



Short Communication

Smokers' and e-cigarette users' perceptions of modified risk warnings for e-cigarettes

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ABSTRACT

The 2009 Family Smoking Prevention and Tobacco Control Act opened the possibility for tobacco companies to apply to market their products as having “modified” or reduced risks. However, research on how to communicate comparative tobacco risks and how such messages are interpreted is limited. This study aimed to qualitatively examine perceptions of potential modified risk statements presented as warning labels for e-cigarettes. We conducted six focus groups between 2014 and 2015 with 27 adult e-cigarette users and cigarette-only smokers who provided comments on two versions of a modified risk warning for e-cigarettes: 1) “WARNING: No tobacco product is safe, but this product presents substantially lower risks to health than cigarettes” (as proposed by two companies for their smokeless tobacco products) and 2) “WARNING: This product may be harmful to health, but is substantially less harmful than cigarettes” (an alternative developed by our team). Although most personally believed that e-cigarettes are safer than cigarettes and some thought the messages were true and accurate, many were skeptical and uncomfortable with the warnings because they did not “seem like a warning” and because use of the phrase “substantially lower risks” could be misleading and difficult to understand. Several thought the second warning was stronger (e.g., more active, more specific). Modified risk messages about e-cigarettes may impact perceptions and use of the product. More research is needed to identify the framing, wording and placement (e.g. within or in addition to a warning) that could potentially increase population-level benefits and minimize harms.

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1. Introduction

There is a growing recognition that different tobacco products pose different levels of risk to individual users (Fiore et al., 2014; Royal College of Physicians, 2007; Zeller and Hatsukami, 2009; Zeller, 2013) and some have advocated that the public should be better informed of these comparative risks (Kiviniemi and Kozłowski, 2015; Kozłowski and Edwards, 2005; O'Connor et al., 2007; Pepper et al., 2015). This is important given that health behavior theories (e.g., Theory of Planned Behavior, Health Belief Model) suggest that individuals' knowledge and beliefs about tobacco products, which may include risk perceptions, may predict use of those products (Glanz et al., 2015). Indeed, longitudinal studies have shown significant relationships between lower tobacco risk perceptions at baseline and product use or experimentation at follow-up (Choi and Forster, 2014; Song et al., 2009a; Song et al., 2009b; Villanti et al., 2015). In its assumption of regulatory authority over tobacco products through the 2009 Tobacco Control Act, the Food and Drug Administration (FDA) opened the possibility for tobacco companies to apply for permission to market their products as having

modified-risks (U.S. Food and Drug Administration, 2012). This application should include evidence that such marketing could reduce harm in smokers who switch to them, without simultaneously introducing population-level harm that outweighs this potential benefit, such as product uptake by non-tobacco users, including youth.

To date, two tobacco companies (Reynolds American Inc. and Swedish Match) have petitioned the FDA to change the wording of a warning label on their smokeless tobacco products (“This product is not a safe alternative to cigarettes”) to read that “No tobacco product is safe but this product presents substantially lower risks to health than cigarettes” (U.S. Food and Drug Administration, 2015a). Reynolds American Inc. (RAI) requested this under a “Citizen Petition” (denied in May 2015) (U.S. Food and Drug Administration, 2015b) while Swedish Match filed a modified-risk tobacco product (MRTP) application. During an April 2015 review, the Tobacco Products Scientific Advisory Committee (TPSAC) to the FDA voted against the warning change, with members noting, among various concerns, inadequate research on the statement's development and consumers' perceptions and understanding of it (U.S. Food and Drug Administration, 2015a). However the FDA

is not obligated to follow TPSAC's recommendations and has not yet delivered a ruling, which could be granted as indicated in the application, granted with some conditions (e.g., some labeling disclosures), or denied.

With the FDA's regulatory authority now extended to e-cigarettes, it is possible that similar modified-risk statements could be proposed for e-cigarettes, given that they are also regarded as posing reduced risks compared to combusted cigarettes (Pepper et al., 2015; Public Health England, 2015; Wackowski et al., 2016a). However, as with smokeless tobacco products, very limited research on this topic exists. One experimental study of non-smokers found that seeing ads with the RAI/SM reduced-risk message lowered perceived harm for moist snuff, but not snus or e-cigarettes (Popova and Ling, 2014). We aimed to contribute to this limited knowledge base by qualitatively examining perceptions of potential modified-risk warnings for e-cigarettes.

