

# ACCEPTABILITY OF CARRAGUARD® AND PLACEBO AMONG HIV-POSITIVE WOMEN AND MEN IN DURBAN, SOUTH AFRICA

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## MAIN FINDINGS



- Both study gels were acceptable.
- Both women and men rated the study product (gel + applicator) favorably.
- Few reported pain or irritation during or after gel use.
- Overall positive response to the gels' characteristics and packaging.
- All women and men would buy the gel to use with their steady partner if available as a microbicide, and would recommend to a friend.

## GEL CHARACTERISTICS: SMELL/COLOR

- Sexually abstinent women:**
- 92% (12/13) gel users liked color.
  - 92% (12/13) gel users liked smell.
- Sexually active women:**
- 86% (12/14) gel users liked color.
  - 79% (11/14) gel users liked smell.
- Sexually abstinent men:**
- 92% (12/13) gel users liked color.
  - 69% (9/13) gel users liked smell.

"I think that what should be inserted in the vagina must not have [a] smell [or] color."  
~Active woman

"[The color] was very fine because you can be able to hide it and insert it without anyone being able to see that you have inserted [it]."  
~Abstinent woman

## LUBRICATION DURING SEX

- Complex relationship between too little, "optimal," and excessive lubrication during sex.
- Dry sex preference not common; generally liked that the gel added lubrication, made sex more enjoyable, less painful for some.
- 93% (13/14) sexually active women gel users felt gel added lubrication during sex.
- 70% felt added lubrication was an advantage.

"Yes, the thing I liked about the gel, it is slippery and smooth...It was soft and didn't make it dry...I didn't have a problem about it except that it [made] me too wet."  
~Active woman

"What I would also like about the gel is not to make you dry and not to make you wet, but just to be neutral."  
~Abstinent woman

## BACKGROUND & METHODS

- Phase I safety trial of Carraguard® among HIV-positive women and men in Durban, South Africa
- Randomized, placebo-controlled, double-blind trial; included Carraguard, placebo and condoms-only arms
- 60 participants; women applied gel vaginally once a day for 14 days, and men applied gel directly to penis once a day for 7 days
- Data still blinded; results for Carraguard and placebo combined
- Acceptability of Carraguard and placebo also assessed:
  - Interviewer-administered questionnaires for all participants (quantitative data)
  - In-depth interviews with sub-set of participants (qualitative data)

## GEL CHARACTERISTICS: APPLICATOR/PACKAGING

- 92% (12/13) of sexually abstinent women and 86% (12/14) of sexually active women gel users said they liked the packaging.
- In qualitative data, many women and men expressed positive attitude toward applicator's color and size.
- Active women's male partners, however, had mixed feelings about the applicator.

"[The applicator] is too long that it doesn't work out. You put it in your pocket. Let's say you [are] going to the club in case you would meet [a woman]. Every time you put it in your pocket, you feel the thing."  
~Male partner

"I had no problem [with the applicator] because it is made for that - each round [of sex] to have its own tube."  
~Male partner



Gel applicator

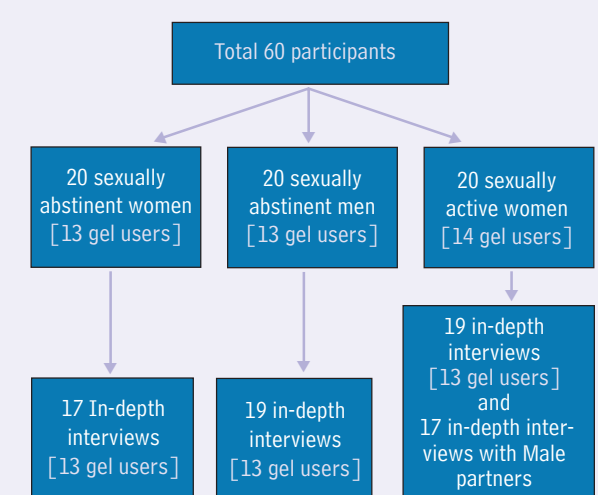
## COVERT USE

- In general, respondents expressed mixed feelings about whether a microbicide could and should be used covertly.
- 21% (3/14) sexually active women said gel could be used without partner's knowledge.
  - 14% (2/14) sexually active women said they would use gel covertly.
  - 42% (8/19) sexually abstinent men said women in general should be able to use gel covertly.

