

Identifying Appropriate Frameworks for Opioid Risk Communication Programs

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Abstract

Objective: The Food and Drug Administration can require drug manufacturers to develop communication plans as part of Risk Evaluation and Mitigation Strategies (REMS). We sought to identify communication frameworks that most successfully changed behavior under different circumstances. Findings can inform development of more effective FDA mandated risk-communication plans.

Methods: We reviewed health communication studies indexed in a health communications database, categorizing programs based on whether they promoted or discouraged a behavior and whether the behavior was addictive. Each program was based on a framework model that guided content. For each of our categories, we identified the framework underlying the most successful programs.

Results: We included 31 studies reporting 51 outcomes. For campaigns discouraging addictive behaviors, Stages of Change programs (which tailor messages based on the extent to which individuals are prepared to or have adopted desired behaviors) were most successful. For campaigns promoting non-addictive behaviors, Social Learning Theory programs (which use positive reinforcement and emphasize consequences) were most successful.

Practice Implications: The Stages of Change framework is appropriate for programs targeting patients, while the Social Learning Theory framework is appropriate for programs targeting prescribers.

Conclusions: More rigorous assessments are needed to ensure REMS communications programs are based on sound science.

Keywords: Food and Drug Administration, Risk Evaluation and Management Strategies,
REMS, opioids.

1. Introduction

Doctors prescribe opioid analgesics for patients with severe, chronic, or unresponsive pain. Americans comprise less than five percent of the world population, but consume 80 percent of all therapeutic opioids.¹ Physicians prescribe opioids to treat debilitating pain, but use of opioids can also result in aberrant behaviors, including abuse and addiction.¹⁻⁴

Federal data suggest that non-medical use of opioids has increased. From 1994 to 2002, surveillance systems from the Substance Abuse and Mental Health Services Administration (SAMHSA) reported a 142% increase in the number of morphine equivalent doses of narcotic analgesics prescribed and a 137% increase the number of emergency room mentions of narcotic analgesics.⁵ Similarly, the Treatment Episodes Data Set (TEDS) reports that admissions to addiction treatment centers for non-heroin opiates increased more than five-fold between 1998 and 2008.⁶

In 2007, in response to the growing concerns about drug safety, Congress authorized the US Food and Drug Administration (FDA) to require prescription drug manufacturers to implement Risk Evaluation and Mitigation Strategies (REMS) for pharmaceuticals with risks potentially exceeding their benefits.⁷ In April, 2011, the FDA finalized a version of REMS for all long-acting opioids (LAO).⁸ The class-wide LAO REMS has two components related to patient communication. First, LAO prescriptions must include a medication guide insert disclosing potential risks and explaining how to safely use both LAOs in general and the specific analgesic prescribed. Second, drug sponsors must develop and implement a blueprint for training prescribers to counsel and communicate with patients about the risks of aberrant behaviors associated with opioid

use- These programs must provide information to patients on the safe use and storage of their prescribed drugs. Some have called for physicians to have to completed doctor-patient communication training programs (e.g., as part of continuing education) before being allowed to prescribe opioids.^{9, 10} Finally, drug manufacturers are required by the FDA to periodically assess the implementation and performance of these communication activities with respect to meeting the goals and objectives of REMS, namely the reduction of abuse and misuse of prescription medications. The guidelines identify a number of approaches that companies use to assess these programs but do not identify an optimal approach.^{9, 11-13}

Satisfying the REMS requirements will depend on successful implementation of communications programs that influence the behavior of both patients (to reduce improper use and mishandling of opioids) and doctors (so that they can most effectively communicate with their patients). Research in the fields of medicine, psychology, economics, and marketing has developed theoretical frameworks that describe factors contributing to changes in individual behavior.^{14, 15} Communication programs incorporate these factors to effect behavioral change (Table 1). For example, the Health Belief Theory posits in part that individuals will adopt a desired behavior if they believe failing to do so can be harmful and that they are capable of effective action.^{16, 17} A program based on this framework might promote smoking cessation by highlighting its negative impact on vitality and by building the target population's confidence in their ability to quit (e.g., by showing that others have successfully done so). The Stages of Change framework posits that motivation and readiness to alter one's behavior proceeds through stages.¹⁸ A smoking cessation program based on this framework would tailor its

messages to segments of the population at different stages. For example, it might promote the possibility of quitting among individuals who have not begun to actively consider it, provide ideas on how to quit among individuals who are ready to take that step (e.g., nicotine patch or Varenicline), and provide information to those who have already quit on how to avoid relapse (e.g., through support groups). A program based on “Social Learning Theory” emphasizes observation of a behavior and its consequences in others as a catalyst for behavioral change.^{14, 15, 17, 19} A smoking cessation program based on this framework might describe how others have benefited from quitting smoking.

