

Assessing the Understandability and Importance of Patient Reported Outcomes Impacting Adherence and Outcomes of a Non-Hormonal Vaginal Microbicide to Prevent and Protect Against Chlamydia Trachomatis (CT) and Neisseria Gonorrhoeae (GC)

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Introduction

- Increasing rates of Chlamydia trachomatis (CT) and Neisseria gonorrhoeae (GC) are a pressing public health concern.
- Adherence to an effective treatment is associated with improved outcomes.
- Adherence can be related to product satisfaction and positive or negative impacts on sexual satisfaction.
- Low adherence can result in sub-optimal outcomes.
- For treatments used as microbicides to lessen the risk of CT and GC, product and overall sexual satisfaction when using the product can contribute to treatment adherence and outcomes.

Objectives

- Develop a model relating treatment, infection outcomes, product satisfaction and sexual satisfaction
- Assess experience with a microbicidal vaginal gel (EVO100) to prevent urogenital CT and GC in the Phase 2b clinical study EVO-003 (NCT03107377)
- Assess understandability and importance of questions/instruments used to assess product and global sexual satisfaction

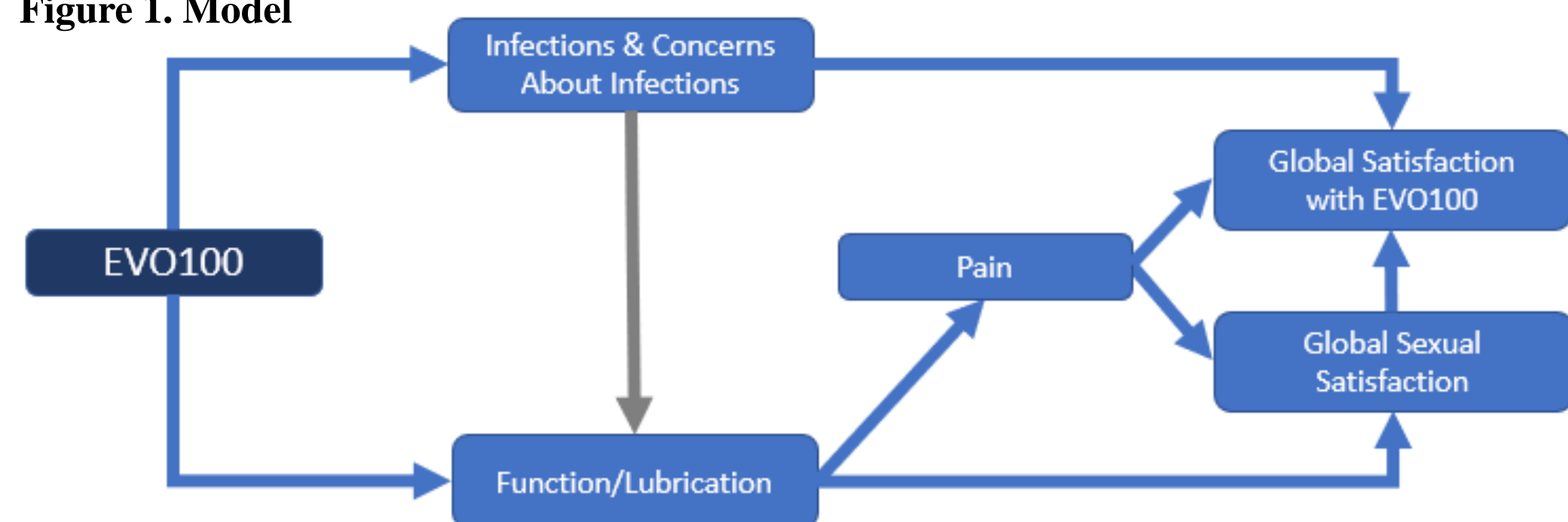
Methods

- Targeted literature review and expert input to develop a model relating treatment, infection outcomes, product satisfaction and sexual satisfaction.
- Concept elicitation and cognitive debriefing interviews were carried out in participants with experience using EVO100.
- Interviews explored experience with EVO100, concepts of sexual satisfaction and understandability of patient-reported outcome measures (PROMs) related to product satisfaction and overall sexual satisfaction used in Clinical Study EVO-003.
- Patient Reported Outcome Measures (PROMs):
 - Global Health Status
 - Female Sexual Function Index (FSFI): A widely used questionnaire assessing female sexual function and satisfaction.[1]
 - Global product satisfaction question (GPSQ)
- Sterling Institutional Review Board (IRB) approval was obtained before study initiation and patients completed an informed consent form.
- Interviews were carried out by experienced female interviewers. The interviews were audio recorded and transcribed verbatim.
- Inclusion criteria:
 - Participants experienced using EVO100 that met the following:
 - At least 18 years of age
 - Availability, willingness, ability and sufficient cognitive awareness to participate in the study interview
 - Ability to understand, read and write English in order to consent to study participation and complete study questionnaire(s)
 - Signed informed consent
- Exclusion criteria:
 - Employed by or related to referring site physician, staff, or interviewer

