

# PREGNANCY INTENDEDNESS WITH VAGINAL PH MODULATOR: RESULTS FROM THE PHASE 3 AMPOWER TRIAL

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## INTRODUCTION

- Vaginal pH modulator (VPM; Phexxi<sup>®</sup>) is a non-hormonal, woman-controlled bioadhesive contraceptive vaginal gel
- VPM has acid-buffering properties and is able to maintain the acidic vaginal environment (pH 3.5-4.5) even in the presence of alkaline semen, resulting in the immobilization of sperm<sup>1,2</sup>
- VPM also provides a layer of gel over the vaginal and cervical surfaces<sup>1</sup>

## AIM

- To better understand women's pregnancy intendedness by demographics, baseline characteristics, and obstetric history

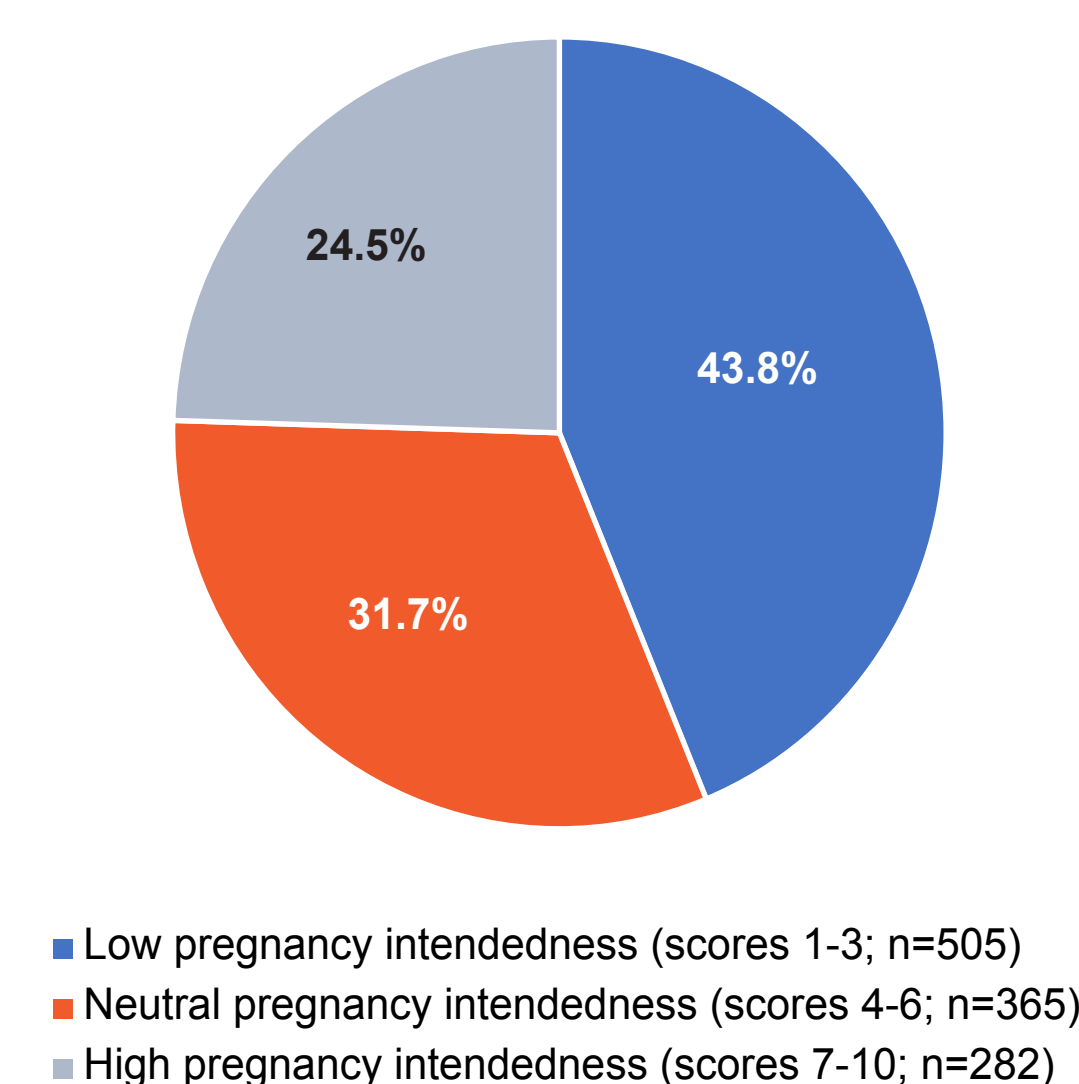
## METHODS

- AMPOWER (NCT03243305) was an IRB-approved, phase 3, single-arm, open-label, 7-cycle trial conducted at 112 US sites
- Women were instructed to administer a single prefilled applicator of study drug intravaginally before each episode of intercourse
- Pregnancy intendedness was an exploratory endpoint in AMPOWER
- Questionnaires were given at baseline and at subsequent study visits to assess how women would feel if they became pregnant (1-10, very unhappy to very happy)
- Additional sensitivity analyses investigated correlations between pregnancy intendedness and women's demographic and obstetric history
