

Perceived risks associated with the use of tobacco and nicotine-containing products: Findings from qualitative research

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Abstract: When evaluating the public health effects of novel tobacco products, such as candidate modified risk tobacco products (cMRTPs), risk perceptions are important as they are potential determinants of product use. In this paper, we describe the development of a conceptual framework of perceived risks associated with the use of tobacco and nicotine-containing products. We conducted a literature review, held 12 focus group discussions in the USA, and elicited expert opinions to identify key concepts related to risk perceptions of tobacco and nicotine-containing products. The literature review, focus groups, and expert opinions provided evidence for triangulation, revealing that the key concepts could form the basis of a conceptual framework in 5 domains: perceived health risk to self, perceived health risk to others, perceived addiction risk, perceived social risk, and perceived practical risk. This new framework can be used to support population-based and clinical research, establish the validity of the current research strategies, and develop evidence-based guidance for the development of new self-report instruments that are needed to evaluate the public health effects of novel tobacco products.

Keywords: Risk perception; Tobacco products; Qualitative research; Conceptual framework

Introduction

The risk associated with the use of tobacco products is an important issue to society and policy makers. With the rapid development of a range of alternatives to cigarettes such as tobacco products employing unconventional technologies^[1], the question arises as to the potential public health impact of those alternative products. To address these concerns, the FDA has produced a Draft Guidance that provides the regulatory framework under which modified risk tobacco products (MRTP) can be marketed in the USA^[2]. In this Draft Guidance, MRTP applicants are required to conduct consumer-based research on the perception of risk associated with tobacco products, as such perception might be a crucial determinant of product use among both current tobacco users and non-users^[3-4]. This

requirement implies understanding the ways consumers evaluate the risk associated with tobacco product use in order to design, implement and meaningfully interpret measures of risk perception that provide accurate data to inform public health policies.

Different strategies have been developed to better understand consumers' risk perceptions^[5]. Studies predominantly fall into research using surveys, which typically assess these risk perceptions with a single direct measure of comparative harm^[6]. However, such relative perceived risk assessment is of limited use if multiple products are to be compared. Another approach is to indirectly compare absolute measures of risk perception, i.e. when several products are assessed separately one at a time. Absolute risk measures have been found to be more discriminative than direct measures^[6]. The majority of these measures, either absolute or comparative, are based on a single summary item, focusing on the global harmfulness of tobacco products, e.g. "how harmful is this product?"^[7-8]. As highlighted by Rees et al.^[5], these measures lack evidence of validity and reliability which are needed to support future regulation of tobacco products. The same

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limitation applies to perceived risk assessment that relies on a small number of items, where limited or no information on how the items were developed is provided^[9-13].

Research that seeks to understand the views or experiences of any particular consumer group needs to use inductive, qualitative methods^[14]. Despite the wealth of qualitative research exploring the perceptions of tobacco products from the consumer perspective, no conceptual framework of perceived risks of tobacco products has yet emerged. Conceptual frameworks developed through qualitative research methods are vital for identifying relevant consumer concepts and for understanding what to measure in clinical or population-based studies on tobacco use^[15]. The present research used insights from three qualitative research methods, i.e., a literature review, consumer focus groups, and expert opinion, to support the development of a conceptual framework on perceived risks associated with the use of tobacco and nicotine-containing products. The generated descriptive data were used to develop a theoretical understanding of risk perceptions. In particular, we used detailed analysis to compare and contrast risk perception of different tobacco and

nicotine-containing products for different subpopulations based on their smoking status^[16].

1 Methods

1.1 Literature review

We sought to identify qualitative and quantitative studies that explicitly referred to perception of risks of tobacco products. The search strategy was based on three types of search terms: tobacco-related, metric-related, and risk perception-related (Table 1). Database searches were undertaken in September 2012 and included Embase® and Medline®. The searches were restricted to peer-reviewed articles published in English between January 2000 and September 2012. Three experts in public health and quality of life, consumer risk perception, and scale development were also consulted to identify additional literature not covered by our search (e.g., articles published before 2000). Papers were included in the review if they were peer-reviewed studies on the development of questionnaires related to attitudes, beliefs and perceptions of risk towards cigarettes or observational studies including a risk perception assessment as an outcome measure. From

Table 1 Search terms used in literature review.

