Assessing Consumer Responses to RRP: Experience at PMI in Developing Fit-for-Purpose Self-Report Instruments

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Introduction

Philip Morris International (PMI) develops Reduced Risk Products (RRP) that present, are likely to present, or have the potential to present less risk of harm to adult smokers who switch to these products versus continued smoking. To assess the full potential of RRPs for individual users and the population as a whole, PMI has implemented an assessment program in which consumer perception and behavior assessment are key components. In this context, valid and reliable self-report measures are needed to assess consumer perceptions and behaviors towards RRPs in comparison with other tobacco and nicotine products (TNPs). Although this need has been acknowledged for quite some time [1], the field of Tobacco Regulatory Research is still lacking scientifically designed, fit-for-purpose and consensus measures, mainly due to the lack of measurement best practices and specific guidelines that would facilitate standardization and comparison across studies. Here, we present the initiative undertaken by PMI to fill this gap, which resulted in the creation of the **ABOUT Toolbox** (**A**ssessment of **B**ehavioral **OU**tcomes related to **T**obacco and nicotine products). The Toolbox development is ongoing to provide new well-defined, psychometrically sound instruments for use in RRP assessment studies (Table 1).

Table 1. Information on the ABOUT Toolbox and access to the instruments

Instrument	Concepts of interest (# items)	Context of use	Target population	Information on accessibility
Perceived risks	Health risk (18) Addiction risk (7) Harm to others (2) Social and practical risk scales are currently under development	All TNPs + Cessation	Adult current, former, and never TNP users	Available in PROQOLID under Perceived Risk Instrument (PRI) eprovide.mapi-trust.org /instruments/perceiver-risk-instrument
Dependence	Loss of control over use of TNPs (urgency to use upon waking up compulsion to use, difficulty to cease using, need to function normally, priority of using over social responsibilities, automaticity of using, self awareness of dependence)	All TNPs	Single or poly-TNP users	Available in PROQOLID towards the end of 2018
Product Experience	Satisfaction (3) Psychological reward (5) Craving reduction (1) Aversion (2) Enjoyment of respiratory tract sensation (1)	All TNPs Different recall periods	Adult current TNP users	Available in PROQOLID towards the end of 2018
Health and functioning	Body structure and function Activity Participation Personal factors Environmental factors	All TNPs + Cessation	Adult current and former TNP users	
Use history	Initiation Cessation Intensity of current and past use	All TNPs	Adult current, former, and never TNP users	Available in PROQOLID under the Smoking Questionnaire (SQ) eprovide.mapi-trust.org/ instruments/smoking-questionnaire2

TNP — tobacco and nicotine product

Methods

to develop the ABOUT Toolbox

Best measurement practices

Several guidelines, including the U.S. Food and Drug Administration's "Guidance for Industry Patient-Reported Outcome Measures: Use in Medical Product Development to Support Labeling Claims" [2], have been used as the foundation for the creation of the ABOUT Toolbox initiative. The application of these best practices requires the use of mixed-methods research and state-of-the-art psychometric methods rooted in the Rasch measurement model (RMM) (see Figure 1).

This ascertains that the instruments that are part of the Toolbox are:

❶ Appropriate to capture the individual perspective and include relevant and meaningful domains (content validity).

❷ Applicable across a wide range of TNPs and suitable for a range of population groups (frame of reference).

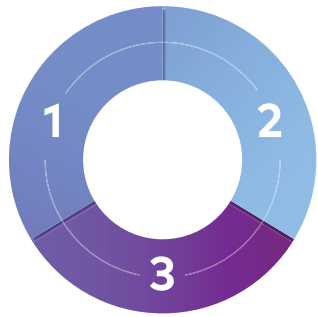
❸ Underpinned by an appropriate psychometric measurement model allowing straightforward interpretation of scoring.

❹ Applicable for clinical and population-based studies.

Figure 1. Iterative process for the development of an ABOUT instrument

Development of the conceptual framework and item generation

① Define concepts of interest, context of use and intended population
② Generate conceptual model based on literature review, qualitative study, expert opinion
③ Generate draft instrument with items best representing concepts of interest, appropriate response options, format, and recall period
④ Evaluate content validity with cognitive debriefing interviews



Confirmation of the conceptual framework and item reduction

① Identify items that best work together to form a scale and ensure items are well targeted
② Ensure response options work as intended
③ Ensure stability of the instrument across different population groups
④ Assess other measurement properties of the reduced-item instrument (construct validity, ability to detect change, score reliability)

Cross-validation of the psychometric properties, scoring rule and cultural adaptation

