

**Are you experienced?**

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**Using the lessons learned from  
marketing research on consumer  
experience to improve the  
research and development of  
new HIV prevention technologies**

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**Are you Experienced?:  
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improve the research and development of new HIV prevention technologies**

**Discussion paper for the aids2031  
Science and Technology Working Group**

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## **Preface**

In the process of preparing this paper for the aids2031 Working Group on Science and Technology, it was never my intention to provide an extensive literature review of the research conducted to date on every single HIV prevention technology currently available or in development. Most of the members of the Working Group are pioneers and global leaders in the field of HIV prevention and, as such, are already intimately familiar with the literature from their own experience in conducting the research. Therefore, no exhaustive literature reviews or meta-analyses are provided here. The references chosen for this paper serve the purpose of providing examples through which I can illustrate or reinforce the various arguments I am making regarding the incorporation of behavioral and social science into large-scale clinical trials of new HIV prevention technologies.

In addressing the charge of focusing on behavioral and social science, there was the potential to discuss the multitudinous ways in which behavioral and social science can contribute to and improve HIV prevention clinical trials, ranging from the conduct of initial community consultations regarding the appropriateness of research questions, to the development of standard operating procedures (SOPs) for prevention and adherence counseling, to assessing the impact of clinical research trials on community level behavior change over time. However, it was my understanding that such broad discussions, while interesting, are beyond the scope of the Science and Technology Working Group. To that end, this paper focuses solely on the process of research and development for new HIV prevention technologies and their eventual adoption by consumers of such technologies (i.e., those at risk of HIV infection).

It should be stated up front that a part of the charge for this paper was to provide “a provocative piece” that contained “out of the box” thinking about HIV prevention research. By reaching out to the field of marketing research for inspiration, this paper will hopefully be successful in prompting discussion of how HIV prevention research can be improved, both in terms of its quality and in terms of its efficiency in answering questions about how new prevention technologies can be more easily introduced and adopted by those at risk. There is still much that must be learned in HIV prevention, and the continuing global pandemic ensures the existence of a consumer base that eagerly awaits (and desperately needs) new, effective, life saving products. With approximately 6800 new infections per day<sup>1</sup>, we truly have no time to lose.

## Introduction

As the world enters the third decade of the fight against HIV/AIDS, the search continues for HIV prevention strategies that can be adopted and utilized by men and women at risk of infection. To date, the majority of prevention efforts have concentrated on the development of behavioral interventions aimed at changing the HIV-related knowledge, attitudes, and risk practices of individuals, couples, social networks, and communities. For reducing risk for sexual transmission of HIV, male condoms and, to a lesser extent, female condoms have been the core component of these interventions. While condom use uptake has certainly increased, its adoption remains problematic to many men and women throughout the world, thus highlighting the need for other strategies that can be added to the HIV prevention toolbox.

Much of the focus in the HIV prevention landscape has shifted towards the research and development of biomedical strategies for prevention of infection. The promising results of the three male circumcision trials in Africa are the first successes in the quest for biomedical prevention strategies, an efforts are underway to scale up male circumcision programs in other heavily affected areas of sub-Saharan Africa. While the research and development efforts on alternative barrier methods (e.g., the diaphragm), topical microbicides, vaccines, and pre-exposure prophylaxis (PrEP) have not yet had the successes that the male circumcision research has enjoyed, clinical trials of candidate strategies and products continue in the hope that some new product or strategy will show efficacy in preventing new infections.

The “biomedicalization” of HIV prevention tools does have a few advantages, the most significant one being the possibility of someday having a wider array of prevention strategies from which to choose. Similarly, given some of the problems that have been noted in the literature with regard to both male and female condom use, having prevention options that can be inserted rectally or vaginally, injected, or taken orally provide hope for populations who are at risk of infection but who cannot or will not adopt condom use. For some, the idea of a pill or a vaccine may resurrect the notion of a “Magic Bullet” against HIV/AIDS that will serve to put an end to the global pandemic.

