FACTORS INFLUENCING CONSUMERS' PERCEIVED RISK OF TOBACCO PRODUCTS

M.J. Atkinson[1], C. Chrea[2], T. Salzberger[3], S. Cano[4], G. Emilien[2], N. Mainy[2], A. Ramazzotti[2], R. Weitkunat[2], F. Lüdicke[2], T. Alfieri[1]

[1]Covance Market Access Inc, San Diego, USA; [2]Philip Morris International, Neuchatel, Switzerland; [3]University of Economics and Business, Vienna, Austria; [4]ScaleReport, Stotfold, UK

Introduction and Objectives

The tobacco industry is developing candidate modified risk tobacco products (cMRTPs) with the potential to reduce individual risk and population harm in comparison to smoking combustible cigarettes. In 2012, the United States (US) Food and Drug Administration (FDA) released its Draft Guidance on MRTPs requesting applicants to conduct research on consumers' perceptions of risk of tobacco products (FDA, 2012). Measures of consumers' perceptions of health risks of MRTPs are being developed to address these requirements. During these measurement design activities, relatively large-scale cognitive debriefing activities provided a unique opportunity to conduct qualitative inquiry into the conceptual basis on which consumers make their risk evaluations.

Study Objective: To report on the use of qualitative methods, described in the 2009 FDA Guidance on Patient-Reported Outcome Measures (FDA, 2009), in cognitive debriefing interviews (CDIs) to better understand how consumers address the conceptual challenges faced when rating the risk of tobacco product use.

Methods

Cognitive Debriefing Interview (CDI) transcripts were used to refine a new measure of consumer self-report risk perception, the Perceived Risk Instrument (PRI), and to examine the ways in which consumers evaluate the health risks associated with the use of various tobacco products.

CDI Interviews (n=48) were conducted over four days in two US cities. Twenty-four individuals completed the PRI to rate the perceived risks of conventional cigarettes (CC), and 24 completed the PRI to rate the perceived risks of a new cMRTP, the Tobacco Heating System (THS), being introduced by Philip Morris International (PMI). The CDI interviews were conducted to ensure that future respondents would understand the various elements of the PRI as intended and be able to use the instrument to provide reliable risk ratings of tobacco products. A "think aloud" interview technique was used to learn about reasons by which (potential) consumers made risk ratings and the difficulties they encountered when using the PRI. Interviewer and observer notes were reviewed at the end of each day, and the instrument was revised for the following day of interviews.

Codification and Thematic Frequency analysis of the 48 interviews followed commonly accepted standards, with a preliminary coding schedule created based on anticipated responses to the Interview Guide. The schedule was modified by 2 experienced qualitative researchers using independent codification and reconciliation of 10% of the transcript materials. Reasons and rationale for CDI informants' perceived risk rating were evaluated using frequency analyses of coded transcript themes describing the reasoning informants used to make risk ratings.

Results

CDI participant samples in Atlanta (n=23) and Los Angeles (n=25) were intentionally recruited to balance age (mean = 38.4 years; standard deviation = 11.2), gender (1:1), and highest level of formal education (half the sample with at least some high school education and half at least some university training).

Two broad thematic coding clusters were examined that informed us of the ways CDI participants make risks ratings and how product familiarity might affect comprehension and experience when responding to the PRI instrument:

1. Dimensions of Risk Appraisal: Various attributional dimensions with which informants base their risk appraisal, and
2. Instrument Comprehension and Respondent Burden: Characteristics of the PRI materials being used to structure and elicit the risk rating tasks.

Dimensions of Risk Appraisal: Given the focus of the CDIs, topics of risk appraisal were the most frequently considered and discussed topics when rating either conventional cigarettes or a cMRTP (see below).