Topic	EMTREE terms ^a	Title/Abstract terms ^a
Tobacco-related	<ul style="list-style-type: none"> • Cigarette smoke • Cigarette smoking • Smoking • Tobacco • Tobacco dependence • Tobacco smoke 	<ul style="list-style-type: none"> • Cigarette(s) • Nicotine • Smokeless tobacco • Smoking • Tobacco
AND		
Survey or questionnaire or question or item	<ul style="list-style-type: none"> • Health surveys • Item • Question(s) • Questionnaire(s) 	<ul style="list-style-type: none"> • Instrument • Item(s) • Measure • Question(s) • Questionnaire • Response(s) • Scale • Survey(s) • Tool
AND		
Risk-perception	<ul style="list-style-type: none"> • Health risk • Health risk and understanding • Perceived risk • Perception • Risk • Risk assessment • Risk awareness • Risk-benefit assessment • Risk-perception 	<ul style="list-style-type: none"> • Attitude • Perceived risk • Perception of risk • Risk • Risk perception

^a Disjunction (OR) at topic-level.

the two complementary search strategies, a total of 172 abstracts were screened for eligibility based on the aforementioned selection criteria, leading to 42 papers selected for further review.

1.2 Focus groups

The objectives of the qualitative focus group study were to explore how individuals evaluate the perceptions of the risk associated with tobacco products and to get a detailed understanding of the risk perception of different subpopulations for different tobacco and nicotine-containing products. This study was an extension of previous focus group studies carried out in three different countries (i.e., Japan, Italy, and United Kingdom) and followed the same methodology [17]. A total of 12 focus groups were conducted in three locations of the USA (four in Atlanta, four in Philadelphia and four in Los Angeles) in August 2013. The study was approved by the New England Institutional Review Board (IRB) and the

focus group participants received complete information about the study before agreeing with an informed consent form (ICF). A purposive stratified sampling of four subpopulations according to the self-reported smoking status at the time of data collection was used to ensure equal representativeness of different subpopulations within each city (Table 2). In addition, within each focus group, participants were balanced in terms of sex and education to ensure a diversity in demographics. Criteria for participation were being of legal age of smoking (minimum 18 years old), ability to read and understand the written information provided, and providing informed consent to participate. Participation in four + focus groups or in one market research study in the past two years and past six months, respectively, was an exclusion criteria, as well as being employed among the following industries: advertising or marketing companies, tobacco manufacturers, journalism, public relations, clinical research, or health care industry. Smoking status was

Table 2 Focus groups participants – demographics.

Characteristic	Philadelphia (n = 31)	Atlanta (n = 30)	Los Angeles (n = 32)	Total (N = 93)
Age				
Mean (SD)	46.9 (13.2)	39.5 (12.0)	36.4 (11.3)	40.9 (12.9)
Sex, n (%)				
Female	13 (42)	14 (47)	16 (50)	43 (46)
Male	18 (58)	16 (53)	16 (50)	50 (54)
Education level, n (%)				
High school degree or equivalent	5 (16)	2 (7)	3 (9)	10 (11)
Some college	12 (38)	13 (43)	13 (41)	38 (41)
College degree	9 (29)	12 (40)	12 (37)	33 (35)
Postgraduate degree	5 (16)	3 (10)	4 (12)	12 (13)
Marital status, n (%)				
Single	9 (29)	12 (40)	18 (56)	39 (42)
Married/common law	15 (48)	13 (43)	11 (34)	39 (42)
Divorced/widowed	7 (23)	5 (17)	3 (9)	15 (16)
Income, n (%)				
<\$25 000	4 (13)	5 (17)	2 (6)	11 (12)
\$25 000–\$50 000	10 (32)	10 (33)	7 (22)	27 (29)
\$51 000–\$75 000	8 (26)	5 (17)	11 (34)	24 (26)
\$76 000–\$100 000	4 (13)	5 (17)	7 (22)	16 (17)
\$101 000–\$150 000	5 (16)	4 (13)	3 (9)	12 (13)
>\$150 000	0 (0)	1 (3)	2 (6)	3 (3)
Ethnicity, n (%)				
Caucasian	23 (74)	18 (60)	17 (53)	58 (62)
African American	4 (13)	11 (37)	5 (16)	20 (22)
Asian	0 (0)	1 (3)	4 (12)	5 (5)
Hispanic	1 (3)	0 (0)	5 (16)	6 (6)
Other	3 (10)	0 (0)	1 (3)	4 (4)

SD = standard deviation.