Results

Model

Figure 1. Model



- Figure 1 conveys the relationship between EVO100, infections and product and overall sexual satisfaction.
- Product satisfaction and global sexual satisfaction with a microbicide are likely key attributes related for use and protection from infections.

Participant Interviews

- Concept elicitation and cognitive debriefing interviews (N=21) were carried out from 5 sites in the US in April and May 2020.
- Participant demographics: (Table 1)
 - Average age was 27.62 (range: 20-42) years
 - 71.43% were single/never married
 - 61.90% lived with their partner or spouse, or family or friends
 - 52.38% were of Hispanic, Latino or Spanish origin
 - 28.57% were students
- Participant current health: (Figure 2)
 - Current health for three (14.3%) participants was excellent, twelve (57.1%) reported having very good health, five (23.8%) reported having good health and one (4.8%) reported having fair health.
 - One participant indicated not having access to EVO100 since the trial lowered her health status

Figure 2. Participant current health

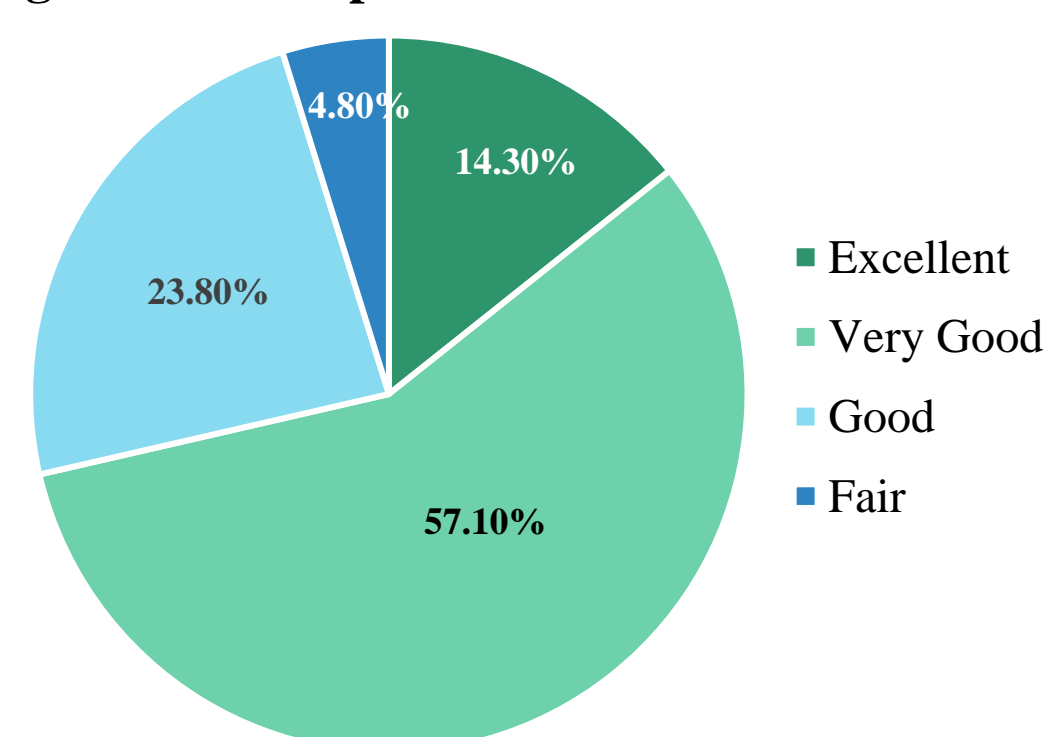


Table 1. Participant demographics

Age	
Mean age, mean (SD)	27.62 (6.00)
Marital status	
Single/never married	71.43%
Married or living in a marriage-like relationship	23.81%
Widowed, separated or divorced	4.76%
Living alone or with others	
Living alone	38.10%
Living with partner or spouse, family or friends	61.90%
Race	
Black or African American	14.29%
Native American	4.76%
White	80.95%
Hispanic, Latino or Spanish origin	
Yes	52.38%
Education	
High school or GED	28.57%
Some college	28.57%
College degree	42.86%
Employment	
Unemployed	9.52%
Student	4.76%
Part-time	14.29%
Part-time and student	4.76%
Full-time	47.62%
Full-time and student	19.05%

