

NATIONAL CANCER INSTITUTE WORKSHOP ON
CIGARETTE WARNING LABELS, PACKAGING & PRODUCT LABELING:
CURRENT SCIENCE & PRACTICE TO IDENTIFY RESEARCH PRIORITIES
OCTOBER 20–21, 2009

Meeting Summary

OPENING REMARKS

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The meeting opened with a delineation of the meeting goals and objectives: (1) to describe the knowledge and beliefs that the general public has concerning smoking and health and to examine factors that influence knowledge, beliefs, and behavior concerning smoking; (2) to review the scientific evidence on the effectiveness of warning labels, packaging, and product labeling of cigarettes; (3) to define the best practices for practical aspects for implementation of warning labels, packaging, and product labeling of cigarettes; and (4) to identify research needs to improve public health effectiveness of cigarette warnings, packaging, and product labeling.

Emphasis was placed on the existing evidence base available for informing public health efforts in tobacco control to develop and implement an effective warning label system as part of a larger, more comprehensive tobacco control program. Important dates were reviewed for the Food and Drug Administration's (FDA) implementation of new warning labels on smokeless tobacco products (2010) and combustible tobacco products (2012). The unique window of opportunity to have a wide-reaching impact on public health through the development and implementation of an evidence-based warning label system was discussed. The instrumental role of the U.S. Department of Health and Human Services (HHS) in overseeing and coordinating the combined efforts of its component Institutes and Centers was described.

Science of Risk Perception and Consumer Behavior – What do we know?

Ellen Peters, PhD
Decision Research
Eugene, Oregon
“The Psychology of Risk”

Linda Cameron, PhD
The University of Auckland
Auckland, New Zealand
“Risk Perception and Graphic Warning Labels: Implications for Research and Policy”

The aims of this session were to provide an overview of and facilitate discussion about the science of risk perception and consumer behavior as it relates to tobacco use. The presentations in this session described the complexity and multidimensional nature of risk perception and risk management. The presentations supplemented the traditional focus on the role of cognition in risk perception with an examination of the role of affect in risk perception. The “affect heuristic” was introduced and defined as the tendency for judgments about risk and benefit to be derived from and mediated through an affective evaluation (emotion-based assessment). Thus, it was argued that affective transfer in the case of tobacco warning labels and subsequent decisionmaking should be considered and systematically evaluated. Risk perceptions were further described as having both analytic (deliberative) and affective (experiential) components.

The evidence base linking risk perceptions with behavioral intentions and behavior was described. Leventhal’s *Common Sense Model of Illness* was described as an integrative framework combining social and contextual factors with cognitive and affective factors to explain lay illness representations. By employing this framework, risky behaviors (such as tobacco use) were described as being influenced, in part, by self-regulatory processes involving illness representations (both emotive and cognitive). In this context, illness threat or risk perception are shaped both by analytic efforts to discern risk and emotional reactions to a given threat/risk. The following components of the *Common Sense Model* were described: (1) Identity– the label assigned to the disease and signs of illness or symptoms; (2) Cause– beliefs about the cause(s) of illness; (3) Timeline– beliefs about the course of illness (e.g., chronic, acute) and its onset during the life course; (4) Consequences– beliefs about the outcomes of illness across life domains (e.g., social or emotional consequences); and (5) Controllability/Cure– beliefs about the potential for a cure or effective treatment.

Key Points from Discussion

- The full impact of warning label systems should be considered within the context of the larger tobacco control effort and implemented in concert with broader health communications efforts (e.g., mass media campaigns).
- While development of messages with broad efficacy and reach is a priority, some consideration should be given to the feasibility and effectiveness of audience segmentation (e.g., various age or risk groups) in developing warning labels and evaluating their effectiveness.
- An individual's risk assessment and ability to judge risk is rather crude; these limitations and biases in risk assessment should be taken into consideration when developing warning labels.

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SESSION 2: Public Knowledge of Tobacco Harm

The Public's Knowledge and Beliefs of Smoking and Health and Their Influencing Factors – What do we know?

Gary A. Giovino, PhD, MS

University at Buffalo, State University of New York

Buffalo, New York

“The Public's Knowledge and Beliefs About Smoking and Health and Their Influencing Factors”

The aims of this session were to provide an epidemiological overview of the public's knowledge and beliefs about smoking and health and to facilitate a discussion about this topic in relation to warning labels and packaging. This session drew upon a diverse body of population survey data and public opinion research data to characterize the public's knowledge of and beliefs about the risks and consequences of smoking and tobacco use. The session provided a comprehensive overview of the existing evidence base that reveals the persistence of misperceptions on the harms of tobacco use. Additionally, disturbing disparities in tobacco-related knowledge exist among subpopulations defined by smoking status, socioeconomic status, level of education, geographic region, and racial or ethnic identity.