<<Table 1 About Here>>

This paper aims to review the peer-reviewed risk-communication literature and identify which frameworks are most successful under different circumstances. The findings can help inform the development of more effective, evidence-based LAO REMS risk-communication plans and materials. Only a small number of previous reviews have compared frameworks in terms of their effectiveness. In a review of trials of behavior modification programs that aim to prevent HIV infection, Noar *et al.*²⁰ found that the Stages of Change model was statistically superior to other interventions, although only a small effect was observed. In a study of nutritional counseling programs targeting individuals with type-2 diabetes, Spahn *et al.*²¹ examined nutritional counseling programs and reported that a program based on a transtheoretical model was effective. They also reported that programs based on social cognitive theory showed no effect. Tests of homogeneity were rejected for the majority of the included studies, suggesting an unobserved factor may account for variance across studies.

2. Methods

2.1 Literature Search

We searched the HealthComm Key (HCK) database, an online database of comprehensive summaries from published peer-reviewed studies related to health communication. The Emory Center for Public Health Communication developed the database with funding from the Association of Schools of Public Health and the US Centers for Disease Control National Center for Health Marketing.²²

Each study included in our analysis was published since 1985 in English and: (1) identified the framework model on which the evaluated program was based; (2) measured the program's impact by comparing a control and intervention group, or by comparing behavior before or after program implementation; (3) studied a population in the US, Canada, or Western Europe; and (4) had enough information to calculate the program's impact on the proportion of subjects engaged in the desired behavior.

To satisfy this last criterion, studies had to report the impact on a behavior. We excluded studies that reported a change in beliefs, but did not measure changes in behavior, and studies that reported only clinical outcomes (e.g. changes in HbA1C) rather than behavioral changes (e.g., the proportion of diabetics exercising at least 2.5 hrs/wk). Studies that reported clinical outcomes can understate a program's impact on behavior (our focus) because a "null" finding may reflect the absence of a link between the behavior and the clinical outcome, rather than the absence of a program effect on the behavior. Likewise, we excluded studies that reported statistical significance, but not the magnitude of the program's impact on behavior.

We also limited attention to studies that reported a program's impact on the proportion of individuals engaged in the desired behavior (i.e., studies that reported behavior change as a binary outcome – yes or no). For example, we would include a smoking cessation study that reported the impact of the intervention on the proportion of recipients who smoked fewer than 20 cigarettes every two weeks, but would exclude a study that only reported program impact on the mean number of cigarettes smoked. Including only those studies that reported binary outcomes facilitated comparison of findings across studies because all retained results can be quantified as a change in the proportion of individuals in the population engaged in a desired behavior.

We searched the HCK database using the keyword “risk*”. Two of us (TS and MC) reviewed all identified abstracts, retrieving full manuscripts deemed by either reviewer to satisfy our inclusion criteria. Eliminated studies were generally proposals for communication campaigns, or surveys of attitudes and knowledge.

For each study, three of us (SB, TS, and MC) recorded demographic information on affected populations, the communication medium, who delivered the message (e.g. doctors, pharmacists, trained counselors, etc.), general message content, the theoretical framework on which the program was based, and each binary behavioral outcome reported.

2.2 Analysis:

We assigned each study result to one of four categories, defined based on behaviors targeted (addictive or non-addictive) and type of campaign promotion (discourage or promote behavior)^{23, 24} (Figure 1). For studies that evaluated programs targeting multiple behaviors (e.g. smoking and alcohol consumption), we recorded

outcomes for each behavior separately. Within each category illustrated in Figure 1, we compared the median effectiveness of programs grouped by the theoretical framework on which they were based. This approach was selected before the analysis was conducted and is consistent with prior Cochrane reviews of disparate communication campaigns.²⁵

