

A Qualitative Evaluation of Women's Experience Receiving Drug Feedback in MTN-025/HOPE - an HIV Prevention Open-label Trial of the Dapivirine Vaginal Ring

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Background

- In MTN-025/HOPE (N=1456), an ongoing open-label extension HIV prevention trial of the dapivirine (DPV) vaginal ring (containing 25 mg and replaced monthly), former MTN-020/ASPIRE participants¹ can choose to use the DPV ring or not, and can change their mind during the study.²
- Adherence to HIV prophylaxis is challenging; as with other PrEP approaches, protection from the DPV ring improves with higher adherence.³
- Providing drug feedback (residual drug levels in returned rings) to participants was feasible to implement in previous HIV prevention clinical research,^{4,5} and was incorporated in HOPE to improve adherence.
- Motivational Interviewing (MI)-based interventions have shared biomarker and self-report data with individuals to increase engagement and motivation to attain behavior change goals.^{6,7}
- We conducted qualitative interviews in HOPE to assess participants' experience with and reaction to receiving drug feedback in the context of MI-based intervention.
- The HOPE qualitative component is taking place at six sub-Saharan African sites (Figure 1).

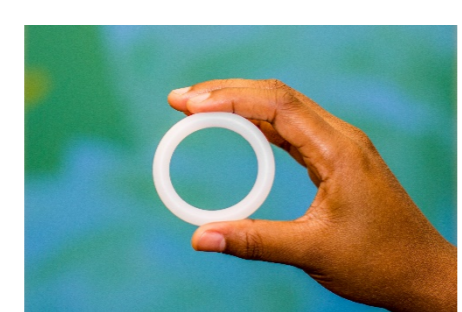
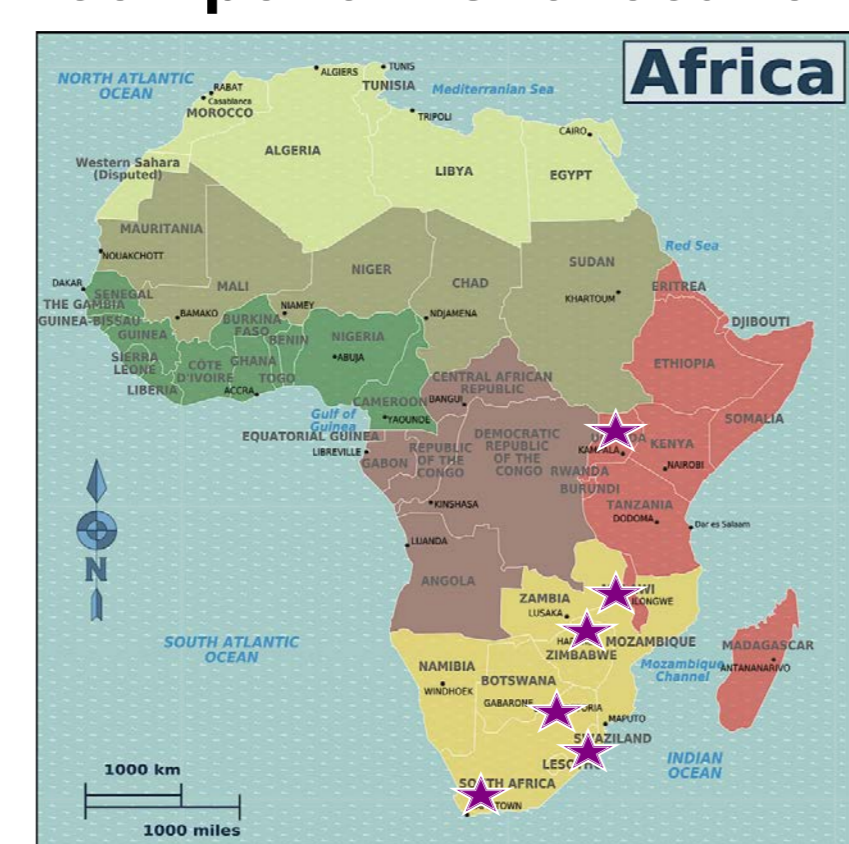


