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An assessment of the relationship between condom labels and HIV-related beliefs and intentions

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Abstract

The aim of this paper is to examine the impact of the FDA's proposed condom package labeling on HIV-related beliefs about condom effectiveness, on intentions to recommend condoms for friends to use, and intentions to use condoms. Using a nationally representative survey we randomized 1,194 adults ages 18-65 years into one of three condom label conditions: the current label on condom packaging; a label with the proposed FDA language; and a label with CDC language on condom effectiveness. In short, there are no significant differences between the proposed FDA label and the current label on HIV-related beliefs and intentions. In contrast, from an HIV prevention perspective, the CDC condom language appears to offer a better alternative to the current condom label for unmarried populations.

Keywords

condom labels; FDA warning labels; HIV prevention

INTRODUCTION

In November 2005, the Food and Drug Administration (FDA) published proposed changes in the way condoms are regulated in the United States (US) and issued draft guidelines for condom labeling (Food and Drug Administration, 2005). The labeling recommendations in the draft guidance were issued after an extensive review by FDA in partnership with the National Institutes for Health (NIH) and the Centers for Disease Control and Prevention (CDC). According to the FDA, the draft guidelines are based on available research literature on the safety and effectiveness of condoms to guard against pregnancy and infectious diseases. The FDA has the authority to set regulatory controls on medical devices. This includes “special controls” on devices and an example of a special control is how a device is labeled. Prior to these draft guidelines being issued, FDA required that condoms be accompanied by use instructions, an expiration date, and a simple latex allergy warning: “Caution: This product contains rubber latex which may cause allergic reactions.”

In the draft guidelines, the FDA suggested that an additional label accompany male condoms over and above the latex allergy warning. The proposed warning language is as follows: “When used correctly every time you have sex, latex condoms greatly reduce, but do not eliminate the risk of pregnancy and the risk of catching or spreading HIV, the virus that causes AIDS.”

After the draft guidelines were issued, there were expressions of support by some groups; however, some felt that the proposed labeling attributed condoms more protective power than

warranted (Coburn, 2005). Others expressed concern that the language noting risk reduction (but not elimination) would cause people not to want to use condoms and thereby increase exposure to infectious diseases including HIV (Neuman and Alonso-Zaldivar, 2005; Planned Parenthood, 2006).

Warning labels are commonly used to inform and often dissuade the public from using a potentially hazardous product such as tobacco (World Bank, 1999), alcohol (Public Law 100-690, 1988), and even violent content on television (Bushman, 2006; Bushman & Stack, 1996). Studies on such labels provide mixed evidence regarding their effectiveness, which often depends largely on characteristics of the labels. Both alcohol and tobacco warning labels were found to be ineffective in preventing alcohol (MacKinnon, et al., 2000) and tobacco use (Robinson & Killen, 1997) among adolescents in the United States. However, tobacco warning labels with graphic imagery and more salient, specific messages like those in Canada and the United Kingdom were successful at increasing smokers' perceived health risks (Hammond et al., 2006) and increasing intentions to quit among smokers (Hammond et al., 2007).

Communication studies provide two main theories on the effects of warning labels: the forbidden fruit hypothesis and the tainted fruit hypothesis (Bushman & Stack, 1996; Bushman, 1998; Bushman, 2006). The forbidden fruit hypothesis is grounded in reactance theory (Brehm, 1966; Bhrem & Bhrem, 1981) which states that attempts to restrict one's freedom to engage in a particular behavior will result in a type of boomerang effect that causes the individual to actually perform that behavior. That is, if warning labels are perceived to limit freedom to use a particular product, consumers will want the product even more (Bushman, 1998). On the other hand, the tainted fruit theory predicts that warning labels would, as intended, decrease the attractiveness of a product by highlighting the harm it might bring to the consumer. In contrast to warning labels, information labels are an alternative that are intended to inform consumers about risks without conveying advice or a "behavioral admonition" as in warning labels (Bushman, 1998). In a study on warning labels and violent content on television, Bushman (2006) found that information labels did not draw attention to violent programs whereas more people were drawn to programs with warning labels.

