



CHARACTERIZATION OF WOMEN ACCORDING TO PREGNANCY STATUS FOLLOWING TREATMENT WITH VAGINAL PH MODULATOR DURING THE AMPOWER STUDY

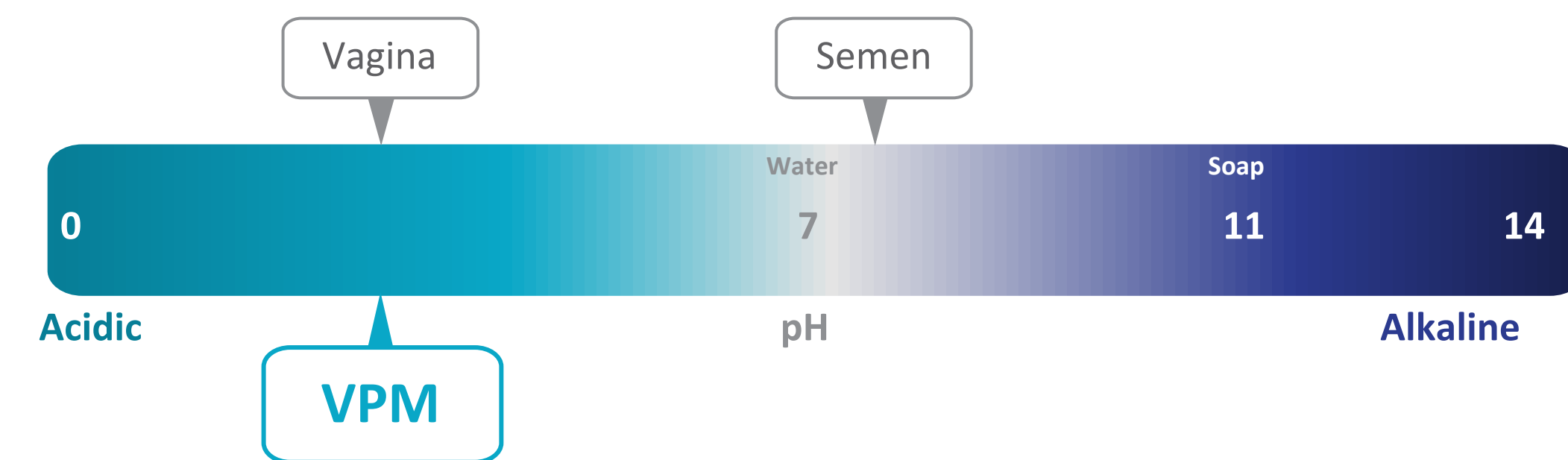
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INTRODUCTION

- The vaginal pH modulator (VPM; Phexxi™) is a novel, non-hormonal, woman-controlled contraceptive vaginal gel
- VPM contains 3 active ingredients (L-lactic acid, citric acid, and potassium bitartrate) and is designed to maintain the acidic vaginal environment even in the presence of alkaline semen (Figure 1)^{1,2}

Figure 1. Acid-buffering Properties of VPM



- Primary results of the phase 3 AMPOWER study, which assessed the efficacy and safety of VPM in 1384 healthy women, have been previously reported and demonstrated that VPM was safe and met the primary endpoint for the 7-cycle cumulative pregnancy percentage³

AIM

- This analysis describes the characteristics of women in the phase 3 AMPOWER trial who became pregnant while on the study vs those who did not become pregnant