Note: Income is denoted in USD.

determined in accordance with the guidelines established by the World Health Organization^[18]. Participants reporting having smoked at least 100 cigarettes in their lifetime and currently smoking at least one cigarette (no brand restrictions) per day (disregarding religious fasting) at the time of data collection were classified as adult current smokers. The latter were further divided into those with, and those without intention to quit, in accordance to Prochaska and DiClemente's Stages of Change model^[19]. Participants reporting that they were former daily smokers and, at the time of study, had been quitting smoking more than 30 days ago, were classified as former smokers. Those who reported that they had never smoked at all, or who had never been daily smokers and had smoked less than 100 cigarettes in their lifetime, were classified as never smokers.

Focus group participants were recruited by market research agencies (Delve Marketing Research [Philadelphia and Atlanta] and Plaza Research [Los Angeles]). A sample size of eight participants per focus group was deemed appropriate in order to ensure interactions and thus promoting self-disclosure among all participants^[20]. To limit the size of the focus groups to an ideal maximum for positive conversation, no more than eight participants were admitted into a focus group, though 10 to 12 participants were recruited for each focus group. The focus groups were conducted at the vendor's facilities. Participants were compensated for participation at the end of the focus group session for an amount of 100 US dollars.

A semi-structured discussion guide was used by an experienced moderator to facilitate the focus groups and to ensure all relevant content areas were discussed in the event participants failed to raise key topics on their own. Groups began with a brief introduction of goals and procedures so that participants were familiar with the moderator's expectations. The moderator invited each participant to introduce himself or herself to the group by sharing basic, innocuous information, such as a favorite hobby. Next, a description and visual example of three tobacco-related products were shared: cigarettes, electronic cigarettes, and nicotine patches (an example of nicotine replacement therapy (NRT)). Then, the discussion focused on how individuals perceive the risks associated with using these products. The conversation emphasized the various risks associated with each product, the risks that were similar among all products, and the risks unique to each product. As with any qualitative inquiry based in grounded theory, new concepts and distinctions made in the earlier part of a series of focus groups were discussed in subsequent group sessions. This process, known as member

checking, was used in addition to lines of questioning and probes that allowed for the verification of new concepts across multiple groups^[21].

Focus groups were tape-recorded and transcribed. Transcripts were analyzed using a content analysis technique^[16]. Content analysis is a systematic and replicable method used for condensing many words of text into fewer content categories based on explicit rules of coding^[16]. In this analysis, the principle of thematic saturation (i.e., point at which no new information or themes are observed in the data) was applied during the transcription and codification process^[22]. Transcripts were coded using a specialized coding software (HyperResearch™ version 3.5.2). A coding schedule was developed deductively a priori based on previous research^[17], and inductively based on themes identified from repeated transcripts readings. Two staff members coded 10% of the transcripts independently. Results from the independent coders were then compared and after the two coders resolved and learned from discrepancies associated with differences in understanding or inconsistencies in code application, one coder then proceeded to finish coding the remaining 90% of the transcripts. Coded text was then re-reviewed to summarize participants' responses into relevant themes and sub-themes.

1.3 Expert opinions

An advisory board consisting of four key opinion leaders (KOLs) and two academic consultants in scale development was convened on February 19, 2013 in Zurich, Switzerland. The KOLs were subject matter experts in fields of nicotine addiction, motivational aspects of consumer perception, and other relevant areas on approaches to measurement (e.g., public health, behavioral epidemiology, regulatory submissions). The meeting was structured as follows. First, in an open elicitation phase, two experienced moderators invited experts to suggest relevant themes related to risk perception of tobacco products. Second, the expert panel was asked to review and respond to themes and concepts uncovered in the literature review and in focus groups conducted in non-US countries^[17]. Finally, the moderators facilitated the discussion among the experts to synthesize the outcomes from the two previous phases in the view to generate a conceptual framework.

2 Results

2.1 Literature review

The literature search identified six papers that discussed the development and validation of a multi-item instrument to measure attitudes, beliefs and

perceptions of the risks, as well as related consequences of addiction. Five instruments were described in these publications: the Attitudes and Beliefs about the Consequences of Smoking Scale (ABS Smoking Scale)^[9], the 42-item Multidimensional Smoking Behavior Questionnaire for adult smokers^[10], the Tobacco Craving Questionnaire (TCQ)^[11], the Smoking Consequences Questionnaire (SCQ)^[12-13], and a risk perception questionnaire developed by Park et al^[23].

