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In “Step” with HIV Vaccines? A Content Analysis of Local Recruitment Campaigns for an International HIV Vaccine Study

PAULA M. FREW, WENDY MACIAS, KAYSHIN CHAN, ASHLEY C. HARDING

During the past two decades of the HIV/AIDS pandemic, several recruitment campaigns were designed to generate community involvement in preventive HIV vaccine clinical trials. These efforts utilized a blend of advertising and marketing strategies mixed with public relations and community education approaches to attract potential study participants to clinical trials (integrated marketing communications). Although more than 30,000 persons worldwide have participated in preventive HIV vaccine studies, no systematic analysis of recruitment campaigns exists. This content analysis study was conducted to examine several United States and Canadian recruitment campaigns for one of the largest-scale HIV vaccine trials to date (the “Step Study”). This study examined persuasive features consistent with the Elaboration Likelihood Model (ELM) including message content, personal relevance of HIV/AIDS and vaccine research, intended audiences, information sources, and other contextual features. The results indicated variation in messages and communication approaches with gay men more exclusively targeted in these regions. Racial/ethnic representations also differed by campaign. Most of the materials promote affective evaluation of the information through heuristic cueing. Implications for subsequent campaigns and research directions are discussed.

Keywords: HIV/AIDS, HIV vaccine, health communication, willingness to participate, clinical trials

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With over 33 million infected with HIV/AIDS worldwide as of November 2007, the advent of an effective HIV/AIDS vaccine may provide one of the greatest public health advances of our time (UNAIDS/WHO, 2007). HIV/AIDS prevalence rates continue to rise, particularly among men-who-have-sex-with-men (MSM) in the United States who account for approximately 49% of newly reported HIV/AIDS diagnoses and who comprise an estimated 54% of AIDS cases (CDC, 2007). Among minority groups, Blacks have been disproportionately affected by HIV/AIDS with 49% of new HIV diagnoses during the period from 2001 to 2005 (CDC, 2007). Minority women also continue to be disproportionately affected by HIV/AIDS with approximately one-half of all diagnosed HIV/AIDS infections (UNAIDS/WHO, 2007). HIV infection is currently the leading cause of death among young Black women (25-34 years) in the United States (CDC, 2006).

While most agree that a vaccine may not be available for some years (Altman & Pollack, 2007; Berkley & Koff, 2007; Solomon, 2005; Tramont & Johnston, 2003), despite President Clinton's call for an HIV vaccine by 2007 (Lawler & Cohen, 1997), the pipeline of vaccines in clinical trials remains robust with more than 30 candidate vaccines in the testing process worldwide (IAVI, 2007). These ongoing clinical trials necessitate the involvement of thousands of willing participants, and future HIV vaccine studies will likely need even larger cohorts of study volunteers.

Investigations of the content of HIV vaccine recruitment, outreach, and communication approaches have not been found in the literature. With an active pipeline of vaccines in the testing phase and concomitant growth of participant cohorts, there is a need to better understand the aspects of existing recruitment campaigns for future HIV vaccine efficacy trials. Understanding these communication approaches will help to determine what gaps exist in the current information available to the public, and will help guide development of prevention research campaigns to effectively reach target audiences. For this reason, a content analysis study is useful to detect themes and patterns in qualitative data to understand meanings or document portrayals of particular subjects (Esterberg, 2002; Patton, 2002). Specifically, our study aims to understand what messages were communicated in local campaigns promoting involvement in one of the most highly visible and anticipated HIV vaccine trials of recent years - the "Step Study." The communication efforts conformed to the widely accepted definition of a public health communication campaign as they were purposive in nature, time-limited (2004 to 2007), and conducted within an organized, coherent manner (Rogers & Storey, 1987).

BACKGROUND AND REVIEW OF THE LITERATURE

HIV/AIDS Vaccine Recruitment Issues

While much is known about the enormous challenges associated with recruitment and retention of high risk populations in HIV vaccine trials (de Bruyn, Hudgens, Sullivan et al., 2005; Koblin, Heagerty, Sheon et al., 1998; Koblin, Holte, Lenderking et al., 2000; Newman, Duan, Rudy et al., 2004), very little is known about communication practices in HIV vaccine studies, particularly related to recruitment, which is the focus of this study. Communication with the public about HIV vaccines and about study participation plays a vital role in the recruitment and enrollment process. In this respect it is not unlike other health media campaigns which employ integrated, multiple venue tactics to disseminate key messages and to generate information-seeking behavior (Backer, Rogers, & Sopory, 1992; Stephenson & Quick, 2005; Tannen, 2003) Understanding how the persuasive elements work in combination may inform the development of other health prevention campaigns targeting populations who are at risk for infectious diseases, and for other types of health promotion efforts.

Recruitment approaches share the goal of educating communities about HIV vaccines and motivating qualified people to take action in the cause. The only previously completed Phase III HIV vaccine study (the “Vaxgen” trial) showed that this was achievable with a population comprising MSMs (N = 5,108) and at-risk women (N = 309) (Francis et al., 2003). Various approaches to recruitment were employed in this trial including “snowball” techniques, media outreach, and advertising (Francis, Heyward, Popovic et al., 2003). Additionally, these methods differed by geographic location to effectively reach the target populations at each of the participating sites (Francis, Heyward, Popovic et al., 2003). In the end, the study showed that the vaccine failed to prevent HIV infection. The aftermath of the trial resulted in confusion among the general public about the vaccine’s efficacy, particularly among ethnic minorities (Jefferys, 2005). With public confidence undermined by inaccurate reports that an HIV vaccine was effective for specific minority subgroups (Blacks and Asians in particular), subsequent recruitment efforts for new HIV vaccine studies became even more challenged in the wake of the distrust.

Previous behavioral studies have indicated that advance disclosure about participant composition in HIV vaccine trials may influence HIV vaccine acceptability, particularly among Black men (Crosby, Holtgrave, Bryant et al., 2004b; Salazar, Holtgrave, Crosby et al., 2005). A high level of mistrust about the medical system, vaccine safety issues, and misperceptions about contracting HIV from the vaccine may factor in the public’s decision to join a vaccine trial and receive HIV vaccines in the future (Crawley, 2001; Crosby, Holtgrave, Bryant et al., 2004b; King, 2003; Strauss, Sengupta, Kegeles et al., 2001; Thapinta, Jenkins, Morgan et al., 2002). The legacy of the Tuskegee syphilis study also

serve as a source of mistrust particularly among Blacks toward the medical establishment (Corbie-Smith, 1999; Crawley, 2001). With respect to gay and bisexual men's views on future HIV/AIDS vaccines, behavioral research points to the need for trial-related information to facilitate HIV/AIDS vaccine acceptance (Salazar, et al., 2005).