While there may indeed be cause for optimism, the fact remains that no matter how user friendly any of these new prevention technologies are, they still require one critical component to make them effective: human engagement. None of these prevention technologies can achieve the desired goal of preventing HIV transmission in the absence of a human behavior, be that behavior the taking of a pill, the application of a topical microbicide, or the seeking out of a care provider who can administer a vaccine. To that end, it is important to ensure that the behavioral and social factors associated with the adoption and continued use of these prevention strategies is examined as vigorously as the safety and efficacy of the prevention strategies themselves.

The purpose of this paper is to provide a framework for a discussion of why behavioral and social science should be routinely incorporated into the development, design, and implementation of clinical trials testing novel HIV prevention technologies and

strategies. To make this case, I will provide a brief overview of what has been learned from the study of the adoption and use of other HIV prevention technologies, as well as examples of the lessons that have been learned from the private sector regarding product development and acceptability in the marketplace. The examination of these lessons learned will provide an argument for why HIV prevention scientists, advocates, and funders should adopt a more consumer-centered approach to the development of HIV prevention technologies similar to those used by private sector corporations that research and design new products for the consumer mass market. To accomplish this, scientists and funders must re-conceptualize HIV prevention clinical trials as being both tests of biomedical and behavioral interventions rather than solely tests of products in absence of the human interface required to utilize these products.

### **What does “incorporating behavioral and social science research” mean?**

The incorporation of behavioral and social science research as a critical component of HIV prevention clinical trials is much more than examining how demographic variables (such as gender, race, socioeconomic status) are associated with a trial’s main outcome variables. Measurement of other product and user-related characteristics, as well as user experiences with the product in different situations and factors associated with adherence to product use over the course of a trial, are also critically important for better understanding potential product acceptability, product adoption, and sustained use in real world contexts.

That being said, it is appropriate and imperative to consider how social and behavioral science can be incorporated into all stages of clinical HIV prevention research. Several published papers have already addressed this issue in relation to topical microbicide research and development<sup>2,3,4</sup> and research pertaining to female-controlled prevention methods<sup>5</sup>. However, despite widespread agreement about the importance of incorporating behavioral and social science research into clinical trials, the actual practice of doing so is relatively rare. When it does happen, it is usually in the context of significantly smaller phase I and II safety and toxicity studies.

Most of the larger (phase III) clinical research trials are not designed to incorporate such comprehensive assessments. Some trials have tried to include measures of product acceptability and other social and behavioral assessments of the participants’ experience with a trial product as part of larger safety and efficacy studies. However, due to concerns about provider and participant burden and (occasionally) budgetary constraints, these more comprehensive assessments are whittled down to much shorter measures focused on whether or not the participant would use the trial product if it were available on the market. Alternately, socio-behavioral components that were once part of a larger, main study protocol may be removed altogether and relegated to substudies which can be implemented only if the behavioral and social scientists interested in those research questions can find their own funding. Given the timing of grant cycles and peer review, not to mention the need for potential revisions and resubmissions, investigators who are successful in obtaining support for research may be so far behind

the start of the original trial that they are forced to settle for recruiting smaller participant samples, potentially weakening the validity and generalizability of the data.

### **What have we learned thus far from the incorporation of behavioral and social science research in studies of HIV prevention technologies?**

When behavioral and social science measures are incorporated into clinical trials testing new HIV prevention technologies, they have focused mostly on user acceptability and physical characteristics of the trial product.

Product acceptability is one of the most frequently assessed behavioral and social science constructs in clinical research trials of new prevention technologies and reasonably so, as acceptability is the primary determinant of actual use effectiveness. However, acceptability is a much larger construct than just an individual's willingness to use a product. It also incorporates factors such as the evaluation of a product's physical properties and characteristics, context of product use, context of service delivery (i.e., where and from whom the consumer obtains the product), and the cost and availability of the product. For those products -- such as microbicides or other barrier methods -- that are to be used in the context of sexual activity, acceptability also relates to how the product performs in the coital context (e.g., changes in physical properties) as well as how the product adds or detracts from sexual pleasure and satisfaction.