- Women's pregnancy intendedness scores were grouped into the following three categories:
  - Low pregnancy intendedness (scores 1-3): very unhappy/unhappy at the prospect of pregnancy
  - Neutral pregnancy intendedness (scores 4-6): pregnancy ambivalence
  - High pregnancy intendedness (scores 7-10): happy/very happy at the prospect of pregnancy

## RESULTS

- Of 1384 women enrolled, 1182 were in the modified intent-to-treat population and 1152 completed pregnancy intendedness questionnaires
- At baseline, women reported a wide range of pregnancy intendedness scores (Figure 1)

Figure 1. Pregnancy Intendedness at Baseline



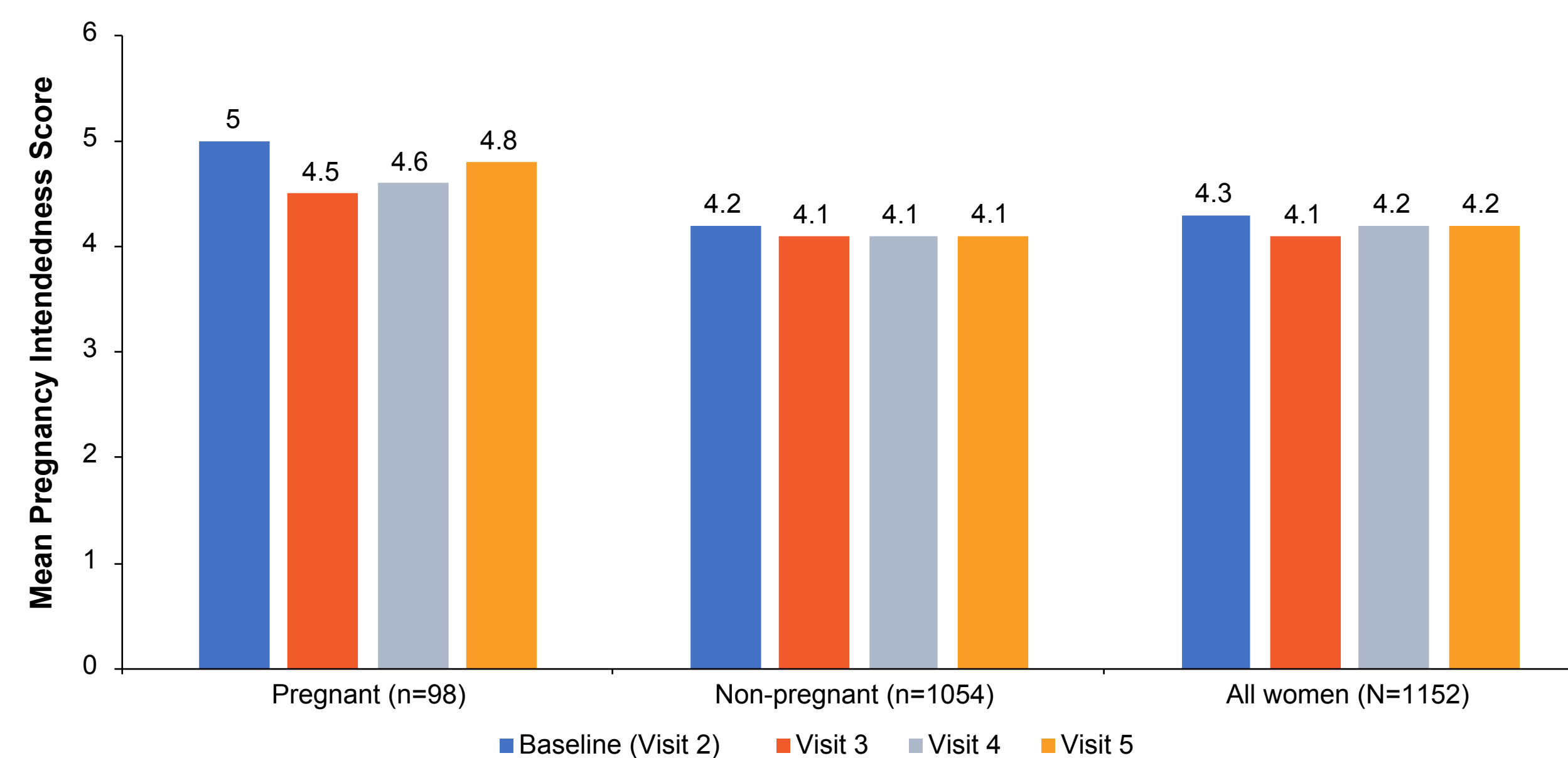
- The mean pregnancy intendedness score at baseline (Visit 2) was 4.3±2.9 and there was very little change at Visits 3-5 (mean change from baseline: -0.1 to -0.2)
- In general, pregnancy intendedness was not associated with differences in demographics, baseline characteristics, or obstetric history (Table 1)
  - One exception was that a greater percentage of women of Hispanic/Latina origin reported low pregnancy intendedness (scores 1-3; very unhappy/unhappy at the prospect of pregnancy) compared to neutral pregnancy intendedness (scores 4-6; ambivalence towards pregnancy) or high pregnancy intendedness (scores 7-10; happy/very happy at the prospect of pregnancy)