From the literature review, we identified four broad domains of perceived risk (Table 3). The most widely addressed aspect of risk was health risk to the individual user of tobacco-products (all 24 papers referenced in Table 3), typically cigarette smokers. In this context, cancer and heart disease (19 and 9 papers, respectively), as well as addiction (7 papers), were most often referenced. In addition, but much less frequently, the literature review disclosed social, financial, and

time-related aspects of perceived risk (8, 2, and 2 papers, respectively).

Besides the identification of domains, the literature review revealed two important insights with regard to health risks. First, short-term risks, i.e., consequences that are likely to set in early, can be considered distinct from long-term risks that become manifest only at a later stage^[24]. Second, the distinction between personal and general risk, i.e., the perceived risk for the individual user of the product (i.e., “what does it mean for me personally”) was distinct from the perceived risk for users in general (i.e., “what does it mean for users in general”) ^[25].

2.2 Focus groups

Thematic analysis of the focus group transcripts identified over all focus group sessions, 809 thematic endorsements across 88 concepts that were grouped into

Table 3 Domains and concepts associated to perceived risks-literature review.

Health	Social	Financial	Time-related
Accelerates aging ^[9]	Bad impression ^[12, 26]	Borrow money to buy cigarettes ^[27]	Being late for class because of smoking ^[27]
Addiction ^[9, 26-31]	Damage reputation ^[26]	Never having any extra money ^[27]	Losing studying time by stopping to have a cigarette ^[26]
Bad colds ^[28-29, 32]	Friends don't like it/get upset ^[12, 28]	Spending a lot of money on cigarettes ^[26]	Wasting a large portion of the day smoking ^[27]
Cancer ^[9, 12, 23, 25-30, 32-41]	Get into trouble ^[28, 32, 42]	Starting accidental fires ^[27]	Wasting a lot of time by having to go outside to smoke ^[27]
Causes cough ^[10, 13, 29, 32, 42]	Irritating/Annoying others ^[27]	Wasting money that could be used for something else ^[27]	
Dependence ^[10]	Less attractive ^[12-13]		
Emphysema ^[27, 34, 38]	Look ridiculous ^[12-13]		
Heart disease, heart attack ^[9, 12, 26-27, 29, 32, 34, 36, 38]	Negative family view ^[26]		
Irritates mouth/throat ^[12]	Negative social impression, negative view from others ^[12]		
Make lungs hurt ^[13]			
Mortality/Premature mortality, die from a smoking-related disease ^[9, 29]	People think less of me if they see me smoking ^[26]		
Physical side effects (e.g., weight gain, breathlessness) ^[9]			
Quality of life ^[31]			
Reduce physical fitness ^[27]			
Shortness of breath, trouble catching breath ^[9, 28-29, 32]			
Smell like an ashtray ^[28-29, 32, 42]			
Smokers are sick more often ^[9]			
Smoking/other drug use ^[9, 26]			
Stroke ^[26]			
Wrinkles on face ^[28-29, 32, 42]			

four thematic clusters: health risks (33 concepts); addiction risks (11 concepts), social risks (24 concepts); and personal risks (20 concepts) (Table 4). For simplicity, health risks to others were analyzed within the health risks domain as all mentions of health risks to others concerned second hand smoke. Concept saturation was reached for health, addiction, social and personal risks after the 10th, 4th, 10th and 9th focus groups session, respectively. Overall, the highest number of risk endorsements were reported by current smokers (225 and 244 endorsements for smokers with and without intention to quit, respectively) compared to former smokers (172 endorsements) and never smokers (168 endorsements), this being particularly true for addiction risks. A greater number of risks were cited for cigarettes than for NRT or e-cigarettes across all domains, although several exceptions were noted, including an increased frequency of skin reaction/irritation (health domain) and misuse/overuse risks (addiction domain) with NRT compared to cigarettes.