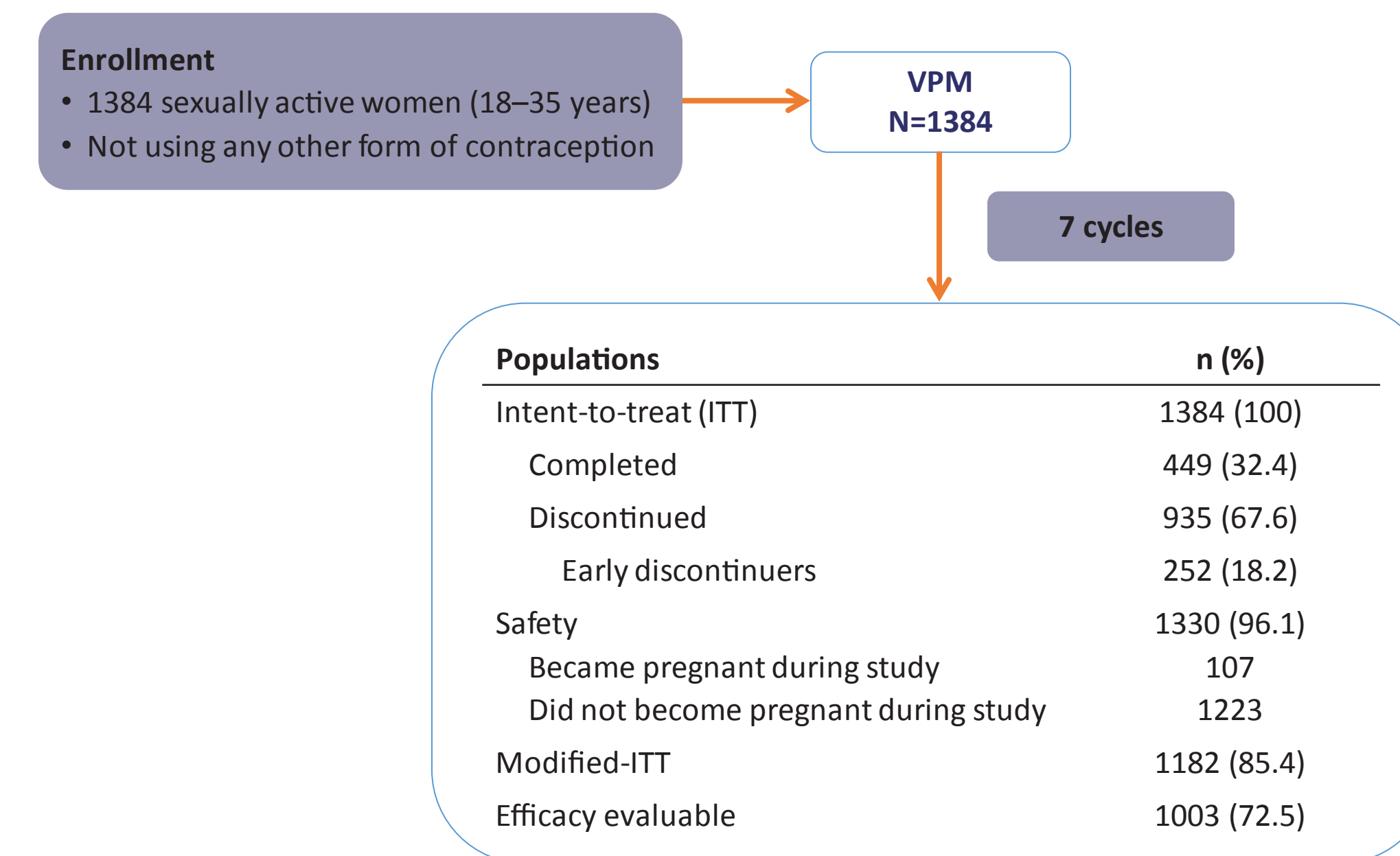
METHODS

- AMPOWER was a single-arm, open-label, IRB-approved, multi-center trial based in the United States (NCT03243305)
- Women, aged 18-35 years, administered VPM intravaginally ≤ 1 hour before each act of vaginal intercourse
- The primary study objective was the cumulative pregnancy percentage over 7 cycles with typical-use calculated by the Kaplan-Meier method
- Demographic, obstetric, and contraceptive history were also recorded
- In this post-hoc analysis, baseline characteristics are described descriptively by pregnancy status on-study

RESULTS

- The post-hoc analysis was based on 1330 women included in the Safety population in the AMPOWER study (Figure 2)
 - Of these 1330 women, 107 became pregnant during the study and 1223 did not