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<<Figure 1 About Here>>

For evaluation studies that compared behavior before and after program implementation, we quantified effectiveness as the ratio of the improvement in behavior (follow-up proportion of individuals engaged in desired behavior minus corresponding baseline proportion) to the proportion of individuals who engaged in the undesired behavior at baseline. For example, if 75% of subjects used seatbelts before a program's implementation and 80% used seatbelts afterwards, the "improvement" (ratio numerator) would be $80\% - 75\% = 5\%$. The ratio denominator is 25% because 25% of individuals at baseline engaged in the undesirable behavior (not using seatbelts). Hence, program effectiveness is 5% divided by 25%, or 20%. For programs using a two-arm design (i.e., studies that compared an intervention group to a control group), we quantified "improvement" as the incremental gain in the treatment arm (follow-up minus baseline rates) compared to the corresponding gain in the control arm. The ratio denominator was calculated by pooling baseline rates for both the treatment and control groups. For example, suppose that at baseline, 45% of control group subjects and 55% of treatment arm subjects smoke, and that these rates drop by 15% and by 25%, respectively. The ratio numerator is 10% (25% - 15%), while the ratio denominator is

50% (average of 45% and 55%). Hence, the program's effectiveness would be 20% (10% divided by 50%).

3. Results:

As illustrated in Figure 2, our search identified 263 studies. Of these, we reviewed full manuscripts for 126 studies and included 31 in our final analysis. These studies reported results for 51 outcomes. Studies not included generally did not disclose the model framework on which the evaluated program was based, reported only qualitative results, or reported only changes in knowledge or beliefs. Table 2 summarizes the results from these studies.

<<Figure 2 About Here>>

<<Table 2 About Here>>

Table 3 summarizes effectiveness by framework for three of the four program categories (we identified no studies that evaluated programs promoting an addictive behavior). Among the studies of programs discouraging addictive behaviors, median effectiveness was greatest for programs based on the Stages of Change theory (63% versus second highest value of 27%). Among the studies of programs promoting non-addictive behaviors, median effectiveness was greatest for programs based on Social Learning theory (31% versus second highest value of 30%). Finally, among studies of programs discouraging non-addictive behaviors, median effect reported by studies that utilize the Social Influence Model.

<<Table 3 About Here>>

4. Discussion and Conclusion

4.1 Discussion

Given the FDA REMS mandate to include an effective risk communication plan for LAOs, there is a clear need to expand and make more rigorous the literature evaluating different types of communications strategies. Evaluations of these programs can yield the most insight by considering the underlying communications framework to guide design of outcome measures. For example, studies of programs based on the Stages of Change framework might measure subject readiness in addition to changes in the targeted behavior (e.g., abuse). The intermediate measure (subject readiness) could provide a more sensitive indicator of how well the program is working. Intermediate outcome results consistent with the program's underlying framework (e.g., a shift towards greater readiness, as hypothesized by the Stages of Change framework) would also lend credibility to study findings with respect to the targeted behavior. The conduct of more studies, along with more rigorous study designs, will help improve the evidence base for REMS plans.

Our review is subject to certain limitations. First, the review considered only those programs catalogued in the HCK database. This database has the following advantages, however. The goal of this database is "*to improve the translation of health communication research by providing accessible, searchable summaries of data-driven, peer-reviewed health communication research and evaluation studies.*" Moreover, HCK is hosted by an academic institution and enjoys sponsorship by the Association of Schools of Public Health and the US Centers for Disease Control, both of which are leading institutions in this field. Given the focus and stated goals of the HCK database, it offers a means to examine a cross-section of the peer-reviewed literature most likely to inform the development of future communication campaigns. Nevertheless, this review

cannot be considered to be a complete description of the literature, although there is reason to believe our findings are similar to what would be found by a more expansive review using general purpose databases, such as PubMed.

Second, we limited attention to studies reporting changes in behavior, and the changes had to be reported as a binary outcome (behavior changed or it did not) to facilitate comparisons across studies. We excluded the many risk communication studies that reported effectiveness in terms of clinical outcomes (e.g. changes in HbA1C instead of proportion of diabetics exercising ≥ 2.5 hrs/wk), because clinical measures represent too indirect a measure of a program's impact on behavior, the focus of this study. Because a change in behavior may not influence clinical outcomes, use of clinical outcomes as an effectiveness measure can understate the program's impact on behavior.