Current labeling on condom packages is an information label that informs the consumer about potential allergic reactions to the product, but does not offer advice about its use. The proposed FDA language for condom labeling is similar to language that appears on products that are potentially harmful to the consumer. In contrast to warning labels on products like tobacco and alcohol, the current informational label on condoms is not meant to discourage use. It is thus unclear whether the forbidden or tainted fruit hypotheses are applicable to labels on condom packaging since in this instance warning language is being applied to a product (i.e., condoms) that is not harmful, but instead protective against STD and HIV transmission (NIAID, 2001).

Such concerns over the proposed labeling are amenable to empirical examination and to our knowledge these concerns have not been directly investigated. Therefore, in this study, we examined the impact of the FDA's proposed labeling on HIV-related beliefs about condom effectiveness as well as on intentions to recommend condoms to friends for use, and, intentions to use condoms. We look at these variables since beliefs about condom effectiveness and intentions to use condoms are consistent predictors of condom use (Albarracín et al., 2001). In particular, we sought to estimate the impact of adding the new "risk reduction but not elimination" warning language over and above a simple latex warning. For comparison purposes, we also examined the relative impact on the outcome measures between FDA's proposed warning language and standard CDC language regarding male condom effectiveness (available on the internet). On its male latex condom fact sheet for public health personnel, CDC states that "(l)atex condoms, when used consistently and correctly, are highly effective in preventing transmission of HIV, the virus that causes AIDS" (CDC, 2007). The standard

CDC language potentially could be used as a more elaborate information label that provides information on how condoms protect against STDs and HIV in addition to the potential for an allergic reaction.

METHODS

Participants

The Annenberg National Health Communication Survey (ANHCS) is a nationally representative cross-sectional survey from a universe of all people 18 years and older living in the United States (Knowledge Networks, 2007). The online survey is administered by a survey research firm that uses list-assisted random digit dialing telephone methodology to provide a probability-based sample of U.S. telephone accessible households. Thus the sampling strategy is the same as other random digit-dialing surveys in that the sample frame consists of the entire U.S. residential telephone population (both listed and unlisted). Once recruited via telephone, enrollment in the study is not limited to current internet users or computer owners. The panel members without internet access are provided with web access and a WebTV box to connect to the internet and a television to enable their participation in internet surveys. As with any random-digit dialing survey, adults without a telephone were excluded from participating. The web-enabled panel tracks closely the U.S. population on age, race, Hispanic ethnicity, geographical region, employment status, and other demographic elements. The sampling methodology is consistent with that used by the U.S. federal government in select surveys such as the National Immunization survey (Knowledge Networks, 2007; Smith et. al., 2001).

Each month a sample for ANHCS is drawn from the firm's participating households. The current study used data collected from December 2005 through March 2006, as well as May 2006. The ANHCS completion rates throughout that time range from 71% to 76%. The survey features a core set of items answered by the entire sample as well as modules randomly assigned to half the sample. The variables used in this analysis were part of the non-core module. We restricted the analysis to adults 18-65 years old, resulting in a total sample of 1,194 respondents.

Measures

Respondents were randomly assigned to one of three experimental conditions, each featuring a different condom label as shown in Table I. The first condition, called the "Allergic" condition, represents the current labeling on condom packages. The second condition ("Proposed FDA Language") is the proposed FDA language that emphasizes the risks associated with having sex, and the third condition ("CDC Condom Language") emphasizes effectiveness of condom in reducing HIV transmission. Note that all 3 labels include the latex allergy warning. Respondents were shown, on their computer monitor, the text from one of the three condom labels. After reading the label, each respondent answered several belief and intention items described below. Our dependent variables are 3 HIV-related beliefs about condoms and 2 intention measures. The belief measures are beliefs about one's chances of getting an allergic reaction to a condom, one's chances of acquiring or transmitting HIV with condom use, and the likelihood that a condom protects someone from acquiring or transmitting HIV. The intention measures are intention to recommend condom use to a friend and intention to use a condom. Specific wording and response categories, as well as the means and standard deviations of the belief and intention items (by condition), are in Table I. In addition to these outcome measures, standard demographic information was also collected.

