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Review

Advancing Tobacco Product Warning Labels Research Methods and Theory: A Summary of a Grantee Meeting Held by the US National Cancer Institute

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Abstract

Background: The World Health Organization's Framework Convention on Tobacco Control recommends prominent pictorial health warnings on tobacco products. To advance research methods, theory and understanding of how tobacco product warning labels (TPWLs) work, the US National Cancer Institute convened a grantee meeting. Our article describes the key insights that emerged from the meeting, situated within the context of the scientific literature.

Results & Recommendations: First, presentations confirmed that large, pictorial TPWLs motivate people to try to quit and encourage smoking cessation. Second, pictorial TPWLs increase attention, knowledge, negative affect, and thinking about the warning. Third, TPWL studies have primarily used brief-exposure laboratory studies and observational studies of sustained exposure through national policy implementation, with a few randomized trials involving several weeks of exposure—with generally consistent results found across study designs. Fourth, novel assessment methods include brain imaging, eye tracking and "best-worst" discrete choice experiments. To make TPWL even more effective, research is needed to confirm the mechanisms of their influence, their impact across vulnerable populations, and their effect on social media posts about tobacco products. Research is also needed on the effect of trial design choices, the predictive validity of new measurement approaches, and warning labels for non-cigarette tobacco products.

Implications: To improve scientific understanding of TPWL effects, this grantee meeting summary describes emerging research methods, theory and study results. Directions for future research include examination of the mechanisms of how warning labels work across diverse tobacco products and across different populations and contexts.

Introduction

A strong evidence base supports the effectiveness of prominent, pictorial tobacco product warning labels (TPWLs), which are recommended by the World Health Organization's Framework Convention on Tobacco Control.[1] In March 2016, the US National Cancer Institute (NCI) convened a grantee meeting including researchers, legal scholars, and research funders with the aim of advancing research methods and theory to understand how and why TPWLs work, in order to further improve their effectiveness. Attendees discussed existing and emerging TPWL research findings, examined the empirical evidence for mechanisms that could explain how TPWLs work, identified the advantages and disadvantages of different TPWL evaluation methods, and explored promising new directions for TPWL research methods and theory. This article describes the key insights that emerged from the grantee meeting, situated within the context of scientific literature. As such, this article aims to guide future research that will improve public health by studying ways to enhance the impact of TPWLs within a rapidly changing landscape of tobacco products and tobacco control policies.

Meeting presentations recognized that WHO FCTC recommendations have spurred the adoption of prominent pictorial TPWLs by more than 100 countries around the world.[2] In the United States, however, TPWLs for cigarettes (and cigarette advertisements) have included the same four text-only warning messages since 1985. In 2009 the Family Smoking Prevention and Tobacco Control Act[3] gave the US Food and Drug Administration (FDA) the authority to select pictorial imagery to accompany nine new TPWL messages that are to cover the top half of the front and back of cigarette packs. After the FDA issued a set of pictorial TPWLs in 2011, the industry sued the government claiming that they violated First Amendment protections for commercial speech.[4] In a 2011 lower court ruling, the presiding judge agreed with the industry, emphasizing that emotional responses to the pictorial warning labels were separate from factual information."[5] This ruling was upheld in US federal appeals court in 2012, leading the FDA to withdraw their proposal and reconsider TPWL content for future implementation. Since this time, research projects to broaden and deepen the evidence base for the implementation of TPWLs have (1) gathered information on the impact of different types of text and pictorial TPWLs and (2) identified conditions under which TPWLs influence smoking-related knowledge, risk perceptions, and behavior.

This article presents a summary of an NCI grantee meeting on TPWLs who described emerging research on TPWLs and highlighted directions for future research in this area. Our summary follows the same structure as the agenda for the grantee meeting, starting with an overview of TPWL policies, their global reach and syntheses of scientific studies on TPWL effects. Presentations within each key topical domain (ie, theoretical mechanisms of TPWL effects; study designs to capture TPWL effects under naturalistic exposure; innovative methodological approaches) are summarized and situated in the context of the broader scientific literature, meeting discussions, and subsequent reflections among meeting participants. Finally, future research directions synthesize key meeting presentations and discussions.

