

Telling the truth in microbicide trials: Using audio computer-assisted self-interview (ACASI) to assess the accuracy of self-reported behavioral data in a phase II clinical trial

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This project is a collaboration between the Population Council, the University of Cape Town, and the Medical University of Southern Africa (MEDUNSA)

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Purpose

To investigate the accuracy of self-reports of sensitive behavior in a Phase II microbicide trial of Carraguard™

- Whether participants ever lied
- Motivations for lying
- Particular topics about which women lied
- Frequency and degree of lying
- Ways to minimize lying in future research

Why use audio computer-assisted self-interview (ACASI)?

- Perceived to be more private, confidential, and/or anonymous
- Automatic data entry
- Facilitated skip patterns
- Easy accommodation of multiple languages

Philosophy

- Approached sensitive topics slowly, later in survey
- Gave careful description of what we were asking about
- Used non-judgmental language (“inaccurate information” or “wrong answer” instead of “lie”)
- Hired new study staff to maximize confidentiality
- Did not collect personal identifiers
- Informed participants that we would not link ACASI results to responses in main trial

ACASI interviewing

- Laptop computers fitted with specialized touch screens
- Hear each question through headphones and see question on screen
- Enter responses by touching the buttons on screen
- Can go back to a prior question, change or delete responses, or replay the audio portion





Protocol

- Women coming for regular study visits invited to participate, consented, and enrolled
- Field workers helped participants complete a practice page before beginning real study
- Staff available to provide technical assistance if necessary
- Participants compensated 10 rand (~\$1 USD)

Study administration

- Survey piloted first at each site (n = 12)
- Interviews (n = 132) took place in August 2001 in Gugulethu and Ga-Rankuwa, South Africa
- Offered in Xhosa, Tswana and English
- Mean interview time ~32 minutes (median: 29 minutes, range: 9 minutes – 2.5 hours)

Results

Participant characteristics

	Gugulethu (n = 68)		Ga-Rankuwa (n = 64)		p-value
	n	%	n	%	
Some high school or higher	49	72%	57	89%	<0.001
< 30 years old	33	49%	48	75%	0.006
Used a computer before	14	21%	21	33%	0.112
> 1 partner in last year	9	13%	18	28%	0.212

Results: Resons for not telling the truth

Did you ever give an wrong answer because of ... ?

	Gugulethu n= 68	Ga-Rankuwa n = 64	p-value
Politeness			
Never	77%	55%	0.003
Sometimes	18%	44%	
Always	6%	2%	
Embarassment			
Never	91%	72%	0.001
Sometimes	6%	28%	
Always	3%	0%	

Did you ever give an wrong answer because of ... (continued)?

	Gugulethu n = 68	Ga-Rankuwa n = 64	p-value
Fear of criticism/want of praise			
Never	81%	70%	0.081
Sometimes	16%	30%	
Always	3%	0%	
Worried about being asked to leave study			
Never	91%	86%	0.295
Sometimes	7%	14%	
Always	0%	2%	

Results: Acceptability of study product

Did you ever give a wrong answer when the interviewer asked you about ... ?

	Gugulethu n = 64	Ga-Rankuwa n = 68	p-value
Messiness of the gel			
Never	91%	83%	0.016
Sometimes	2%	14%	
Always	7%	3%	
Liking the applicator			
Never	87%	88%	0.983
Sometimes	3%	3%	
Always	10%	9%	

Results: Compliance with study product

Reports of vaginal sex

- 72% of all women (n = 95) reported ever having vaginal sex during the main study
- Of these, 5% (n = 5) reported that they sometimes or always lied to the interviewer about whether they had vaginal sex
- 4 women actually had *more* vaginal sex than they told the interviewer, while 1 woman had less

Reports of anal sex

- 7% of all women (n = 9) reported ever having anal sex during the main study
- Of these, one-third (n = 3) reported that they sometimes or always lied to the interviewer about whether they had anal sex
- 1 woman actually had *more* anal sex than she told the interviewer, while 2 women had less

Use of study gel during sex

Did you ever give a wrong answer when the interviewer asked you how often ... ?