Table 1. Demographics, Baseline Characteristics, and Obstetric History by Baseline Pregnancy Intendedness Category

Parameter Category/Statistic	Low Pregnancy Intendedness (n=505)	Neutral Pregnancy Intendedness (n=365)	High Pregnancy Intendedness (n=282)
Age (yrs), mean (SD)	27.1 (4.6)	28.2 (4.3)	28.4 (4.3)
Ethnicity, n (%)			
Hispanic or Latina origin	255 (50.5)	139 (38.1)	95 (33.7)
Not Hispanic or Latina origin	247 (48.9)	224 (61.4)	185 (65.6)
Not reported	3 (0.6)	2 (0.5)	2 (0.7)
Race, n (%)			
Asian	13 (2.6)	10 (2.7)	3 (1.1)
Black or African American	104 (20.6)	85 (23.3)	80 (28.4)
White	375 (74.3)	259 (71.0)	184 (65.2)
Other	13 (2.6)	11 (3.0)	15 (5.3)
Body mass index (kg/m <sup>2</sup> ), mean (SD)	27.1 (6.3)	29.9 (8.6)	29.8 (8.7)
Number of prior pregnancies, mean (SD)	1.4 (1.9)	1.5 (1.7)	1.7 (1.8)

- In women who became pregnant during the AMPOWER study and who completed the pregnancy intendedness questionnaire, the mean pregnancy intendedness score at baseline was slightly higher (5.0±2.5) than that of women who did not become pregnant (4.2±2.9) (Figure 2)