A review of the findings on Vaxgen trial participant motivation is enlightening (Colfax, Buchbinder, Vamshidar et al., 2005). Most participants indicated that they wanted to "help find a vaccine" and "help the community" (Colfax et al., 2005, p. 362), with 75% motivated to "gain current information on HIV/AIDS" (Colfax et al., 2005, p. 360). Nearly 50% joined to reduce risk behavior or to receive protection from HIV/AIDS, with a third of participants motivated by HIV/AIDS testing, a component of the study protocol (Colfax, Buchbinder, Vamshidar et al., 2005). Moreover, very few individuals in the study pointed to compensation or medical care as key factors influencing their decision to participate in the study (Colfax, Buchbinder, Vamshidar et al., 2005). These results mirror those from other studies that have examined attributes of other HIV/AIDS vaccine trial enrollees (Crumbo, Rybczyk, & Wagner, 1997; Francis, Heyward, Popovic et al., 2003; Jenkins, Chinaworapong, Morgan et al., 1998; Perisse, Schechter, Moreira et al., 2000; Thapinta, Jenkins, Morgan et al., 2002).

The Step Study

In December 2004 a new HIV vaccine advanced to an efficacy trial after successful Phase I testing and was widely considered to be the most promising HIV vaccine candidate in recent years (Altman & Pollack, 2007; Cohen, 2007; Evans, 2007; Merck/HVTN, 2005). The "Step study," a Phase IIb efficacy trial ("proof of concept" study), enrolled 3,000 high risk persons at sites throughout North and South America, the Caribbean, and Australia (in regions of the world where HIV subtype B is the predominant strain of HIV). Although the study began in 13 cities with an initial projected enrollment of 1,500 persons, by mid-2005, the study doubled in size when it was decided that individuals with higher pre-existing immunity to the adenovirus serotype 5 vector could be included (Cohen, 2007). Additional research centers were added to the roster resulting in a total of 34 study sites in 27 cities on three continents that participated in the investigational effort.

The significance of the Step Study is far-reaching for the healthcare field, as it tested a novel vaccine approach of great promise for HIV immunization. With most public health and clinical experts in agreement that a vaccine against HIV is the best hope of ending the pandemic, this highly visible Step Study examined the leading candidate vaccine in a new class of experimental products believed to be the first that would offer partial immunity against HIV (Berkley, 2007; Chase & Schoofs, 2007).

The goal of the Step Study was to determine the vaccine's ability to prevent HIV infection or suppress HIV viral load in subjects who became infected during the trial period.

The populations recruited included men and women ages 18 to 45 years, and who were HIV negative at inception of the study. Men who engaged in risk behaviors, such as unprotected anal sex, were included in the risk definition, as were women who had heterosexual relations with HIV-infected men, or women who engaged in sex work or crack cocaine drug use (Cohen, 2007; Moriarty, 2005). Although participant vaccinations in the trial were discontinued in September 2007 when the vaccine was found to offer no protection, the study remains one of the most closely scrutinized efforts in the prevention research arena with ongoing subject follow-up and continued study data analyses (Cohen, 2007; Merck/HVTN, 2007). The lessons learned from the Step study have far-reaching implications not only for the HIV vaccine field, but for other biomedical prevention research efforts such as microbicide development and pre-exposure prophylaxis (PrEP) studies.

Conceptual Dimensions

Persuasive communication theory suggests that attitudes and beliefs are influenced by the interplay of variables when the audience (recipient) evaluates a message and source within a specific context (Dutta-Bergman, 2005; Petty & Cacioppo, 1983; Slater, 2006). The Elaboration Likelihood Model's (ELM) focus on the relationship of motivational attributes (e.g., issue-relevance) with the receiver's ability to process information provides a useful conceptual framework for content analysis of recruitment campaigns (Petty & Cacioppo, 1986; Petty, Strathman, Cacioppo et al., 1994). Application of the model would suggest that those who consider participating in an HIV vaccine clinical trial would evaluate the argument, source, and relevance of the health concern. The degree in which they engage in thinking about the study information would vary according to the perceived personal relevance of HIV/AIDS to their lives (Petty, Strathman, Cacioppo et al., 1994). Such a high degree of cognitive engagement (i.e., "high involvement" processing) would theoretically sustain counterpersuasion efforts (e.g., friends and family's negative reactions to participation) and would result in temporal persistence and predicted behavioral outcomes (e.g., study participation).

A few health communication studies have examined the role of persuasion in the context of HIV/AIDS, vaccine development, and clinical trials issues (Campbell & Babrow, 2004; Curbow, Fogarty, McDonnell et al., 2006; Igartua, Cheng, & Lopes, 2003). Overall, these studies suggest a moderate degree of cognitive engagement occurs in message processing. Strong affective evaluations of information most clearly resulted with manipulation of variables, subsequently observed as direct effects. Emotional responses (i.e., "low involvement" processing) following stimuli are also theorized to be moderated by the unique nature of the health issue (HIV/AIDS) (Campbell & Babrow, 2004) or affective appraisal of the clinical trial encounter (Curbow, Fogarty, McDonnell et al., 2006). In these situations, attention to heuristic cues may have a stronger influence on message processing via the low

involvement route. Thus, evaluation of the source characteristics (e.g., physician-researcher, institutional credibility) in combination with attendance to health issue relevance (i.e., HIV/AIDS) may generate sufficient audience motivation to form a favorable attitude toward involvement. In other words, some may think more or less on the messages and arguments presented in these campaigns before forming an attitude on the subject. For those whom HIV/AIDS is of concern, greater elaboration on the reasons to participate may ensue.

Content Analysis

The purpose of this content analysis study is to understand what persuasive influences were incorporated into the Step Study recruitment campaign materials. Because the decision to participate in an HIV vaccine study may be promoted by factors aligned with the conceptual pathways such as message content, issue relevance, and source and situational cues (i.e., heuristics), this study investigates how the operation of these sets of characteristics within specific geographic locales promote recruitment goals. Thus the overarching objective is to understand how recruitment campaigns vary among the selected North American sites and to inform future efforts for prevention campaigns. Specifically, the research questions are:

- What is the breadth of communication approaches utilized to recruit local target audiences to the Step Study?
- What messages are contained in the campaigns to promote cognitive appraisal of information?
- What elements promote issue-relevant thinking on HIV/AIDS and HIV vaccine research?
- What source and situational cues are contained in the campaigns?
- What is the readability level of the campaign materials? Do they differ by site?