Risk Appraisal Dimensions of Conventional Cigarettes

	Day1	Day2	Day3	Day4	Total
Degree of Risk	5	4	2	3	**14**
Frame of Reference (personal vs. general risk)	7	2	0	0	**9**
Degree of Problems	5	2	0	0	**7**
Risk Time Frame (near, medium, long-term risk)	2	2	1	0	**5**
Difficulty envisioning risk scenario	0	2	0	0	**2**
TOTAL Mentions of Cigarette Risks					**37**

Risk Appraisal Dimensions of Tobacco Heating System (THS)

Degree of Risk	5	3	2	1	**11**
Degree of Problems	5	4	1	0	**10**
Frame of Reference (personal vs. general risk)	4	5	0	0	**9**
Unfamiliarity with THS	3	0	3	0	**6**
Risk Time Frame (near, medium, long-term risk)	2	1	0	0	**3**
TOTAL Mentions of THS Risk					**39**

Table note: Presented are the frequencies of individuals who mentioned a topic at least once during their interview. For any coding category, multiple uses of the same code for a transcript was only counted once; however, total scores across categories can represent different perceptions of a single interviewee.

Rating of Health Risk was described as a complex task: one influenced by an individual's understanding of the term "risk," the type of health risk, one's personal experience of the health risk, knowledge of the public health research, familiarity with the product, length of product use, the time frame in which the health risk is being rated, and potential risk-moderation factors, such as age, health status, and lifestyle practices.

Evaluation of Risk and Problems were based on two distinctions:

1. The anticipated *severity or impact of a future disease if it were to occur* and
2. The *likelihood of a disease event occurring within a given time frame*.

➔Ratings based on these two different considerations resulted in very different magnitudes of risk responses to the same health condition.

Frame of Reference

- Some informants evaluated the likelihood of illness based on their first-hand (personal or interpersonal) experiences. For example, smokers rating risk based on personal experience rated shortness of breath higher than illness events that they had not experienced, such as emphysema or cancer.
- Generally, younger informants (<30 years old) had experienced fewer health impairments associated with tobacco use than older informants and made less reference to published population risk research. Older respondents tended to make risk ratings both based on more extensive personal experience with illness and behavioral health-risk research.
- Although risk perceptions based solely on personal experience limit the generalizability of risk ratings, the Health Beliefs Model of Risk Behavior suggests that such personal beliefs may still be motivational and serve as a predictor of risk behavior.

Time Frame

- Respondents under the age of 30 years more often expressed difficulties evaluating the future risk of current tobacco use. These informants' confidence in health-risk ratings became more uncertain the further out they were asked to rate potential disease events.
- Irrespective of age, many respondents considered multiple causes that moderate long-term tobacco risk, including lifestyle factors, such as exercise and nutrition, and how tobacco products are used.

Product Familiarity: Respondents stated that their perceptions of health risks associated with both conventional tobacco and THS would include a number of considerations;

- Differences in the types of potentially harmful components in the products and the different causal effects on specific disease outcomes.
- The length of product use, the amount and ways it was consumed, and the length of time since discontinuation of its use.
- Unfamiliarity with the product and inadequate knowledge of public health risks associated with the product were mentioned almost exclusively when evaluating the risks of THS.

Instrument Comprehension and Respondent Burden: Difficulties with complex phraseology, difficult medical terminology, and instrument length were mentioned equally when rating health risks of cigarettes or THS. Over the four days of interviewing, ongoing revisions to the PRI reduced the mention of such problems.

Conclusions

- **Understanding how consumers evaluate the risks associated with tobacco product use informs the design, implementation of risk perception ratings.**
- **Qualitative methods applied during CDIs can inform cognitive-behavioral research into perception of, and engagement in health-risk behaviors.**
- **Such activities contribute to population-based research initiatives intended to inform future public health policies and regulatory guidance.**

United States Food and Drug Administration (US FDA), Department of Health and Human Services (2012). Draft Guidance for Industry: Modified Risk Tobacco Product Applications. Rockville, MD, USA: US FDA.
United States Food and Drug Administration (US FDA), Department of Health and Human Services (2009). Guidance for Industry—Patient-Reported Outcome Measures: Use in Medical Product Development to Support Labeling Claims. Rockville, MD, USA: US FDA.

COMPETING FINANCIAL INTERESTS
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