4.3 Practice Implications

These findings can inform the development of risk-communication plans incorporated into LAO REMS. Our findings suggest that for programs targeting patients, the Stages of Change model is appropriate because the goal is to discourage potentially addictive behaviors. The Stages of Change framework was developed to address another addictive behavior – smoking¹⁸. Our findings also suggest that the Social Learning Theory framework^{17, 19} is appropriate for programs targeting prescribers, as the goal is to encourage a non-addictive behavior (management of prescription opioids).

4.4 Conclusion

Based on our findings, we draw the following conclusions. First, programs discouraging non-addictive behaviors are generally less effective than those discouraging addictive behaviors. This finding may reflect the fact that there is a social stigma

associated with many addictive behaviors and the influence of stigma on the behavior of the population targeted by the communications program. Studies investigating the influence of these informal social factors on addictive and non-addictive behaviors should evaluate the extent to which a formal communication strategy enhances this phenomenon.

Second, communications program success depends in part on the appropriateness of the underlying framework given the program's goal. To discourage addictive behaviors, the Stages of Change Framework may be an appropriate basis for developing communications programs. To encourage favorable prescription and communications practices among physicians, a program based on Social Learning Theory may be most appropriate. While these conclusions do suggest optimal frameworks identified, this survey found generally weak studies and points to a need for both more studies and more rigorous studies in this field.

FDA-mandated evaluations of REMS programs can help to fill this research gap. Moreover, if the programs for different medications and by different companies are based on the same framework (when appropriate), comparing the results will be more straightforward. In particular, it will be easier to identify factors contributing to differences in results across programs if the programs being evaluated are more similar. Comparisons across programs can be further facilitated if FDA encourages uniform assessment methodologies. Collaboration between industry, academia, and the FDA would aid the development of rigorous and more-uniform evaluation methodologies for REMS programs. Just as FDA demands biological risks associated with new drugs are evaluated using systematic clinical trial methods, so too should rigorous methods be applied to

evaluating communications programs required to mitigate risky behaviors associated with
LAO use.

Table 1: Description of Identified Frameworks

Framework	Framework Description ^{14, 15}	Communications Program Design
Health Belief Model	Individuals will address a health condition if they believe (1) they are susceptible, (2) the condition is serious, (3) they are capable of effective action, and (4) the benefits of acting exceed their costs.	Increased perceived risk of the health condition, Communicate benefits of the desired behavior, and enhance confidence to engage in action (e.g., through mechanisms such as peer support).
Theory of Reasoned Action	Action depends on perceived “objective” consequences and how it is expected that others will perceive the action (or inaction).	Provide objective information that the desired behavior has a positive impact on members of the target population and that failing to engage in that behavior is socially unacceptable.
Theory of Planned Behavior	Adds an additional parameter to the Theory of Reasoned Action – perceived control and ability/power to change behavior.	Similar to Theory of Reasoned Action, but would also add messages to foster an enhanced perception of control over behavior and ability to change.
Stages of Change & Transtheoretical Model	Behavioral change proceeds through stages of increasing motivation and readiness. Stages include: (1) precontemplation of behavioral change, (2) contemplation and decision – active consideration and planning, and (3) action and maintenance of the behavior.	Develop messages tailored to help individuals at each stage – e.g., messages describing importance of action for individuals in stage (1) and resources to help individuals in stage (3) avoid relapse.
Social Learning Theory	Describes adoption of new behaviors by observing others and remembering the rewards they gain. Observing others helps build self-confidence and influences future actions.	Portray desired behavior using video or by having target population directly observe others; provide opportunity to practice the behavior through role-playing.
Diffusion of Innovation	Defines subgroups that can help disseminate new ideas or practices: Innovators, Early Adopters, Early Majority, Late Majority, Laggards.	Use innovators and early adopters to influence others to adopt new behaviors.
Social Influence Model	Posits that perception of communication is a subjective and socially constructed phenomenon. Influenced by TRA and SLT: attitudes, statements and behaviors of those in social proximity are key to the perception and acceptance of a message. ²⁷	Identify and leverage those individuals with the most proximal social contacts in order to influence people within the targeted population.
Mental Model	Adopts and synthesizes the health belief model and theory of planned behavior. Model emphasizes identifies aspects of behavior most relevant to the decision process of the target population and most in need of intervention. ^{28, 29}	Iterative versions of communications materials are tested by focus groups composed from the intended audience, determining the extent to which materials are realistic, culturally appropriate, relevant, and provide useful information to implement risk-reduction strategies/behaviors.
Persuasive Health Message Framework	Synthesizes elements from (1) theory of reasoned action, (2) elaboration likelihood model, and (3) protection motivation theory. Provides a ‘cookbook’ to message generation by highlighting communication factors constant to any campaign: the threat, the efficacy/benefit, cues to action, and audience profile; alongside transient factors such as message goals, salient belief and referents, and cultural environment. ³⁰	Research into the target audience’s perceived threat and efficacy of message is researched beforehand, cultural and environmental constraints are assessed to develop the audience profile and cues. Then these transient factors influence constants (threat due to inaction, efficacy from action, cue to action) to ultimately develop arguments of the communication message.
Adherence Model	Synthesizes components of the theory of reasoned action/planned behavior, Transtheoretical model, precede model, and social influence theory, while including self-efficacy, social support, perceived control, coping style, and psychological distress. Posits an important roles for perceived susceptibility, barriers hampering action and cues and support to attempt to overcome these barriers. ³¹	Increased perceived risk of inaction, benefits of action, and messages that produce a simultaneous self-identification– crystallizing a notion of susceptibility. Where possible, incorporate reminders to serve as cues to action and offer anecdotes that address perceived barriers and strategies for overcoming them.

