THE PERCEIVED RISK INSTRUMENT (PRI) TO MEASURE PERCEIVED RISKS ASSOCIATED WITH THE USE OF NICOTINE AND TOBACCO PRODUCTS

Christelle Chrea[1], Gerard Emilien[1], Thomas Salzberger[2], Stefan Cano[3], Thomas Alfieri[4], Nelly Mainy[1], Antonio Ramazzotti[5], Rolf Weitkunat[1], Frank Lüdicke[1]

[1] Philip Morris International Research & Development, Neuchâtel, Switzerland; [2] University of Economics and Business, Vienna, Austria; [3] ScaleReport, Stotfold, UK; [4] Covance Market Access Inc, San Diego, USA; [5] Philip Morris International Management SA Market Research & Innovation, Lausanne, Switzerland

Introduction and Objectives

In their Draft Guidance, the US Food and Drug Administration (FDA) highlights the importance of measuring the perceived risks of Modified Risk Tobacco Products (MRTPs) compared to existing tobacco products and cessation aids.

There is a need for a consensus on the conceptualization of perceived risks and for the development of validated instruments to measure perceived risks associated with the use of nicotine and tobacco products.

The objectives of the studies reported here are to develop and validate a psychometric instrument (potentially consisting of multiple scales) that quantifies the levels of perceived risks associated with the use of nicotine and tobacco 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 nicotine containing products
- National and cultural boundaries

Methods

A three-phase approach was used in line with the guidelines for the development and validation of self-report instruments (FDA, 2009)

Phase 1: Development of Conceptual Framework & Item Generation

- Develop conceptual framework based on consumer inputs, expert panels and scientific literature
- Develop draft instrument and test for comprehension
  - → Literature review on risk perception and available instruments
  - → 29 focus groups, run in 4 countries (UK, US, Italy and Japan)
  - → 1 KOL meeting and 15 workshops with experts for instrument development
  - → 98 Cognitive Debriefing Interviews (CDIs) conducted in the UK and the US to test comprehension, and 20 CDIs conducted in Italy and Japan for linguistic validation of translated versions

Phase 2: Item Reduction and Scale Formation

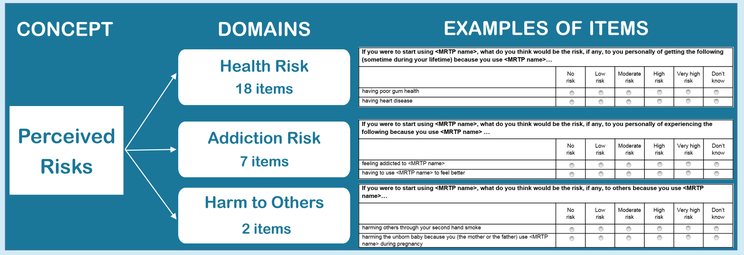
- Field-test pilot instrument in large representative sample of target population to confirm the conceptual framework
- Revise or eliminate items and finalize instrument
  - → Cross-sectional web-survey conducted among 2020 respondents from the US population
  - → Psychometric analyses to identify items that best perform as a scale for different sub-populations and different tobacco products
  - → Identification of items that have the ability to discriminate between products

Phase 3: Final Psychometric Validation of the Instrument

- Confirm conceptual framework with scoring rule
- Assess score reliability, construct validity and ability to detect differences
- Finalize instruments and document measurement development
  - → Cross-sectional web-survey conducted among 1640 respondents from the US population
  - → Psychometric analyses to define final scales, scoring rule
  - → Final documentation of the instrument (User Manual)

Results

- The PRI includes three main domains: *Health Risk*, *Addiction Risk* and *Harm to Others*. Independent uni-dimensional scales (18-item *Health Risk* scale and 7-item *Addiction Risk* scale) were constructed for two of the identified domains, complemented by two global items assessing perceived *Harm to others*
- The *Health Risk* scale and the *Addiction Risk* scale fulfilled Rasch and traditional psychometric criteria (including targeting [86% and 77% of person measurements covered, respectively], reliability [person separation index 0.97 to 0.94; Cronbach's alpha 0.99 to 0.98, respectively] and comparability across different tobacco products and different sub-populations [Differential Item Functioning (DIF) p>0.05])
- For each of the independent scales (*Health Risk* and *Addiction Risk*), a scoring table was derived, converting unweighted sum scores into linear measures in the original Rasch logit metric as well as in a transformed 0-to-100 scale
- A summary measure is provided for each independent scale and raw scores on the two global items, but no overall or total PRI score



Conclusions

- The PRI fills an important methodological gap and provides a psychometric instrument for measuring and comparing the perceived risks of nicotine and tobacco products
- The PRI takes into account the personal smoking history of the respondent. The wording of the items can also be adapted for specific nicotine or tobacco products
- By quantifying important aspects of perceived risk, the PRI can support clinical and population-based studies and evidence-based product assessments
- Final psychometric validation of the PRI is currently ongoing to assess its cross-cultural applicability

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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