Research Method

Method of Data Collection

This content analysis study utilized a convenience sample but made every effort to include all materials developed for Step Study recruitment as of October, 2005. One of the study sponsors, the HIV Vaccine Trials Network (HVTN) compiled recruitment materials produced by many of the participating international sites prior to, and during, the study recruitment period. These documents were made centrally available to all site staff and sponsors through an online repository. These online documents were accessed by our study team and any missing items were located through our discussions with other Step Study research sites.

The materials from the US/Canadian sites were retrieved and downloaded from the restricted website. It was determined by the research team that only US/Canadian materials would be included in the sample due to language barriers. The few materials that contained Spanish were discernable as they were identical to their English language counterparts. All materials were catalogued by site location (city) and type of recruitment material. Subsequently, our research team contacted the HVTN to obtain additional materials from sites that did not have any examples posted online and that may have been in use during the period from January 2005 through October 2005, the early recruitment phase. The HVTN staff submitted additional requests to those sites and later forwarded the items back to the research team for review.

After adding new items to the catalogued list of materials, the researchers systematically contacted the sites to confirm that 1) the materials identified for their site was specifically used for Step Study recruitment during the initial enrollment period, and 2) that the catalogue of items for that site was representative. These discussions with other site staff lead to subsequent submissions to the research team of other materials not housed on the restricted website and added further revisions to the catalogue of materials. Finally, all materials were compiled and organized by location to ensure completeness of the sample.

Sample

This study employed a sample of 117 individual recruitment materials from the sites that had regulatory approval by December 2005, and HVTN sponsor materials (10 campaigns/recruitment sites) (additional sites were subsequently added in 2006 to complete Step enrollment but were not included in this study's analyses). The participating cities included in this study were Atlanta, Boston, Houston, Los Angeles, New York City, San Francisco, St. Louis, Seattle, and Toronto. A few cities that were actively recruiting in 2005 did not participate in this study. They included Chicago, Denver, Miami, and Philadelphia site locations. The Chicago site did not produce recruitment materials; the clinics in Denver and Philadelphia were in the process of institutional review board review at the time of the HVTN request for submissions. The Miami site did provide their materials to the HVTN repository or to our team of researchers for review in this content analysis.

Coding Scheme Development

A detailed coding scheme was developed to record information on how and what the HVTN and other field sites were communicating with prospective study volunteers. The coding scheme consisted of the following main categories: message content (appeal type, argument quality, language, misconceptions, participatory benefits, participation details, taglines, vaccine trial information), issue relevance (HIV/AIDS, relevant health statistics,

TABLE 1
ASSESSED THEORETICAL VARIABLES

| Message Content | Issue Relevance | Heuristic Cues |
|--|--|--|
| <i>(Cognitive appraisal of information and assessment of argument quality)</i> | <i>(Involvement with HIV/AIDS and HIV vaccine research issues)</i> | <i>(Source and situational cues)</i> |
| Appeal Type | HIV/AIDS Issue Highlighted | Ethnic and Gender Representation |
| Argument Quality | HIV/AIDS Statistics Presented | Institutional/Project/Program Logo |
| Language | Risk Behavior Identified | Model Affect |
| Misconceptions Addressed | | Model Sexual Orientation |
| Participatory Benefits | | Physician-Researcher Source Identification |
| Participation Details | | Salient Object |
| Tagline | | Site (Institution) Details |
| Vaccine Trial Information | | Volunteer Depicted (Credible Source) |

risk behavior), source and situational cues (investigator name, institutional/project/program logo, contact information), intended audience/recipient (race/ethnicity, age, gender), and communication channels (e.g., print, mass media, internet, other). These coding categories were operationalized according to the conceptual framework with sub-themes developed based on the available literature documenting motivational factors influencing HIV vaccine study accrual (Colfax, Buchbinder, Vamshidar et al., 2005; Fernandez, Varga, Perrino et al., 2004; Flora, 1990; Harro, Judson, Gorse et al., 2004; Hennessy, MacQueen, McKirnan et al., 1996; Priddy, Cheng, Salazar et al., 2006). Table 1 provides an overview of the assessed theoretical variables.

Message

The literature offers some indication of the motivational messages that may encourage participation as it may be applied to campaign appeal language (Colfax, Buchbinder, Vamshidar et al., 2005; Priddy, Cheng, Salazar et al., 2006). Through this review, we developed categorical appeal variables to assess differences in linguistic approaches including taglines and general argument quality (declarative versus inquiry-oriented). Taglines are an important part of communicating an organization's purpose in a memorable way, and are commonly used in advertisements, commercials or films, and on websites (Klein, 2005). Argument quality is theorized to generate motivation to attend to message,

with the inquiring form (active process) thought to promote greater cognitive response for message assessment (Petty, Strathman, Cacioppo et al., 1994). Direct questioning approaches have been incorporated in health communication message design to engage the recipient in cognitive appraisal of the message (Parrott, 1995). A categorical example from this study is “Here I am. Why not you?” Additionally, key myths and misconceptions related to HIV vaccine research such as getting HIV from the vaccine, and that a safe and effective HIV vaccine exists but has been withheld from the public, was included in the coding evaluation scheme. These concerns may be of vital importance in the critical evaluation of the messages presented on HIV vaccine research.

The taxonomy of appeal types was developed through extensive review of HIV vaccine trial behavioral studies and of message design literature (Buchbinder, Metch, Holte et al., 2004; Kreuter & Wray, 2003; Maibach & Parrott, 1995; Newman, Duan, Roberts et al., 2006; Salazar, Holtgrave, Crosby et al., 2005). For example, we mapped constructs to the appeal classification schemes. A campaign was considered “encouraging” with language such as “Pitchers and Catchers Wanted.” Advocacy and altruistically-oriented messages were categorized with sentiments that highlighted collective action and a sense of volunteerism (e.g., “help us fight HIV”).

We also assessed the nature of benefits extended to prospective study participants that may encourage enrollment. Therefore, we examined the text of the campaign materials to ascertain if they would encourage issue-relevant cogitation, specifically related to benefits of study involvement and toward the realization of new HIV/AIDS prevention options. Previous studies have suggested that other benefits associated with involvement, as well as providing details about study processes, may affect a person’s willingness to participate in future HIV vaccine research efforts (Colfax et al., 2005; Jenkins et al., 1998; Koblin et al., 1998; Newman et al., 2004; Strauss et al., 2001).