Figure 1. HOPE qualitative component site locations



Methods

- Ring residual drug levels (RDL) in returned rings are used as a biomarker of ring adherence.^{1,8}
- RDL scores are calculated by dividing amount of residual DPV in ring by coverage period.²
- During MI-based adherence counseling, counselors preface drug feedback with an introduction aimed at minimizing resistance to receiving feedback and facilitating open discussion of the results (Figure 2).
- Counseling messages frame RDL results in terms of HIV protection, from no protection (score=0) to high protection (score=3). RDL is discussed with participants during counseling sessions ~2-3 months after the ring is returned (Figure 3).
- In-depth-Interviews (IDIs) about RDL were conducted with a subset of HOPE qualitative participants (n=55) who accept to use the ring at enrollment or at any point during follow-up, and special case IDIs (e.g. seroconverters or those experiencing social harm) (Figure 4).
- IDIs, conducted in local languages using semi-structured guides, were summarized in reports for rapid thematic analysis.

Figure 2. Introduction to RDL feedback

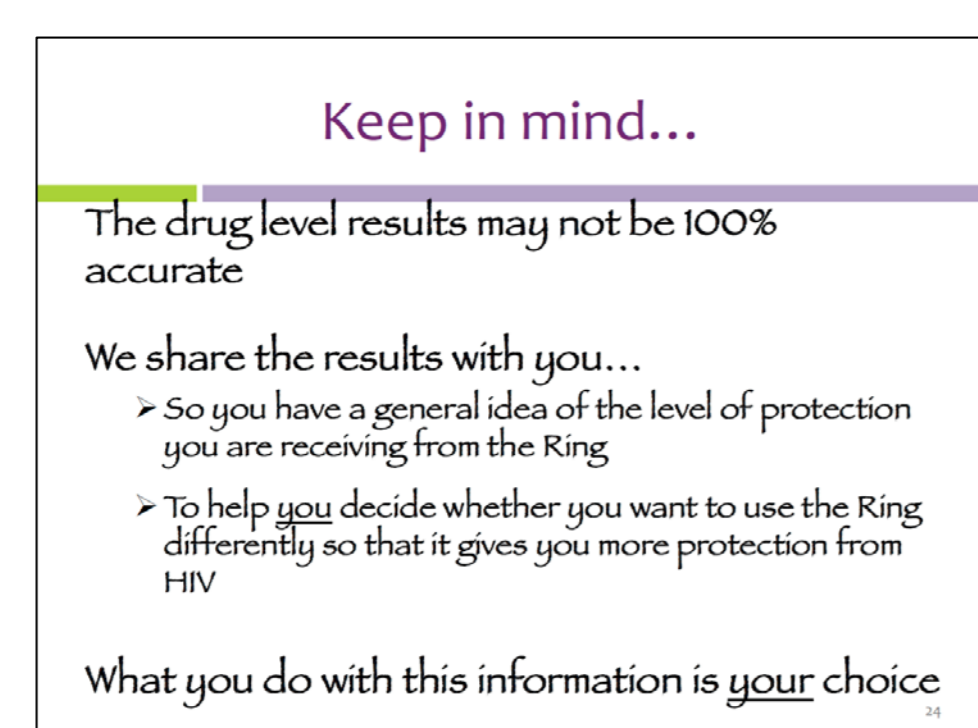


Figure 3. Explanation of RDL scores

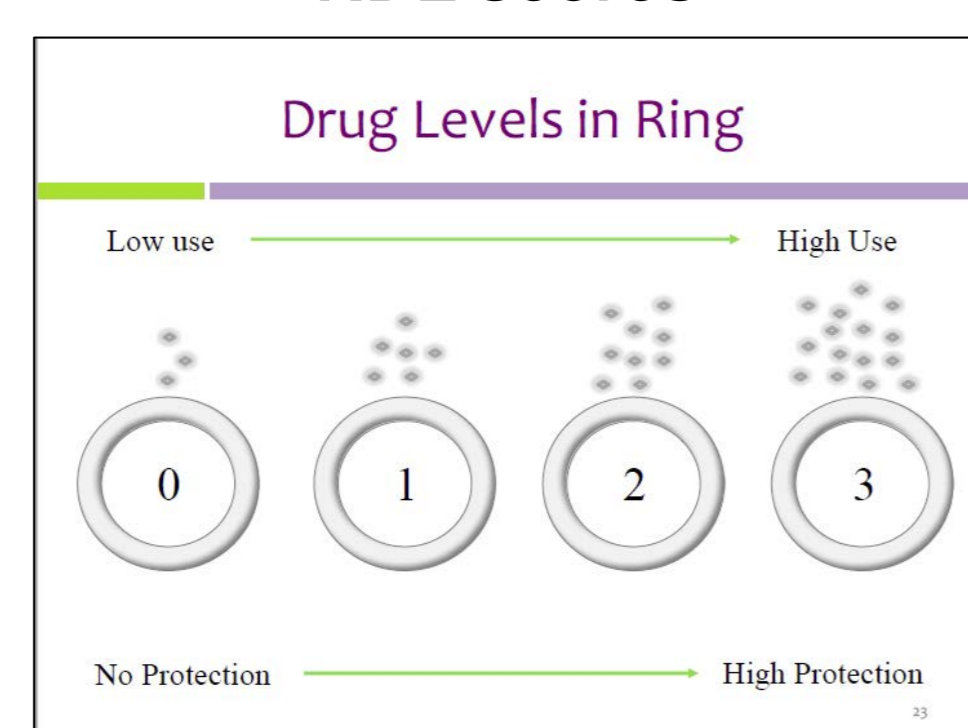
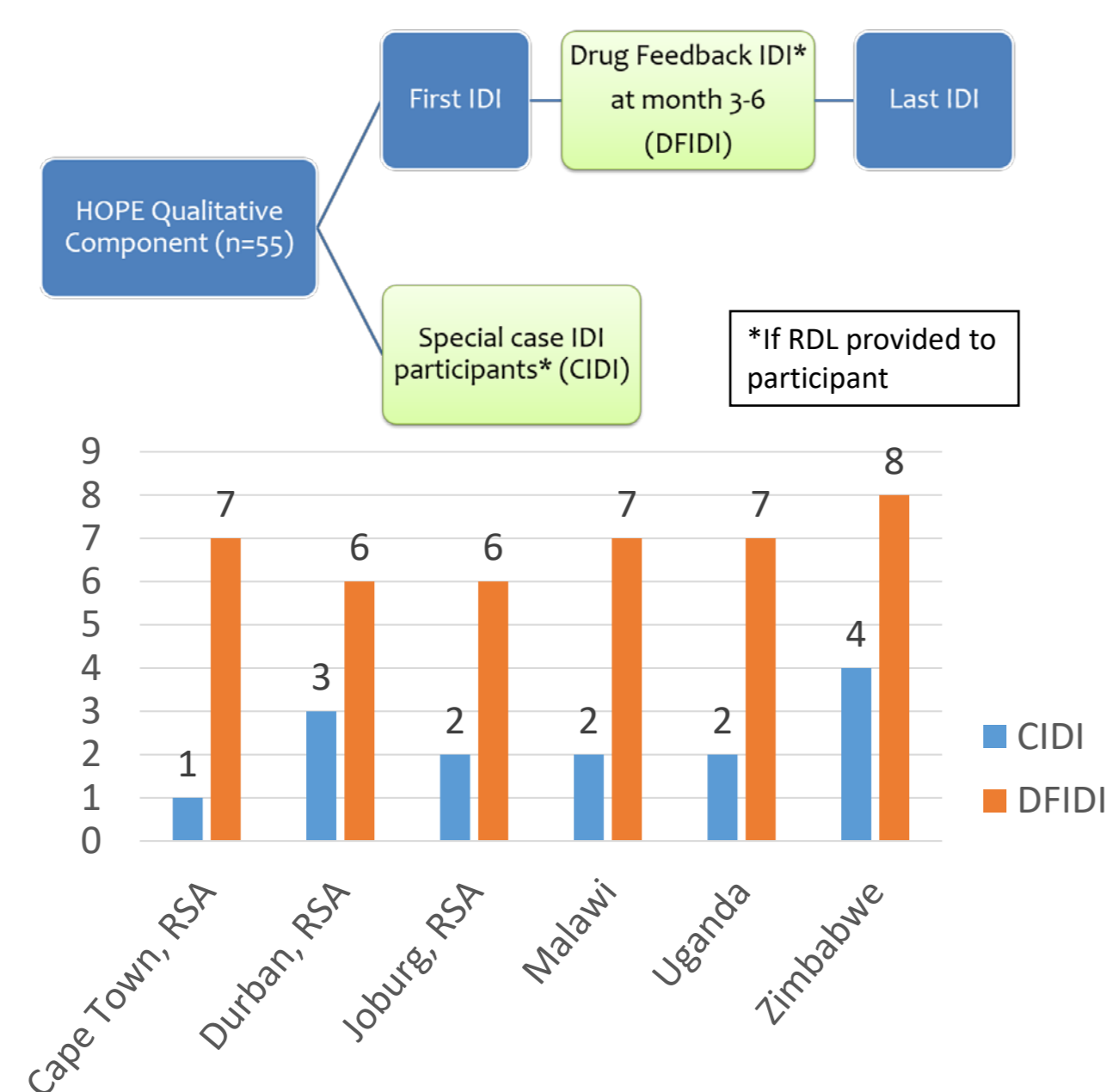