"I do not think that the woman can be able to use that thing without informing her partner...Maybe it must be something that they have to drink and stay in the blood and not [apply] it underneath."  
~Male partner

"I think we as females since we are going to use the gel maybe the [majority] of women will use it as secret."  
~Abstinent woman

## STUDY DESIGN: ACCEPTABILITY



## GEL CHARACTERISTICS: VOLUME/CONSISTENCY

- Sexually abstinent women:**
- 77% (10/13) gel users liked the amount of gel they had to insert.
  - 85% (11/13) gel users said gel never felt too sticky.
  - Mixed on whether gel felt too wet—5/13 said never; 3/13 said sometimes or often; 5/13 said always.
- Sexually active women:**
- 71% (10/14) gel users liked the amount of gel they had to insert.
  - 79% (11/14) gel users said gel never or rarely felt too sticky.
  - Mixed on whether gel felt too wet—6/14 said never or rarely; 1/14 said sometimes; 7/14 said always.
- Sexually abstinent men:**
- 54% (7/13) gel users liked the amount of gel they had to apply.
  - 62% (8/13) of gel users said gel never felt too sticky.
  - Mixed on whether gel felt too wet—6/13 said never; 2/13 said often; 5/13 almost always or always.

"I can say that the gel is good...There were no unusual fluids [during sex]... it was the dampness of the gel."  
~Active woman

## THE NEED FOR MICROBICIDES

- The majority of respondents expressed a strong need for microbicides.
- 100% (27/27) women gel users said they would buy the gel to use with their partner and would recommend it to a friend.
  - 100% (19/19) sexually abstinent men said they would buy the gel to use with their partner and would recommend it to a friend.

"I wanted to be part of [this research] so as to help the community [and] the people. For instance, maybe there is a gel or something that might arise that will help the people who have HIV..."  
~Abstinent man

"My opinion about [using the gel] is [that] you will be able to talk with your partner knowing each other's HIV status... if there is something that can be a protection measure that will serve as if nothing has happened [to] the married couple."  
~Male partner who also participated in Abstinent men cohort

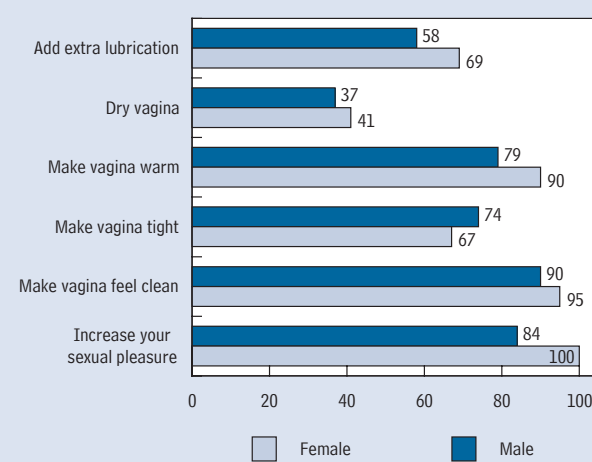
## DEMOGRAPHIC DATA

	Sexually abstinent women (n=20)	Sexually active women (n=20)	Sexually abstinent men (n=20)
Median age in years (range)	30 (19-42)	28 (22-41)	32 (21-50)
Mean education in years (range)	12 (6-15)	12 (5-14)	10 (4-16)
Married*/steady partner (proportion)	80% (16/20)	100% (20/20)	90% (18/20)
Mean live births (range)	1.80 (0-5)	1.85 (0-5)	Not applicable

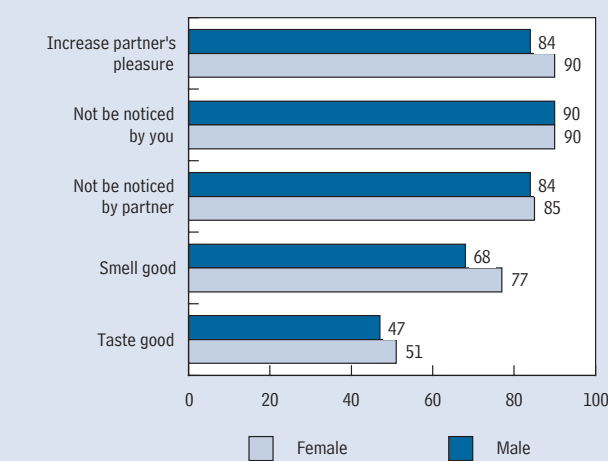
\* Defined as legally married or some lobola (i.e. bride-price) paid.