Personal Relevance

We explored the amount of information contained in the items about HIV/AIDS and risk behavior because of their potential to capture attention (Stephenson & Witte, 2001; Witte, 1994; Witte & Allen, 2000) and engage the target audience in the personal relevance of the health issue. Arousal of empathy to effectively promote persuasive messages related to HIV/AIDS prevention has been demonstrated in other studies (Campbell & Babrow, 2004; Petty, Strathman, Cacioppo et al., 1994). Ads with risk messages have been shown to be effective (Witte & Allen, 2000), but they may also invoke protective cognitive appraisal (Witte, 1994). In this context, it is theorized that greater involvement with the issues of HIV/AIDS and HIV vaccine research theoretically lends to “central route” message processing in the promotion of attitude change (Petty & Cacioppo, 1983; Petty, Strathman, Cacioppo et al., 1994).

Source

Persuasive appeals have the potential to alter behavior with messages that invoke particular types of meanings and relevant symbolic representations (Young & Cline, 2005). Although "central processing" may be affected by motivation and ability to attend to the message as issue-relevant thinking is generated, previous studies have indicated that heuristic cues may favorably shape attitudes towards participation in clinical research (Curbow, Fogarty, McDonnell et al., 2006; Petty, Strathman, Cacioppo et al., 1994) and have the potential to generate strong reactions to HIV/AIDS prevention messages (Igartua, Cheng, & Lopes, 2003). We therefore examined the source features contained in the campaign materials (e.g., site and investigator details) that may serve as simple cues to the formation of attitude on the merit of the message.

Affective appraisal of source characteristics likely has an impact on clinical trial participation (Verheggen, Nieman, & Jonkers, 1998). Preferences for certain types of healthcare facilities (i.e., university and community-based hospitals) and access to minority providers may instill a sense of trust in the clinical research enterprise (Cooper-Patrick, Gallo, Gonzales et al., 1999; Corbie-Smith, Thomas, & Marie, 2002; Verheggen, Nieman, & Jonkers, 1998). A respected physician-researcher and credible institution may therefore serve as important source heuristic cues in the evaluation process.

Intended Audience

The ethnicities of the people depicted in the campaigns may serve as motivational cues as they induce target audiences to identify with and relate to those portrayed. Findings from the literature indicate HIV vaccine acceptability may depend, in part, on the diversity of trial participants (Crosby, Holtgrave, Bryant et al., 2004a; Crosby, Holtgrave, Bryant et al., 2004b). Thus, we assessed the presence of volunteers in the materials as to interpret the degree of source credibility present in the campaigns. The presence of patient spokespersons may alter the persuasive nature of the appeal in that those depicted may be viewed as highly knowledgeable and trustworthy among similar peers. Additional codes assessed the presence or absence of sexual orientation language and depictions of sexual activity.

The controversy stemming from the Vaxgen trial findings also reinvigorated efforts to recruit adequate numbers of minority participants for generalizability of study findings, among other reasons (Djomand, Katzman, di Tommaso et al., 2005; Jefferys, 2005). Therefore, codes were developed to assess the campaign designers' intended audiences. These include race/ethnicity (White, Black, Asian, Hispanic, and Other/Multiple Ethnicity), specification of study volunteer age range, and gender (male/female). With some materials containing more than one depiction of persons, the racial composition of the materials was also analyzed according to racial/ethnic subcategory.

The images selected for many campaign materials depict persons with a spectrum of expressions. Such affective cues may also have an impact on generating motivation to evaluate information. Affective appraisal of actors has been previously shown to impact clinical trial acceptance (Curbow, Fogarty, McDonnell et al., 2006; Petty, Strathman, Cacioppo et al., 1994). For example, recent findings indicate that clinical trial encounters with (actor) physicians who were highly enthusiastic in the promotion of participation were viewed with caution among study volunteers (Curbow, Fogarty, McDonnell et al., 2006).

Communication Channels

Recruitment budgets for the local campaigns varied by site depending on allocated slots for enrollment and previous experiences recruiting similar populations. Each site negotiated with the sponsors for recruitment funding in advance of the study implementation and budgetary requests were revised throughout the recruitment phase to reach targeted goals in each location. The HVTN also provided centralized support to sites to meet recruitment objectives in the form of materials development and media purchases.

With very limited resources allocated to recruitment efforts at the local level, an assessment of the extent of reach was of interest to this study. Therefore, the coding scheme included codes for print advertisement for newspapers (i.e., Southern Voice/Houston Voice), outdoor media (e.g., billboards), and magazines (i.e., David magazine), internet (banner) advertising (e.g., bigmusclebears.com, nakedconciierge.com, manhunt.net) and recruitment websites, print material (e.g., flyers, posters, information cards), and other types of promotion (e.g., study-related key chains, condom packages with insert information). Understanding what was implemented by the sites would offer initial insight on how limited resources were allocated to various communication approaches for fulfillment of recruitment objectives.

The overall code scheme development therefore enabled a complete assessment of the range of campaign materials developed by each site inclusive of messages, personal relevance, sources, and intended audiences. This analytic strategy enabled comprehensive assessment of integrated marketing communication (IMC) plans in action. For example, the San Francisco site highlighted its website (“www.SFisready.org”) as a primary vehicle to reach an intended audience of young men-who-have-sex-with-men (MSM) with fear and advocacy-oriented messages.

Readability Level

The readability level, also referred to as reading grade level, was calculated for each piece of communication using the SMOG readability formula (McLaughlin, 1969). Essentially this involved counting the number of polysyllabic words and sentences and

inserting into the "formula for shorter passages" (<http://www.utexas.edu/vp/ecs/communications/SMOG.pdf>). We compared this method to the Flesch-Kincaid readability formula (which is also common) and made the determination of reliability.