Figure 4. HOPE qualitative component RDL IDI types, and count by IDI type and site (N=55)

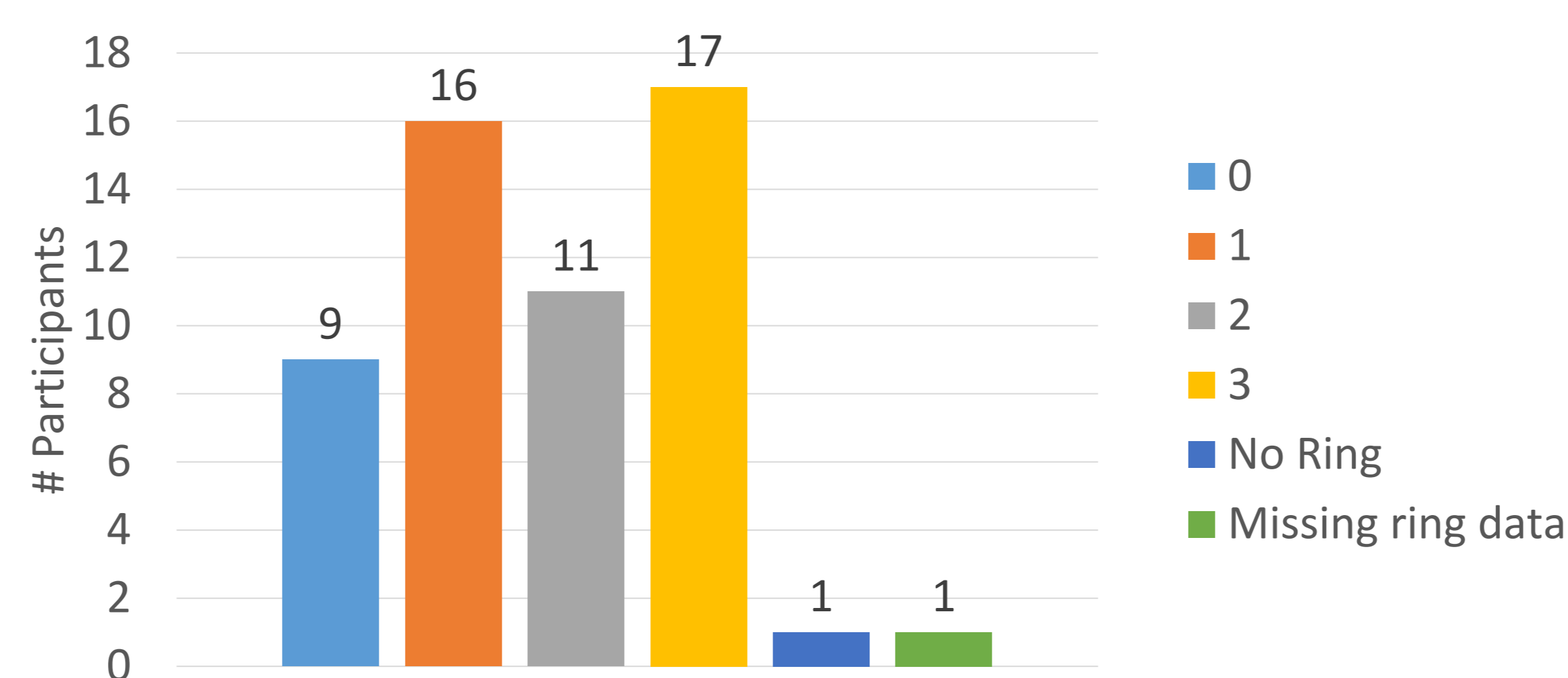


Results

RESULTS 1: RDL in Enrollment Rings

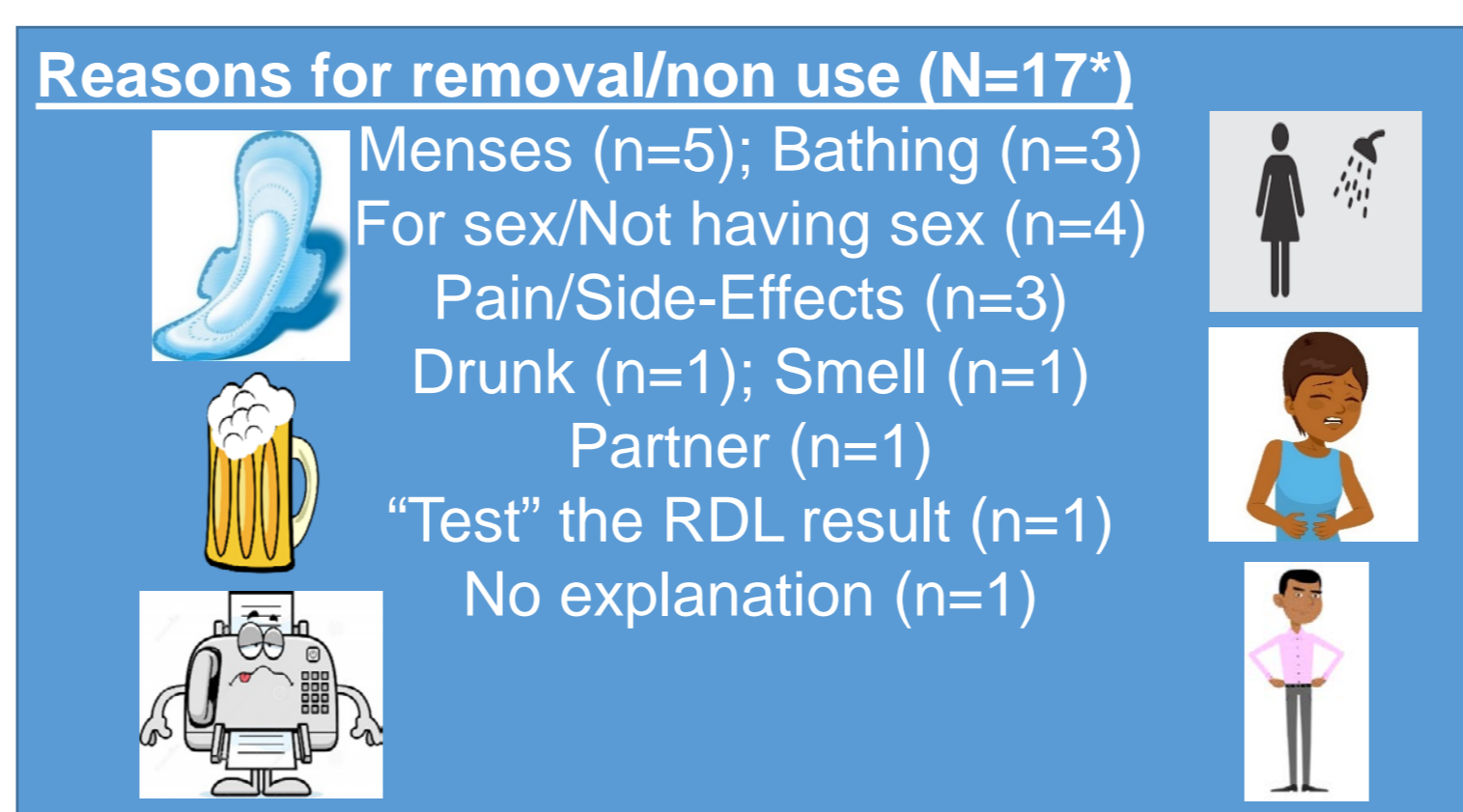
- Of the 55 qualitative participants, 76% completed a DFIDI between Month 3 - 6, after receiving the RDL results for their enrollment (and possibly later) ring(s).
- RDL for enrollment rings (Figure 5) showed that:
 - 51% had evidence of good to high protection (RDL score = 2-3)
 - 17% had no evidence of protection (RDL score = 0)

