquharson RG. Pregnancy testing prior to sterilisation. *BJOG*. 2000;107(11):1407-1409.