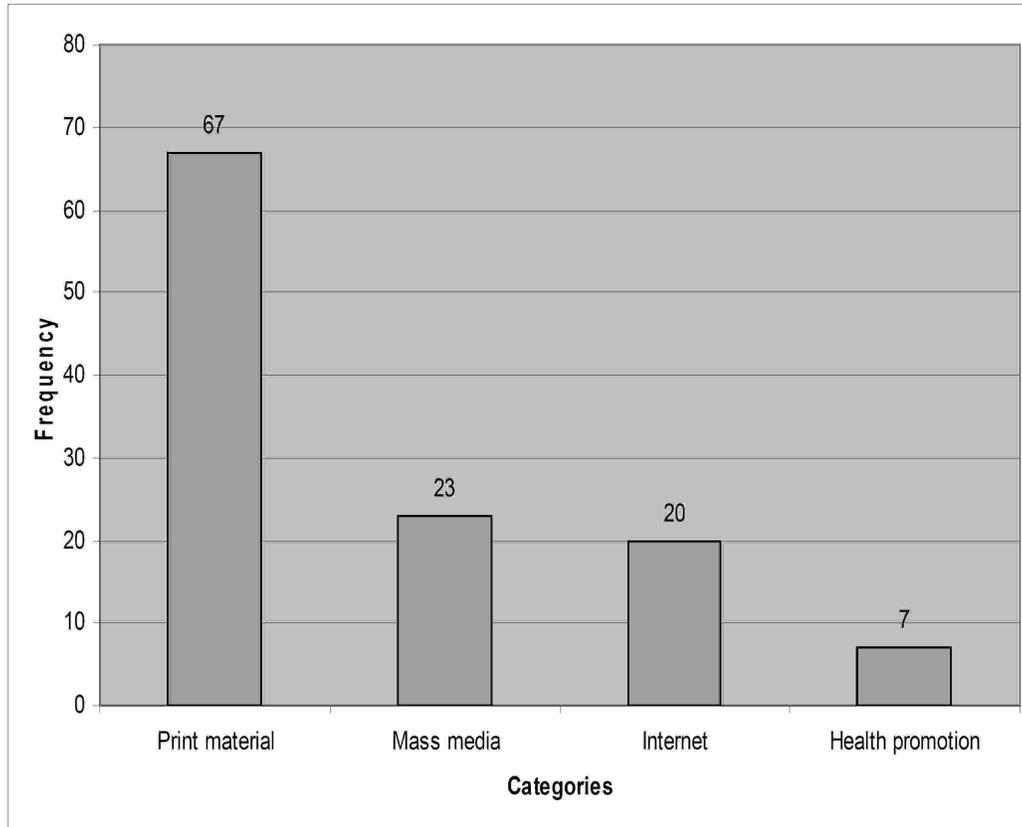
Procedure

Three coders (two researchers and one graduate student) were thoroughly trained on the code sheet and corresponding definitions. In the initial coding process, the coders reviewed a small sample of printed materials that were available on the Step Study website but not specifically used for this campaign. They independently coded the materials in an effort to establish pretest reliability ($\kappa \geq 0.80$) and refine any unclear areas of the code sheet and corresponding definitions. Upon review of those materials, the coders modified some of the definitions and expanded the code sheet to include specific aspects not identified through initial development process (e.g., age). Once pretest reliability was established, coders began to work with the sample. In order to code, the researchers reviewed each piece carefully, and determined presence or absence of the word, feature, or other attribute in the materials.

Statistical Analyses

We selected the individual campaign materials (e.g., print ad, internet ad, etc.) as the unit of analysis ($N=117$) with descriptive statistics serving as the primary analytic tool. We coded for presence or absence of most variables with dichotomized codes. In some cases, we also collapsed attributes (e.g., presence or absence of Blacks, Asians, Hispanics, Others) to create more general variables (i.e., ethnicity depicted). Cross-tabulations with chi-square statistics were performed. The chi-square statistic was specifically computed for total communication approaches. Two members of the research team independently coded all of the materials. Additionally, the coders selected ten percent of the sample to cross-code for reliability. Inter-coder reliability was established using the coefficient of reliability (Holsti, 1969; Krippendorff, 1980; Riffe, Lacy, & Fico, 1998). The overall reliability of the sample was mean $k=0.942$. This is well above the minimal 80% agreement level (Riffe, Lacy, & Fico, 1998). The individual variables achieved a high level of agreement, ranging from 67% to 100%, with a median of 97% and a mode of 100%. Only one variable, "study purpose" fell below 80% threshold (67%) and is therefore not reported in the analysis. It is believed that there were differing interpretations of the word "purpose" between the coders, one definition being more specific to the Step Study purpose and one definition being more focused on a general sense of purpose in engaging with HIV vaccine research. Thus, different definitions of "purpose" subsequently contributed to the unreliability of the measure.

FIGURE 1
COMMUNICATION APPROACHES (N=117)



$\chi^2 (3, n = 117) = 69.906, p < .001$

RESULTS

RQ1: What communication approaches are utilized to recruit target audiences?

Campaign items were not evenly distributed across sites, $\chi^2 (3, n = 117) = 69.906, p < .001$. Print materials (flyers, posters, handbills, etc) were most frequent (n = 67, 57.3%), with internet advertisements (n = 23, 19.7%) and other forms of print and mass media advertising including print and billboard advertisements (n = 20, 17.1%) also prevalent.

Other forms of promotion were utilized less frequently across sites ($n = 7$, 6.0%) such as promotional t-shirts, key chains, and other study giveaways.

Campaign Approaches

Developing print materials was by far the most commonly used communication strategy, with 9 of the 10 sites developing local materials (90%). The amount of print materials (e.g., flyers, informational cards, and "palm cards") produced for the study by New York City ($n = 20$), Toronto ($n = 12$), San Francisco ($n = 7$) and Los Angeles ($n = 7$) may be indicative of reliance on street encounter, community event, and interpersonal outreach approaches to recruit the target populations in those locations. Specifically, New York's "Why Not You?" and "Inspire" campaigns contain the greatest number of flyers and cards of all of the sites ($n = 20$) to reach MSMs in bar and club venues, and other gathering spots in downtown and central Manhattan, and the Upper West Side, as well as high risk women in settings within the Bronx. Staff members at the New York sites (Columbia University, New York University, and the Bronx clinic) have historically conducted recruitment through street outreach such as "flyering" city blocks, discussing HIV vaccine studies with groups in community locations, and providing information to people in MSM-oriented venues. The Boston site ($n = 3$) has employed similar tactics in previous studies (Seage, Holte, Metzger et al., 2001). Toronto's site ($n = 12$ of sample) benefits from a strong community presence with posters and flyers in city venues, and therefore utilized "pick up" cards to capture prospective volunteer contact information in field settings.