Physical characteristics of trial products are an important part of measuring acceptability. Studies conducted on the acceptability of spermicidal gels, foams, and suppositories have found that users typically find formulations that are too wet or too messy as less acceptable<sup>6,7</sup>. In one particular study, the way that users addressed the messiness factor was to reduce the amount of product that was used<sup>8</sup>. This could have dangerous implications for HIV prevention if efficacy is linked to the quantity of product that is used. To that end, it is critical to also examine how people cope with any potentially unpleasant characteristics of a product and how those "coping strategies" affect efficacy, adoption of the technology, and adherence to use.

In addition to the acceptability of the product per se, it is also important to examine how a new technology interacts with the use of existing prevention technologies, such as male or female condoms. This issue of combination use is critical, particularly since forthcoming prevention technologies (e.g., such as microbicides, PrEP, vaccines, etc.) are likely to be only partially efficacious and, therefore, will be recommended for use in conjunction with traditional barrier methods such as male and female condoms. Examining factors associated with combination use may be most relevant to the acceptability and adoption of topical microbicides which, if formulated in a way that allows them to function and be marketed as lubricants, may increase sexual pleasure when used in conjunction with male and female condoms. Nevertheless, combination use may also be an issue for prevention strategies that employ antiretroviral drugs as their active ingredient; in this case, the safety of the consumer may be an issue if

incorrect usage of ARV-based prevention technologies (e.g., PrEP and a topical microbicide) combinations results in increased systemic toxicity, damage to vaginal or rectal flora or epithelia, or affect viral set point if the individual seroconverts.

Another important factor to examine in relation to potential product adoption and sustained use is how the introduction of a new technology might influence the communication and behavioral repertoires of sexual partners, as well as other aspects of users' everyday lives. This issue is particularly relevant in social and cultural contexts where gender inequity is present and/or where male partners dictate what happens as part of the sexual repertoire. For example, while topical microbicides have long been touted as a "female-controlled" prevention strategy (despite the fact that microbicides would be used by both women and men) with the potential for covert use, studies of microbicide acceptability have consistently shown that not all women are comfortable with the idea of covert use, and would inform their partner if they were to use the product<sup>9,10,11,12,13</sup>. Other studies of male attitudes towards microbicides indicate that such products may be less acceptable to married men because they fear that the product would increase promiscuity among their wives<sup>14</sup>. Similarly, some men do not think that women should have the ability to use microbicides without informing male partners and receiving approval<sup>15</sup>. With such concerns, men may refuse to allow their wives to use microbicides or other female-initiated prevention strategies (such as PrEP) because it would signal the woman's infidelity, signal that the wife is questioning her partner's fidelity (even when there is good reason to do so), or erode the authority of the man in the marital relationship<sup>16</sup>.

Similarly, studies of the acceptability of the female condom show that there are a variety of factors in play that affect acceptability, adoption, and sustained use. While early studies of the female condom indicate high acceptability<sup>17</sup>, these ratings of acceptability have only applied to short-term adoption of the device and have not generalized to widespread acceptance by larger populations<sup>18</sup>. Indeed, long term uptake of the female condom is poor due to a variety of reasons including: cost<sup>19,20</sup>; the continued need for couples to agree (or a woman to get permission) to use it prior to sexual activity<sup>21,22</sup>; partner dissatisfaction with or lack of comfort/trust in the device<sup>23,24,25</sup>; loss of sensation during sexual activity<sup>26</sup>; and the stigma associated with using barrier methods in primary or married relationships<sup>27</sup>. Moreover, despite the female condom being a "female controlled" or "female initiated" device, studies have found that partner cooperation is necessary in order for the device to be used effectively<sup>28,29</sup>.