TPWL Influence on Smoking Behavior

Much of what we know about how TPWLs work comes from international observational studies in countries that have implemented TPWLs. Over four billion people, 58% of the world's population, live in countries that have finalized regulations for pictorial TPWLs.[2] Several countries, including Australia, Canada, the United Kingdom, and Uruguay, have increased the strength of their pictorial TPWLs by increasing their size and changing their content,[2] and these changes, too, have enhanced TPWL effectiveness.

Most narrative, systematic, and meta-analytic reviews of the evidence conclude that large, pictorial TPWLs improve knowledge of tobacco-related risks and encourage smoking cessation.[6–9] A meta-analysis of controlled experiments concluded that pictorial TPWLs are more effective than text-only TPWLs at increasing intentions to not smoke.[9] Another meta-analysis of longitudinal panel studies concluded that implementing national policies that strengthened TPWLs (increasing size or prominence, often through the addition of pictures illustrating tobacco's health effects) is associated with more quit intentions, higher rates of smoking cessation, and reduced smoking prevalence.[10] Although one review found insufficient evidence on whether pictorial TPWLs increase smoking cessation,[8] a more recent large randomized controlled trial found that cigarette packs with FDA's 2011 pictorial TPWLs increased the odds of 7-day abstinence by 52% when compared to current US text-only labels.[11] These findings provided the foundation for subsequent meeting presentations.

Theoretical Mechanisms for How TPWLs Work

Researchers have identified several psychological mechanisms to explain how pictorial TPWLs on cigarette packs influence smoking behavior. Pictorial TPWLs elicit greater attention and encoding into memory, according to a recent meta-analysis[10] and corroborated by a large field trial.[11] Thus, it makes sense that naturalistic studies of policy implementation find that strengthening TPWLs (eg, by adding imagery, increasing size) is associated with increased knowledge of smoking-related harms.[10]

Pictorial TPWLs encourage smokers to think more deeply and more often about the harms of smoking.[12–15] However, research has not shown that the TPWLs directly increase perceptions of the likelihood of harm.[9,11] This may be because pictorial TPWLs typically visually depict information about the harm caused and the severity of the harm, but not the likelihood of harm. However, pictorial TPWLs increase scrutiny of the warnings and warning credibility, both of which are associated with higher perceived risk.[13] Furthermore, TPWLs that address less well-known risks may be more likely to influence risk perceptions, perhaps because poorly known risks provide more room for improvement.[16]

Pictorial TPWLs also elicit more negative affect than text-only warnings, including fear, sadness, and disgust.[10,11,13] In the 2011 lower court decision that delayed implementation of pictorial TPWLs in the United States, the judge wrote that "the emotional response [the pictorial warning labels] were crafted to induce is … an objective wholly apart from disseminating purely factual and uncontroversial information".[5] Thus, the decision to halt the implementation of pictorial TPWLs presumed a separation of feelings and factual understanding, but evidence indicates that this separation is artificial and these two constructs influence one another.[17]

In particular, people process information in judgment and choice using two separate but interacting ways of thinking—one more thoughtful and deliberative, the other more affective and experiential.[18–20] The deliberative mode is conscious, analytical, reason-based, verbal, and relatively slow. Historically, researchers and policy makers have focused on this mode, examining cognitive reasons for choices or providing more information so that greater deliberation

would lead to better choices.[21,22] The experiential mode, in contrast, processes feelings about objects and information in a relatively effortless and spontaneous manner. Past experiences and repeated exposures shape these feelings, which are integral parts of the meaning of the object or information.[23,24] Without affect to provide guidance, risk information does not inform judgment or choice because it has limited meaning.[20,25]

Positive and negative affect towards potential hazards have at least three distinct effects in judgments and choices: Affect acts (1) as information, (2) as a motivator, and (3) as a spotlight to direct thinking about information congruent with the affective reaction (health warning information in the case of TPWLs). First, humans rely on an affect heuristic by using feelings as information to guide judgment and choice including quick reactions to danger that are critical for avoiding hazards such as smoking.[13,20,25,26] Second, when affect acts as a motivator, it prompts actions towards choices that feel good or away from things that feel bad and should be avoided. For example, affect can motivate smokers' behaviors and behavioral intentions, including quit intentions.[11,13,27] Finally, affect can act as a spotlight in a two-stage process that first focuses the smoker on the warning information contained on TPWLs and then that information, rather than the feelings, guides further judgments and choices.[27] Although a common belief (that appears to be shared by the courts) is that emotional appeals encourage a non-fact-based decision process, emotional appeals can promote more deliberate and informed decision making among current and potential smokers by according more rather than less weight to factual information presented in the warnings.[13,17] The negative affect from pictorial TPWLs thus produces a cascade of psychological effects that allow for healthier decisions.