Mass media advertisements were developed by 8 of the 10 sites (80%). St. Louis ($n = 5$), San Francisco ($n = 5$), Seattle ($n = 4$), and Atlanta ($n = 4$) each developed a number of mass media advertisements to support their local campaigns. These ads have been produced in print and televised formats to reach the target audiences. For example, the Atlanta site created print advertisements featuring only MSMs to run in papers such as *Southern Voice* and its affiliated magazine, *David*. The site also developed transit television advertisements featuring men and women, in 30-second commercial format airing on mass transit buses, and similar color print ads to run in community papers such as *Creative Loafing* and *The Sunday Paper* to reach high risk women. Other sites (e.g., Seattle, $n = 4$) have produced ads featuring men and women that run in free publications and local magazines including *Odyssey*.

Communication strategies involving the Internet were also used by 8 of the 10 sites (80%). The Seattle ($n = 9$) and HVTN ($n = 5$) sites created a number of web banner advertisements for MSM-oriented websites. Web advertisements developed by HVTN were used by all sites to help support their local recruitment campaigns. Notably, both HVTN and San Francisco produced study-specific websites to address specific questions about HIV,

TABLE 2
CAMPAIGN MESSAGE FRAMING (TAGLINE EXAMPLES)

| Appeal Category | Tagline Example | Framing Percentage Distributions |
|---|---|---|
| Encouraging | “Pitchers and Catchers Wanted” “AIDS will be STOPPED by people just like YOU” | 30.8% (n = 36) |
| Direct Questioning/ Inquiry-Oriented | “Here I am. Why not you?” “Top? Bottom? Versatile?” | 28.2% (n = 33) |
| Advocacy | “Help us fight HIV” “Join the fight for your community. For your family. For you.” | 16.2% (n = 19) |
| Urgency | “There is no time to spare...Join an HIV vaccine trial. Together we will get there.” | 12.8% (n = 15) |
| Fear | “We are all at risk.” “I freak out sometimes thinking I got HIV. Finding a vaccine would be a relief.” | 12.0% (n = 14) |

the vaccine, and field study-related concerns and inquiries through interactive mediums (www.sfisready.org and www.stepstudies.com).

Though health promotion materials were only used by 4 of the 10 sites (40%), it is important to examine what types of materials were used in these campaigns. St. Louis (n = 3) focused on niche marketing to the MSM “leather” and “bear” communities through dissemination of handbills, condom packages with study information, and through keychain and “sizzle card” distribution in bars.

RQ2: What messages are contained in the campaigns to promote cognitive appraisal of information?

Message Framing

As seen in Table 2, the most common appeals included “encouraging” (n = 36, 30.8%), “direct questioning/inquiry-oriented” (n = 33, 28.2%), “advocacy” (n = 19, 16.2%), “urgency” (n = 15, 12.8%), and “fear” (n = 14, 12%) messages. Overall, the promotional

appeals and recruitment text utilize declarative language such as "Tops and Bottoms Wanted" (n = 103, 88.0%). Inquiring statements such as "Top, Bottom, Versatile?" were also observed; the vernacular in the gay community for sexual position preference (n = 46, 39.3%).

Study Involvement Benefits

The results indicate that approximately 60% of all of the materials mention study compensation (n = 70, 59.8%). An additional 31% describe other benefits associated with participation (e.g., free and confidential HIV testing and counseling) (n = 37, 31.6%). However, only 12% of the sample offered a description about what is involved if they participate, such as the number of study visits required, giving blood samples, or randomly receiving either vaccine or placebo (n = 14).

Other Message Factors

Misconceptions about HIV vaccine were addressed by 60.7% of the materials (n = 71), and study specific taglines were included in 76.9% of the sample (n = 90).

RQ3: What elements promote issue-relevant thinking on HIV/AIDS and HIV vaccine research?

HIV/AIDS Information

Although information about HIV/AIDS is included in approximately 68.4% of the materials (n = 80), less than 10% provide any extensive details (i.e., epidemiologic data) about the relevance of HIV to populations with behavioral risk (n = 10, 8.5%). An example piece from the Boston site included a billboard targeting Blacks. The message focused on promotion of high relevance with the argument, "FACT: 62% of the people in the U.S. who are infected with HIV are Black or Hispanic."

At Risk Populations

At least one source of risk was mentioned in 38.5% of the materials (n = 45). Approximately 20% of all materials contained some reference to anal sex criteria (n = 22, 18.8%). Anal sex with two or more partners and female risk criteria (such as smoking crack or having sex with an injection drug user) were mentioned in 10% of materials, and the lack of condom use was mentioned in only 5.1% (n = 6).

Men were the most commonly mentioned group in the materials ($n = 52, 44.4\%$), with MSMs being the second most commonly mentioned group ($n = 24, 20.5\%$). Women were the least often mentioned group ($n = 21, 17.9\%$).

RQ4: What are the source and situational cues contained in the campaigns?

Ethnic Considerations

There was some variance in ethnic depictions across sites, with White/Caucasians consistently represented across the sample materials. Black/African Americans were represented in materials at 8 of the 10 sites analyzed (80%), and Hispanic/Latino as were portrayed in the campaigns at 6 of 10 sites (60%). More importantly, the data demonstrate that just over one-half of the materials across all sites contained persons representing different ethnic groups ($n=59, 50.4\%$). The other half of the materials did not contain any specific group ($n=58, 49.6\%$), given use of text or other object.

It is noted that the majority of items were produced in English ($n = 105, 89.7\%$), followed by those containing Spanish ($n = 7, 6.0\%$), and a combination of English and Spanish ($n= 3, 2.6\%$).

Gender and Sexual Representations

A majority of the materials contained images of people ($n = 92, 78.6\%$). Almost 70% of all the materials included pictures of men ($n = 81, 69.2\%$), while only 18% of the materials had pictures of women ($n = 21$). Few materials contained images of both men and women ($n = 12, 10.3\%$). Of the images featuring two men ($n = 24, 20.5\%$), most feature some form of sexual relation ($n = 17, 70.8\%$).

Approximately 18% of the materials contained text only ($n = 21, 17.9\%$). For example, a series of flyers from New York City contained inspirational quotes and study information, without any images of people or other salient objects. About 30% of the materials included other objects showcased within the ad as a salient object for targeted communities (i.e., a teddy bear as representative of the gay “bear community”) ($n = 34, 29.1\%$). Also, the results show that 18% of the items contained images of actual study volunteers as confirmed by query with each site representative ($n = 21$). Eagly and Chaiken (1993) argue such cues may enhance source characteristics appraisal.