Table 2: Included Studies

Citation	Health Behavior	Theory	Communication Synopsis	Comparator	Post-intervention	Relative Fraction Behavioral Change
Addictive; Discourage behavior						
Shi <i>et al.</i> *** (1992) ³²	Cigarette smoking	Social Learning Theory	Interpersonal communication, combined interventions of Health Risk Assessment, bimonthly health newsletter, health resource center, free self-care books, behavior change workshops/classes with trained facilitators, and environmental improvement including exercise spaces, smoking policies, and incentives	0.140	0.080	0.429
	Alcohol Consumption \geq 7 drinks/wk			0.260	0.21	0.192
Murray <i>et al.</i> (1994) ³³	Smoking \geq 1 cigarette/week	Social Influence Model	Mass ad, multi-media campaign across several media channels	0.126	0.103	0.183
Goodman <i>et al.</i> (1995) ³⁴	Current Smoker	Social Learning Theory	Community-wide campaigns leveraging pre-existing organizations; walk-a-thons, and presentations by community volunteers	0.255	0.243	0.047
Sussman <i>et al.</i> (2002) ³⁵	Use of Cigarettes	Social Influence Model	Interpersonal communication, project staff health educators presenting 12 40-minute sessions highlighting risks, myths, and denial confrontation; plus two 30-minute sessions highlighting alcohol and marijuana facts	-	-	0.270 [†]
	Use of Alcohol			-	-	0.090 [†]
	Use of non-marijuana 'hard' drugs			-	-	0.260 [†]
	Use of marijuana			-	-	0.220 [*]
VanDyke <i>et al.</i> (2002) ³⁶	Current Smoker; goal smoking cessation	Theory of Reasoned Action	Mass ad, other communication, five modules including slide show, video, poster contest, curriculum deployment, and jump-rope-a-thon for health awareness	0.432	0.311	0.280
Werch <i>et al.</i> (2003) ³⁷	Alcohol binge consumption (5+ drinks in one sitting) and commensurate problematic behavior	Theory of planned behavior	Interpersonal communication, consultation administered by a nurse consisting of prevention messages tailored to the student's stage of alcohol consumption and emphasizing sports and influence of alcohol on sports ability	0.300	0.14	0.533
			Intervention as described above; followed by an alcohol preventive consultation addressing five risk/protective factors, social norms, negative and positive expectancies, and self-efficacy	0.870	0.64	0.264
			Intervention as described above; plus: five mailed cards to parents with broader fitness focus, list of check-off facts, and concluding statement	0.520	0.45	0.135

