Drivers of vaginal drug delivery system acceptability from internet based conjoint analysis

Rachel J. Primrose [1], Toral Zaveri [1], Gregory R. Ziegler [1], Howard R. Moskowitz [2], John E. Hayes [1]

1 Department of Food Science, College of Agricultural Sciences, The Pennsylvania State University, University Park, PA.

2 Moskowitz Jacobs Inc., White Plains, NY.

Background

• Sexually transmitted infections (STIs) remain a global public health threat; nearly 36 million adults and children are living with HIV and nearly 350 million adults have other, curable STIs.

• The use of vaginal delivery systems containing antiretrovirals is a promising option for HIV prevention, as some recent clinical trials of microbicides have been successful in reducing HIV transmission. However, user acceptability impacts user adherence, which substantially moderates the efficacy of microbicides in these trials.

• The overall goal of our research team is to incorporate user acceptability data early in the microbicide design process and therefore optimize vaginal delivery systems so they are highly acceptable to women. By understanding what women find to be most important regarding a product's function and sensory attributes, we aim to formulate an ideal product, in the hope that this will reduce barriers to successful use.

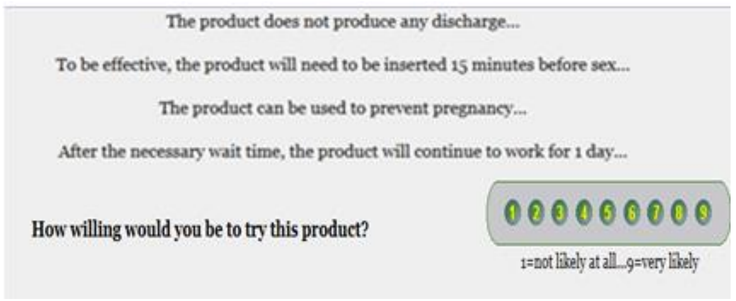
• Accordingly, we have sought to capture the various tradeoffs among product characteristics. These include shape, color, wait time, partner awareness, messiness, leakage, functionality, duration of protection, etc.

• Conjoint analysis is a technique often used in market research to determine what combination of elements influence a consumer's willingness to use or try a product. Using this technique and by better understanding what sexually active women want in an ideal microbicide product, developers can use this information to formulate a product that we hope will increase a woman's willingness to try and use the product.

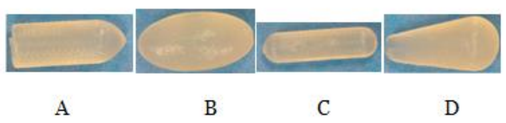
Methods

Participants – A convenience sample was recruited by flyers and word of mouth around the Penn State campus in University Park, PA. Participation was voluntary and all responses were anonymous. Eligibility criteria included: 18-35 years old, female and sexually active (had vaginal sex within a man in the past 12 months). All procedures were approved by the Penn State IRB (Protocol ID 44741).

Study Protocol– Screening and surveying data was collected anonymously online using SurveyMonkey (screener) and IdeaMap® (conjoint survey). The IdeaMap® platform is a modified conjoint method that can assess the effect of a grouping of independent variables by evaluating their effect on one another. Attributes used in this study were divided into 7 Categories and 4 Elements (49 Concepts). The 7 categories included: 1) images; 2) messiness and leakage; 3) wait time; 4) product function; 5) partner awareness; 6) duration of protection; and 7) color. Unlike prior conjoint studies on microbicides, we were able to present images of prototype microbicide products illustrating the shape of the microbicide. Shapes were based on other recent work by our team. For each category, four elements (word phrases) relating to their category were used. A 1 to 9 scale (not likely at all to very likely) was used to evaluate a participant's willingness to try the described product.



Screen shot illustrating a sample of one of the vignettes participants would have seen in IdeaMap®



Images shown to participants illustrating shape: bullet (A); tampon (B); oval (C); tear drop (D)

Following data collection, analysis was performed with the IdeaMap® software to determine the baseline and additive effects of the various elements on the group's willingness to try the product.