## TRAITS OF AN IDEAL MICROBICIDE

Important for microbicide to:



Important for microbicide to:



## BASELINE HIV AND SEXUAL BEHAVIOR DATA

	Sexually abstinent women (n=20)	Sexually active women (n=20)	Sexually abstinent men (n=20)
Male condom use in last month* (proportion)	64% (7/11)	90% (18/20)	62% (8/13)
Mean lifetime sex partners (range)	3.1 (1-15)	3.2 (1-6)	15.2 (3-90)
Mean number vaginal sex acts in last month (range)	2.7 (1-4)	5.5 (1-18)	5.2 (1-30)
Percent ever tested for HIV (proportion)	85% (17/20)	100% (20/20)	80% (16/20)

\* Among those who reported vaginal sex in last month.

## PRODUCT USE

The majority of respondents felt product was easy to use

- 85% (11/13) sexually abstinent women gel users said they liked inserting the applicator into the vagina.
- 100% (14/14) sexually active women gel users said they liked inserting the applicator into the vagina.
- 77% (10/13) sexually abstinent men gel users said they liked applying the gel to the penis.

"I used to make it a point that in whatever I was doing just to let [my wife] know [that I needed to apply gel]... and what made it easy was [using gel] each and every time I took a bath."  
~ Abstinent man

"We got used to [inserting the gel] even [though] it was difficult because you have to be alone and avoid the many people. It's something that is not easy to do... You have to remember and it is [a] responsibility to do."  
~ Active woman

## GEL CHARACTERISTICS: FEEL

**Sexually abstinent women:**

- 85% (11/13) gel users said gel never caused pain or irritation during insertion; 92% (12/13) said gel never caused pain or irritation after insertion.
  - 85% (11/13) gel users said gel never dried too quickly.
- Sexually active women:**
- 100% (14/14) gel users said gel never caused pain or irritation during or after insertion.
  - 86% (12/14) gel users said gel never or rarely dried too quickly.

"[The gel] didn't have any effects in my body because I couldn't feel that there was something."  
~Abstinent woman

"What I liked about it is that cold sensation. It constantly reminded me of the presence of my penis."  
~Male partner

**Sexually abstinent men:**

- 100% (13/13) said gel never caused pain or irritation during or after direct application to the penis.
- 62% (8/13) said gel never or rarely dried too quickly.

## EFFECTS ON SEX

- Sexually active women inserted gel average of 61 minutes before sex.
- 100% (14/14) said it was never difficult to remember to use gel before sex.
- 71% (10/14) said gel made sex more pleasurable.
- 36% (5/14) said gel made them have sex more often.
- Male partners had overall positive feelings about the gel; many preferred the gel over condoms.
- Many men felt added lubrication was an advantage; gel made sex more enjoyable, less painful for some.

"It's that it made sex simpler... [I]t made it slippery when you are having sex. And there is nothing which is tight and there is no pain."  
~Active woman

**Timing of gel use and sex**

- In general, women and men did not understand that gel should be inserted "up to 1 hour" before sex; many waited >1 hour after gel insertion to have sex.
- Most expressed a preference for gel to be inserted immediately before sex.

"You feel warm if [the gel] is inserted by a female...Its friction is not like a condom. It also makes the vagina to come closer...It made me to love [sex]."  
~ Male partner

## CONCLUSIONS

- Study gels were acceptable
  - Few participants reported side effects from gel.
  - Product generally easy to use.
- Overall positive response to gel and applicator characteristics
  - Preference for white applicator and colorless gel.
- Important for a microbicide to improve or have no effect on sex
  - Optimal use immediately before sex; timing of use needs to be carefully conveyed to users.
  - More important for a microbicide to warm and tighten the vagina than to dry it during sex.
  - Effect of microbicides on lubrication during sex needs to be studied further.
  - Covert use not desirable to all participants, but could be an option.

## ACKNOWLEDGMENTS

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