Citation	Health Behavior	Theory	Communication Synopsis	Comparator	Post-intervention	Relative Fraction Behavioral Change
Lenert <i>et al.</i> (2004) ³⁸	Did not initiate a smoking cessation quit attempt	Stages of Change	Series of automated emails sent over a period of time encouraging setting a quit smoking date and reinforcing the attempt to quit smoking	0.460	0.170	0.630
Not-Addictive, Adopt Behavior						
Weinstein <i>et al.</i> (1985) ³⁹	Adoption of seat-belt use while driving passenger vehicle	Health Belief Model	Print communication, seat belt reminder stickers; cafeteria messages; parking deck signs	0.317	0.411	0.136
Sharpe <i>et al.</i> (1992) ⁴⁰	Increase physical fitness	Health Belief Model	Interpersonal communication, health promotion activities	0.593	0.610	0.043
Shi <i>et al.</i> *** (1992) ³²	Adopt Exercise to reduce body weight within 120% desired body weight	Social Learning Theory	Interpersonal communication, combined interventions of Health Risk Assessment, bimonthly health newsletter, Health resource center, free self-care books, behavior change workshops/classes with trained facilitators, and environmental improvement including exercise spaces, smoking policies, and incentives	0.670	0.710	0.121
	Improve dietary habits; total cholesterol \leq 210			0.530	0.760	0.489
	Behaviors to control hypertension: \leq 140/90 mmHg			0.780	0.840	0.273
O'Donnell <i>et al.</i> (1995) ⁴¹	Condom use and purchase	Health Belief Model	Interpersonal communication, clinic trained facilitator	0.220	0.414	0.248
	Condom use and purchase		TV communication, culturally sensitive video sharing concerns and values of condom use	0.220	0.274	0.069
Santelli <i>et al.</i> (1995) ⁴²	Used condom last sexual intercourse event	Social Learning Theory	Interpersonal communication, outreach worker who made contact with subjects, distributed media materials including comic books, newsletters, pamphlets, and condom envelopes	0.230	0.470	0.311
Fielding <i>et al.</i> (1994) ⁴³	Initiation of blood pressure medication	Stages of Change	Monthly 10-min. sessions at work site with counselor assessing behaviors, readiness to change, and perceived vulnerability	0.096	0.265	0.187
Talpin <i>et al.</i> (1994) ⁴⁴	Obtain mammogram within one year	Health Belief Model	Interpersonal communication, invitation to mammogram from primary care physician	0.468	0.456	-0.023
	Obtain mammogram within one year		Print communication, mailed postcard reminder invitation to mammogram	0.468	0.585	0.219
	Obtain mammogram within one year		Interpersonal communication, both invitation to mammogram from primary care physician and mailed postcard reminder invitation to mammogram	0.468	0.617	0.280

Citation	Health Behavior	Theory	Communication Synopsis	Comparator	Post-intervention	Relative Fraction Behavioral Change
Yancey <i>et al.</i> (1995) ⁴⁵	Follow-up appointments that included screening for cancer.	Health Belief Model	TV communication, video on cervical and breast cancer screening alternating Spanish and English with total running time of ~50min; shown w/in physician waiting rooms	0.103	0.146	0.048
	Follow-up appointments that included screening for cancer.		TV communication, video presenting interviews with non-patient and patient members of population and targeting beliefs, fears, misconceptions, and other feelings in relation to cancer risk; shown w/in physician waiting rooms	0.194	0.269	0.093
Kelly <i>et al.</i> (1997) ⁴⁶	Usage of condom when engaging in anal-intercourse	Theory of Reasoned Action	Printed HIV-education materials including wall posters, graphics, and brochures; materials replaced every three months	0.447	0.668	0.400
Tilly <i>et al.</i> (1997) ⁴⁷	Increased consumption of dietary fiber	Theory of Reasoned Action	Interpersonal communication, Classes offered during work hours and newsletter	0.660	0.650	-0.029
Alcalay <i>et al.</i> (1999) ⁴⁸	Demonstration of knowledge of at least three ways to prevent CVD	Theory of planned behavior	Mass media advertizing, including print and video communication	0.450	0.610	0.290
Bastani <i>et al.</i> (1999) ³¹	Mammography screening	Adherence Model	Print communication including personalized (tailored) risk notification, educational booklet, notepad, and bookmark	0.550	0.652	0.227
Detweiler <i>et al.</i> (1999) ⁴⁹	Sunscreen use	Health Belief Model	Print communication, 'gain-framed' brochures on sunscreen use with post-manipulation questions	0.728	0.881	0.562
	Sunscreen use		Print communication, 'loss-framed' brochures on sunscreen use with post-manipulation questions	0.728	0.750	0.081
Taylor <i>et al.</i> (1999) ⁵⁰	Mammogram screening	Social Learning Theory	Interpersonal communication, discussion and video with project nurse emphasizing role modeling and addressing barriers to mammography	0.220	0.490	0.346
Kennedy <i>et al.</i> (2000) ⁵¹	Condom use with main sex partner	Theory of Reasoned Action	Multimedia campaign involving radio PSAs, printed posters and assorted promotional materials, peer-outreach, skill-building workshops let by community-based organizations, and a telephone information line	0.686	0.729	0.137
Poscente <i>et al.</i> (2002) ⁵²	Moderate activity or exercise	Stages of Change/	Print communication, workbook and activities guide emphasizing overcoming challenges and increasing physical activity	0.785	0.908	0.572