Experience with EVO100

- Qualitative interviews began by asking participants to discuss their experience in the EVO-003 trial and their thoughts on EVO100. Descriptions were grouped as favorable and unfavorable attributes. Unfavorable attribute comments were in response to asking directly for anything that was not ideal about EVO100. (Figures 3 and 4)

Figure 3. Favorable Attributes

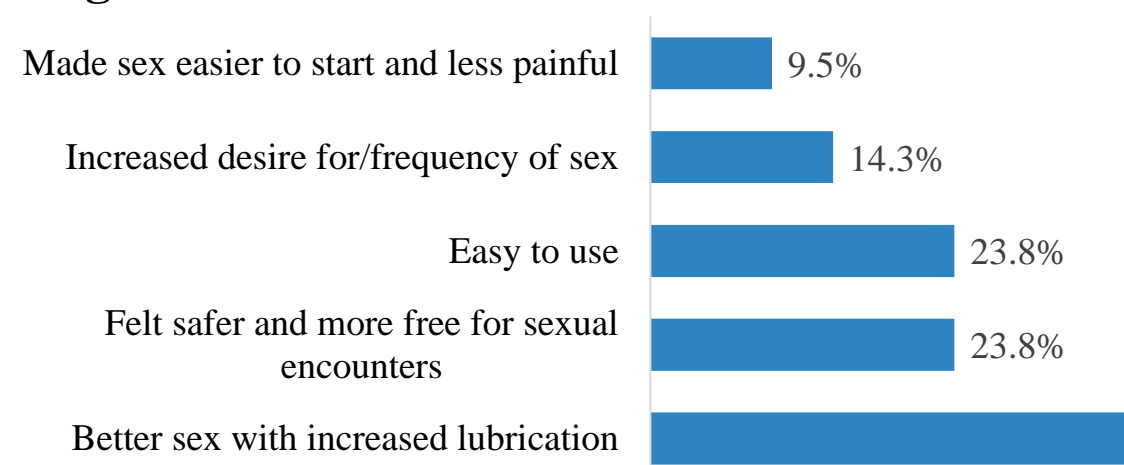
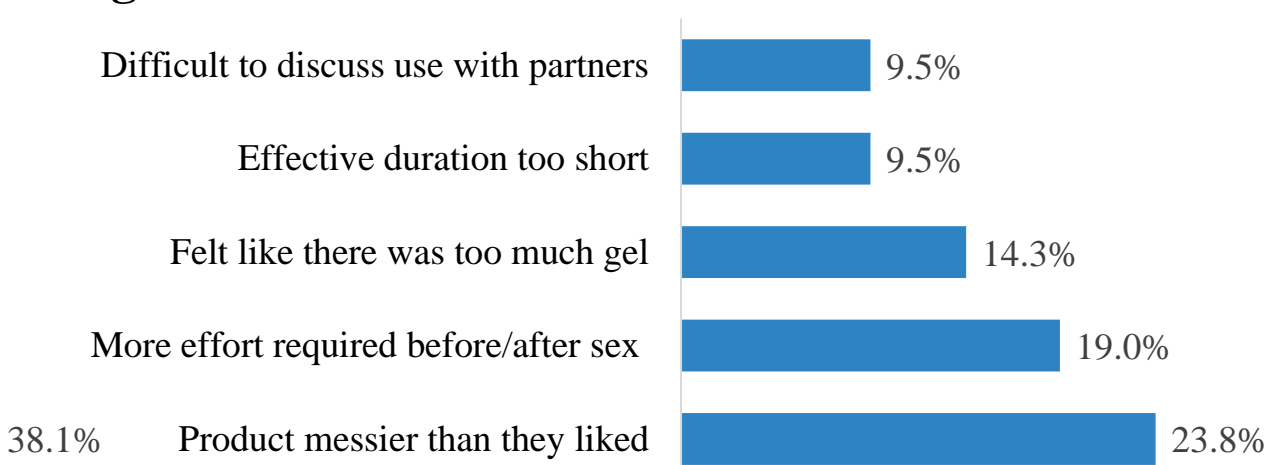
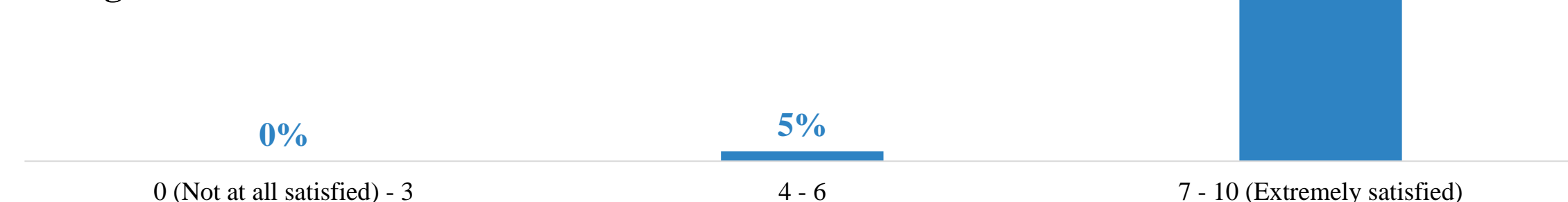