Key Points from Discussion

- Factors related to the nature of the product (e.g., additives, filter vents), variability between products (e.g., roll your own, combustible vs. non-combustible tobacco), and industry marketing efforts (e.g., deceptive warning labels and descriptors) shape/skew risk perceptions.
- In order to effectively engage smokers in a way that personalizes risk, it was proposed that communication of risk messages should convey empathy rather than blame, be believable, be personally relevant, and should illicit cognitive responses and negative emotional reaction.

- Efforts to disabuse smokers and the public of misperceptions on the risks of smoking should be a priority.

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SESSION 3: Tobacco Warning Labels

Health Warning Labels – What do we know?

Geoffrey T. Fong, PhD

University of Waterloo, Waterloo, Ontario

Ontario Institute for Cancer Research, Toronto, Ontario

“Tobacco Warning Labels: Findings from the ITC Project and Thoughts on a Labels Research Agenda”

K. Michael Cummings, PhD, MPH

Roswell Park Cancer Institute

Buffalo, New York

“Two Questions and a Comment: What Do we Know? What Do We Need to Know?”

This session provided an overview of the science and facilitated a discussion on health warning labels (e.g., size, placement, language, graphics, number in use at one time, rotation, source credibility, literacy level). Presentations in this session focused on the evidence of the impact of warning labels and characteristics thereof on consumer knowledge, risk perceptions, intentions, and behavior. The overarching message from the body of evidence reviewed is that warning labels that are graphic, large, and most complete in terms of conveying risk information are most effective. The session presentations revealed that health warning labels directly influence consumer knowledge about the risks of smoking. In the United States, consumer deficits in knowledge about tobacco risks, including the impact of tobacco use on addiction, heart disease, stroke, and impotence, etc., can be traced in part to the failure to effectively warn smokers about these risks. Low levels of knowledge about the ingredients used in manufacturing cigarettes and the constituents of tobacco smoke were also demonstrated. The evidence presented revealed the prominent role of warning labels on cigarette packs as a source of health information.

Key Points from Discussion

- Graphic and text components of warning labels must explain the severity of risk in a synergistic fashion; the text provides supportive explanatory and contextual information for the graphics.
- Where appropriate, highly emotive messages about risk should be presented in combination with information that engenders self-efficacy and provides resources for reducing risk (e.g., smoking cessation quitlines).

- Considerable research in health messaging has focused on the importance of emotion in creating effective messages. This principle should be employed in the development of warning labels.
- Emerging evidence suggests that warning labels that are negative in affect or emotional content and that create high arousal are most effective.
- An effective warning labels system will be comprised of multiple warning labels, conveying both risk messages and cessation messages. Messages should be rotated over time because repeated exposure over time leads to the lessening of effectiveness (“wear out”).
- Ideally, warning label systems should be implemented as part of a larger communication effort to include mass media, Internet, and other outreach and educational efforts to inform consumers about risk.
- Efforts should be made to continually develop and test highly emotive and graphic warning labels that have broad appeal. Additional efforts should be made to discern the psychosocial/demographic characteristics of audiences to conduct population sub-analyses of effectiveness.
- Warning labels, especially in the context of a broader, effective tobacco control program, can increase demand for cessation services and products.
- The tobacco industry will work to undermine effective warning label systems; thus, attention should be paid to the ways in which the industry may use product packaging and other mechanisms to undermine warning labels effect.
- Consideration should be given to the most effective source for warning label attributions (e.g., the FDA, U.S. Government, or Surgeon General).
- Pre- and post-implementation research/focus groups should be conducted to assess warning label efficacy and impact.
- Monitoring and evaluation systems are essential for assessing the overall effectiveness of a warning label system and for providing evidence that can inform the preparation of the next round of warning labels. Evaluation should take place at the level of individual warning labels and at the level of the overall set of warning labels.
- Warning label systems should aim to increase cessation and decrease youth initiation of smoking.
- Competing organizations will want to promote their messages through warning label systems; attempts to synthesize and prioritize these messages should be made.

Packaging – What do we know?

David Hammond, PhD
University of Waterloo
Waterloo, Ontario
“What We Know About Packaging?”