2. Materials and methods

Results are from a larger focus group study on perceptions of potential e-cigarette warning statements. Six focus groups (targeted for 5–6 participants each) were conducted with a convenience sample of New Jersey adults between December 2014 and January 2015. Three groups were conducted with adult current e-cigarette users (i.e., smokers or former smokers who have used e-cigarettes for more than 1 day in the last 30 days) and three with adult current cigarette smokers (i.e., have ever smoked 100 cigarettes and now smoke every day or some days) who may have ever tried e-cigarettes but were not currently active users (referred to from here on as “non-e-cigarette users”).

Participants discussed their perceptions about six draft warning statements. These referred to e-cigarettes as being potentially addictive, poisonous, containing toxins, having unknown health effects, unapproved for smoking cessation, and not safe alternatives to cigarettes. Results of these are presented elsewhere (Wackowski, 2016b). Afterwards, participants commented on two versions of a modified-risk message for e-cigarettes, presented in the style of a warning: 1) “WARNING: No tobacco product is safe, but this product presents substantially lower risks to health than cigarettes” (as proposed by RAI and SM) and 2) “WARNING: This product may be harmful to health, but is substantially less harmful than cigarettes” (an alternative message developed by our team). The presentation order of these was randomized across groups. Reactions to these warnings are the focus of this report.

Participants were debriefed, given a smoking cessation resource sheet and a \$50 gift card after the session. Transcripts were coded with Atlas.ti qualitative software, using codes developed deductively a priori and inductively based on themes identified from repeated transcript readings. Coded text was then re-reviewed to summarize major themes and select illustrative participant quotes (in some cases edited for brevity and clarity). This study was approved by the Rutgers University Institutional Review Board.

3. Results

Most participants ($n = 27$) were male (67%), white (63%) and had at least some college or technical school education (74%). Non-white participants were black (14.8%), Asian (14.8%) or of other race (7.4%). Current e-cigarette users ($n = 14$) were younger on average (27 years) than the non-user participants (40 years) (age range, 19–58). All of the non-e-cigarette users were current smokers and most (77%) were daily smokers who intended to quit in the next six months (77%) and had tried e-cigarettes (84.6%). Among current e-cigarette users, 57% still smoked tobacco cigarettes every day or some days. On average, these dual users used e-cigarettes on 21 of the last 30 days. The rest of the current e-cigarette users were former smokers who now exclusively used e-cigarettes (an average of 29 of the past 30 days).

3.1. Overall perceptions of reduced risk statements

There was general understanding among participants that both versions of the reduced-risk statements conveyed that e-cigarettes are not necessarily safe, but are safer than regular cigarettes. Most also appeared to agree that the phrase “substantially lower risks” meant that e-cigarettes are safer, and some specifically noted that it meant e-cigarettes present “a lot less” risks to health than regular cigarettes. Two e-cigarette users quantified “substantially lower” as meaning “more than half” and two other e-cigarette users thought it suggested that “You might not get cancer” from using e-cigarettes, and that the risks are “obviously” lower.

Participants across all groups also agreed that the statements would make e-cigarettes seem appealing, particularly to smokers, and would likely encourage their use (Table 1, Section A). Several e-cigarette users, agreed that the reduced-risk messages were “true” and “accurate,” and what they wanted to hear.

However, several participants, including current and non-e-cigarette users, commented that the messages didn't “seem like a warning” and/or that they felt more like e-cigarette advertisements (Table 1, Section B) and did not really warn about any specific risks (Table 1, Section C). One e-cigarette/cigarette dual user explained that the messages would not be appropriate as a “Surgeon General warning” because “it would definitely have to say if it has some kind of actual health risk like cancer or anything like that,” but that such information could be “a good thing to put on, like, maybe the box that it comes in.”