Figure 4. Unfavorable Attributes



- After reviewing favorable and unfavorable attributes of EVO100 participants were asked to take into account everything they experienced while taking EVO100 and what it did for them (evaluating the medicine itself) and rate how satisfied they were on a 0-10 scale, where 0 meant Not at all satisfied and 10 is Extremely Satisfied. (Figure 5)

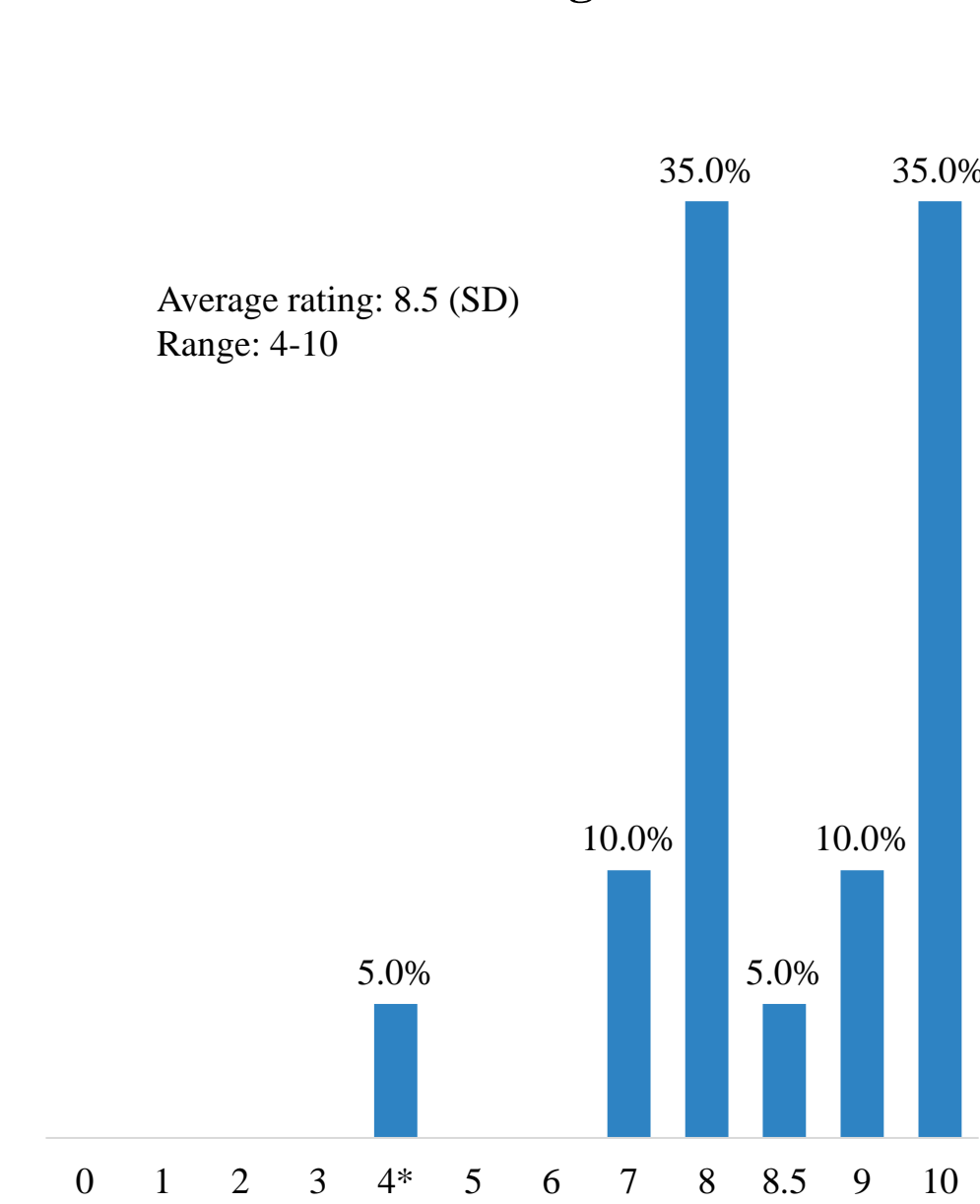
Figure 5. Overall satisfaction with EVO100