Figure 2. Subject Disposition in AMPOWER



Baseline Demographics by Pregnancy Status

- Baseline demographic characteristics by age, race, and body mass index (BMI) were similar between women who became pregnant during the study and those who did not (Table 1); women of Hispanic or Latina origin represented a higher percentage of women in the non-pregnant sub-group vs the pregnant sub-group

Table 1. Baseline Demographic Characteristics by Pregnancy Status On-Study

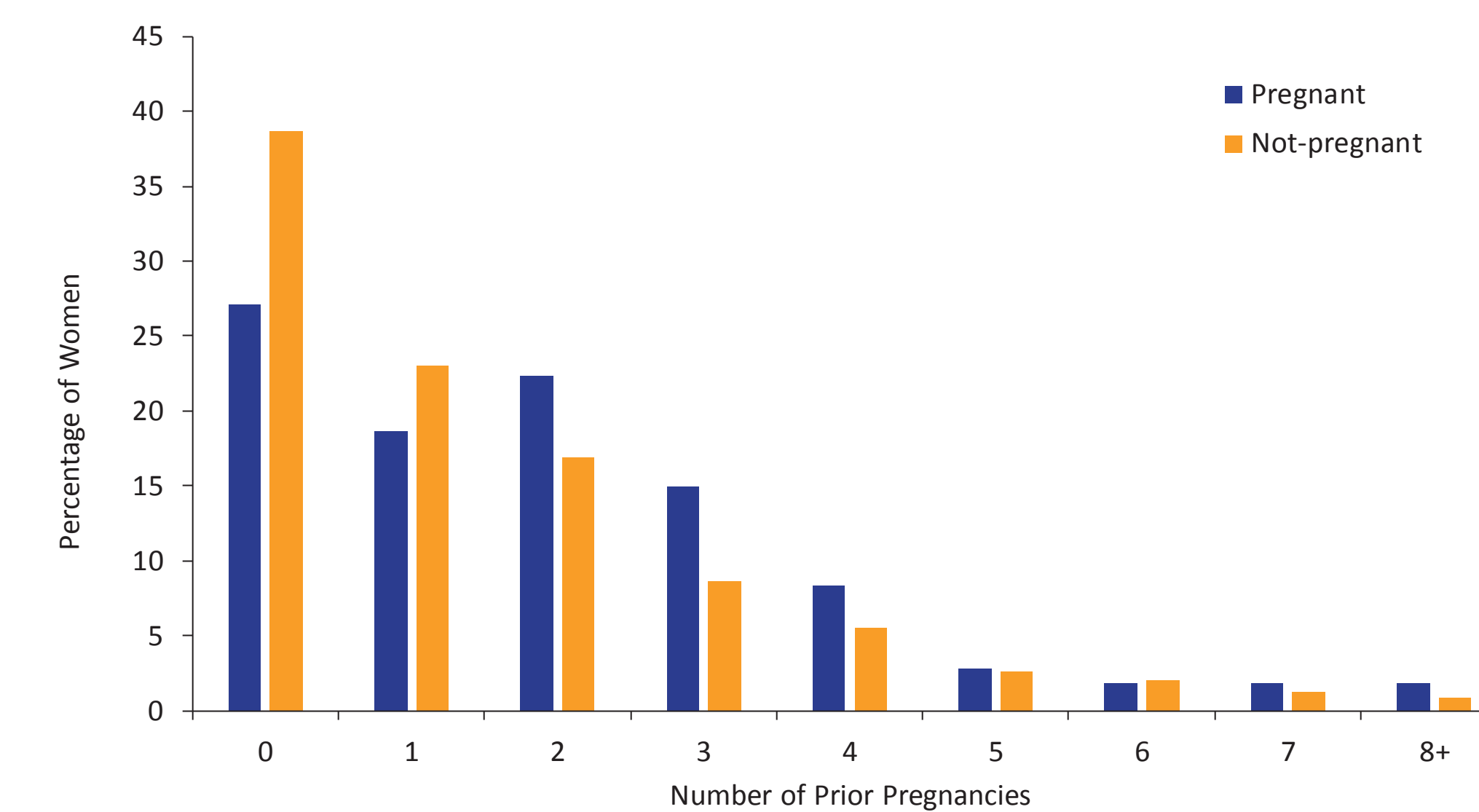
Characteristic	Pregnant (n=107)	Non-pregnant (n=1223)
Age, yrs (SD)	27.5 (4.4)	27.7 (4.5)
Ethnicity, n (%)		
Hispanic or Latina origin	24 (22.4)	526 (43.0)
Not Hispanic or Latina origin	83 (77.6)	689 (56.3)
Not Reported	0	8 (0.7)
Race, n (%)		
Asian	5 (4.7)	29 (2.4)
Black or African American	23 (21.5)	303 (24.8)
White	78 (72.9)	848 (69.3)
Other	1 (0.9)	43 (3.5)
BMI, kg/m ² (SD)	29.1 (8.7)	28.8 (8.1)