The lack of consistent association between measures of acceptability, choice, satisfaction, and use of new prevention technologies suggests a need to reframe how product acceptability is evaluated in prevention research so that it is more predictive of method use. Doing so not only requires more comprehensive behavioral and social science research to better understand the barriers and facilitators of use and adoption, but may also lead to the design and integration of behavioral interventions into trials where new products are being introduced. Such interventions can be instrumental in providing trial participants with more comprehensive education about new prevention technologies, thus helping to address and overcome some of the barriers that deter

adoption and adherence at the time when participants are dealing with those issues. An example of the effectiveness of this strategy can be seen in a study of female condom use among HIV-positive women in which researchers found that exposure to a behavioral intervention designed to increase trial use of sexual barrier methods in general had a positive impact on increasing acceptability of the female condom<sup>30</sup>.

In addition to addressing issues of user acceptability of new prevention technologies, it is also important to consider the perspectives of those who will be introducing or providing the prevention technologies to individuals. As with any new technology associated with sexual and reproductive health, provider perception of the technology is an important factor associated with consumer adoption. Parallels can be drawn between the uptake of the female condom and the uptake of the tampon. Initially, the tampon was met with great resistance and lack of acceptability, both by the provider community and by consumers<sup>31</sup>. Studies of acceptability and use showed that it took about a decade for the tampon to reach a modest proportion of use. In the case of the female condom, provider attitudes to the female condom were neutral, despite the fact that client enthusiasm for the device was high<sup>32</sup>. Since providers will have a critical role in introducing any new prevention technology to clients, it is important to assess provider attitudes and acceptability, as these attitudes may shape the way in which the innovation is “marketed” or even whether it is offered to clients at all. Sadly, there are too few studies that examine provider attitudes and acceptability about new prevention technologies. Filling this knowledge gap will be critical for when products are shown to be effective and are ready to be introduced to a wider consumer base.

Despite the research that has been conducted to date on the acceptability of these various HIV prevention tools, the fact of the matter is that there is insufficient data on the user-related and situationally-specific factors that influence the adoption, sustained use, and use discontinuation of most of these technologies. Although the devastation already wrought by the HIV/AIDS pandemic certainly justifies the investment into the research and development of new prevention technologies, funders cannot continue to spend millions of dollars developing products under the assumption that men and women across the globe will gleefully, willingly, consistently, and correctly use these products simply because they exist. Consistent and correct use of anything is highly unlikely in normal human behavior, and some individuals will opt to forego HIV risk reduction practices even when they are knowledgeable about infection risk and have a range of preventive options from which to choose. Therefore, it is critical that researchers examine the intrapersonal, interpersonal, and socio-contextual factors affecting product utilization behavior *at the same time that these products are being tested* for safety and efficacy so that the products will more likely be adopted if and when they are proven to be efficacious.

### **Lessons learned from the private sector about product introduction and acceptability**

In the product development and marketing, behavioral and social science research plays a substantial role in helping manufacturers determine which products are popular among consumers, why they are popular, and whether or not innovations introduced to the marketplace will succeed in gaining enough market share to become profitable.

In the course of an average year, corporations spend millions of dollars on marketing research for new products. Determining the actual resources spent on market research compared to advertising is difficult, as spending will vary according to the type of product being introduced and the resources available to the corporation producing the item. However, it might be possible to get some perspective on the resources allocated to market research by examining the investments made on promotional advertising compared to those made for product research and development. Using the example of pharmaceutical marketing expenditures in the United States based on data from 2004, a recent study found that market research tracking firms estimated that companies spent approximately \$57.5 billion in promotional spending. This investment is substantially greater than the \$35.5 billion (including public funds) spent on domestic industrial pharmaceutical R&D in that same year<sup>33</sup>. Given that advertising is only one component of the larger marketing process, one can only guess the magnitude of the overall investment.