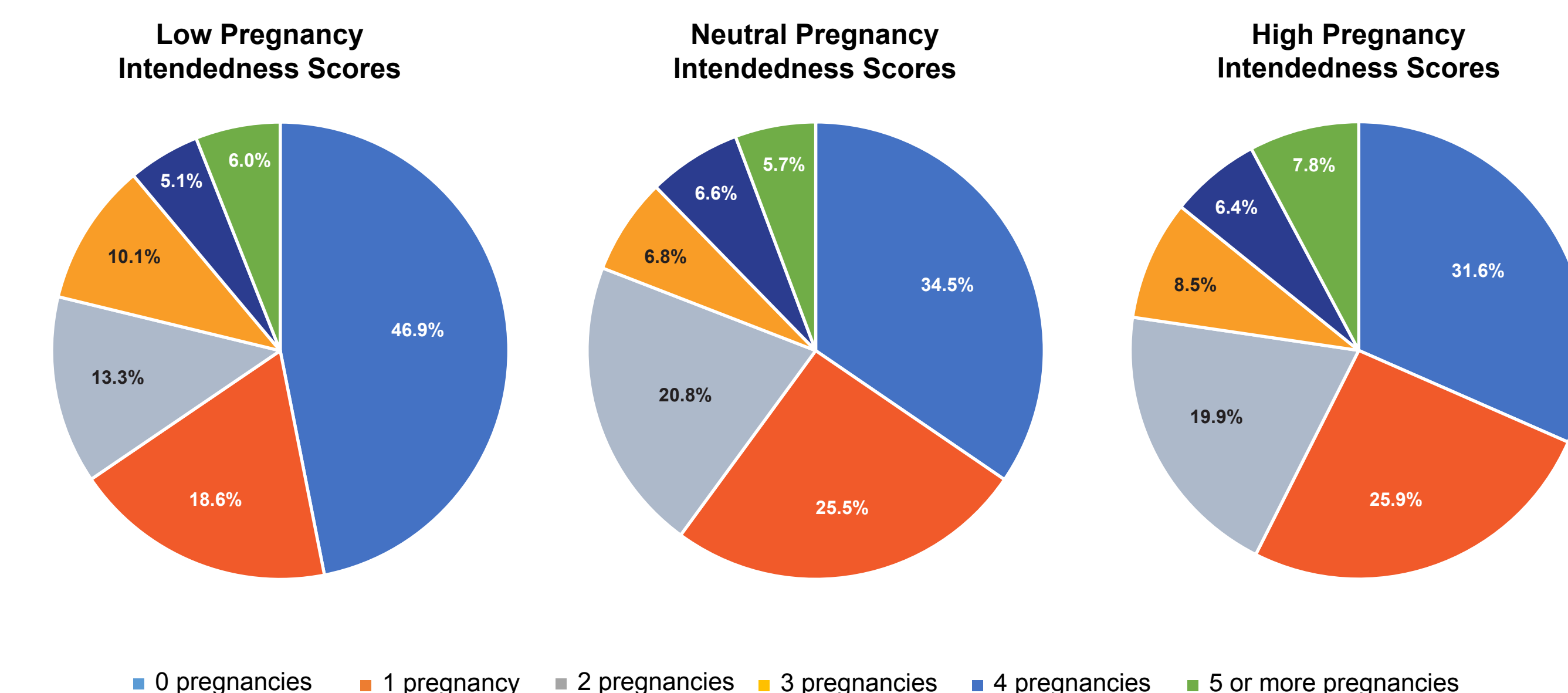
Figure 2. Mean Pregnancy Intendedness Score by AMPOWER Pregnancy Status\*



\*Includes pregnancies that occurred pre-, on-, or post-treatment.

- Additionally, more women with low pregnancy intendedness scores at baseline had never been previously pregnant (scores 1-3: 46.9%, 237/505), compared with women with neutral (scores 4-6: 34.5%, 126/365) or high scores (scores 7-10: 31.6%, 89/282) (Figure 3)

Figure 3. Number of Previous Pregnancies by Baseline Pregnancy Intendedness Category in AMPOWER



## CONCLUSIONS/IMPLICATIONS

- Throughout the study, women reported a wide range of feelings about pregnancy suggesting that efficacy may not always be the most important characteristic with contraceptive use, even when enrolled in a contraceptive clinical trial
- Women who became pregnant reported slightly higher pregnancy intendedness scores than women who did not

## REFERENCES

- Garg S, et al. *Contraception*. 2001;64:67-75.
- Bayer LL, et al. *Contraception*. 2014;90:11-18.

## ACKNOWLEDGEMENTS

The study was sponsored by Evoform Biosciences, Inc. Medical writing assistance was provided by PharmaWrite, LLC (Princeton, NJ, USA) and funded by Evoform Biosciences, Inc. (San Diego, CA, USA).

## DISCLOSURES

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