Although many participants personally believed that e-cigarettes are safer than regular cigarettes, they nevertheless appeared somewhat skeptical and uncomfortable with the reduced-risk statements as warnings because the actual risks of e-cigarettes are still unknown. These sentiments were expressed in both exclusive and dual e-cigarette/cigarette users. At least some of this concern was directly related to the statements' use of the phrasing “substantially lower risks,” which some participants did not believe had been clearly established yet and could be misleading (Table 2, Section D). For some, the phrase also made them wonder how much lower the risks were specifically, and how such differences were known/measured. Participants also noted that some people, including younger and less educated people, may not know or understand the word “substantially.” One participant admitted himself that: ‘I don't know the exact definition of substantially. I am not stupid but I just don't know’ (male, non-e-cigarette user, age 31).

3.2. Message comparisons

While participants initially indicated that the two versions of the reduced-risk statements were very similar (same idea, different words) some perceived differences were revealed upon discussion. Across groups, some participants felt that use of the word “may” in the “may be harmful to health” warning suggested uncertainty about whether e-cigarettes are harmful at all, making it weaker than the “No tobacco product is safe” phrase. However, many participants across groups appeared to find the “harmful” statement to be a stronger warning overall and to be less favorable towards e-cigarettes, particularly when asked about changing the phrasing from “may be harmful” to “is harmful.” Some participants appeared to think that the harmful statement was stronger because it felt less like an advertisement, more specifically communicated about e-cigarettes (rather than tobacco products in general), and/or more actively communicated that e-cigarettes may cause harm (Table 2). Lastly, while one person thought the “No tobacco product is safe” statement was stronger because it connected e-cigarettes to “tobacco” which is known to be harmful, others thought this language was inappropriate for an e-cigarette because they did not view it as being a tobacco product.

Table 1
Select example quotes of participants' perceptions of proposed reduced risk statements,^{a,b} by theme.

A. Perceptions that proposed reduced risk statements would make e-cigarettes seem appealing and likely encourage their use
<ul style="list-style-type: none"> • "It makes it sound a whole lot better...like 'okay yeah, all right, if it's that much less harmful I might as well check it out.'" (female non-e-cigarette user, age 49) • "...I think a lot of younger people would see this and be like 'oh well, I don't really smoke but it's not as bad as cigarettes so why not start this?'...And that's why warning labels that commend the product aren't really you know, present..." (male exclusive e-cigarette user, age 19)
B. Perceptions that proposed reduced risk statements don't seem like a warning or are not appropriate as a warning
<ul style="list-style-type: none"> • "It just seems like a sales pitch for electronic cigarettes to me..." (male non-e-cigarette user, age 29) • "Yeah, it's not um – it doesn't seem like a warning...This is more advisory than warning..." (male non-e-cigarette user, age 39) • "This is like saying, 'Hey buy me, take me home,'...as a warning I would say, it's looking pretty positive for somebody that wants to move on to an e-cigarette." (female non-e-cigarette user, age 58) • "I think it's good marketing, but not for a warning label." (male exclusive e-cigarette user, age 31) • "I don't think they should be legally allowed to put this until you can tell me the health risks." (female exclusive e-cigarette user, age 33) • "I feel like that's what the companies want to put on their label." (male dual e-cigarette/cigarette user, age 23) • "...that's like an advertisement kind of..." (male dual e-cigarette/cigarette user, age 20)
C. Perceptions that proposed reduced risk statements were too general, did not warn about any specific risks
<ul style="list-style-type: none"> • "Yeah well this is just uh like a broad warning I guess, so they're not going in depth about what's in the product...It's more like 'hey we made this, it's not safe but you can trust us that it's better than cigarettes.'" (male exclusive e-cigarette user, age 23), • "You're gonna tell me it's bad for my health. Why? Am I gonna turn it over and see the woman going [holds hand up to throat in suggestion of a stoma]. You know so like what am I talking about here?" (female exclusive e-cigarette user, age 33) • "...Cause I wanna know what is it gonna do, you know? How is it gonna be harmful to me? ...Because we know what cigarettes can do to people, you know, we see the commercials with the lady with the hole in her throat... is e-cigs gonna do this to me or is it just...I donno, you know?" (female dual e-cigarette/cigarette user, age 26) • "Yeah well I mean, no tobacco product is safe...That's like... everybody knows that." (female non-e-cigarette user, age 49) • "It's too simple, it's saying 'okay it's harmful but less harmful.' It's telling me something but not enough...I mean we kinda knew that." (female non-e-cigarette user, age 49)
D. Skepticism about use of term "substantially lower risks"
<ul style="list-style-type: none"> • "My first thought with that was 'prove it.' Because we don't know. We don't know exactly how much healthier it is...with the words 'substantially less harmful,' it could give certain people the thought 'oh well this one can't give me cancer so... game on.' Um, when that's not necessarily accurate..." (female exclusive e-cigarette user, age 33) • "We haven't studied it yet. We don't know if it's <i>substantially</i> lower. I mean I could almost probably guarantee that it's lower but <i>substantially</i> is a very vague term... You can't say that. The FDA's not gonna let you put that on a label because they don't...[know that]..." (male dual e-cigarette/cigarette, age 20) • "And yes, there is like lower risk than cigarettes. But the whole 'substantially,' I'm like 'ehhhhhhh'. It's a little iffy." (male dual e-cigarette/cigarette, age 19) • "I feel like if you put this on a label then I could sue you in 10 years. Cause you said I can't get lung cancer cause it's substantially lower. Guess what, I got lung cancer." (female exclusive e-cigarette user, age 33) • "...we don't know...So they can't say that it is [substantially less harmful]... but what happens 15 years from now?" (male exclusive e-cigarette user, age 31) • "There has to be some research behind the... to be able to put substantially down." (male exclusive e-cigarette user, age 53) • "...that 'substantially' could be anybody's level. I mean how are they measuring that? People want to know more, they are going to investigate that because that can mean just about anything." (male non-e-cigarette user, age 32)