2.2.1 Health risks

The domain of health risk contained the greatest number of themes and specific concepts. Risks associated with different forms of cancer (4 concepts, 27 endorsements), cardiac disease (3 concepts, 24 endorsements), and respiratory disease (6 concepts, 38 endorsements) were commonly mentioned. Less serious forms of health risk, such as problems associated with skin aging (3 concepts, 27 endorsements), and general health concerns, such as decay and loss of teeth or gum disease (25 endorsements), were also frequently mentioned. Interestingly, unknown risks were also commonly mentioned (3 concepts, 35 endorsements).

2.2.2 Addiction risks

Participants provided 108 endorsements associated with addiction risk. Six concepts (obtaining 58 endorsements) concerned the addiction concept of being “a slave” to the product or having “no control” of product use. The mood-altering properties of using the various products (e.g., anxiety arising when use of the product is not allowed) obtained 29 endorsement (4 concepts). The concept of misuse or overuse of the product was associated with 17 endorsements.

2.2.3 Social risks

Major themes of the social risk domain consisted of bad appearances or impressions (5 concepts, 54 endorsements), social alienation (6 concepts, 61 endorsements), and negative social perceptions (3 concepts, 69 endorsements). One of the key elements of social alienation was “social isolation”, including

missing out on social events because one smokes. Increased problems with relationships and becoming a burden on one’s family were also aspects of social alienation. Negative self-perception (5 concepts, 44 endorsements) and use in restricted situations (5 concepts, 45 endorsements) were also expressed as important themes of social risks.

2.2.4 Personal risks

Major themes of the personal risk domain consisted of material risks (6 concepts, 51 endorsements), financial risks (5 concepts, 84 endorsements), and other risks associated to specific products (9 concepts, 53 endorsements).

2.3 Expert opinions

2.3.1 Open elicitation

More than 60 specific content themes were discussed by the experts during the open elicitation (Table 5).

2.3.2 Review of findings from literature review and focus groups

The conclusions of the panel meeting widely supported the literature review and the input from focus groups. The expert view provided two additional insights. First, the experts emphasized the role of health risks to others, albeit as part of the physical (health) risk domain. Second, they suggested framing perceived addiction risk as a separate theme in association with emotional risks.

Of particular note, the domain of physical aspects suggested by the experts corresponded with the health domain recognized in the literature and corroborated by the focus groups. Regarding perceived addiction risk, the experts strongly suggested its distinction from physical health risks. Thus, perceived addiction risk was specified as a separate domain. In addition, health aspects related to adverse consequences to third parties was deemed to be separate from self-harm. Convergence was noticed for the domain of social risk from all three sources of input considered. The aspects of time and financial resources, considered minor compared to health or social risks, were merged following expert advice into one global domain termed practical risk which encompasses both the financial and time-related burden of using tobacco products.

Some concepts, such as anxiety and stress, under the umbrella of emotional risk as suggested by the experts, were, on closer scrutiny, more closely associated with the domain of perceived addiction risk and re-categorized accordingly. Other aspects of emotional risk, such as *coping ability* and *anticipation of relief from*

Table 4 Domains, themes and concepts associated to perceived risks – focus groups.

Health	Addiction	Social	Personal
Cancer risks (27)	Symptoms (58)	Bad impression (54)	Material risks (51)
Cancer risk	Nicotine withdrawal	Bad appearance	Stains to clothes, drapes, etc.
Lung cancer	Anxiety associated with quitting	Smell	Stains to self (e.g., teeth or hair)
Mouth cancer	Inability to stop or quit	Permeating odor	Possibility of fires or burns
Throat cancer	A slave, no control	Product visible (patch)	Burns to self (e.g., skin)
Cardiac risks (24)	Uncontrollable cravings	Hide from others	Burns to clothes, house, etc.
Cardiac risk	Constant thoughts of use	Social alienation (61)	Burn public property or land
Heart attack	Mood-altering properties (29)	Social isolation	
Heart disease	Mood change	Less chance of finding work	
Respiratory risks (38)	Anxious with using	Problems with relationships	
Respiratory risks	Depressed mood not using	Increased family burden	
Breathing difficulties	Irritable when not using		
Allergic react - respiratory	Misuse or overuse (17)	Negative social perception (69)	Financial risks (84)
Emphysema		Negative social perception	General costs
COPD		Social stigma	Higher insurance costs
Asthma		Negative reaction when e-cigarette appears like CC	Product cost
General risks (32)			Indirect costs
General health concerns		Restricted use (45)	Reduced work productivity
Reduced stamina		Loss or lack of freedom to use	
Decreased concentration		Environmentally unfriendly	Other risks (53)
General health risk of nicotine		Setting a bad example	Loss or waste of time
		Social annoyance	Unhygienic
		Having to change behavior	Inconvenient
Skin risks (27)		Negative self-perception (44)	False sense of safety
Skin health		Feeling self-conscious	Risky product seems cool
Skin reaction or irritation		Feeling foolish for a risky habit	Provides false sense of satisfaction
Premature aging/wrinkling		Feel inferior	Ineffective as aid to quit
		Social misfit	Loss hand-mouth behavior
Premature death (7)		Feel guilt	Lead you to smoke a cigarette
Reproduction risks (10)			
Risk to pregnancy			
Sexual dysfunction			
Unknown risks (35)			
Unknown health risks			
Unknown risk of chemicals			
Unknown risks of use			
Other unknown health risks			
Health concerns (25)			
Decay and loss of teeth			
Gum disease			
Immune system deficiency			
Loss of taste			
Loss of appetite			
Vivid dreams/nightmares			
Health risks to others (19)			

