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

Introduction

- Increasing rates of Chlamydia trachomatis (CT) and Neisseria gonorrhoeae (GC) are posing a growing public health concern.
- Adherence to active treatment is important in managing these infections.
- Adherence can be related to product satisfaction and positive or negative impacts on sexual satisfaction.
- Low adherence can result in sub-optimal outcomes.
- Treatments used as microbicides to lessen the risk of CT and GC and overall sexual satisfaction when using the product can contribute to treatment adherence and outcomes.

Objectives

- Developing a model for adherence, treatment outcome, product satisfaction, and sexual satisfaction.
- Assessing adherence with a microbicidal vaginal gel (EVO100) to prevent asymptomatic CT and GC in the Phase 2b clinical study EUO-003.
- Assess understanding and importance of questionnaire items used to assess product and sexual global satisfaction.

Methods

- Targeted literature review and expert input to develop a model for adherence, treatment outcome, 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 interest and were well understood and deemed important.
- Assessing understanding and importance of questionnaire items used to assess product and sexual global satisfaction.

Results

- Table 1. Participant demographics.
- Figure 1. Model.
- Figure 2. EVO100 overall satisfaction rating.
- Table 3. Characteristics for questions mentioned as being most important.
- Figure 3. Favorable Attributes.
- Figure 4. Unfavorable Attributes.
- Figure 5. Overall satisfaction with EVO100.
- Figure 6. Overall satisfaction with EVO100.

Participant Interviews

- Concept elicitation and cognitive debriefing interviews (N=21) were carried out for 5 sites in the US in April and May 2020.
- Interviews explored experience with EVO100, concepts of interest and were well understood and deemed important.
- Participant demographics (Table 1).
- Average age was 27.62 (range: 20-47).
- 52.38% were of Hispanic, Latino or Spanish origin.
- Student: 14.29%.
- White: 28.57%.
- Living alone: 57.10%.
- Good health: 57.10%.
- Living with partner or spouse, family or friends: 42.86%.
- Good sexual desire and arousal: 52.38%.
- College degree or more: 52.38%.

Experience with EVO100

- Qualitative interviews began by asking participants to discuss their experience in the EVO group and their thoughts on EVO100 as favorable and unfavorable attributes.
- Unfavorable and favorable comments were in response to asking directly for anything that was not ideal about EVO100.

Figure 3. Favorable Attributes.

- Participants were asked to review the overall sexual satisfaction item in the FSFI (0.016) and their thoughts on EVO100 as favorable and unfavorable attributes.
- The distribution of satisfaction ratings resulted in two mode

Figure 4. Unfavorable Attributes.

- After reviewing favorable and unfavorable attributes of EVO100, participants were asked to take accounts of everything they experienced using EVO100 and what it did for them in evaluating the maximum and how they saw that they were on a 10 scale, where 0 meant Not at all satisfied and 10 is Extremely Satisfied.

Figure 5. Overall satisfaction with EVO100.

- Figure 6. EVO100 overall satisfaction rating.

Conclusion

- Overall, participants experienced with EVO100 were highly satisfied with the product.
- Participants were asked to review the overall sexual satisfaction item in the FSFI (0.016) and their thoughts on EVO100 as favorable and unfavorable attributes.
- Participants were asked if Q16 was or would be important to those using or considering using EVO100.
- Exclusion criteria:
- Employed or related to the study site, physician, staff, or interviewer.

Overall Sexual Satisfaction (FSFI Q16)

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