Note: within each section of table, quotes presented are from unique individuals.

^a "WARNING: No tobacco product is safe, but this product presents substantially lower risks to health than cigarettes".

^b "WARNING: This product may be harmful to health, but is substantially less harmful than cigarettes".

4. Discussion and conclusions

This is the first qualitative study on perceptions of modified-risk warnings for a tobacco product, finding mixed feelings about them among consumers. Although most believed e-cigarettes are safer than

Table 2

Select example quotes of participants' perceptions that the "more harmful" statement^a was stronger than the "not safe" modified risk statement^b.

<ul style="list-style-type: none"> • "Because <i>is harmful</i> is more effective than 'no tobacco product is safe', everybody knows that already and they don't care...It is smoother and it is more direct." (male non-e-cigarette user, age 32)
<ul style="list-style-type: none"> • "This second one [Harmful statement] jumped out at me...was stronger than the first one [Not Safe statement]...because it's telling me that it is, it is harmful to your health...whereas the first one is saying it's substantially... it's not telling me that." (female non-e-cigarette user, age 57)
<ul style="list-style-type: none"> • "It is saying that it is harmful, it is letting us know for sure it is harmful... There is no doubt to it that it is going to hurt you, it is going to put a damper on your health." (female non-e-cigarette user, age 50)
<ul style="list-style-type: none"> • "Same message, different wording. But for the second one, it just...the second one kind of speaks to me more. It's a little more effective. Um, it seems like less of a sales pitch uh than the first one, only because of wording." (male non-e-cigarette user, age 29)
<ul style="list-style-type: none"> • "...this one saying 'no tobacco product is safe'- it is talking about regular cigarettes but this one is saying '<i>this</i> product may be harmful to your health', this is talking directly about e-cigarettes. So I feel like this one [Harmful statement] is specifically talking about e-cigarettes more than this one [Not Safe]." (male non-e-cigarette user, age 19)
<ul style="list-style-type: none"> • "Yeah, it's [Not Safe statement] not saying that it's gonna be harmful to your health like the other one is [harmful statement]. This is just saying 'no tobacco is safe, but this one's better for you!'" (female non-e-cigarette user, age 58)
<ul style="list-style-type: none"> • "I think message 7 [Not Safe statement] is it's almost like they're trying to sway you like 'hey listen nothing's really safe out there, but we've got some good stuff that's not so bad.' ...where I feel like 7a [Harmful statement] is actually talking about your health... It's becoming more specific..." (female exclusive e-cigarette user, age 33)
<ul style="list-style-type: none"> • "This [Not Safe statement] just does sound like it's saying 'hey buy this.' But this [Harmful statement] says 'this is going to hurt you, but it's gonna hurt you less.'" (male dual e-cigarette/cigarette user, age 19)
<ul style="list-style-type: none"> • "...it [Harmful statement] says that it's harmful to your health but it's less than... I think that this one [Harmful statement] would make me think a little twice... the one before it [Not Safe statement] I think was letting me know to buy it." (female dual e-cigarette/cigarette user, age 35)