Pictorial TPWLs also elicit more anger than text-only warnings, as part of a larger pattern of message rejection called reactance.[28,29] Some have drawn attention to the potentially negative effects of fear- or anger-arousing pictorial TPWLs, suggesting they may result in widespread avoidance or rejection of TPWL messages.[30] In some experimental studies, for example, the finding that some smokers engage in defensive avoidance (assessed by objective measures of attention to the TPWL with eye tracking technology[31] or self-reported reactance[32,33]) has been interpreted as lack of TPWL effectiveness. However, observational studies have found that self-reported attempts to avoid TPWLs are either unassociated or positively associated with cessation outcomes.[34–40] These results are consistent with the idea that negative arousal can promote desired behavior,[13,41] patterns that are consistent with the affect heuristic[42,43] and theories of implicit motivation.[44,45]

The aforementioned line of theory and TWPL research suggest that perceptions of facts inevitably contain some affect (see also Zajonc[46]). Across evolutionary history, this affective meaning has assisted humans in understanding and using information about risks.[20,47] Damasio[48] proposes that good decision making is a product of the analytical as well as the experiential mind, "The strategies of human reason probably did not develop, in either evolution or any single individual, without the guiding force of the mechanisms of biological regulation, of which emotion and feeling are notable expressions. Moreover, even after reasoning strategies become established … their effective deployment probably depends, to a considerable extent, on a continued ability to experience feelings" (Demasio[48], p.xii). Thus, pictorial TPWLs and their accompanying affect enhance the meaning of presented health risks, with affect as an important and active component of effective pictorial TPWLs.

Approaches to Study TPWL Effects in Ecological Context

Presenters identified several key considerations of different study designs, with a focus on protocols that aim to maximize naturalistic conditions of TPWL exposure. Observational and RCT approaches where smokers repeatedly see TPWLs on cigarette packs every day[9] contrast with brief laboratory experiments that expose participants for a few seconds to TPWLs in artificial contexts (eg, in isolation, on generic pack images, or on packaging for a brand that is usually not the participant's own brand[10]). In RCT's conducted since 2015, researchers have randomized smokers to receive different TPWLs on their cigarette packs and assessed behavioral outcomes over time, including quit attempts.[11,13,49] Despite having some advantages over other study designs (eg, control for potential confounders), RCTs also present challenges that include a limited number of practical TPWL manipulations within the same study (eg, size, placement, content). The characteristics of control stimuli relative to the experimental TPWLs also influence interpretation regarding the TPWL characteristics that account for any observed effects. For example, the control group for one RCT used the current US text-only TPWLs affixed to the side of the pack, whereas the experimental group included much larger, differently worded TPWLs that included imagery and were affixed to a more prominent place on the front of the pack.[11] Hence, it was not possible to isolate the independent effects of size, prominence, novel content, and use of pictorial imagery.

Practical considerations for RCTs include how to expose individuals to TPWLs in a naturalistic way. Some studies have used TPWL stickers that researchers or participants place on packs. Although asking participants to place stickers on packs is feasible and allows for extended follow-up because participants may not need to return to the lab, the act of putting the sticker on one's packs could enhance demand effects, may enhance the intervention's effect, or may result in low (or unknown) adherence to the protocol, particularly in longer trials.[49,50] Provision of free packs with TPWLs as part of participant compensation is also feasible,[13,51] but it raises the possibility that the reduced cost of smoking will increase consumption during the trial. The extent of this issue may be assessed by examining cigarette consumption for some period before or after the trial[52] or could be resolved if participants purchase their own supply of cigarettes for the study period.[11] However, upfront large expenditures on cigarettes may be infeasible for some smokers and could potentially exclude vulnerable populations (eg, lower SES groups) from trials.