Study Details

The most commonly included study details were phone number ($n = 100, 85.5\%$, web contact information ($n = 86, 73.5\%$), and study location ($n = 64, 54.7\%$). Approximately half

of all the materials included an institutional, program, or project logo ($n = 57$, 48.7%), and less than 10 materials included information about the investigator responsible for the study at that site ($n = 9$, 7.7%). Despite having a recruitment presence in the online environment with paid advertisements and free listings on websites, few sites offered email addresses as means of communication ($n = 5$, 4.3%). This element promotes direct communication of potential volunteers with site recruiters.

RQ5: What is the readability level of the campaigns? Do they differ by site?

The mean readability grade level for all communications in the sample was 7.5, or almost 8th grade, with scores ranging from 3 (25%) to 13 (2%). The majority of the communications were at an 8th grade or lower (67%). The site with the lowest grade level (5th grade) was HVTN, followed by St. Louis (6th grade). The highest readability level (10th grade) was found at Toronto, Boston and Houston. An ANOVA showed a statistically significant difference between the reading grade level of the various sites, $F(9, N=117) = 3.572, p < .001$.

DISCUSSION

Given the variety of materials produced by the sites, it can be inferred that the items were created for specific types of recruitment approaches including mass media advertising, community event appearances, bar and club exchanges, interpersonal outreach mechanisms, and online recruiting. Previous large-scale HIV vaccine study recruitment experiences likely informed the development of these approaches for the Step Study effort (Francis, Heyward, Popovic et al., 2003; Humphries, Solomon, Cohen et al., 2001).

The online approach used by HVTN and on the West Coast is well-supported by the behavioral literature that links online activity to increased MSM risk behaviors (Anderton & Valdiserri, 2005; Fernandez, Varga, Perrino et al., 2004; Klausner, Levine, & Kent, 2004; Klausner, Wolf, Ponce et al., 2000). "E-recruitment" of clinical trial participants also is an efficient and cost-effective mass communication mechanism to accrue subjects in a timely manner (Smith & Manna, 2005). Similarly, the personal communication approaches suggest that the sites using them (e.g., New York City, Toronto, San Francisco and Los Angeles) continue to be well-positioned to disseminate the information through established communication channels, including strong interpersonal connections with the populations in those areas.

The inclusion of participatory benefits in recruitment efforts may have a motivational influence on study participation (Hennessy, MacQueen, McKirnan et al., 1996). If messages are perceived as having high relevance, argument details may contribute to greater cognitive appraisal of information. Even though 60% of all of the materials mention study compensation, only 12% included detailed information about participation. Given the

limited amount of elasticity allowed by institutional review boards to incentivize participation, any sanctioned promotion of tangible or latent benefits may influence the perceived strength of the argument (Petty, Strathman, Cacioppo et al., 1994).

According to ELM, the degree of personal relevance afforded to a health issue is critical in attitude formation. Factors promoting issue relevance are important in the determination of involvement with presented messages. Although 68.4% of the items made reference to HIV/AIDS ($n = 80$), HIV/AIDS statistics and detailed description of risk behaviors were identified in less than 10% of the materials. Including tailored information on the salience of HIV/AIDS as a health concern may be beneficial for prospective study volunteers to increase the perceived importance of HIV vaccine research in the local and global context (Koblin et al., 2005; Colfax et al., 2005).

A strong reliance on source and situational cues was observed across all sites. Approximately half of the communications also included an institutional, program, or project logo, which have been found to enhance credibility of the research effort and for the site conducting the work (Curbow, Fogarty, McDonnell et al., 2006; Petty, Strathman, Cacioppo et al., 1994). Appraisal of such source characteristics may serve as important heuristic cues affecting the persuasive potential of clinical trial promotion (Curbow, Fogarty, McDonnell et al., 2006). In addition, a majority of materials contained pictures of men, phone numbers, and website information.

The analysis of images in the materials showed that 18% were actual study volunteers. While study sites and their institutional review boards may grapple with concerns about study participants' privacy, confidentiality, and issues related to coercion about volunteer depictions, findings from behavioral/communication research suggests that volunteer (patient) inclusion may offer both short-term (study enrollment) and long-term benefits (vaccine uptake) among minority populations (Crosby et al., 2004, Salazar et al., 2005). Testimonials have also been effective in other types of health-related messages (i.e., youth antismoking advertisements) (Terry-McElrath, Wakefield, Ruel et al., 2005). Such vivid portrayals may enhance source characteristic appraisal, particularly if the source is favorably regarded (Hale & Dillard, 1995; Petty, Strathman, Cacioppo et al., 1994).

Gender and ethnic diversity representations were also analyzed as situational cues in campaign materials. It was found that the representations are reflective of the HIV epidemic in the US. The high degree of male representation indicates MSMs as the primary audience for the Step Study in North America, mirroring the fact that MSMs have experienced increased rates of HIV infection from 2001 to 2005 and comprised half of all HIV/AIDS cases in 2005 (CDC, 2007). Women who meet the behavioral risk criteria are also included in the study population, but for HIV vaccine studies they are generally reached through established interpersonal communication approaches (e.g., peer networks) compared to other mass media efforts (Brown-Peterside, Chiasson, Ren et al., 2000).

The portrayal of ethnic diversity varied across sites. White/Caucasian persons were consistently represented in materials. Black/African Americans were represented in materials at 8 of the 10 sites analyzed (80%), and Hispanic/Latino/as were portrayed in the campaigns at 6 of 10 sites (60%). The ethnic subgroup representation approximates new HIV prevalence trends (CDC, 2007). However, as Blacks represented nearly 50% of all HIV/AIDS cases diagnosed in 2005, ideally all US sites would have included this group (CDC, 2007).

Although 25% of the communications were at the third grade level, the advanced reading grade level of many of these communications is a concern and should be addressed in future communication campaigns by reducing the number of polysyllabic words. This is not only an ethical imperative for clinical research in general, but an effective communication strategy (Backer, Rogers, & Sopory, 1992; Gazmararian, Curran, Parker et al., 2005; Kreps & Thornton, 1992; Murphy, O'Keefe, & Kaufman, 1999). When factors such as high reading levels converge with technological barriers (i.e., the ability to access internet sources), the ability of the receiver to access and understand campaign messages is compromised (Gazmararian, Curran, Parker et al., 2005).

However, the intent of each form of communication should also be taken into account. Some the Step mass communication materials may be attempting to drive the individual to get more information (banner ad or postcard) and others may be trying to educate them about the protocol in a more detailed manner (FAQ card). In these cases, varying grade levels for these communications makes sense.