Themes related to each risk domain are presented along with their specific concepts when appropriate. For each theme, the number of endorsements is presented in brackets.

Table 5 Domains and concepts associated to perceived risks – expert opinions.

Physical	Social	Emotional	Addiction	Practical
Withdrawal symptoms	Praise (for use	Stress	Craving	Time
Earlier death	toward quitting)	Boredom	Difficulty quitting	Loss of time while
Breathing issues	Pressure to quit	Anxiety	Lower self-esteem	using the product
Infertility	Being part of a group	Perceived harm	Feeling dependent on	Loss of time going to
Low birth weight/ Down Syndrome	Second-hand smoke	Anticipation of relief from negative	product	buy the product
Heart attack, stroke, cardiac effects	Self-identity (part of person's social life as part of a group)	emotions	Financial burden of buying product if addicted	Time to complete the act
Asthma	Self-image (giving bad impression	Something to do with your hands	Anger, depression, loss of control,	Time to charge device
Smoker's cough	to others)	Mood modulation	irritability, distress	Financial
Cancer	Stigma		Lower mood	Replacement of
Risks of accidents/ fire/burns to smoker and property	Feeling judged		Withdrawal	property from smoke
Effects in far distance for young users	Social exclusion/ rejection		symptoms	or fire damage
Lung-related problems	Lower self-esteem		Self-identity as "not in control"	Cost of product
Aesthetic decrements: skin/teeth coloration, and facial wrinkles	Role-modeling negative behavior (one's children smoking)		Lack of self-efficacy	Cost (money spent better in other ways)
Sexual performance	Smelling badly (like an ashtray)		Loss of control	Cost (affordability of product)
Blood pressure	Social consequence			
Fear of unknown (not knowing long-term consequences)	(fire that affects others or others' property)			
Bad breath	Social image (not fitting in with group)			
Sensation	Social consequences			
Loss of sense of smell acuity	of having bad breath			
Loss of sense of taste acuity	Social consequences of having clothes that smell			
Diminished ability to enjoy food	Negative effect on dating (looks bad)			

negative emotions, did not represent adverse consequences due to product use but to the contrary, due to the discontinued use of product. This was confirmed by focus groups data showing that respondents associated coping ability and anticipated relief from negative emotions as benefits of product use. These aspects were therefore excluded from the conceptual framework of perceived risks.

2.4 Generation of the conceptual framework

Given the broad agreement of the findings from the

literature review, the focus groups, and expert opinion (Table 6), a conceptual framework consisting of five domains was developed :

- *Perceived health risk to self*. The perceived negative risk (or impact) of product use to the user's physical health, going from minor immediate concrete manifestations of health risk (e.g. having poor gum health) to more serious long-term ones (e.g. having lung cancer);
- *Perceived addiction risk*. The perceived negative risk (or impact) that product use may have on the user's

Table 6 Development of the conceptual framework.