BMI, body mass index; SD, standard deviation. Values are means unless otherwise indicated.

Obstetric History by Pregnancy Status

- The number of prior pregnancies reported by women at enrollment is shown in Figure 3 for those women who became pregnant on the study vs those who did not
 - More non-pregnant women reported having had no prior pregnancies compared to pregnant women
 - Slightly more non-pregnant women reported having had only 1 prior pregnancy compared to pregnant women
- Among women who became pregnant on-study, 27.1% had no previous pregnancies, 64.5% had 1-4, and 8.4% had ≥ 5
- Among women who did not become pregnant on-study, 38.7% had no previous pregnancies, 54.4% had 1-4, and 7.0% had ≥ 5

Figure 3. Prior Pregnancies by Pregnancy Status On-Study



- Both groups had similar history of full-term deliveries (mean \pm SD; 1.3 \pm 1.3 pregnant, 0.9 \pm 1.3 not pregnant)

Contraceptive History by Pregnancy Status

- Previous contraceptive use did not vary substantially by pregnancy status (Table 2)
 - For both pregnant and non-pregnant women, the contraceptives most commonly used in the last 12 months were male condom, oral contraceptives, and withdrawal method
 - Slightly less women had used the male condom in the pregnant vs non-pregnant group (68.2% vs 73.0%, respectively), whereas slightly more women had used oral contraceptives (35.5% vs 28.5%, respectively) and the withdrawal method (21.5% vs 18.7%, respectively) in the pregnant vs non-pregnant group

Table 2. Previous Contraceptive Methods Used in the Past 12 Months by Pregnancy Status On-Study

	Pregnant (n=107)	Non-pregnant (n=1223)
Male Condom	73 (68.2)	893 (73.0)
Oral Contraceptive	38 (35.5)	348 (28.5)
Withdrawal Method	23 (21.5)	229 (18.7)
Vaginal Ring	11 (10.3)	90 (7.4)
Injectable Contraceptive	9 (8.4)	108 (8.8)
Progestin IUD	9 (8.4)	73 (6.0)
Rhythm Method (Fertility Awareness)	7 (6.5)	79 (6.5)
Emergency Contraception	7 (6.5)	74 (6.1)
Abstinence	7 (6.5)	45 (3.7)
Contraceptive Implant	6 (5.6)	40 (3.3)
Contraceptive Patch	5 (4.7)	64 (5.2)
Non-Hormonal IUD	4 (3.7)	28 (2.3)
Spermicide	3 (2.8)	41 (3.4)
Female Condom	1 (0.9)	32 (2.6)
Other	1 (0.9)	5 (0.4)
Diaphragm, Cervical Cap, or Sponge	0	8 (0.7)

CONCLUSIONS

- Demographic characteristics and prior contraceptive methods were similar among women who did become pregnant during the AMPOWER study compared to those who did not
- More women not becoming pregnant during the study had no prior pregnancies compared to women who became pregnant
- Slightly more women who became pregnant reported 1-4 or ≥ 5 previous pregnancies compared to women who did not become pregnant

REFERENCES

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DISCLOSURES

BM: Research support and consultant, Evoform Biosciences, Inc.
KC, BH: Employees, Evoform Biosciences Inc.
CD: Employee, Health Decisions, which received funding from Evoform Biosciences, Inc., to help conduct this study.