Other RCT design considerations include time to follow-up and frequency and mode of data collection. The frequency of data collection is generally associated with the period of follow-up, ranging from every 2 days for week-long follow-up[47] to weekly or monthly follow-up.[11] In a large sample (n > 2000), 4 weeks of follow-up was adequate to detect a difference in quit attempts when comparing prominent pictorial TPWL with current TPWLs in the United States.[11] Longer follow-up would be necessary to study sustained cessation behavior, but that may not be practical and may be unnecessary when trial outcomes are focused on short-term changes, such as foregoing cigarettes or quit intentions, that are associated with subsequent cessation attempts. Ecological momentary assessment (EMA) or studies of TPWLs that involve multiple surveys each day[53,54] may provide more nuanced understanding of these and other TPWL effects. However, researchers should carefully consider reactivity effects that may accompany questioning around TPWL exposure events.

Results from observational research findings are generally consistent with those from other study designs. A key advantage of observational studies concerns opportunities to assess longer term outcomes, particularly cessation behaviors that may be more difficult to evaluate in experimental designs. The addictive nature of tobacco and the frequency of relapse makes longer term follow-up important to answer cessation research questions. The main limitation of observational studies is the absence of comparison group(s) that are equivalent on all factors except for TPWL exposure.

Recent observational studies have indicated opportunities for enhancing TPWL effects. As in anti-tobacco media campaigns,[55–59] studies from a variety of countries find that frequency of interpersonal communication about TPWLs independently predicts cessation behavior.[60] Smokers' interpersonal communications about TPWLs may embed the issue of smoking-related harms within social networks, facilitating the elaboration of messages.[61,62] TPWL messages on cigarette pack exteriors can also be complemented with "inserts" (ie, small leaflets inside of cigarette packs). In Canada, for example, attention to inserts with messages on the benefits of quitting and with cessation recommendations has been associated with downstream increased self-efficacy to quit, quit attempts, and sustained smoking cessation.[63,64]

Emerging observational approaches to research on TPWLs include "infodemiology," which involves the study of information exchange on the internet. For example, depending on the sample size, resources and complexity of the coding scheme, human-coding or machine-based learning approaches can characterize social media content, including product type, brand names or imagery (visual detection software), source (company vs. private individual), and even source characteristics.[65] These approaches may help determine whether stronger, more prominent TPWLs reduce sharing of images of tobacco packs on social media. Posting selfies on Instagram along with a branded pack that does not have a visible TPWL likely sends a very different message regarding social-image compared to a selfie with a pack that has a prominent, pictorial TPWL. Such approaches should be considered alongside more traditional observational studies and RCTs, in order to characterize the effects of TPWL policies.

Innovative Methodological Approaches

Recent TPWL studies have applied novel objective assessment methods to try to elucidate the underpinnings of what makes a TPWL effective. Functional magnetic resonance imaging (fMRI) studies measure real-time neural responses to TPWLs by measuring blood flow to specific regions of the brain that appear critical to early information processing.[66] Much of the early processing of the message (eg, that emerges as a result of the affect heuristic) involves neural processes that may be difficult to assess through self-report or other ways. Indeed, models that integrate neuroimaging data explain approximately double the variance in subsequent behavior change relative to self-reported measures of TPWL responses and behavioral intentions.[66–68] fMRI studies that integrate measurement of other biological, psychological and behavioral outcomes are promising for explaining how TPWLs influence behavior. For example, work by Wang and colleagues (2015)[69] has demonstrated how fMRI-assessed amygdala activation in response to the TPWLs is meaningful for public health when analyzed along with recognition memory for TPWLs and subjective ratings of cravings. Specifically, greater amygdala activation was associated with greater recall—an indicator of encoding in memory—of high emotionally salient TPWLs, which was also associated with decreased urge to smoke. fMRI has also shown promise as a tool for understanding how TPWLs on "plain" product packaging (ie, no logos, distinctive colors or design elements) can elicit increased amygdala activation and greater salience of risk messages.[70]