While marketing research does have implications for how companies advertise their final product, it can also provide a wealth of data on a variety of consumer constructs including:

- the nature of consumer buying decisions;
- the demographic characteristics of potential or actual consumers;
- psychographic characteristics of potential or actual consumers, such as social class or status, lifestyle, behaviors, values and opinions, and other indicators of “culture”<sup>34</sup>;
- consumer motivations to purchase or use a product, as well as expectations about how that product will perform; and
- loyalty segments, ranging from those actively seeking a new product to those who have no interest in or intention to shift to a different product.

Estimates of new consumer product failure rates vary. According to one source<sup>35</sup>, for every four products that enter development, only one proceeds to market and, at the time of product launch, at least one of every three products fails despite research and planning. Moreover, an estimated 46% of all resources allocated to product development and commercialization by U.S. firms is spent on products that are cancelled or fail to yield an adequate financial return. Given the potential for significant financial losses if a product fails to be accepted or adopted, it behooves the manufacturer or developer of the product to thoroughly research how his product will be received by both target consumers as well as the general consumer population. Marketing research can serve to provide these data, as well as provide data that can help to understand consumer characteristics, elucidate consumer needs and preferences, and provide feedback on how changes to or refinements of the product will affect consumer adoption.

One of the most important predictors of product success is the experience that the consumer has with the product. To illustrate this point, let us consider the examples of two innovative products: The Kodak camera and the Itera bicycle.

### Case Study 1: The Kodak Camera

An excellent example of a product that was designed with the user experience in mind was the Kodak camera designed by George Eastman in 1888<sup>36</sup>. Although the camera itself was actually an incremental improvement on the original model of the camera (in that it used roll film instead of photographic plates), Eastman focused on designing the camera in a way that allowed the user to easily do what mattered most to them: capture the image of their photographic subject. By capitalizing on the user experience via his advertising strategy (“You press the button, we do the rest”), paying appropriate attention to the experience that people were having with the product, and developing relationships with customers to ensure user satisfaction, Eastman ensured the adoption, popularity, and continued use of his product.



*“Why is it that what Eastman figured out over 100 years ago seems forgotten today? Why do so few products seem concerned with how they fit into the lives of their customers?...Why is it that people still approach products as isolated entities, unconnected with the world around them?”*

*-- Peter Merholz*

### Case study 2: The Itera bicycle<sup>37</sup>

Cycling has gained popularity in recent years as a means of reducing dependency on petroleum products and the carbon emissions that come from motor vehicle use. However, this trend is by no means novel. The 1973-74 oil crisis left many individuals considering alternative means of transportation in order to avoid the rising cost of filling the gas tanks of their cars.

This was indeed the case in Sweden. While bicycle use was always a part of life in the country, bicycle sales in the early 1970s were diminishing rapidly. However, the oil crisis and the resulting rapid increase in gas prices resulted in a veritable bicycle boom<sup>38</sup>. In a few years' time, new bicycle sales increased to 450,000, implying that 1 out of every 20 individuals had bought a new bicycle<sup>39</sup>.

In late 1977 and early 1978, the Volvo Company started investigating the conditions for producing a minicar using plastic composite materials as alternatives to steel. In addition to applying this research to the construction of automobiles, they simultaneously decided to expand their research on alternative materials to include the

use of these materials for other applications. Seeking to capitalize on the bicycle trend, the company developed the design for a bicycle made completely from plastic. Spurred on by promising results from a preliminary market study, the team obtained a 54,000 Swedish Krona (SEK)<sup>40</sup> grant in October 1978 from the Swedish National Board for

Technical Development to finance production of a prototype.



Figure 1. The Itera plastic bicycle.