Note: within each section of table, quotes presented are from unique individuals.

^a "WARNING: This product may be harmful to health, but is substantially less harmful than cigarettes".

^b "WARNING: No tobacco product is safe, but this product presents substantially lower risks to health than cigarettes".

regular cigarettes, several participants nevertheless seemed somewhat surprised by and uncomfortable with the messages in the form of a “warning”, as they didn’t actually warn about any particular risks, and didn’t “feel” like a warning. These findings were consistent with sentiments expressed during the TPSAC meeting on SM’s MRTTP application, where several committee members supported the idea of communicating relative product risks but did not find SM’s proposed message to be an appropriate standalone “warning” per se (U.S. Food and Drug Administration, 2015a). Findings were also consistent with SM’s consumer perception study which found that respondents perceived the proposed modified-risk warning to be significantly less “believable” than the existing smokeless tobacco warnings (U.S. Food and Drug Administration, 2015a). More research on the degree to which a single warning label could effectively and simultaneously communicate a product’s direct risk and relative risk to others is needed. These findings might also suggest that reduced-risk messages might be more appropriate in other formats, such as claims on advertisements, rather than in warning labels. However, a recent study that examined reduced-risk claims in manipulated snus ads also found greater consumer skepticism of these ads versus a control ad (Adkison et al., 2016), perhaps in part because of a belief that they originated from the tobacco company. Reduced-risk messages may play an important role in tobacco harm-reduction, but more research is needed on their understanding, their optimal placement and their potential impact (e.g., on risk perceptions, source credibility, product initiation and use).

Our findings also point to the importance of wording and framing in modified-risk messages. Even though both statements presented included a modified-risk message, changing the “warning” in the first part of the statement from “no tobacco product is safe” to “this product is harmful to health” seemed to make the overall statement somewhat more credible and acceptable as a warning. Our findings with respect to the statements’ use of the term “substantially” point to potential public interpretation problems when labels use vague descriptors, particularly ones that assume high literacy (U.S. Food and Drug Administration, 2015a). However, one potential alternative to this, i.e., quantifying the degree of risk-reduction, is also complicated given that such estimates may not be exactly known, can depend on product type and use and be difficult to understand, as suggested by literature on innumeracy in risk communication (Nelson et al., 2009; Peters, 2008). More research into how reduced-risk tobacco information should be communicated is important.

Study limitations included use of a small local convenience sample which did not include non-smokers or youth, whom such messages have potential to attract. Also, participants viewed these reduced-risk statements after other more traditional proposed e-cigarette warnings, which may have biased them to be more skeptical of such messages then if they were presented first or were the main focus of the study.

As alternative approaches to communicating tobacco-related harms are examined (Kaufman et al., 2016), there is a need to identify messages and methods that both accurately communicate health risks and convey modified risks of specific products. Our study provides insight into the tensions between these two areas and the need for more research on these topics. As any new reduced-risk messages are deployed, post-market surveillance will also be essential for monitoring how they are interpreted and how they might impact perceptions and behavior in tobacco users and non-users.

Conflicts of interest

Authors (OW, CD, AS, RO, AV) have received grant or contract funding from the Food and Drug Administration Center for Tobacco Products. DH has provided expert testimony in tobacco company legal cases. During the time of this study, RO was a member of the FDA’s Tobacco Products Scientific Advisory Committee. Any opinions expressed

in this article are the authors’ and should not be construed to reflect those of the committee or the FDA.

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