PERCEIVED RISKS SCALE ON USE OF TOBACCO AND NICOTINE-CONTAINING PRODUCTS: QUALITATIVE RESEARCH FINDINGS

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Introduction

New forms of tobacco products (TPs) or nicotine-containing products (NCPs) are currently being developed with the intention to reduce tobacco-related morbidity and mortality. To understand how consumers perceive the risks of using such products, psychometric scale development was undertaken, as currently no validated instruments are available for that purpose.

Objective

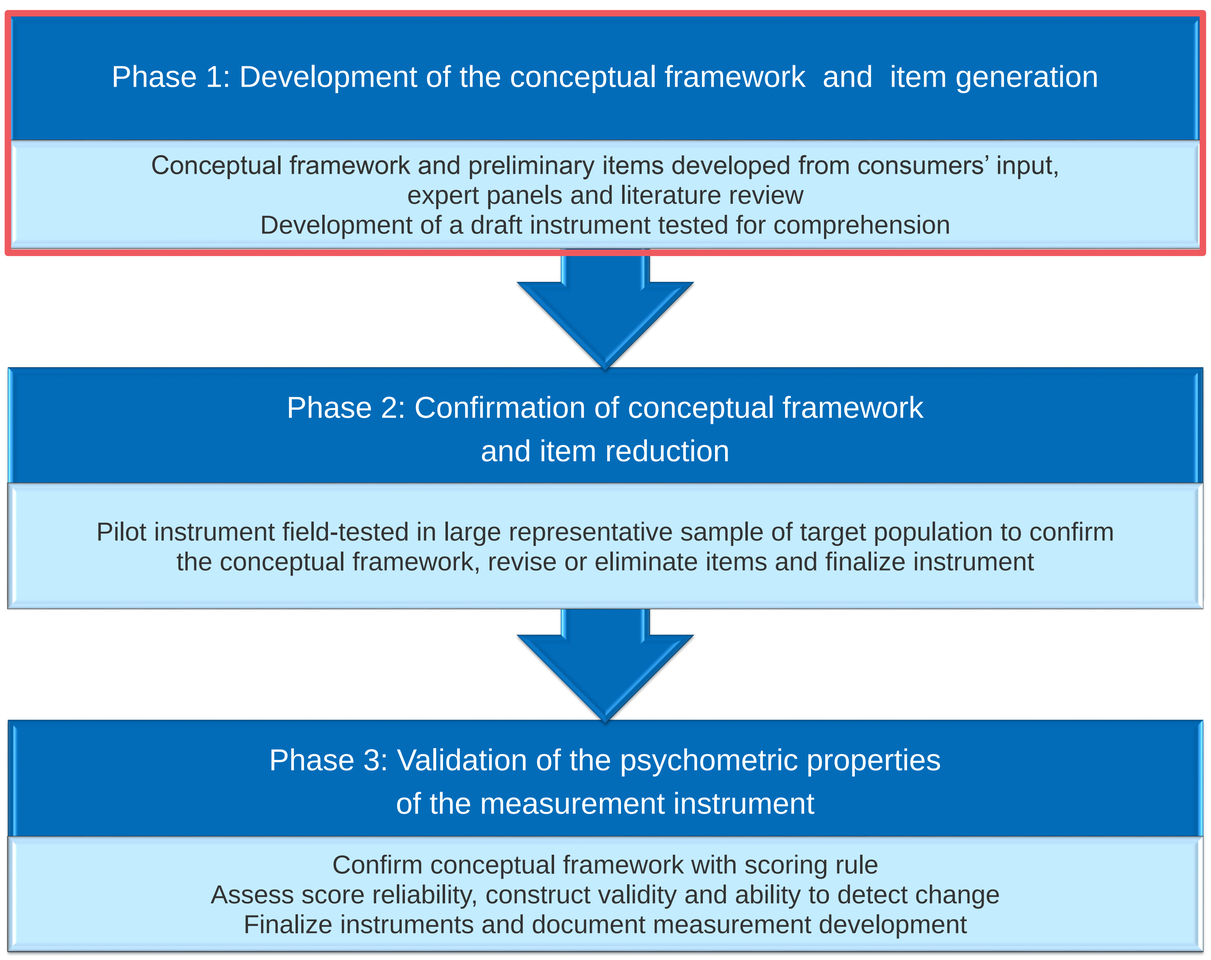
To develop and validate a measurement instrument (potentially consisting of multiple scales) that allows for measuring the levels of perceived risks associated with the use of tobacco-related products and provides measures that are comparable across:

- different subpopulations such as adult smokers of Conventional Cigarettes (CC) with no intention to quit; adult smokers with the intention to quit; adult former smokers; and adult never smokers
- different TPs and NCPs
- national and cultural boundaries

Methods

A three-phase methodology (see Figure 1) was used to adhere to good practice guidelines for the development and validation of self-report instruments in quality of life health-related research (Food and Drug Administration, 2009). Qualitative Research conducted in US consumers was approved by the New England Institutional Review Board.

