The need for valid methods to measure consumer responses to new tobacco products has been widely acknowledged [1]. Philip Morris International undertook the development of a new self-reported psychometric instrument, the Perceived Risk Instrument (PRI), that aims at quantifying perceived risks of various types of tobacco and nicotine-containing products in adult smokers and adult non-smokers. Initial items were constructed on the basis of a literature review, consumer focus groups and expert opinions [2]. This contribution reports the findings on the two-stage field-testing of the instrument. Stage 1 focused on scale formation and Stage 2 on the full psychometric evaluation and cross-cultural comparability of the PRI.

### Methods

#### Study Design and Participants

Cross-sectional, population-based internet surveys (US for Stage 1 and US, Italy and Japan for Stage 2) were conducted with stratified sampling of four subpopulations (current smokers with and without intention to quit smoking; former smokers and never smokers).

2020 US participants (aged 18-68 years) completed Stage 1 and 4984 participants completed Stage 2 (US N=1640, aged 18-92 years; Italy N=1623, aged 18-76 years; Japan N=1618, aged 20-81 years).

#### Measures

The Pilot PRI in Stage 1 and its reduced version in Stage 2 (based on Stage 1 findings) were administered to participants for conventional cigarettes; THS 2.2, a heat-not-burn tobacco product; nicotine replacement therapy products; e-cigarettes (only in Stage 2) and cessation (having quit smoking successfully).

Five items on short-term and long-term consequences of smoking (STLCs) [3], and two visual analog scales (VAS) on overall health and addiction risks, were administered as convergent measures.

Psychometric assessment was based on Classical Test Theory (CTT) and Rasch Measurement Theory (RMT).

### Results

#### Psychometric Evaluation of the PRI

CTT and RMT psychometric evaluation conducted in both stages supported the formation of an 18-item Perceived Health Risk scale and a 7-item Perceived Addiction Risk scale (Table 1):

- **Targeting:** Person measurements were well covered (75% to 87%).
- **Suitability:** Response option thresholds were correctly defined for all items (see Figure for Perceived Health Risk scale).
- **Item Fit:** Overall fit to the Rasch Model was good. All items had non-significant fit values.
- **Reliability:** Satisfactory person separation indices (≥-0.93), Cronbach’s alphas (≥0.98) and item-total correlations (0.88 to 0.95).
- **Item Invariance:** No differential item functioning (DIF) by smoking status, gender, age, and education, supporting the stability of item psychometric performance in these subgroups.
- **Scale Calibration:** Using US-based data (N=2020 + 1640), a conversion table was produced for each scale, which converts unweighted sum scores to logit measures, finally transformed to 0-100 scale.

In addition to the two unidimensional scales, two single items on Perceived Harm to Others (i.e., risk of secondhand smoke and risk for the unborn baby) were included in the final PRI.

#### Summary of PRI Psychometric Analysis

<table>
<thead>
<tr>
<th>PRI</th>
<th>Scale (2 items)</th>
<th>Stage 1</th>
<th>Distribution of Item thresholds (% coverage)</th>
<th>RMT Analysis</th>
<th>CTT Analysis</th>
<th>Person separation index</th>
<th>Item separation index</th>
<th>Person reliability</th>
<th>Item reliability</th>
<th>Vision separation index</th>
<th>0% item with significant DIF</th>
<th>0% item with significant α</th>
<th>CTT Analysis (Mean, Range)</th>
<th>RMT Analysis (Mean, Range)</th>
</tr>
</thead>
<tbody>
<tr>
<td></td>
<td>Health Risk (%)</td>
<td>1</td>
<td>89 100</td>
<td>0.93</td>
<td>0.98</td>
<td>0.99</td>
<td>0.99 (0.91-0.99)</td>
<td>0.99 (0.90-0.99)</td>
<td>0.99 (0.91-0.99)</td>
<td>0.99 (0.90-0.99)</td>
<td>0.95 (0.92-0.99)</td>
<td>0.94 (0.92-0.99)</td>
<td>0.95 (0.92-0.99)</td>
<td>0.94 (0.92-0.99)</td>
</tr>
<tr>
<td></td>
<td>Addiction Risk (%)</td>
<td>2</td>
<td>75 100</td>
<td>0.93</td>
<td>0.98</td>
<td>0.99</td>
<td>0.99 (0.91-0.99)</td>
<td>0.99 (0.90-0.99)</td>
<td>0.99 (0.91-0.99)</td>
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<td>0.94 (0.92-0.99)</td>
</tr>
</tbody>
</table>

#### Construct Validity of the PRI

Convergent Validity: Supported by moderate correlations with the two VAS (r=0.52 to 0.67) and with the five STLCs items (r=0.10 to 0.46).

Known Group Validity: Supported by significant PRI scale score differences (t-tests at α>0.05) in the expected direction (e.g., perceived risk of smoking was lower for current smokers than for never smokers).

#### Cultural Adaptation of the PRI

Cross-cultural comparability: Supported by (i) the satisfactory psychometric performance of the two PRI scales with the Italian and Japanese data and (ii) the absence of DIF by country.

### Conclusions

- The PRI is applicable for various types of tobacco and nicotine-containing products, and provides a comparable measurement between adult smokers and adult non-smokers.
- By quantifying important aspects of perceived risk, the PRI can support clinical and population-based studies and allow comparison of data across regions (see [4] for an application).
- Detailed information on the conditions to access and use the PRI is provided by the Mapi Research Trust (e-mail: PRD-information@mapi-trust.org).

### References


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**Final Psychometric Evaluation and Cultural Adaptation of the Perceived Risk Instrument (PRI) to Measure Perceived Risks Associated with the Use of Tobacco and Nicotine-Containing Products**

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**Results**

**Threshold Map for all Items of the Perceived Health Risk Scale**

The vertical axis shows the 18 items of the Perceived Health Risk scale. The upper x-axis (in logits ranging from 18 to 7) represents the perceived health risks construct assessed by the scale. The lower x-axis shows the corresponding 0–100 scale.

**Cultural Adaptation of the PRI**

Cross-cultural comparability: Supported by (i) the satisfactory psychometric performance of the two PRI scales with the Italian and Japanese data and (ii) the absence of DIF by country.