Results

Element N=302 Constant=25	Additive Score
The product will provide HIV and STD protection and can also be used to prevent pregnancy…	17
The product can be used to prevent pregnancy…	14
The product does not produce any discharge…	9
The product will provide protection against HIV and other STDs…	9
To be effective, the product will need to be inserted at least 2 minutes before sex…	7
After the necessary wait time, the product will continue to work for 2-3 days…	6
The product will not be noticed by your sexual partner…	5
The product will be translucent/clear in color…	3
Bullet Shaped	1
Tampon Shaped	1
Oval Shaped	1
After the necessary wait time, the product will continue to work for 1 day…	0
Tear Drop Shaped	0
The product produces some discharge, but does not require a panty liner…	0
The product will be pearlescent in color (i.e. the color and shine of a pearl in color…	-1
The product produces some discharge, which is similar to increased vaginal discharge during sex…	-1
To be effective, the product will need to be inserted 15 minutes before sex…	-1
To be effective, the product will need to be inserted 30 minutes before sex…	-3
To be effective, the product will need to be inserted an hour before sex…	-3
After necessary wait time, the product will continue to work for 4 hours…	-4
The product will provide protection against HIV only…	-4
The product will be a pale, bubblegum pink in color…	-6
The product will be white/chalky in color…	-6
The product may or may not be noticed by your sexual partner…	-8
After the necessary wait time, the product will continue to work for 1 hour…	-9
The product will be noticed by your sexual partner…	-16
The product will leave residue on your sexual partner…	-16
The product produces a lot of discharge and will require a panty liner…	-17

Topline interest value for microbicide product elements in 302 women

Results Continued

• The additive constant value is a baseline indicator of the group's overall willingness to try the product. That is, it reflects the level of interest to trying microbicides which is not attributable to any specific element. This value can be interpreted as the percentage of subjects that would respond favorably (a score of 7 or higher on a 9 pt scale) if no elements were present.

• An interest value is the percentage to be added to the constant, which indicates the impact that individual element has compared to the constant or other elements. A positive element score represents an increase in willingness to try the product across the group, while a negative element score indicates that the element decreases the group's willingness to try the product. A number near zero signifies that the element, or attribute, is relatively unimportant in this decision.

• In this cohort, the constant value (i.e. baseline) was 25. In other words, 25% of participants would respond favorably to the microbicide product in the absence of any other elements. The additive effect of the various elements tested is shown in the table to the left.

• There were 11 elements with a positive additive score. Two of the highest additive effect elements were related to product function. "*The product will provide HIV and STD protection and can also be used to prevent pregnancy…*" and "*the product can be used to prevent pregnancy…*" and received interest values of 17 and 14 respectively.

• Conversely, 14 attributes received negative values. Two of the lowest scoring elements were related to consequences of use. They included: "*The product produces a lot of discharge and will require a panty liner…*" and "*the product will leave residue on your sexual partner...*" and those elements received an interest value of -16 and -17 respectively.

• Three of the twenty-eight elements did not influence willingness to try; these included: "*after the necessary wait time, the product will continue to work for 1 day…*" "*tear drop shaped…*" and "the product produces some discharge, but does not require a panty liner…"

• The majority of participants in this study were between the ages of 18 and 24 years, and self identified as Caucasian or White, and were currently students. In addition, over 1/2 of the group had only had one sexual partner within the last 12 months and more than half had been screened for STDs/HIV within the last 3 years. Within this group, only 8% of the group had ever been diagnosed with a sexually transmitted disease (STD) before.

Discussion

• Among these participants, several patterns are apparent. All statements which suggested a long wait time before efficacy (more than 15 minutes), short duration of protection (less than 4 hours), a color other than clear/translucent, and elements suggesting the product will be in some way noticed by one's partner all had a negative effect on the group's willingness to try the product.

• As might be expected from the demographics of the participants (college aged white women of relatively low risk) positive effects were seen with elements related to multi-functionality, suggesting pregnancy protection may be more salient than STI protection in these women. Other factors like short wait time for efficacy (2 minutes), longer duration of protection (2-3 days), and covert use (will not be noticed by one's sexual partner) also had a positive effect on the group's willingness to use the product.

• While the information collected to date gives us an improved understanding of the tradeoffs that affect a woman's willingness to try our hypothetical microbicide products, these data were collected from primarily college educated white woman who were recruited primarily from the Penn State campus. We are currently working to expand our data collection to a larger group of higher risk women to better reflect the normal range of responses in the broader population.

(Funded by the Pennsylvania State University and a National Institutes of Health grant from the National Institutes of Health National Institute of Allergy and Infectious Diseases [AI094514] to JEH and GRZ)