Figure 1. Development of the Perceived Risk Instrument: A three-phase iterative process



Phase 1-Conceptual framework and item generation

- **Literature review:** to identify existing instruments and published studies on risk perception associated with the use of TPs and NCPs
  - Search strategy in MEDLINE and EMBASE: 20 articles published in English between Jan. 2000 and Sept. 2012 based on combination of keywords
  - Additional articles identified by experts
- **Expert panels:** to provide input on key documents and deliverables and assist in the consensus building process for the development of the instrument
- **Qualitative research:** to ascertain concept elicitation from the target population
  - 29 focus groups conducted in Italy, Japan, UK and US (demographics summarized in Table 1) to achieve a global diversity.
  - Saturation grids computed to ensure completeness of the concepts expressed during the focus groups
  - Transcripts coded and findings developed into conceptual framework of important concepts of risk perception in smokers and non-smokers
- **Cognitive Debriefing Interviews:** to confirm content validity and ensure comprehensibility of instructions, items and response options of the instrument
  - 98 interviews (40 UK-based and 48 US-based) with consumers representative of the four sub-populations
  - Item tracking matrix computed to document modifications to the instrument

Results

- Literature review provided evidence that there is no consensus on the conceptualization of perceived risks nor a validated instrument to measure risk perception of different tobacco-related products.
- Analysis of the Focus Groups results identified 88 concepts that were grouped in three main thematic clusters (Table 2).

Table 1. Focus Group Participants Demographics

Characteristics	UK[a] n = 72	Italy[b] n = 32	Japan[c] n = 32	US[d] n = 93	Total n = 229
Age					
Mean (SD)	40.4 (11.1)	44.5 (11.6)	29.2 (9.4)	40.7 (13.8)	39.7 (12.7)
18–25 years, n	4	3	18	9	34
26–50 years, n	48	19	13	56	136
51–65 years, n	20	10	1	28	59
Gender, n					
Female	40	16	8	45	109
Male	32	16	24	48	120
Education level, n					
High school and below	44	6	8	10	68
Some college and beyond	25	10	24	83	142
Other	3	16	-	-	19
Smoking status, n					
Smokers with intention to quit	-	8	8	23	39
Smokers with no intention to quit	24	8	15	24	71
Former smokers	24	8	7	23	62
Never smokers	24	8	2	23	57

[a] Nine focus groups conducted in London, Birmingham, Glasgow
[b] Four focus groups conducted in Rome
[c] Four focus groups conducted in Tokyo
[d] Twelve focus groups conducted in Atlanta, Los Angeles and Philadelphia

Table 2. Thematic Clusters Across All Focus Groups

Thematic Clusters	Broad definition and examples	Total Number of Occurrences UK (n = 72)	Italy (n = 32)	Japan (n = 32)	US (n = 93)	Total (n = 229)
Health Risks	Any reference to general or specific risks to healthy function or illness, including any physical harm to the body, and addiction	263	99	69	329	760
Societal and Social Risks	Any adverse experience in social settings or reaction from people associated with smoking, including harm from or to others, smell and unfavorable social appearance/reaction	232	72	65	292	661
Personal Risks	This includes risk to personal material, financial risks or other personal risks of product use; including property damage, expenses as well as uncertainty unknown risks or that the product would not meet users expectations, product unavailability	133	55	77	188	453

- Expert input helped to refine and finalize the generation of the conceptual framework as illustrated in Figure 2 based on preliminary concepts identified through literature and focus groups.

Figure 2. Preliminary conceptual framework derived from literature, expert input and qualitative focus groups analysis.

- 5 scales were developed to include the items that best represented the elements of each of the 5 domains underlying the conceptual framework.
- Cognitive Debriefing Interviews confirmed content validity and helped to identify minor issues with instructions, response options and items for each of the five domains.

Summary and Conclusion

- Since currently neither a consensus on the conceptualization of perceived risks nor a validated instrument exist for new TPs, the present development fills an important gap.
- The qualitative research findings extend previous conceptualizations of risk perception of products that contain tobacco and/or nicotine, especially on relevant non-health-related issues that potentially influence smoking behavior.
- This approach was designed to adhere to best research practices and follow current FDA guidance for Patient Related Outcome (PRO) instrument development and validation to generate evidence from a range of qualitative research.
- The instrument is currently being field-tested quantitatively (phase 2) in order to validate the conceptual framework and to ensure the validity of the instrument based on state of the art psychometric methods.

References

Food and Drug Administration. Guidance for Industry - Patient-Reported Outcome Measures: Use in Medical Product Development to Support Labeling Claims. 2009.

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