Improving acceptability of vaginal drug delivery systems by using sensory methods

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Background

Vaginal microbicides contain pharmaceutical agents that block the transmission of HIV and other sexually transmitted diseases; these products can be inserted into the vagina prior to coitus, empowering women to protect themselves with a product they can control. Prior clinical trials indicate microbicides can reduce HIV transmission, but effectiveness depends on user compliance. Thus, user acceptability is critical for the success of these products.

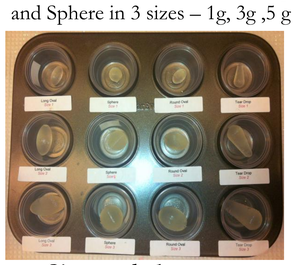
We are investigating carrageenan-based microbicide prototypes in the form of gel ovules which when inserted vaginally will function as drug delivery vehicles. To understand how women's preferences and willingness to use are governed by the product's physical attributes, we have prepared gel ovules of varying size, shape and firmness. We are conducting focus groups to get an idea of women's preferences for such a vaginal drug delivery product. The opinion we get from the women will be used to fine tune the product design to produce a product which will be biologically effective as well as well-accepted by women for effective continuous use.

Methods

57 sexually active women in the age range of 18-45 years have been recruited to participate in 9 focus groups to understand women's preferences about vaginal products and get feedback on softgel ovule prototypes prepared in the lab. Women were placed in one of three group formed on the basis of age- 18-22, 23-30 and 31-45. The women evaluated the softgel ovules based on size, shape and firmness (Figure 1). Women also gave us their preferences for smell and color as well as use preferences such as need for applicator and duration of protection. After the discussion women answered a short survey containing demographic as well as information regarding their sexual practices and prior vaginal product use.

Sample Tray Presentation

Long oval, Round oval, Tear drop and Sphere in 3 sizes – 1g, 3g ,5 g



Size and shape tray in firmness 3



Firmness tray in round oval size 2

Figure 1

Demographic data

Age	# women
18-22	18
23-30	21
31-45	18
Race	
Caucasian or White	43
Black or African American	3
Asian	8
South Asian	1
Other.	2
Marital status	
Now married	18
Divorced	1
Separated	1
Never married	37

Results

Shape Preference

Majority of women preferred the oval shapes particularly the long oval followed by round oval. Women particularly disliked the sphere. These choices were governed by a number of factors such as

A) Ovals look more medicinal
B) Other vaginal products that they have used such as tampons and yeast infection vaginal suppositories come in the ovular shape
C) A belief based on the knowledge of anatomy that certain shape will fit better
D) Perceived ease of insertion as well as having an applicator

When I imagine my vagina it's the long tunnel and I feel like a sphere being in the middle of it would corrupt the edges of it, so I would definitely prefer either a teardrop—actually I'm leaning more towards the long oval and maybe because it does resemble the little circle that I've seen on a Vagisil box. (22 Y, White)

The sphere looks like a gumball to me…I don't like the shape. It wouldn't hinder me from using the product, but if I have my choice I really prefer either the long oval or the teardrop…The long oval one, it looks like a vitamin and I'm like you, where you said it doesn't look like it would be fun. It just looks like, again, it would be more effective, like it's more responsible, it's more something. The teardrop just looks like it would—even though I'm sure all of them are easy to insert—it looks like it would insert easier. I think it's just that's the way the shape is. It just looks like it would. (33 Y, White)

Well, if it's already in the applicator, like if it comes as a tampon does, if you don't see it, I don't think it[shape] matters as much.(20 Y, White)

Size Preference

Women preferred Size 2 as compared to the other two sizes as Size 1 was thought to be not as effective and difficult to insert whereas with Size 3, some women thought it may be too big to the point of being uncomfortable once inserted. This choice was also greatly influenced depending on whether an applicator would be used for insertion.

Yeah, the long oval in the size two I thought was the most ideal out of all the shapes and the previous sizes. I think this would be really easy to put in an applicator similar to a tampon, and I would feel like if I inserted this it would feel comfortable. Also, I would get an effective perception from it. (22 Y White)

I would be afraid of size three being noticeable, that I will be aware that it is in there. I think for how long it takes to dissolve. Size one, too small. I would be worried about handling and dropping it, or size two, just looks small enough to be comfortable, big enough to be easy to handle, and the more I hear about the teardrop in the bigger size, it makes sense, too, so teardrop or the long oval, either shape in my opinion would be the easiest to apply without applicator. (40 Y White)

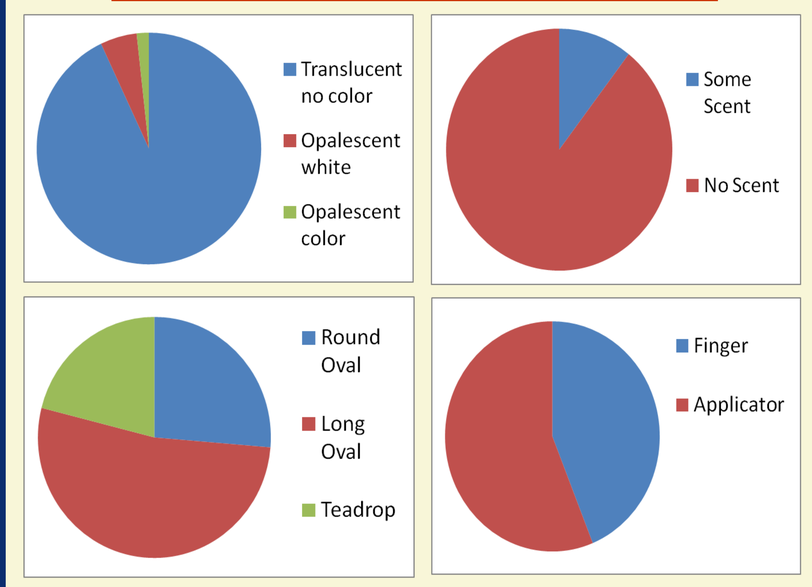
Firmness Preference

Women's firmness preference largely depended on whether an applicator will be used for insertion. In general, women preferred softer firmness levels with an applicator as they believed it would dissolve faster and be more comfortable.

You might feel uncomfortable with this [F4 and F5] (26 Y, Asian)

If there was an applicator, firmness one because I think the faster the better, dissolving wise. For covert use, if I wouldn't want an applicator sitting around and a higher firmness level would be better so two or three if no applicator.(29 Y, White)

Women have clear preferences for, color, scent, shape and need for an applicator



Discussion

The preferences for size shape and firmness given by the women largely depended upon handling of the product and ease of insertion, especially for women who preferred manual insertion as opposed to applicators.

Majority of the women (79%) preferred the oval shapes (round and long) because of shape symmetry, association with medications and similarity to other vaginal products such as tampons. The remaining women preferred the tear drop: no one preferred the sphere.

As vaginal product use and preferences vary across countries and cultures, some focus groups were conducted with women originally from Asia.

Incorporating women's opinion during the initial stages of product development will result in a product design that women prefer hence, ensuring better user compliance especially for critical applications such as prevention of HIV transmission.

Acknowledgements

This work is supported by a R21 grant from the Microbicide Innovation Program by the NIH awarded to Dr Hayes and Dr Ziegler.