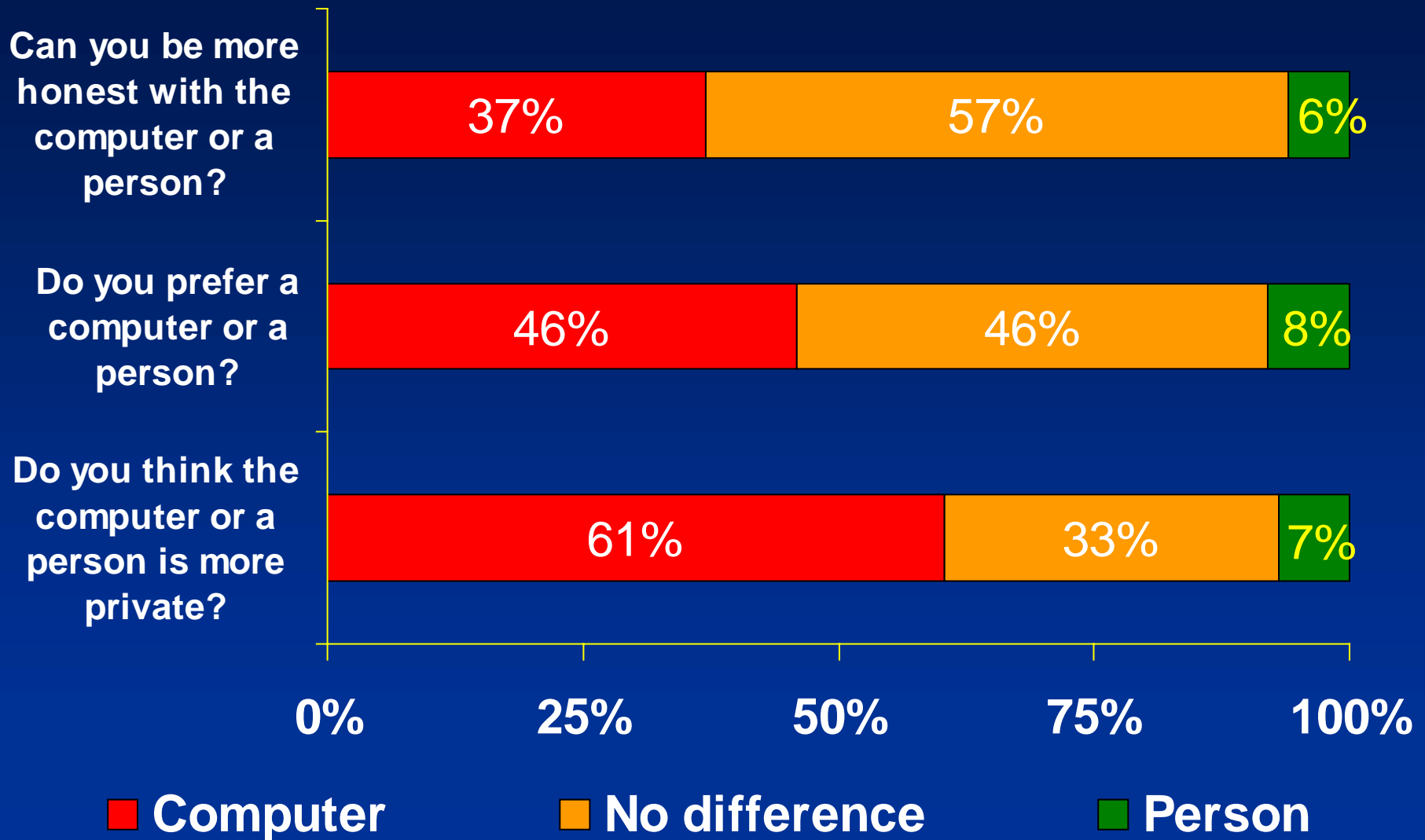
	Gugulethu n = 39		Ga-Rankuwa n = 56		p-value
	n	%	n	%	
You used the study gel with condoms					
Never	34	87%	45	80%	0.079
Sometimes/always	5	13%	11	20%	
You used study gel alone					
Never	27	70%	45	80%	<0.001
Sometimes/always	12	31%	11	20%	
You used neither the gel nor condoms					
Never	30	77%	46	82%	0.592
Sometimes/always	9	23%	10	18%	

Under- versus over-reporting

In general, women who reported giving inaccurate information ...

- actually had *less* sex using the study gel together with condoms than they reported during Phase II (*i.e.*, *over-reported gel and condom use*)
- actually had *more* sex using the study gel alone than they reported during Phase II (*i.e.*, *under-reported gel-alone use*)
- actually had *less* sex using neither the study gel nor condoms than they reported during Phase II (*i.e.*, *over-reported unprotected sex*)

Acceptability of ACASI



Feasibility of ACASI

(n = 135)

- 97% found the computer survey easy
- 93% found using the touch screen easy
- 91% found it easy to change their answers if they wanted to
- 93% were confident they did not make mistakes using the computer

Limitations

- Women may have misunderstood some questions based on questionnaire order
- Cannot be certain that ACASI results are necessarily correct
- Technological problems resulted in loss of 3 interviews

Conclusions

- More women than expected reported giving incorrect information
- Nearly all women reporting inaccurate information were actually exposed to gel *more* often than they reported during the main trial, reinforcing safety conclusions
- Interviewer and counselor training key for minimizing biases of face-to-face interviewing
- ACASI highly acceptable and feasible in this population

Thank you