Melanie Wakefield, PhD
Centre for Behavioural Research in Cancer, Cancer Council Victoria
Melbourne, Australia
“Australia's National Mass Media Cessation Campaign to Support Graphic Health Warnings”

The primary goals of this session were to provide an overview of the science of what is already known and facilitate a discussion to identify research needs in packaging (e.g., color, brand, plain packaging, size, shape, graphics, fonts, and product wrapping). Presentations described the significant role of tobacco product packaging in communicating and promoting tobacco brand image—particularly at the point of purchase and repeatedly at the time of use. In short, the tobacco pack is at the core of tobacco marketing, especially within the larger context of shrinking alternatives for advertising. The package serves as a powerful and reinforcing tool of addiction for several key reasons including presence at point of purchase decision, extensive and broad reach to potential consumers, potential to convey misleading information, and repeated and intimate exposure among consumers. The powerful impact of branding in shaping smokers' perceptions of risk and reinforcing continued product use was described. Tobacco product packaging has the potential to undermine effective communication of risk through diminishing the effectiveness and prominence of health warning labels. Through influencing expectations, packaging elements ultimately influence smokers' evaluation of attributes of cigarettes when they are smoked, including attributes related to perceived risk. The significant impact of the product package and brand on smokers' perceptions of risk and smoking behavior, together with the ability of certain product design features (e.g., vented filters) to convey misleading information about risk, suggest that there is a great need to regulate tobacco packaging. To most effectively offset tobacco industry efforts to undermine warning labels through creative packaging, consideration ought to be given to regulation of additional packaging features including size and shape of package, the materials from which packages are made, and specific design and functional elements (e.g., color, font, style of opening).

Key Points from Discussion

- Various product descriptors, colors, numbering, etc., convey misleading information.
- Efforts to eradicate misperceptions around reduced risk of certain tobacco products (e.g., light cigarettes) must include changes in product characteristics that influence taste and experience.
- A call was made for standardized/plain packaging to reduce and eliminate misleading messages and information.
- Packs should be standardized in shape and size.
- Warnings, packages, and products must be simultaneously addressed to minimize the impact of packaging on risk misperceptions. Package reforms and regulations must apply to the product as well. For example, the cigarettes must be a standard color and length and must not be branded or otherwise embellished. This would help convey the clear message that all cigarettes are essentially the same and reduce the misperception that certain products are less harmful than others.

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SESSION 5: Tobacco Product Labeling

Product Labeling – What do we know?

Ron Borland, PhD
VicHealth Centre for Tobacco Control
Victoria, Australia
“Misleading Aspects of Cigarette Pack Labeling and Design”

Lois Biener, PhD
University of Massachusetts
Boston, Massachusetts
“Constituent and Emission Labeling”

The goals of this session were to provide an overview of the science and facilitate a discussion to identify research needs in constituents and emission labeling (e.g., numbers, description, literacy level). Presentations examined ways in which product labeling leads to misperceptions about risk and relative risk of tobacco products. In particular, use of certain product labeling, such as “light” or “smooth” or alternative labeling, including “blue” or “silver,” was cited as a deliberate (and unfortunately successful) effort by the tobacco industry to mislead consumers about product risk. This practice, coupled with specific product design features that serve to create an experiential reinforcement of deceptive product labeling, misleads consumers. Tobacco control efforts around product labeling should strive to ensure that packaging and labeling do not falsely promote tobacco products or convey misleading information about the risks of the product. This needs to start with the realization that a major factor underlying smoker misunderstanding is that some cigarettes are engineered to taste milder/lighter, but actually deliver the same levels of tar as other cigarettes. Correcting smokers’ misperceptions must include

consideration of cigarette engineering, most importantly filter-venting, the main means of making cigarettes appear artificially low in tar when subjected to machine-measurement. The research examined in this series of presentations revealed that the public has considerable misperceptions regarding the relative risks of various tobacco products.

Key Points from Discussion

- The tobacco industry modifies their products in ways that change perceptions of risk, but do not actually reduce harm (e.g., filter venting).
- Misconceptions about the relative risk of tobacco products are common.
- Efforts should be made to develop effective means for conveying information about tobacco smoke constituents in a manner that is understandable and meaningful to the consumer.
- Further research around identifying meaningful quantitative information to convey to consumers about tobacco and tobacco smoke constituents and emissions is advised. However, this requires valid measures of actual human exposure, or at least measures of yield that are strongly correlated with actual human exposures. Even with such measures, it is not clear whether providing this information on tobacco packaging will necessarily result in consumers making more informed choices and, in fact, could lead to the misuse of quantitative information and symbols to inaccurately convey low or lower risk across brands.