Figure 5. Distribution of RDL Scores: Enrollment rings (N=55)



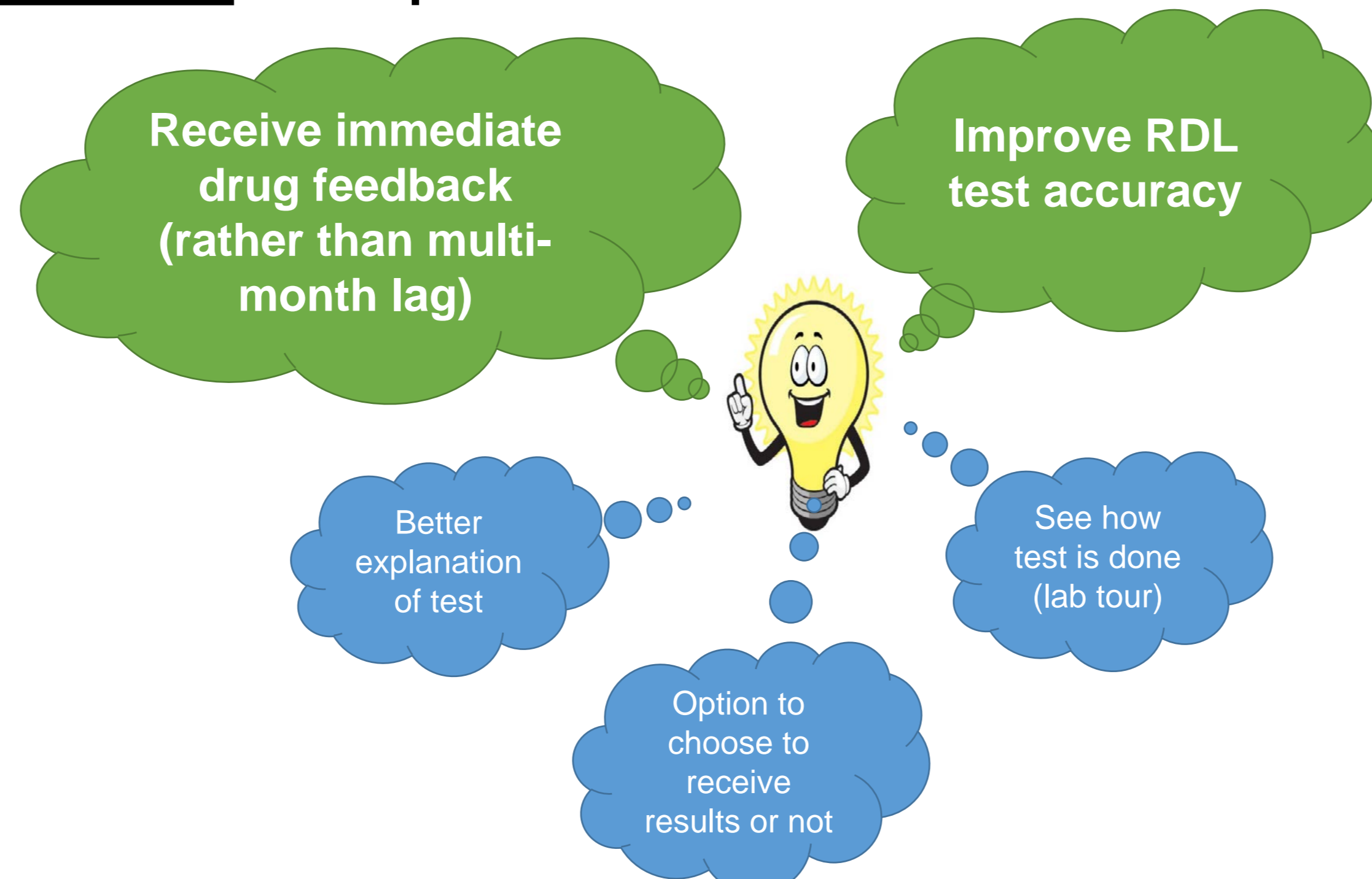
RESULTS 3: Reported Ring Adherence Behavior