Citation	Health Behavior	Theory	Communication Synopsis	Comparator	Post-intervention	Relative Fraction Behavioral Change
Grindel <i>et al.</i> (2004) ⁵³	Obtain a mammogram within the previous 12 months	Persuasive Health Message Framework	Video presentation highlighted with positive upbeat message encouraging mammogram	0.353	0.661	0.422
			Video presentation highlighting a negative/fear based message encouraging mammogram	0.510	0.642	0.269
			Video highlighting neutral/cognitive message encouraging mammogram	0.635	0.505	-0.356
Buller <i>et al.</i> (2005) ⁵⁴	Application of sunscreen; measured as reduction of sunburns	Diffusion of Innovation	Print communication	0.540	0.680	0.304
Emmons <i>et al.</i> ** (2005) ⁵⁵	Increase consumption of fruits and vegetables \geq 5/d	Social Influence Model	Interpersonal communication, 20 minute session with college-educated health counselor followed by four follow-up telephone counseling sessions with health advisor and six sets of written pamphlets tailored for low-literacy populations, and links to relevant local activities	0.139	0.172	0.038
	Increase physical activity, \geq 2.5h/wk.			0.666	0.664	-0.006
	Increase consumption of an OTC multivitamin, \geq 6x/wk			0.392	0.686	0.484
Petrella <i>et al.</i> (2005) ⁵⁶	High blood pressure knowledge and adoption of behaviors to reduce HBP	Health Belief Model	Mass ad, other communication, Campaign incorporating television, radio, print, direct to patient, and interactive techniques	0.377	0.415	0.117
Sorensen, <i>et al</i> (2005) ⁵⁷	Increase fruit and vegetable consumption \geq 5 servings/wk	Theory of Reasoned Action	Interpersonal communication from Healthy Directions study staff at table-top displays and demos; small group discussions; worksite-wise events like health fairs, interaction with managers to adopt environmental or organizational level policies	0.154	0.208	0.063
	Increase physical activity \geq 2.5 hours/wk			0.696	0.750	0.178
	Multivitamin intake \geq 6x/wk			0.271	0.368	0.133
Not-Addictive; Discourage Behavior						
Shi <i>et al.</i> *** (1992) ³²	Unsafe Driving \geq 10 miles over speed limit	Social Learning Theory	Interpersonal communication, combined interventions of Health Risk Assessment, bimonthly health newsletter, health resource center, free self-care books, behavior change workshops/classes with	0.34	0.38	-0.118

Citation	Health Behavior	Theory	Communication Synopsis	Comparator	Post-intervention	Relative Fraction Behavioral Change
			trained facilitators, and environmental improvement including exercise spaces, smoking policies, and incentives			
Tilly <i>et al.</i> (1997) ⁴⁷	Exhibiting behaviors to decrease consumption of dietary fat	Theory of Reasoned Action	Interpersonal communication, classes offered during work hours and newsletter	0.300	0.270	0.100
Simon <i>et al.</i> (2002) ⁵⁸	Perpetration of violence	Theory of Reasoned Action	Interpersonal communication, trained health educators providing information pertaining motivation, listening, information about chemical dependency and its effects on others, alternative methods of coping, information regarding peer norms, and decision making	0.620	0.582	0.061
	Weapon Carrying			0.427	0.339	0.206
Clapp <i>et al.</i> (2005) ⁵⁹	Drinking and driving 12 months	Theory of Reasoned Action	Interpersonal communication social marketing involving law enforcement and members of the media	0.290	0.220	0.241
Downs <i>et al.</i> (2004) ²⁸	Lack of sexual abstinence, prev. 3 months	Mental Model	TV communication with interactive video	0.890	0.820	0.079
Emmons <i>et al.</i> (2005) ⁵⁵	Consumption of red meat ≥ 3 servings/wk	Social Influence Model	Interpersonal communication, 20-minute session with college-educated health counselor followed by four follow-up telephone counseling sessions with health advisor and six sets of written pamphlets tailored for low-literacy populations, and links to relevant local activities.	0.512	0.394	0.230
Sorensen, <i>et al.</i> (2005) ⁵⁷	Consumption of red meat ≥ 3 servings/wk	Theory of Reasoned Action	Interpersonal communication, Healthy Directions Study Staff (interactions at table-top displays and demos; small group discussions; worksite-wise events like health fairs, interaction with managers to adopt environmental/organizational level policies)	0.677	0.636	0.061