Although the Volvo Company had abandoned the work on the minicar, three members of the original product development team continued their work on the bicycle continued and, in February 1980, produced the first prototype of a rideable, all plastic bicycle. The team demonstrated the bicycle to the state-owned bank and obtained a loan of 6 million SEK<sup>4142</sup> to form the Itera Development Center, a company whose sole purpose was to design, produce, and market composite material bicycles.

In September 1981, the first Itera bicycles were shown to retailers and the press. Consumer research conducted in autumn of that year indicated that well over 100,000 Swedes were interested in buying the product. With high expectations for success, the Itera Development Center started larger scale production of the bicycle in early 1982 with massive press coverage.

However, when the final product rolled into the marketplace, consumer receptivity was low. Sales were slow and the media --and everyone else, it seemed -- had lost interest. Over the next couple of years, many bicycle retailers had stopped selling the Itera cycle and inventory piled up in the factory. Despite various attempts to salvage the product, production of the Itera bicycle ceased in 1985.

Analyses of the Itera bicycle story identified several factors that attributed to the failure of the product, including the waning of the bicycle trend in Sweden, the unconventional styling of the product, and the substantially higher cost of the bicycle compared to standard model bicycles. Interestingly, one of the key factors that led to the demise of the Itera bicycle was the construction of the product itself. Although the bicycle was completely rideable, the necessity for using more composite material to ensure that the bicycle was sufficiently sturdy meant that the bicycle was heavier than traditional models. Additionally, because the frame of the bicycle was straight (rather than curved), shock absorption from the road occurred in the handlebars rather than the wheel forks. These design changes resulted in a substantially different user experience, causing riders to feel insecure about the safety of the product. The plastic components gained a reputation as being "false" and less dependable. In the end, the fact that the Itera bicycle "felt different" led to the failure of this innovation.

## **What can HIV prevention research learn from the Itera bicycle?**

One of the greatest lessons that can be learned from the example of the Itera bicycle is that, despite extensive research into the creative use of alternative materials, innovative product design, and the best intentions of the manufacturers, the final product that went to market was completely uninformed by the perspectives of the individuals who would prospectively be using the product on a regular basis. In other words, the lack of attention to user experience played a key role in the product's demise. Had they conducted more thorough market research during the various stages of the bicycle's design and manufacturing processes, they may have gleaned insights on how the final product could have been made more attractive to potential consumers.

Drawing the parallel to the research and development of HIV prevention technologies, a great deal of effort and resources are spent developing products that might answer the question, "will it work to prevent HIV infection?" However, precious few resources are spent on addressing the question, "Will people use it to prevent HIV infection?" As evidenced by the literature on condom uptake, simply creating an effective product does not guarantee its use. Moreover, existing literature on the acceptability and adoption of male and female condoms indicates that people's subjective experiences with condoms are a critical factor in determining whether or not these devices are actually used, and that these experiences are more than what can be reflected in objective measures of acceptability. Although the data on microbicide acceptability may be promising, these data reflect the user experience in the artificial context of clinical trials and, as such, cannot be relied upon to predict acceptability and use in a real world context where participants are not receiving education, counseling, and state of the science health care on a consistent basis. Addressing these shortcomings requires that researchers and sponsors think differently about product development, and address the research question from both the "public health" perspective and the "market research" perspective, which necessitates significantly greater commitment to and investment in inclusion of behavioral and social science research so that effective products can be created with the consumer perspective in mind.

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- <sup>39</sup> Hult 1992, op. cit. (see reference 35).
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and Williamson SH. Purchasing power of money in the United States from 1774 to 2008. *Measuring Worth*, 2008. Available at [www.measuringworth.com](http://www.measuringworth.com).

<sup>41</sup> Note: 6,000,000 SEK in 1978 was equivalent to approximately 1,438,400 USD. In 2007 USD, the amount would be equivalent to approximately \$3,620,306. Resources: Officer LH and Williamson SH. Purchasing power of money in the United States from 1774 to 2008. *Measuring Worth*, 2008. Available at [www.measuringworth.com](http://www.measuringworth.com)