- 29% reported at least one reason for removal



*Some participants reported more than one reason

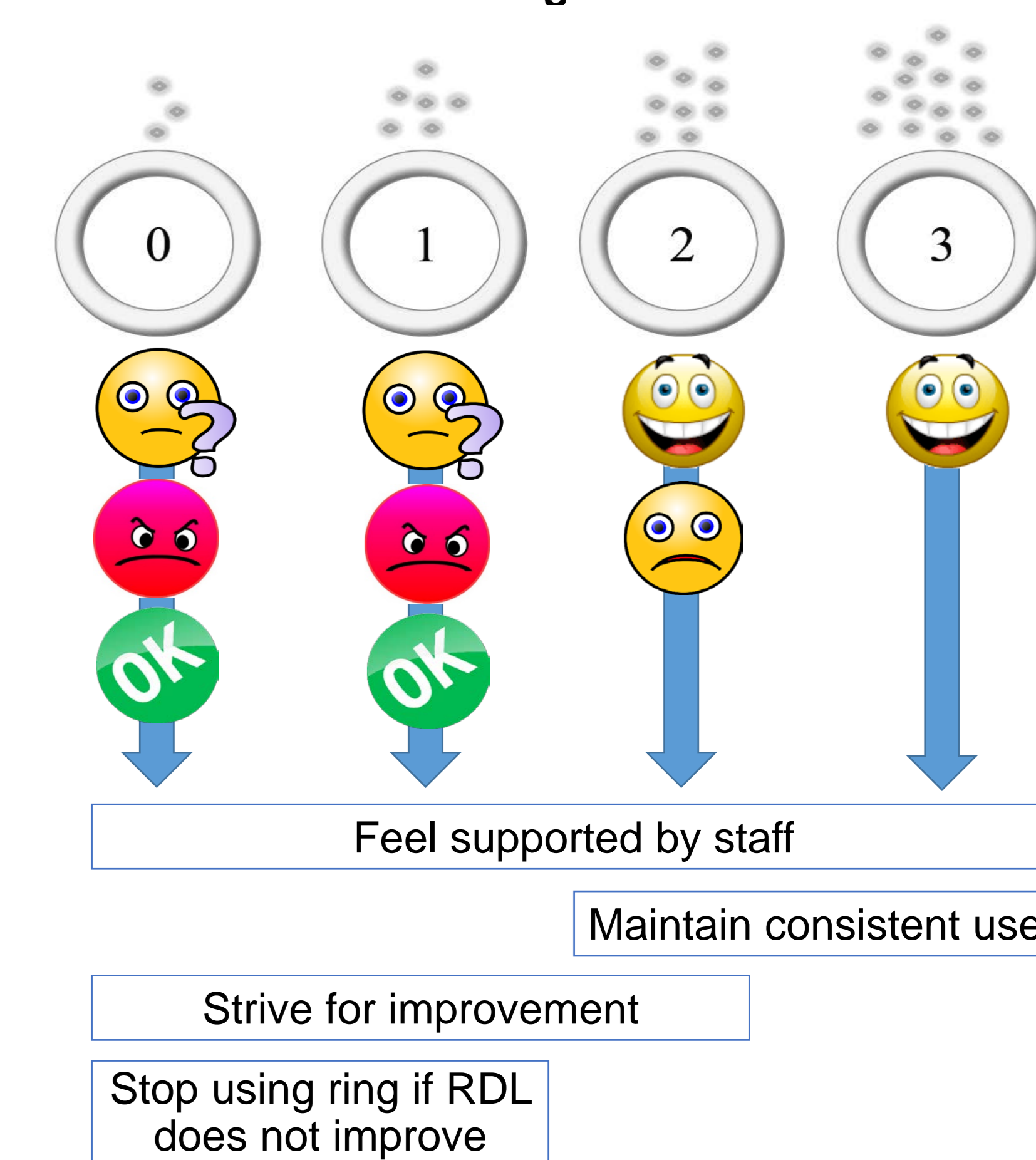
RESULTS 5: Participants' recommendations