FSFI

- The distribution of satisfaction ratings resulted in two mode statistics with seven participants rating EVO100 an 8 out of 10 and another seven rating EVO100 a 10 out of 10 (the highest possible rating).
- Of the twenty participants that rated EVO100, the average rating was 8.5 and ranged from 4 to 10. (Figure 6)
- The 19 items in the FSFIs were all well understood, however, several questions were identified as not relevant for those using EVO100:
 - Nearly a quarter (23.8%) of participants thought that the question about emotional closeness (Q14) and/or satisfaction with your partner (Q15) did not have anything to do with the product and how it impacted their sex lives.
 - One participant explained "because you don't have to be emotionally close to somebody to have sex with them". Another participant indicated that Q14-15 may not be relevant "because I don't know if any women are married using the product. I don't think it would be important to know if they were emotionally close." A similar line of reasoning was provided by two (9.5%) participants regarding the desire question (Q1) and another two (9.5%) participants thought the sexual arousal questions (Q3-6) were not needed as EVO100 should not impact these concepts (according to these participants).
 - Questions identified as the most important in the FSFI had to do with lubrication, pain and the impact on overall sexual satisfaction.

Figure 6. EVO100 overall satisfaction rating



*Participant with rating of 4 was concerned about being in a trial where she could be getting a placebo and not have been protected.

Overall Sexual Satisfaction (FSFI Q16)

- Participants were asked to review the overall sexual satisfaction item in the FSFI (Q16) in more depth. When asked what Q16 was asking about, fifteen (71.4%) indicated it was asking about their overall sexual life which meant how happy or satisfied they are with their sex life taking everything in to account. Seven (33.3%) indicated that it was related to being able to orgasm and four (19.0%) indicated it considered feeling desire and arousal during intercourse and pleasing their partner.
- Q16 was well understood and the only recommended change from two participants was to add the product name in the question. The recall period was acceptable and nearly all participants felt that looking back over the last 4 weeks was the right period of time and they could easily recall their experiences over this timeframe. All participants felt the response options were easy to understand.
- Participants were asked if Q16 was or would be important to those using or considering using EVO100. There was strong and unanimous support concerning the importance of this question. Participants highlighted the importance of not causing a negative impact on overall sexual satisfaction and understanding (for some) the possibility of improvement in sexual satisfaction as key information that would be important for those using or considering using EVO100.

Global Product Satisfaction

- When asked what the global product satisfaction question was asking about, 19 (90.5%) indicated it was asking about their overall satisfaction with the product, that is, if they liked it. Two (9.5%) expressed this satisfaction with the product question as being happy or unhappy with the product and one (4.8%) indicated this question was asking how well the product worked.
- All 21 participants reported the question was well understood and there were no recommendations to change the basic question. However, participants identified that the response options were not balanced. The response options were very satisfied, satisfied, somewhat satisfied, somewhat dissatisfied, and dissatisfied. The recommendation was to have a balanced set of response options with a viable midpoint.
- Of the 21 participants, twenty (95.2%) indicated that this was an important question for those using or considering use of EVO100 and one (4.8%) participant did not comment on the importance of this question.

Conclusion

- Overall, participants experienced with EVO100 were highly satisfied with the product.
- Interviews confirmed the model (Figure 1) and importance of understanding product and sexual satisfaction
- Participants in the interviews indicated that in addition to protection from infections, the impact of a product on overall sexual satisfaction were of importance.
- The FSFI Q16 and the Global Product Satisfaction question assessed the concepts of interest and were well understood and deemed important to the participants and to others considering treatment options.
- Reporting product and overall sexual satisfaction associated with products or treatments for STIs is important to women considering treatment options.

References

1. Rosen R, Brown C, Heiman J, et al. The Female Sexual Function Index (FSFI): A multidimensional self-report instrument for the assessment of female sexual function. J Sex Marital Ther 2000;26:191-208.