Data Analyses

Equivalency tests on the on the means, variances, and covariances of the outcome measures were conducted to justify pooling the data across months. Fit statistics (Chi-square, RMSEA,

and TLI) (Kline, 2005) assuming no differences between months were consistent with the assumption of no change over time, thus the data were pooled.

Because the dependent variables are related to one another, the data were analyzed using multivariate regression. We used the Breusch-Pagan test to test for independence of the dependent variables (Kennedy, 2003). First we regressed dummy variables for the experimental condition (“Allergic” was the reference group) on each of the dependent variables, and then reran the models controlling for age, gender, marital status, and race/ethnicity. We also tested for interactions with condition and age and marital status since condom use in general is more relevant to younger and/or unmarried adults.

RESULTS

Our sample was 51.8% female with a mean age of 42.34 (SD 12.92). Approximately 60% of respondents were married and the remaining were single/never married (25.5%), divorced (10.4%), widowed (2.4%), or separated (1.7%). For the purposes of analysis we combined all unmarried respondents into a single category since condom use is more relevant to this population. Non-Hispanic White and African-Americans represented 74.6% and 9.9% of the sample respectively; Hispanics were 11.6% and non-Hispanic others were 3.9%.

The results of the regression analysis adjusted for demographic characteristics are presented in Table II. The inclusion of the demographic variables did not change any of the relationships between the conditions/label type and the dependent variables (results of models without demographics not presented). As shown in Table II, the “CDC Condom Language” compared to the “Allergic” label was associated with an increase in the belief about one's chances of having an allergic reaction. The type of condom label was not significantly associated with any of the other belief or intention dependent variables.

However, “CDC Condom Language” packaging interacted significantly with marital status on 3 of the 5 dependent variables. (Interactions of condition and age were not significant, thus the coefficients shown in Table II represent the final model which only included an interaction by condition and marital status.) The adjusted means and standard errors for the significant interactions terms are in Table II. The belief that using a condom with the CDC language would protect someone from acquiring or transmitting HIV was higher among unmarried respondents than their married counterparts. Unmarried respondents who saw the “CDC Condom Language” label were also more likely to recommend condom use to a friend compared to married respondents. Finally, unmarried respondents who saw the “CDC Condom Language” label reported that they were less likely to acquire HIV on any one occasion if they use a condom with that label. The interaction of “Proposed FDA Language” and marital status was not significant for any of the dependent variables.

DISCUSSION

In summary, our analysis did not find any association between the proposed FDA condom label (when compared to the current label) and HIV-related beliefs about condoms, intentions to use condoms, or intentions to recommend condom use to a friend. Except for increased beliefs about the chances of having an allergic reaction to latex, the CDC condom language was also not related to any HIV-related beliefs or intentions. We are unsure as to why the CDC condom language drew attention to the allergy warning – perhaps the additional text from what the respondents were typically used to prompted a more careful reading of the label. However, if this were the case we would have expected similar findings with respect to the proposed FDA language.