RESULTS 2: Participant Reactions to RDL Feedback

- Reactions to RDL were often emotional (Figure 6):
 - Participants with scores indicative of high protection usually responded with relief and happiness.
 - For some, even a score of 2 created distress.
 - Participants with lower scores who insistently reported high adherence often appeared upset; some remained perplexed by their results, while others provided alternative explanations (see Results 4).
- Many accepted their results and reported practices that could explain lower scores (see Results 3).
- Overwhelmingly, counselors were described as caring, friendly and non-judgmental; providing support to participants to a) maintain consistent use, b) strive for improvement or c) choose an alternative prevention method if the ring was not a suitable option.

Figure 6. Reactions to RDL and effect of receiving feedback



RESULTS 4: Participants' Alternative Explanations to RDL Results



Machine or device errors were blamed for some of the RDL scores

- Inaccurate tests, laboratory errors
- Dysfunctional ring



Suspected interactions between ring and:

- Herbs/medications
- Menses/vaginal fluids
- Not having sex/no semen exposure (thought to be needed to release drug from ring)
- Not using condoms (no explanation provided)



Ring not working due to:

- Incorrect use
- Incompatibility with participant's body (e.g. drug not "flowing" into her system)

Conclusions

- RDL feedback interactions are complex; participants valued the monitoring of protection level against HIV, but results evoked strong emotional responses and were at times difficult to accept.
- Client-centered counseling helped to channel emotions and behavioral reactions positively.
- Emphasis on protection (rather than adherence) minimized confrontational interactions and facilitated alternative, but at times implausible, explanations.
- Participants recommended more rapid feedback and improved test accuracy to more precisely reflect product use.

References

¹Baeten, NEJM 2016; ²Baeten, CROI 2018; ³Brown, IAS 2016; ⁴van der Straten, AIDS 2015; ⁵Cranston, Clin Infect Dis 2017; ⁶Samson, J Stud Alcohol Drugs 2015; ⁷Balán, AIDS Behav 2018; ⁸Nel, PLOS One 2016