DEVELOPMENT OF A NEW INSTRUMENT TO MEASURE PERCEIVED RISKS ASSOCIATED WITH THE USE OF TOBACCO AND NICOTINE-CONTAINING PRODUCTS

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Introduction

Tobacco products and nicotine-containing products (NCPs) are being developed with the intention to reduce tobacco-related morbidity and mortality. In their Draft Guidance, the Food and Drug Administration (FDA) highlights the importance of measuring the perceived risks of using these Modified Risk Tobacco Products (MRTPs).

To understand how consumers perceive the risks associated with using such products, psychometric scale development was undertaken by Philip Morris International, as currently no validated instruments are available for that purpose.

Objectives

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

- Different sub-populations such as adult smokers of combustible cigarettes (CC) with no intention to quit; adult smokers with the intention to quit; adult former smokers; and adult never smokers
- Different tobacco products and NCPs
- National and cultural boundaries

Methods

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

Phase 1: Development of Conceptual Framework & Item Generation

- Develop conceptual framework and preliminary items from consumers' input, expert panels and literature review
- Develop draft instrument and test for comprehension

Phase 2: Confirmation of Conceptual Framework & Item Reduction

- Pilot instrument field-tested in large representative sample of target population to confirm the conceptual framework
- Revise or eliminate items and finalize instrument

Phase 3: Psychometric Validation of the Instrument

- Confirm conceptual framework with scoring rule
- Assess score reliability, construct validity and ability to detect change
- Finalize instruments and document measurement development

Phase 1: Development of Conceptual Framework & Item Generation

Literature Review: to identify existing instruments and published studies on risk perception associated with the use of tobacco products and NCPs

- Search strategy in MEDLINE and EMBASE: 20 articles published in English (Jan 2000 to Sep 2012) based on a combination of keywords
- Additional articles identified by experts and references

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 presented below) 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 representing four identified 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 3 main thematic clusters: "Health Risks", "Societal and Social Risks", and "Personal Risk".

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)
Age Group, n	18–25 years	4	3	18	9	34
	26–50 years	48	19	13	56	136
	51–65 years	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 (London, Birmingham, Glasgow)
[b] Four focus groups (Rome)
[c] Four focus groups (Tokyo)
[d] Twelve focus groups (Atlanta, Los Angeles, Philadelphia)

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	Reference to general or specific risks to healthy function or illness, including physical harm to the body, and addiction	263	99	69	329	760
Societal and Social Risks	Adverse experiences 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	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

Conceptual Framework - derived from literature, expert input and qualitative focus groups

Health Risk to Self | Health Risk to Others | Addiction Risk | Social Risk | Practical Risk

- 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.

Conclusions

- Currently neither a consensus on the conceptualization of risk perception nor a validated instrument exists to assess perceived risk of new tobacco products, this development fills an important gap.
- The psychometric validation of the Perceived Risk Instrument (PRI) is currently ongoing and the first field testing of the pilot instrument has allowed to refine the conceptual framework around the three health-related perceived risks and to reduce the number of items (Phase 2).
- A second quantitative study will provide the final psychometric assessment of the PRI to ensure the reliability and validity of the instrument and its cultural adaptability based on state of the art psychometric methods (Phase 3).

SRNT – Europe
Santiago de Compostela, Spain
18-20 September 2014

REFERENCES

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COMPETING FINANCIAL INTERESTS

The research described in this poster was financially supported by Philip Morris International

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