CONCLUSIONS, LIMITATIONS, AND IMPLICATIONS

Conclusions

For this study, persuasive features informed by the Elaboration Likelihood Model were analyzed in the communication materials promoting study enrollment for the Step Study. Specifically, variables assessing message content, issue relevance, and heuristic cues were examined. The theory suggests that persuasion can occur through two central routes of involvement, depending on the level of relevance and motivation the audience has through engagement with the message. Attitudinal formation is a key effect realized through this process, and results may be enduring or more transient in nature depending on the route of involvement (Petty & Cacioppo, 1986). Within the context of HIV vaccine research, the ability to favorably influence the public's willingness-to-participate has important implications for behavioral outcomes (i.e., study enrollment). Thus, examination of the campaigns from the vantage point of ELM is useful in understanding the potential of the campaigns to assist in reaching recruitment goals.

There is evidence of a high level of creative impetus for the Step Study campaigns, with notable variations in messages, source features, and campaign approaches across sites. Most of the items featured taglines such as “Inspire to Make a Difference”, “Step Up!”, “Tops and Bottoms Wanted”, and “Why Not You?” to engage intended audiences, particularly with advocacy-oriented and encouraging language. Many of the sites developed an array of materials for recruitment including posters, flyers, mass media advertisements, web banners, and assorted other products. This suggests that sites positioned themselves to utilize multiple communication channels (websites, print media, interpersonal communications, and others) through integrated marketing communications (IMC) and social marketing frameworks (Percy & Elliott, 2005) to target populations with behavioral risk factors for HIV infection, particularly gay men.

Although an assortment of materials were created for HIV vaccine recruitment efforts, many of these communicated few details about HIV/AIDS, HIV vaccines, and they lacked information about study involvement. While some materials included statistics to emphasize the point that HIV continues to be a health threat among those engaging in high risk behaviors, only a few pieces provided information about how HIV/AIDS is affecting MSM and women. These may or may not influence willingness to participate among these groups, particularly as personal relevance of the health threat was not conveyed through the information.

Some behavioral studies have indicated that risk information may be needed to facilitate decision-making processes (“monitors”), although fear-invoking or negative affect wording in prevention advertising may disrupt elaboration among others (“blunters”) (Allen, Liang, Salvia et al., 2005; Blumberg, 2000; Hays & Kegeles, 1999; Miller, 1996; Strauss, Sengupta, Kegeles et al., 2001). Thus, it can be inferred that campaign designers understood the potential negative reaction to fear messages and generally avoided their usage. Additionally, given the word and space limitations associated with specific formats (i.e. ads, web banners), in some cases it would be counterproductive to produce material with too much information for the audience to engage in message assessment (Blumberg, 2000). Therefore, to increase awareness of the urgent need for an HIV vaccine in the communities most affected by HIV/AIDS, campaign developers may consider expanding study-related website reach and creating frequently asked questions (FAQ) materials and fact sheets that can be disseminated over a period of time to prospective volunteers.

There were low levels of message content factors present in the materials, especially specific details about participation involvement. Of these, 60% of materials did address HIV vaccine misconceptions with phrases like “HIV free,” or “There is no HIV in this investigational vaccine.” However, several other known myths and misconceptions are not addressed in the items, such as the myth that an HIV vaccine exists and is being withheld from the public or the belief that people must place themselves at risk for contracting HIV to see if the vaccine works (Allen, Liang, Salvia et al., 2005; National Institutes of Health,

2003). Notably, the San Francisco and HVTN websites included this information in their online pages. Future materials may need to continue to address enduring misconceptions about study involvement.

Limitations

There were some limitations to consider for this study. The researchers included materials developed for the first phase of recruitment (January 2005 through October 2005) and included those from sites that were willing to let our team examine their materials. As noted earlier, additional sites were added to increase enrollment after we collected our sample.

Although the taxonomy of appeal types was developed through extensive literature review, some appeal categories in the coding scheme, may not have adequately captured the intention of the campaign designers. Given the complexity of the appeals, it was difficult at times to distinctly categorize each one within our narrow framework. Future research could further explore this area by conducting in-depth interviews with the campaign designers to determine their intent and rationale. Additionally, the determination of purpose resulted in an unreliable measure for this variable. Exclusion of this variable from the analyses may have constrained our assessment of message content within the theoretical model.

It should also be noted that most of the sites recruiting women to the study chose not to develop materials in an effort to maintain risk status confidentiality and reduce social harms. With women being recruited from areas such as prostitution strolls, it could be inferred by law enforcement agencies that women who have Step Study information may be engaged in drug use, sex work, or other high risk behavioral activity. It could be revealing of their illegal income-producing activity. Therefore, this study does not contain an entirely representative sample of communication efforts for recruitment, especially with respect to women recruited through interpersonal communication efforts. The focus of the materials studied was recruiting volunteers from mediated communication campaigns and not interpersonal communication.

Future research should extend these results by looking at other recruitment materials employed by other HIV vaccine trials during the different study phases. It would be highly beneficial to include materials across all sites, including the international locations, in subsequent analysis. Correlational and tracking studies may be useful in examining communication methods with achievement of enrollment goals. By examining site campaign approaches with enrollee data, these studies may demonstrate which methods are most effective for recruitment.

Implications

Overall, the findings suggest greater emphasis on heuristic cueing for opinion formation given the greater degree of affective components incorporated into the items. The local campaigns' "low involvement" approaches may pose a challenge the recruitment efforts, particularly as effects realized may be less enduring in their persuasive appeal (Petty, Cacioppo, & Goldman, 1981). Thus, reliance on heuristic cues such as credible source information, including perceived trustworthiness, and appraisal of model attributes may promote lower involvement processing via attendance to situational cues (Petty, Strathman, Cacioppo et al., 1994). This theorized effect results in short-term attitude change that is conceptualized as more transient in nature.

The ELM model suggests that a greater degree of personalization of health information will lead to evaluation of one's own situation. Thus, the emphasis on HIV/AIDS across these campaigns increases its prioritization as a topical health issue for the target populations. Focusing on HIV/AIDS as a concern in the present context has greater potential to engage recipients in future-oriented thinking. Future recruitment campaigns may therefore benefit from the development of materials and communication approaches that encourage greater message evaluation through issue-relevant consideration. With provision of such information, it is theorized that viewers of the materials will be more inclined to engage in higher level cogitation about trial participation. Campaign planners may therefore consider including more message details on study aims and research goals. Engaging potential volunteers in this manner will ideally result in a more enduring and favorable attitudes toward involvement in future prevention research efforts.

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