Although in the overall sample the different condom labels were not distinct from one another as predictors of HIV-related beliefs and intentions, the labels were associated with differences in beliefs and intentions among unmarried respondents who may be a key target for condom use. Again, these effects were limited to the CDC condom language and not the proposed FDA language. Even among those most likely to use condoms (i.e., the unmarried), varying the label content was not associated with intention to use a condom. However, among the unmarried the “CDC Condom Language” was associated with the intention *to recommend* condom use to a friend. Those who received the “CDC Condom Language” were more likely to recommend condoms to a friend than those who did not. Similarly, unmarried respondents receiving “CDC Condom Language” were also more likely than those receiving the standard allergy label to (correctly) believe that a condom would convey protection against acquiring or transmitting HIV and that their chances of acquiring HIV at any one occasion are lower if they used a condom. The total R-squared (as seen in Table II) is low, however, thus the potential effect size due to the use of labels utilizing the CDC language may be modest. Additionally, it is possible that variables not included in our analysis (e.g., exposure to HIV messages in the media) may explain the relationship between the labels and our outcomes of interest.

The warning language of the proposed FDA label did not appear to arouse reactance among the participants, nor did it appear to discourage them from using condoms. The “CDC Condom Language” label, which was a more specific information label without risk language, led unmarried participants to form beliefs and intentions associated with using condoms. This is consistent with the finding that labels with more salient and specific health information are more effective in preventing smoking compared to broad warnings like that on the labels of cigarettes in the United States (Hammond et al, 2007). But in contrast to the comprehensive tobacco labels which *discouraged* the product on which they appeared, the “CDC Condom Language” label seemed to be more effective in *encouraging* condom use than either the broader allergy warning or the proposed FDA risk language. It seems that the proposed FDA risk language, although not significantly associated with intentions to use (or not) in our experiment, is comparable to how potentially harmful products are labeled. The FDA proposed message conveys the “risk” of using condoms while the CDC language conveys a message on “efficacy.”

One possible limitation of the study is that the condom label was read by participants on a computer screen and not on an actual condom package. Since the label was read out of context from how it would typically be presented, participants may have assumed that the study was about condoms and this may have influenced their responses with respect to questions about their intentions to use condoms. In addition, respondents may be less likely to read the label when they actually buy or use condoms, than when they are exposed to the label on a computer screen.

In summary, despite these limitations, since condom use may be more salient to unmarried adults, these findings are significant as the debate on changes to the current condom packaging ensues. The CDC language conveys a message of condom efficacy and HIV prevention that is reflected in respondents' belief about a condom as a means of protection against HIV, but the CDC language also raises consciousness about the risk of acquiring HIV. More importantly, recommending condom use to a friend is of great consequence since perceived peer approval and/or use of condoms is associated with greater use of condoms (Albarracín et al., 2001). In short, the effect of the proposed FDA label on HIV-related beliefs and intentions does not differ from that of the current allergic reaction warning. In contrast, from an HIV prevention perspective, the CDC condom language appears to offer a better alternative to the current condom label for reaching unmarried populations.

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Table I

Condom Labels and Outcome Measures

Condom Labels				
<i>Condition 1, "Allergic":</i> Caution: This product contains natural rubber latex which may cause allergic reactions.				
<i>Condition 2, "Proposed FDA Language":</i> When used correctly every time you have sex, latex condoms greatly reduce, but do not eliminate, the risk of pregnancy and the risk of catching or spreading HIV, the virus that causes AIDS. Caution: This Product Contains Natural Rubber Latex Which May Cause Allergic Reactions.				
<i>Condition 3, "CDC Condom Language":</i> Latex condoms, when used consistently and correctly, are highly effective in preventing transmission of HIV, the virus that causes AIDS. Caution: This Product Contains Natural Rubber Latex Which May Cause Allergic Reactions.				
Beliefs about Condom Efficacy (Scale 0 to 100%) If you did use a condom that came in a package with this label...	Mean (SD) and Sample Size by Condition			
	Total	"Allergic"	"Proposed FDA Language"	"CDC Condom Language"
	n=1,194 ^a	n=395 ^b	n=400 ^c	n=399 ^d
... what do you think would be your chances of having an allergic reaction on any one occasion?	12.09 (23.15)	11.13 (23.14)	10.92 (20.16)	14.21 (25.74)
... what do you think would be your chances of acquiring or transmitting HIV on any one occasion?	18.42 (25.90)	18.42 (27.52)	19.01 (24.90)	17.83 (25.30)
If all latex condom packages contained this label... (Scale -3, extremely unlikely to 3, extremely likely)				
...how likely do you think it is that condom use would protect someone from acquiring or transmitting HIV?	0.80 (1.66)	0.65 (1.81)	0.86 (1.57)	0.89 (1.57)
Intentions (Scale -3, extremely unlikely to 3, extremely likely)				
If all latex condom packages contained this label, how likely is it	0.88 (1.81)	0.88 (1.78)	0.90 (1.83)	0.86 (1.83)