Eye tracking is a second laboratory-based methodology for identifying what makes a TPWL effective. Eye tracking represents a direct means of assessing visual attention that has shown great promise in the limited number of tobacco-specific communication research studies utilizing this approach.[71] Eye tracking permits the quantitative measurement of visual fixations and attention regions, which can then characterize viewer engagement with measures such as dwell time, fixations, time to gain attention, and viewing order.[72–74] Eye tracking can identify features or formats of TPWLs that gain and hold attention, which is important because attention is a central construct of activation and memory theory and strongly associated with recall. Research employing eye tracking demonstrates how cigarette smokers engage with TPWLs on cigarette packs[68] and print advertising.[75] Across a series of studies, eye tracking has been used to demonstrate differences in viewing patterns based on formats and features, such as comparing pictorial and text-only TPWLs[74,76] and understanding why text-only warnings are not viewed or recalled well.[73] In addition to characterizing features of TPWLs that gain and sustain viewing attention, eye tracking studies can examine associations between viewing and recall of information, which is an important goal of health communication.[73] Recent work shows that eye tracking can be easily performed repeatedly,[77] including over the course of extended periods of time when smokers are provisioned with cigarette packs with manipulated TPWLs. This repeated, objective measurement of attention to TPWLs may better approximate routine engagement with TPWLs under naturalistic exposure conditions, thereby enhancing external validity and bridging an important gap between single session laboratory experiments and real world observational studies.

A third innovative approach to understanding TPWL effectiveness is using empirical research to design and implement novel TPWLs and then experimentally estimate their effectiveness in target groups of interest. One such example of this work is the ASPIRE2025 (New Zealand) program, a partnership of tobacco-control researchers and health service groups in New Zealand to achieve a tobacco-free nation by 2025. This Smokefree Message, Interpretations, Responses and Quitting (SMIRQ) project used a mixed-methods approach to identify TPWL that would motivate quitting in young adults aged 16–30 while deterring initiation among susceptible non-smokers in the same age group. Thirty-six in-depth interviews explored responses to images representing themes identified in the research literature, including social risks, second hand smoke exposure risks, tobacco industry denormalization, and proximal health risks. The TPWLs identified as most effective typically aroused high levels of disgust and sadness. Two sets of nine TPWLs (one set comprising TPWLs identified as most effective at prompting quitting and the other set those most likely to deter initiation) were then featured in standardized packs and used in a "best-worst" choice experiment, a methodology that expands upon discrete choice experiments. Findings from this study suggest expanding TPWLs to include themes other than health may more effectively influence young adults' smoking behaviors than TPWLs that focus on smoking-related health effects that youth find less salient and not to affect them for many years.

Integrating fMRI or eye tracking into research studies that collect self-report or other observational data can provide a unique

understanding of how people engage with TPWL at the time of exposure. Examining how these objective measures are associated with other relevant outcome measures, including recall, knowledge, behaviors, and biochemical outcomes, may provide important context to TPWL effectiveness. Objective measures can identify aspects of TPWLs that are most effective at garnering attention, increasing ability to recall, and promoting behavior change.[74,78,79] Applying endpoints such as fMRI[79,80] and other brain psychophysiological measures[69] help assess real-time response to TPWL presentation. Behavioral modeling, such as the "best-worst" study conducted by the ASPIRE2025 group is innovative and offers insights into smokers' likely actions that data from fMRI and eye tracking studies do not provide. However, while ASPIRE2025's approach provides an opportunity to estimate likely behavior, limitations on design complexity and sample size mean surrendering some ability to isolate unique attributes of effective TPWLs. Nonetheless, conducting systematic evaluations of potential TPWL content has high value in understanding the potential real-world impact those TPWLs will have.[81–83]

Future Research Directions

During the grantee meeting, researchers who study TPWL effects summarized the sizeable amount of research across countries, which indicates that large, pictorial TPWLs are effective in enhancing knowledge about the range of smoking-related harms, promoting interest in quitting, and reducing smoking prevalence. Participants emphasized that TPWL research published in recent years has used diverse study designs, each with different strengths and weaknesses, but that all provide complementary and important insights into the effects of TPWLs. It is noteworthy that studies using different approaches across different countries and sociocultural contexts have produced a fairly consistent pattern of results: more prominent TPWLs with pictorial imagery can enhance message understanding (eg, knowledge about tobacco-related risks) and promote cessation intentions and behaviors, with negative affect and the frequency of thinking about risks playing an important role. Participants also highlighted areas for future research to continue to expand and build on this evidence base.