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SESSION 6: Implementing Tobacco Warning Label Systems

Practical Aspects for Implementation – What do we know?

Garfield Mahood
The Non-Smokers' Rights Association
Toronto, Ontario, Canada
“Canadian Non-Profit Experience”

Murray Kaiserman, PhD, MBA
Health Canada
Ottawa, Ontario, Canada
“Development of Health Warning Messages: The Canadian Experience”

James F. Thrasher, PhD
University of South Carolina
Columbia, South Carolina
“The Road to Stronger Cigarette Health Warning Label Policy: A Case study of Mexico’s Experience”

Melanie Wakefield, PhD
Centre for Behavioural Research in Cancer, Cancer Council Victoria
Melbourne, Australia
“Australia's Experience”

This session presented case studies from countries that have implemented strong warning label and packaging regulations and identified lessons learned from these efforts. The presentations given in this session reviewed the processes involved in governmental control of tobacco labeling as experienced in Canada, Australia, and Mexico. The presentations covered a broad scope of considerations including development and prioritization of the scientific evidence base underlying specific tobacco control efforts, development of appropriate capacity and resources (e.g., tobacco quitlines), and shaping legislation to support tobacco control efforts. Some of the more consistently identified lessons learned from the implementation of government warning label systems included the following:

1. Warning labels are an effective, low-cost means to increase population knowledge of the risks of tobacco use and to motivate cessation.
2. Warning label systems should be integrated within a comprehensive tobacco control effort.
3. Pictorial/graphic warning labels, particularly those that elicit emotional responses, are generally more effective than text-only labels.
4. Pictorial warnings that evoke strong emotional responses appear most likely to promote cessation.
5. Packaging regulation and standardization will improve the effectiveness of warning labels.
6. Bigger is better. Evidence from other countries suggests that, in order to be effective, at least 50% of the front and back of the cigarette package should be devoted to the warning label.
7. Warning labels should include graphic and emotive information on the harms of tobacco smoking, and be supplemented by advice about cessation.
8. Warning messages should be rotated to avoid wear out.
9. The effectiveness of warning labels may be augmented when accompanied by mass media campaigns that support and reinforce messages and imagery in health warning labels.

Key Points from Discussion

- When making regulations around product labeling and packaging, clear specifications about multiple characteristics (e.g., color, contrast, font, size) should be made.
- Conducting public opinion research to discern impact of warning labels is essential.
- Warnings should convey both the nature and magnitude of risk, including information about the likelihood of developing tobacco-related illness and disease.
- Messages/warnings should be believable, accurate, emotive, from a credible source, and should provide support for cessation.
- Limited findings from empirical testing of warning labels suggest that graphic depictions of diseased organs perform better than images of the social and emotional consequences of smoking.

Factors Influencing Health Message Effectiveness – What do we know?

Annette Kaufman, PhD

National Cancer Institute, U.S. National Institutes of Health

“Factors Influencing Health Message Effectiveness: What Do We Know?”

Gregory N. Connolly, DMD, MPH

Harvard School of Public Health

Boston, Massachusetts

“The Tobacco Industry Packaging and Warning Labels”

Jack E. Henningfield, PhD

Pinney Associates

Bethesda, Maryland

“Tobacco Product Characteristics: Implications and Challenges for Labeling”

The key objectives of this session were to provide an overview of the science and facilitate a discussion to identify research needs for factors influencing consumer perception of risk (e.g., FDA regulation, industry response/activities, and product characteristics). The presentations in this session raised the issue of considering public perception of FDA regulation and subsequent impact of perceptions of risk and behavior. Research in this area is limited, but suggests that without proper efforts to educate the public, misperceptions on the regulatory authority of the FDA may lead some people to falsely assume that tobacco products are less hazardous under FDA regulation. The session reiterated the goals of warning label systems to promote cessation and discourage initiation and use. The session emphasized the importance of tracking the tobacco industry’s response to warning label implementation through pre- and post-market research and surveillance.

Key Points from Discussion

- The goals of labeling are to discourage tobacco use and support cessation.
- Post-market surveillance of tobacco industry response should be conducted beginning at 3 months following implementation of a warning label system.
- The success of new warning labels will be limited, unless implemented within an integrated and comprehensive tobacco control plan.
- The goals of product labeling and warning labels need to be defined.
- Baseline surveys to ascertain public perceptions around FDA regulation of tobacco need to be conducted.

DISCUSSION

Identify Research Needs and Priorities: This discussion focused on identifying and prioritizing research needs addressing the public's knowledge, beliefs, and behaviors concerning smoking and on extracting consistent themes emerging from the existing evidence base around tobacco warning labels, packaging, and product labeling. A further aim of this session was to consider lessons learned for practical application.