that you would
recommend condom use to
a friend?

If you were worried about transmitting or acquiring HIV (the virus that causes AIDS), and if all condom packages contained this label, how likely is it that you would use a condom?	1.59 (1.79)	1.54 (1.86)	1.62 (1.80)	1.61 (1.70)
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^a Cell sizes range from n=1,155-1,173

^b n=380-388

^c n=389-396

^d n=384-390.

Multivariate Regression Results

Table II

	Dependent Variables (n= 1,134)					
	Beliefs about Condoms			Intentions		
	Chances of getting an allergic reaction	Chances of acquiring or transmitting HIV	Likely that condom use would protect from acquiring or transmitting HIV	Likely to recommend condom use to a friend	Likely to use a condom	
	b (SE)	b (SE)	b (SE)	b (SE)	b (SE)	
"Allergic" label (referent group)	-	-	-	-	-	
"Proposed FDA Language" label	0.958 (2.11)	2.33 (2.39)	0.128 (0.15)	-0.119 (0.17)	0.048 (0.16)	
"CDC Condom Language" label	5.03 (2.12) *	2.94 (2.40)	0.013 (0.16)	-0.258 (0.17)	0.024 (0.17)	
Age	-0.021 (0.059)	-0.001 (0.07)	0.005 (0.00)	-0.004 (0.00)	0.001 (0.00)	
Female	7.37 (1.35)	1.09 (1.53)	-0.004 (0.10)	0.254 (0.11) *	0.140 (0.11)	
Unmarried	0.855 (2.68)	6.19 (3.03)	-0.054 (0.20)	-0.156 (0.21)	0.023 (0.21)	
Black	4.87 (2.34) *	7.37 (2.65) *	-0.304 (0.17)	-0.090 (0.18)	-0.267 (0.18)	
Hispanic	3.56 (2.15)	2.33 (2.43)	-0.182 (0.16)	-0.157 (0.17)	-0.335 (0.17) *	
Other	0.218 (2.44)	-0.781 (2.77)	-0.181 (0.18)	0.034 (0.19)	-0.072 (0.19)	
"Proposed FDA Language" * Unmarried	-1.70 (3.40)	-6.20 (3.84)	0.209 (0.25)	0.397 (0.27)	0.152 (0.27)	
"CDC Condom Language" * Unmarried	-3.49 (3.39)	-10.29 (3.83) **	0.522 (0.25) *	0.595 (0.27) *	0.177 (0.27)	
R-squared	0.04	0.02	0.01	0.01	0.01	
		Adjusted Means (SE)	Adjusted Means (SE)	Adjusted Means (SE)		
Unmarried, "CDC Condom Language" condition		15.16 (2.25)	1.24 (0.15)	1.16 (0.16)		
Married, "CDC Condom Language" condition		19.26 (1.91)	0.776 (0.12)	0.718 (0.13)		
Unmarried, "Allergic" condition		22.51 (2.13)	0.710 (0.14)	0.819 (0.15)		
Married, "Allergic" condition		16.32 (1.55)	0.764 (0.10)	0.975 (0.11)		

Notes: Breusch-Pagan test of independence for dependence: $\chi^2 (10) = 927.561, p < .00$

* p < .05

^{**}
p<.01.