First, researchers can further test mediation models to better understand constructs that explain how TPWLs work (eg, Emery et al.[84]; Evans et al.[13]; Yong et al.[85]; Thrasher et al.[64]). This will help with the refinement and development of new theories that may better explain TPWL impacts. Such conceptual models and evidence are needed to better understand: (1) how and under what conditions TPWLs exert their effects; (2) the timeline over which TPWLs exert their effects; (3) trajectories of TPWL wear-out, including difference by TPWL content; (4) strategies to maximize TPWL effectiveness over time; (5) characteristics of TPWLs that make them most effective; (6) potentially negative effects of TPWLs, such as those suggested by some theories (eg, reactance), and how these effects can be minimized; (7) differences in TWPL effects across key subpopulations, such as youth, smokers from disadvantaged groups, and smokers at different levels of nicotine dependence, self-efficacy to quit, and readiness to quit; and (8) implications of research in this area for development of national TWPL policies. Research that makes use of one or more of the various methodological strategies described above has strong potential to enhance the evidence base for TWPL design and effects.

Second, studies should assess the efficiencies and potential biases associated with different RCT designs, including incentive schemes, survey mode, and frequency. These study features (including strengths and weaknesses) should be reported in publications and, if possible, systematically assessed for their impact on study quality (eg, participation rates, follow-up rates). To better approximate the experience of purchasing tobacco products with different TPWLs, future RCTs may consider designs where participants purchase labeled tobacco products in retail environments, whether using real-world retailers, physical labs that simulate the retail environment,[86] or virtual retail environments.

Third, research should further test the predictive validity of fMRI and eye tracking for designing TPWLs as compared to, or in addition to, other assessment approaches, including other physiological measurement approaches used to study attention and perception (eg, event-related potentials[87]), self-reports, and attitude accessibility (eg, Riddle et al.[80]; Falk et al.[88]; Lochbuehler et al.[73]). Such data could help overcome concerns about the misuse of fMRI,[89] as well as key limitations to using fMRI and eye tracking for TPWL research, such as its relatively high cost, low sample sizes, artificial conditions of exposure, and generalizability. The ability to observe brain-level and eye tracking responses to TPWLs provides a potentially compelling methodology for examining TPWL impact at initial exposures and study designs could be integrated into RCTs to account for naturalistic exposures.

Fourth, research should expand the population base from which researchers have tested the effectiveness of TPWLs. The focus of prior research on adult smokers of conventional cigarettes is understandable given that they are most frequently exposed to TPWLs. Most existing research with youth has used more traditional, randomized experiments, although some studies have tracked the magnitude and impact of TPWL exposure in ecological contexts where large, pictorial TPWLs have been implemented.[36,90–92] TPWLs reach youth whose parents smoke, and experimental studies indicate that adolescents' responses to TPWLs are similar to those of adult smokers, albeit stronger.[93] More research focused on youth may help public health officials better anticipate the likely effects of TPWLs on this populations.

Fifth, studies are needed to assess TPWLs for other tobacco products, as most studies have examined combustible cigarettes. TPWLs for other types of tobacco products present unique challenges around the medium type (eg, vaping devices, e-liquid containers, shisha tobacco packaging, hookah), frequency of exposure to TPWLs (eg, depending on the product and TWPL present/absent/location), and context of use (eg, context of use such as solitary vs. social settings). All of these characteristics may influence TPWL effectiveness, independent of TPWL content.

Finally, TPWL policies should be analyzed for their potential to disrupt the communication of brand affiliation via social media. Computational and machine-learning strategies could analyze large volumes of social media data and thereby assess differential exposure to TPWLs across product categories, as well as whether the valence or content of messaging differs by product category. Research into the source, product type and views may help characterize message patterns, and their relationship to TPWLs, across the new media environment. In addition, research should continue tracking efforts to blunt or repeal laws requiring prominent TPWLs and marketing strategies that may mitigate the laws' impact.

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Declaration of Interests

None declared.

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