

Use of Computer-assisted Self-interview to Assess Product Use in Microbicide Trials: Lessons Learned in HPTN 035

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Abstract

Background:

Reliable and valid adherence and sexual behavior data are needed to better understand the HIV epidemic, to make predictions, to assess individual risk, and to help evaluate the effectiveness and efficacy of HIV prevention interventions. Most microbicide trials have relied on self-reported face-to-face interviews to collect such information, but the quality of the data generated by this mode of data collection has been questioned frequently.

Objective:

To describe the successes and limitations associated with the collection of audio computer-assisted self-interview (ACASI) data in a vaginal microbicide safety and effectiveness trial (HPTN 035).

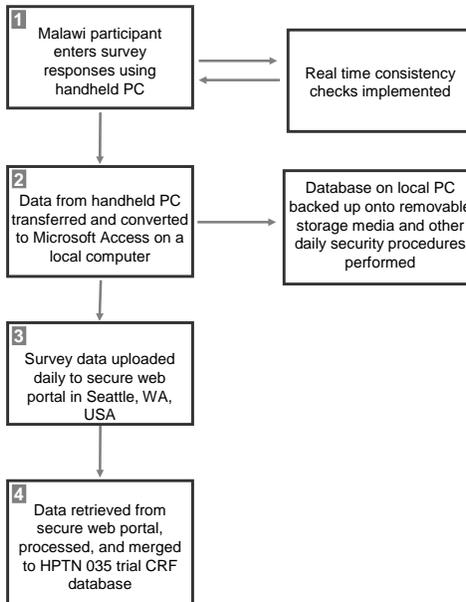
Methods:

Women enrolled in the Phase IIb trial of BufferGel and Pro 2000 Gel (HPTN 035) at the Blantyre and Lilongwe, Malawi sites were asked to complete an ACASI survey on sexual behavior and adherence to study product use using handheld personal computers (HPCs) after they completed a quarterly face-to-face interview. Participants entered their responses directly into the HPC. Preprogrammed audio, text, graphics, and skip patterns guided the participant through the ACASI survey. Consistency checks allowed the participant to loop back and reconcile responses to questions that compared the number of sex acts when product was used to the total number of sex acts. Upon completion of the survey, site staff exported the data to a designated local computer and deleted the participant's responses from the handheld for security purposes. Each day the HPC was used, the ACASI surveys were saved, backed up, merged to a central site computer, and then uploaded to a secure web portal hosted by the study data management center in Seattle, WA, USA.

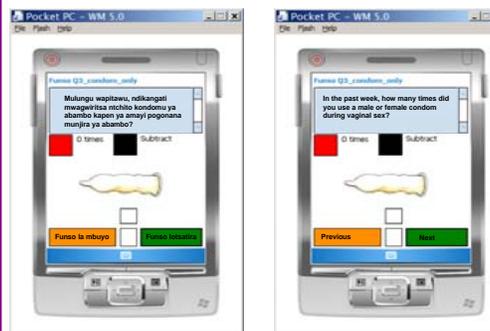
Results:

A total of 672 ACASI surveys were completed. All surveys were successfully exported from the HPC and uploaded and only nine needed to be excluded due to duplicate surveys (n=3), missing data (n=4), administration of the wrong survey (n=1), or inconsistent survey dates (n=1). Of the 663 surveys included in the analysis, 166 were surveys with 6 questions answered by participants in the study's no gel group and 497 surveys with 10 questions answered by participants in the study gel groups. The median time to complete the survey was 4.89 minutes for the no gel group and 9.55 minutes for the gel group. While few technical problems arose, in some instances battery drainage resulted in resetting of internal HPC dates, leading to erroneous survey dates.

ACASI Data Flow



Screen shots in English and local language on iPAQ hx200 Pocket PC with Windows Mobile 5.0



Summary Results

Table 1. Reasons for missing and excluded HPTN 035b ACASI surveys

Total number of ACASI surveys completed	672
Number of ACASI surveys included in analysis	663
Number of excluded ACASI surveys	9
Reasons for excluded surveys:	
Duplicate surveys	3
Missing data	4
Wrong survey administered	1
Inconsistent survey date	1

Table 2. Median number of minutes to complete ACASI surveys

Survey type	Number of surveys completed (n= 663)	Median time in minutes
No study gel group (6 questions)	166	4.89
Study gel group (10 questions)	497	9.55

Table 3: Issues related to handheld battery drainage

Number of ACASI surveys included in analysis	663
Number of wrong visit dates related to handheld PC battery drainage	70
Internal date was reset to a date in 2005 for handheld PC that ran out of battery which resulted in a wrong survey date.	
For all of those, the date of the actual visit was obtained from the visit code that was captured on the handheld PC.	

Conclusions

In addition to providing anonymity to the participant, the advantages of using HPC with ACASI to collect sexual behavior and adherence data include real-time consistency checks, reliable data transfers, and daily data updates. Battery drainage resulting in incorrect dates was the major problem faced, although this can be avoided by using well defined study procedures to deal with HPC batteries. Given the few other technical issues encountered with administration of ACASI surveys in this study, and the fact that these issues can be readily addressed and resolved in future implementation, ACASI will be used in Microbicide Trials Network clinical trials to collect adherence and sexual behavior data.