① Test cross-cultural equivalence (linguistic validation, psychometric properties, scoring)
② Finalize instrument (document content, formats, psychometric properties and scoring rule in a user manual)
③ Document instrument development and validation in publications
④ Make the instrument publically available

Generation of a conceptual framework

The development of each instrument starts with the generation of a conceptual framework, which is grounded in theory and supported by the triangulation of evidence data from literature reviews, consumer input, and expert opinions. This is done in close partnership with scientific experts from academic and commercial organizations with expertise in the fields of nicotine addiction, motivational aspects of consumer perception, and relevant areas on approaches to measurement (e.g., patient-reported outcomes, cross-cultural adaptation, psychometrics, and regulatory submissions). The role of the experts is to provide input and assist in the consensus-building process throughout the development of the instrument.

Cross-cultural equivalence of the ABOUT instruments

Cross-national stability of a measure is of key importance and is ensured for any ABOUT instrument by the rigorous linguistic validation process recommended by the International Society for Pharmacoeconomics and Outcomes Research [3] (Figure 2).

Appropriate access, use and translations of the validated instruments

The validated instruments included in the ABOUT Toolbox are made publicly available through PROQOLID web platform managed by Mapi Research Trust (eprovide.mapi-trust.org/about/about-proqolid).

Figure 2. Linguistic Validation process for an ABOUT instrument

Step	Participants	Process	Outcomes
1 Conceptual analysis of source questionnaire	① Coordinating center ② Author or original	Review of instructions, items and response options to clarify meaning and provide translation tips	List of concepts for harmonization of translations across countries
2 Forward translation	① Coordinating center ② In-country consultant ③ 2 translators	Development of 2 forward translations, discussion, reconciliation to create 1 forward translation out of the 2, and quality control	Target language version 1
3 Backward translation	① Coordinating center ② In-country consultant ③ Author or original ④ 1 translator	Development of 1 backward translation, comparison forward/backward, discussion, and quality control	Target language version 2
4 Test: Interviews and external review	① Coordinating center ② In-country consultant ③ Author or original ④ 6–10 subjects and 1 external reviewer	Analysis of interviews, discussion, and quality control	Target language version 3
5 Proofreading and finalization	① Coordinating center ② In-country consultant ③ 1 translator	Analysis, discussion, and quality control	Target language final version
D Final documents delivered to client	① Final target language version ② Linguistic validation certificate ③ Report		

Inventory

of the ABOUT Toolbox RRP Scenarios

The ABOUT Toolbox currently comprises five measurement instruments that are either already available or still under validation (Table 1). The initial inclusion of these current instruments was informed extensively by existing research and domains that have been prioritized based on public health impact and issues of key importance to tobacco regulatory research.

Advantages

of Using Instruments from the ABOUT Toolbox

❶ Developed and validated with state-of-the-science methods to be psychometrically sound, straightforward to implement in clinical and population-based studies, and easy to interpret

❷ Created to be relevant and applicable across the whole spectrum of TNPs and across various population groups

❸ Designed to enhance standardization and comparison of data on perception and behaviors towards RRPs across academic, industry and public health research communities

❹ Envisioning a rapidly expanding knowledge base with the goals of:

① informing further interpretation of consumer perception data comparing a large spectrum of TNPs

② enabling public health and regulatory communities to make better-informed decisions for future regulation of RRPs and enhance surveillance activities associated with smoking-related disease.

Our RRPs

Reduced-risk products ("RRPs") is the term we use to refer to products that present, are likely to present, or have the potential to present less risk of harm to smokers who switch to these products versus continued smoking. We have a range of RRPs in various stages of development, scientific assessment and commercialization. Because our RRPs do not burn tobacco, they produce an aerosol that contains far lower quantities of harmful and potentially harmful constituents than found in cigarette smoke.

Competing financial interest

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References

[1] Rees VW, Kreslake JM, Cummings KM, O'Connor RJ, Hatsukami DK, Parascandola M, Shields PG, Connolly GN: Assessing consumer responses to potential reduced-exposure tobacco products: a review of tobacco industry and independent research methods. Cancer Epidemiol Biomarkers Prev 2009, 18:3225-3240.

[2] FDA (Food and Drug Administration): Guidance for industry - Patient-reported outcome measures: use in medical product development to support labeling claims.2009.

[3] Wild D, Eremenco S, Mear I, Martin M, Houchin C, Gawlicki M, Hareendran A, Wiklund I, Chong LY, von Maltzahn R, et al: Multinational trials-recommendations on the translations required, approaches to using the same language in different countries, and the approaches to support pooling the data: the ISPOR Patient-Reported Outcomes Translation and Linguistic Validation Good Research Practices Task Force report. Value Health 2009, 12:430-440.

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