Adherence Measurement and Optimization of Long-Acting ARV-Based Vaginal Rings

Development and Pyschometric Validation of Measures for Vaginal Ring Adherence – Metadata

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Data Overview

We used a tablet-based survey administered by same-sex interviewers with a total of 709 women who were former participants of vaginal ring or other HIV prevention clinical trials and similar trial-naïve women. The goal of the survey was to obtain self-report data with which to develop a set of validated vaginal ring adherence scales that are inexpensive and easy to administer, with better predictive validity than current self-report adherence measures. This was a cross-sectional survey that included both closed-ended and possible brief open-ended responses. The primary objectives were to:

1. Identify a reduced set of items that measure:
    a. Ongoing barriers and facilitators to "enacted" adherence to a vaginal ring, and
    b. Propensity to adhere to vaginal ring use in a future trial; and
2. Assess content and construct validity of draft measures.

The survey was divided into three sections. All women regardless of trial experience responded to 76 "screener" items measuring potential predictors of adherence; 26 items from the Crowne-Marlowe social desirability scale were also distributed in groups within this section. Only former trial participants responded to an additional set of 48 monitoring items assessing product-specific adherence attitudes and behaviors. The last section, administered to all participants, included additional demographic and psychosocial variables.

Data Gathering Methodology

The survey was administered using ODK Collect 1.4.5 on Samsung Galaxy Tablet 2 (7.0) and ASUS MeMO Pad (7.0). Data were gathered over 14 weeks from January-April 2016. Women were eligible to participate if they were over the age of 18 and 1) had exited from an earlier clinical trial of an HIV prevention product and had provided consent to be contacted for future studies, or 2) had never participated in a clinical trial for an HIV prevention product. The primary target populations for this scale development research include African populations of women aged 18 and older, who had recently

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exited from a trial of HIV prevention vaginal rings. Similar trial-naïve women from the study sites were invited to participate in survey activities related to the adherence screener only.

Geographic Location

The survey was administered at four different clinical trial sites in South Africa in which a range of HIV prevention clinical trials, including trials to assess the Dapivirine ring are currently underway. These included sites in:

- Johannesburg, Gauteng province
- Brits, Northwest province
- Ladysmith, KwaZulu-Natal province
- Cape Town, Western Cape province

Data Redactions

The informed consent process was included in the ODK Collect survey and the data pertaining to it were part of the original dataset. These data included personally identifiable information (PII), such as the names of participants and data collectors, and have been redacted to ensure the privacy of the participants.

Data Quality

These data meet the quality standards set by USAID, such as outlined in ADS 203.3.11. Missing data is minimal and skip patterns are designated in the data. Some items experience a ceiling or floor effect, not unexpected with Likert scale data[1], and may be assessed for inclusion in analyses.

Data Limitations

This survey is cross-sectional and used a convenience sampling method. The results are therefore useful for understanding the potential range of responses among former participants of vaginal ring or other HIV prevention clinical trials and similar trial-naïve women by cannot be assumed to be representative of the larger population.

[1] Clason, D. L. & Dormody, T. J. (1994). Analyzing Data Measured by Individual Likert-Type Items. *Journal of Agricultural Education*, *35*(4), 31-35.

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