Literature review	Focus groups	Expert opinions	Conceptual framework
Health/addiction risk	Addiction risk	Addiction risk/Emotional risk	Addiction risk
	Health risk	Physical risk/Health risk to self	Health risk to self Health risk to others
	Social risk	Social risk	Social risk
Financial risk	Personal risk	Practical risk	Practical risk
Time risk			

sense of being addicted to using the product;

- *Perceived health risk to others.* The perceived negative risk (or impact) to the physical health of nonsmokers when being around during product use (not to be confused with the category of general risk, i.e., the risk of active use of tobacco products for active users in general);
- *Perceived social risk.* The perceived negative risk (or impact) that product use will affect interpersonal interactions adversely or how the user is perceived by others;
- *Perceived practical risk.* The perceived negative risk (or impact) that product use may have on the user’s time and finances.

3 Discussion

The importance of adequately measuring risk perception, when evaluating the effect of a new tobacco product on public health, reflects the wider issue of the need for rigorous and interpretable population-based and clinical research. This requires a full understanding of the key concepts in relation to the perceived risks associated with the use of tobacco and nicotine-containing products. In this paper, we used qualitative research to identify the key important domains of perceived risk, and proposed a new conceptual framework for risk perception associated with the use of tobacco and nicotine-containing products.

Based on the triangulation of the information gathered from the literature review, the focus groups, and the expert panel, we established the key domains of risk perception (i.e., perceived health risk to self, perceived health risk to others, perceived addiction risk, perceived social risk, and perceived practical risk) for the subpopulations with different smoking status (i.e., adult smokers with intention to quit, adult smokers with no intention to quit, adult former smokers, and adult never smokers) in relation to different tobacco and nicotine-containing products (i.e., cigarettes, potentially reduced risk products, NRT products). Thus, the present research findings fill an important gap, and while confirming the importance of health-related aspects of

risk perception, it extends the conceptualization to non-health-related issues, such as social stigmatization, financial burden, and wasting of time due to tobacco use.

The conceptual framework aims at specifying the most important aspects of the concept of interest in a given population. It can be used to guide the development of an assessment strategy. In instances where existing instruments are lacking, the conceptual framework also provides the necessary rationale for developing new instruments. As highlighted by the literature review we conducted, no suitable instrument currently exists that would allow the comparative assessment of different tobacco and nicotine-containing products by different subpopulations based on smoking status. Though, this is of key relevance in the recent regulatory context which requires a reliable and valid assessment of the impact of new products on use behavior among current users and nonusers of tobacco. The qualitative research we undertook may thus be considered for further investigation into the development of instruments that would be fit for purpose in this respect.

There are three main limitations to this research. First, the literature search was confined to publications from 2000 onwards. However, through reference follow-up via consultation of experts beyond the restrictions of the literature search, the evidence we gathered suggests that we have not omitted any relevant peer reviewed published research. Second, while the main objective of developing a conceptual framework on perceived risks was fully achieved, its applicability might not extend to all possible combinations of smoking status groups and tobacco and nicotine-containing products. Specifically, the qualitative findings suggested that it is not meaningful to apply such a framework to never smokers for products they could never imagine using, such as NRT. Third, although we developed the conceptual framework on the basis of a variety of tobacco and nicotine-containing products, it was not possible to explore risk perceptions of all possible products. It thus remains to be investigated whether the conceptual framework would

be confirmed or expanded when considering other products such as smokeless tobacco products or heat-not-burn products.

Despite the limitations outlined above, overall the objectives of the qualitative research were met. We envisage that, by qualifying important aspects of perceived risks, the resulting conceptual framework will be able to support clinical and population-based studies by pinpointing the main domains of risk perception to be considered in an assessment study.

4 Conclusions

The goal of this research was to gain a deeper understanding of the key aspects of risks associated with the use of tobacco and nicotine-containing products. In terms of research prospects, the conceptual framework provides the basis to inform future research aiming at developing measurement instruments capturing all, or some, domains of perceived risk. A psychometrically valid instrument, implying the present conceptual framework being empirically confirmed and its measurement properties being satisfactory, would be particularly appropriate 1) to support clinical and population-based studies and 2) to allow comparison of data across subpopulations based on smoking status, different tobacco and nicotine-containing products, and potentially different countries.

List of Abbreviation

ABS scale: Attitudes and Beliefs about the Consequences of Smoking Scale; FDA: Food Drug Administration; ICF: informed consent form; IRB: international review board; KOL: key opinion leader; MRTP: modified risk tobacco product; NRT: nicotine replacement therapy; TCQ: tobacco craving questionnaire; SD: standard deviation; USA: United State of America.

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