Evidence-Based Principles

Warning Labels

- Warning labels should clearly convey the actual magnitude and nature of the risk of tobacco use.
- Warning labels should communicate to a broad audience including current, former, and potential smokers.
- Warning labels should balance graphic and emotionally salient descriptions of real harm, with opportunities for efficacy and action.
- The most effective messages have been found to:
 - Depict the nature and magnitude of the harms of tobacco use in a realistic manner and
 - Elicit an emotional response—dramatic and negative.
- Other research strongly suggests the following are effective components of warning labels:
 - Explain the ways in which tobacco risks compare with other more familiar risks,
 - Offer assistance or resources for cessation, and
 - Empathize with, rather than blame, the smoker.
- Graphic warning labels can be more effective than text only, but not if the graphics are weak, do not relate to the written component, or do not evoke harm caused by tobacco use.
 - Position and relative size of graphics are key: more prominent and larger graphics are more effective.
- Ideally, warnings are integrated into an overall campaign to curb tobacco use including linked mass media, point-of-purchase counter advertising, industry packaging, etc. This approach has been proven effective in Australia.
- Warnings have multiple purposes, including directing smokers to more sources of information and treatment, addressing the tobacco industry's misuse of the package to convey false expectations and beliefs, and communicating accurate facts about tobacco use and the negative health consequences of smoking.
- Much has been learned from the ground-breaking work of countries that have used warning labels as strong tools of communication. However, continued research is needed, including formative evaluation and re-evaluation of warning strategies and

messages. Additionally, warning systems must be flexible to adapt to different national and campaign conditions.

- The messenger must maintain credibility by assuring the tone and messages are accurate, truthful, respectful of the smoker, and believable.

Packaging and Product Labeling

- Careful attention should be paid to brand descriptors that consumers wrongly interpret to imply modification or reduction of risk.
- Careful consideration should be given to use of words, colors, and graphics.
- The tobacco industry should be closely monitored to assess compliance and application of regulations.
- Consideration should be given to package size, design, and text font.

Practical Application

Maximum public health impact of warning labels will be achieved through strategic placement within a more comprehensive, integrated, and sustained tobacco control program. The existing evidence base justifies the current actions:

- Strong graphic warnings about the harms of cigarette smoking on all cigarette packaging should be implemented.
- The consensus is that misleading terms, such as “light” and “low-tar,” are misleading and therefore should be disallowed. Furthermore, research finds that not only terms such as “light” and “low-tar” are misleading, but other terms such as “cool” or “smooth” are also misleading, and should, therefore, be removed from all cigarette packages. Furthermore, packaging features such as color or design that imply “light” or “low-tar” should be disallowed.
- Design features and engineering features that are the basis of consumer misunderstandings of the harm of “light” or “low-tar” cigarettes should be removed.

Research Questions

Suggestions for future/continued research efforts include the following:

Warning Labels

- Identify and develop appropriate baseline survey questions to be fielded prior to the implementation of new warning labels
- Further development of cessation messaging
- Further exploration of the most effective ways to communicate about addiction
- Evaluation of novel approaches to communicate warnings at point of sale and use
- Ongoing qualitative research to maintain evidence base for health/warning messages.
- Evaluation of affective and cognitive impacts of communication
- Transdisciplinary efforts to explore the impact of messages on behavior
- Assess the impact of blame attribution (i.e., blaming the tobacco industry) on warning label effectiveness
- Assess the impact of warning labels within key subpopulations (e.g., socioeconomic status, literacy level, culture, language)
- Examine the flow of information around warning labels within social networks

- Identify optimal rotation regimens for messages.

Packaging and Product Labeling

- Research to explore the impact of plain and standard packaging and the extent to which the pack can be considered advertisement
- Explore different methodological approaches to analyzing the actual product and impact of product variability on behavior.

Review of Existing Data to Inform Warning Messages

- Analysis and review of existing qualitative data
- Analysis and review of existing survey data.

Planning and Evaluation Research

- Pre-market evaluation
- Planning for post-market evaluation
- Legal research on first amendment implications for warning labels
- The scope of engineering/design features of cigarettes and other forms of tobacco that should be restricted or prohibited in the interests of public health.

Research on Public Perceptions of Tobacco Industry and FDA Regulation

- Research public awareness and perceptions of the FDA and their regulatory authority
- Review of tobacco industry documents to determine public perception of tobacco industry and FDA regulation.

Selected Research

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