Notes: †: Original article reports relative change in behavior from baseline
 **: Article has outcomes in two quadrants (e.g. discouraging both addictive and non-addictive behaviors);
 ***: Article has outcomes in three quadrants (i.e. all except promote addictive behavior)

Table 3: Model Effectiveness by Program Category

Program Category and Theoretical Model	Median Effectiveness ^(a)	Studies Using Model
Programs Discouraging Addictive Behavior		
Stages of Change/Transtheoretical Model	63%	38
Theory of Reasoned Action/Planned Behavior	27%	36, 37
Social Influence Model	22%	33, 35
Programs Promoting Non-Addictive Behavior		
Social Learning Theory	31%	32, 42, 50
Diffusion of Innovation	30%	54
Persuasive Health Message Framework	27%	53
Programs Discouraging Non-Addictive Behavior		
Social Influence Model	23%	55
Theory of Reasoned Action	10%	47, 57-59
Mental Model	8%	28

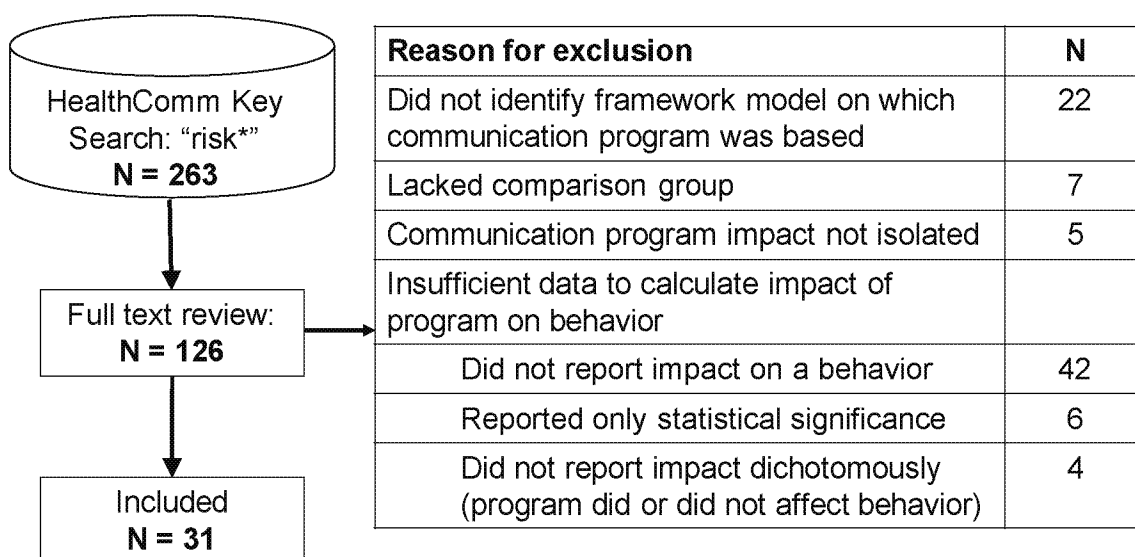
Notes:

- (a) As explained in the text, “effectiveness” is defined as the ratio of the change in the proportion of individuals engaged in the desired behavior to the proportion of individuals engaged in the undesired behavior in the control group or at baseline. Due to equivalent treatment within literature^{14, 15}, we aggregated TRA and TPB. Median of effectiveness across all measured outcomes reported.

Figure 1: Program Categories and Examples

<div> <div>Behavior Trait</div> <div>Campaign Promotion</div> </div>	<i>Addictive Behavior</i>	<i>Non-addictive Behavior</i>
	<i>Discourage Behavior</i>	Smoking cessation
<i>Promote Behavior</i>		Diet campaigns
		Seat belt campaigns, gun safety

Figure 2: Literature Search Results



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