

# **Rectal Microbicide Acceptability**

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# I. Volume Escalation Trial

- **Specific aim:** Determine the maximum acceptable volume of gel that men are willing to use during receptive anal intercourse (RAI)
- **Population:** HIV negative men with recent history of unprotected RAI with and HIV+ or status unknown partner

# Volume Escalation Trial Protocol

- Baseline in-depth interview exploring
- Clinical exam
- Solo trial: Initial 5 ml gel application and Volume Acceptability Assessment (VAA)

# Volume Escalation Trial Protocol (cont'd.)

- Volume escalation: 20, 35, and 50 ml gel applications and VAA rating
- Wash out period
- Quantitative and qualitative assessment of experience using the gel
- Determination of Maximum Acceptable Volume (MAV)
- Trial with sex: Use of MAV in 3 occasions of RAI with VAA
- Final acceptability assessment

# **Volume Acceptability Assessment**

The volume of gel you used today was: 20 ml

Please indicate your opinion. Overall, this volume felt ...

**Completely unacceptable (1)**

**Somewhat unacceptable (2)**

**Somewhat acceptable (3)**

**Highly acceptable (4)**

# Sample Characteristics

	<u>Solo trial</u>		<u>Trial with sex</u>	
	(N=18)	%	(N=14)	%
<b>Race</b>				
<b>API</b>	1	5	1	7
<b>Black</b>	3	17	3	21
<b>Latino</b>	5	28	3	21
<b>White</b>	9	50	7	50
<b>Age (mean)</b>	39		40	
<b>Education (mean)</b>	college graduate		college graduate	
<b>Income (mean)</b>	\$30,000		\$30,000	

# Maximum Acceptable Volume

Number of men rating volume “acceptable”:

	<u>Solo trial</u> (N=18)
5 ml	18
20 ml	18
35 ml	15
50 ml	9

# Changes in acceptability from solo trial to trial during sex

- Three men reduced their MAV when used during sex
  - ▶ 50 to 35
  - ▶ 50 to 20
  - ▶ 35 to 20

# Maximum Acceptable Volume

Number of men rating volume “acceptable”:

	<u>Trial with sex</u> (N=14)
5 ml	14
20 ml	14
35 ml	9
50 ml	4

# Preliminary Conclusions

- Up to 35 ml. of gel applied intrarrectally are acceptable to the majority of MSM who have RAI.
- On average, most participants said they would be “very likely” to use a rectal microbicide gel once it becomes available.
- Solo ratings may overestimate acceptability when compared to use during sex.
- As volume increases, so does discomfort.
- The higher the volume, the less acceptable the gel is.

# Next Phase

- **Product preference**
  - ▶ **Suppository vs. gel**
  - ▶ **N = 100 MSM**
  
- **Women's study**
  - ▶ **In-depth interview**
  - ▶ **N = 28 (20 already interviewed)**

# Impotence cream on the horizon? New Jersey company's Alprox-TD in late-stage testing, could challenge pills.

August 11, 2005: 12:44 PM EDT

By Aaron Smith, CNN/Money staff writer

**NEW YORK (CNN/Money) - Since Pfizer launched Viagra back in 1999, patients have gotten used to the idea of popping pills to make impotence go away. But what would they think of a skin cream that treats erectile dysfunction?**

[NexMed](#) ([Research](#)), a small company based in Robbinsville, N.J., is conducting late-stage tests on Alprox-TD, a cream that restores blood circulation for men who have trouble getting erections. Alprox-TD comes in a tube and is applied into the penis, as demonstrated in a graphic on NexMed's Web site.

**Thank you!**

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