

Developing fit-for-purpose self-report instruments for assessing consumer responses to tobacco and nicotine products: the ABOUT™ Toolbox initiative

Chrea C¹, Spies E¹, Afolalu E¹, Mainy N¹, Gallot S¹, Binggeli P¹, Clerc E¹, Weitkunat R¹, Salzberger T², Cano S³, Acquadro C⁴, Arnould B⁴, Lambert J⁴, Brunel V⁴, Marcucilli C⁴, Abetz-Webb L⁵, Rose J⁶, Fagerström K⁷

¹Philip Morris International, Neuchâtel, Switzerland; ²University of Economics and Business, Vienna, Austria; ³ScaleReport, Ltd, Stotfold, UK; ⁴Mapi, an ICON plc Company, Lyon, France; ⁵Patient-Centered Outcomes Assessments, Ltd, Macclesfield Cheshire, UK; ⁶Rose Research Center, Raleigh, USA; ⁷K. Fagerström Consulting AB, Vaxholm, Sweden

Introduction

- Tobacco harm reduction is an approach recognized by the U.S. Food and Drug Administration (FDA) and others as part of a solution to more rapidly reduce the burden of preventable deaths and smoking-related diseases¹⁻⁴. In the U.S., this has given rise to a regulatory framework⁵ for manufacturers to market modified risk tobacco products (MRTPs), defined as "any tobacco product that is sold or distributed for use to reduce harm or the risk of tobacco-related disease associated with commercially marketed tobacco products." To implement this approach successfully, consistent, transparent, and evidence-based science on the reduced risk potential of alternative tobacco and nicotine products (TNPs) is paramount.
- In alignment with the FDA's draft guidance on MRTPs, consumer perception and behavior assessments are key components of assessing the full public health impact of tobacco harm reduction. Valid and reliable self-report measures are needed to assess consumer responses to MRTPs in comparison with other commercially available TNPs. Although this need has been acknowledged for quite some time⁶, 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.
- We present an ongoing collaborative effort to develop fit-for-purpose measurement instruments (i.e., concept-driven instruments providing interpretable outcomes for the purpose intended) to enhance the scientific framework of tobacco harm reduction. This new initiative has resulted in the creation of the ABOUT™ Toolbox (Assessment of Behavioral Outcomes related to Tobacco and nicotine products).
- The goals of this communication are:
 - To describe the methodological steps followed for the development and validation of the measurement instruments included in the ABOUT™ Toolbox; and
 - To present a summary of the high-priority tobacco-related domains that are currently covered in the ABOUT™ Toolbox.

Methods

The ABOUT™ Toolbox has been developed: 1) using Best Measurement Development Practices, and 2) as the manifest of an underpinning Behavioral Conceptual Model for Tobacco and Nicotine Products.

Best Measurement Development Practices

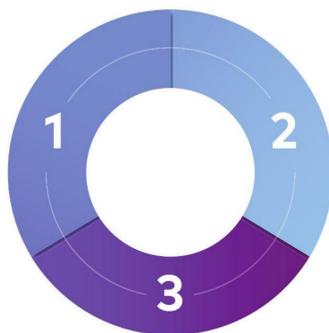
Several guidelines, including the FDA's "Guidance for Industry Patient-Reported Outcome Measures: Use in Medical Product Development to Support Labeling Claims,"⁷ have been used as the foundation for the creation of the ABOUT™ Toolbox initiative. The application of these best practices requires the use of mixed-methods research and state-of-the-art psychometric methods rooted in the Rasch measurement model⁸ (Figure 1).

- 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-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^{9,10} (Figure 2).

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

Development of the conceptual framework and item generation

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



Confirmation of the conceptual framework and item reduction

- Identify items that best work together to form a scale and ensure items are well targeted
- Ensure response options work as intended
- Ensure stability of the instrument across different population groups
- 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

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

Behavioral Conceptual Model for Tobacco and Nicotine Products

- This model encompasses several levels of assessment, i.e., individual, product and environment. Each of those levels includes several categories for which concepts/variables are defined. For instance, the individual level includes Individual Traits (e.g., dependence), Attitudes and Beliefs towards products (e.g., perceived-risk), Response to the Product (e.g., satisfaction), Self-Reported Product Behavior (e.g., consumption changes), and Functional Health and Quality of Life.
- The ABOUT™ Toolbox instruments are intended to be used within this conceptual model to measure the concepts of interest.

The developmental and conceptual approach ascertains that the instruments that are part of the Toolbox are:

- Appropriate to capture the individual perspective and include relevant and meaningful domains (content validity);
- Applicable across a wide range of TNPs and suitable for a range of population groups (frame of reference);
- Underpinned by an appropriate psychometric measurement model allowing straightforward interpretation of scoring;
- Applicable for clinical and population-based studies.

Appropriate Access, Use, and Translations of the Validated Instruments

The validated instruments included in the ABOUT™ Toolbox are made publicly available through the Patient-Reported Outcome and Quality of Life Instruments Database (PROQOLID™) web platform managed by Mapi Research Trust (eprovide.mapi-trust.org/about/about-proqolid).

References

- U.S. Department of Health and Human Services, National Center for Chronic Disease Prevention and Health Promotion, Office on Smoking and Health: The health consequences of smoking - 50 years of progress: a report of the Surgeon General; 2014.
- Zeller M et al. Tob Control. 2009;18(4):324-332.
- Institute of Medicine: Clearing the smoke - Assessing the science base for tobacco harm reduction. Washington, DC: The National Academies Press; 2001.
- World Health Organization: Monograph: advancing knowledge on regulating tobacco products. Geneva: World Health Organization; 2009.
- U.S. Department of Health and Human Services, Food and Drug Administration: Guidance for industry - Modified risk tobacco product applications - Draft Guidance; 2012.
- Rees VW et al. Cancer Epidemiol Biomarkers Prev. 2009;18(12):3225-3240.

Methods

Figure 2. Linguistic validation process for the development of an ABOUT™ instrument



Results

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.



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

Instrument	Concept of interest (# items)	Context of use	Target population	Accessibility/Publications
Perceived Risk	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 ABOUT™ - Perceived Risk at: eprovide.mapi-trust.org/instruments/about-perceived-risk-formally-perceived-risk-instrument-pri References: - Salzberger T et al. <i>Tobacco Science and Technology</i> . 2017;50(Suppl 1):32-42. - Cano S et al. <i>Health Qual Life Outcomes</i> . 2018 Sep 21;16(1):192.
Dependence	Time to first and last product use (2) Attitudinal evaluation (5) Behavioral evaluation (5)	All TNPs	Adult 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	Development initiated beginning of 2018
Use History	Initiation Cessation Intensity of current and past use	All TNPs	Adult current, former, and never TNP users	Available in PROQOLID™ under Smoking Questionnaire (SQ) eprovide.mapi-trust.org/instruments/smoking-questionnaire2 References: - Weitkunat R et al. <i>Contributions to Tobacco Research</i> . 2013;25(7):638-648. - Sponsiello-Wang Z et al. <i>Contributions to Tobacco Research</i> . 2017;27(8):224-239.

PROQOLID™: Patient-Reported Outcome and Quality of Life Instruments Database; TNP: Tobacco and nicotine product

Conclusions

- The current ABOUT™ Toolbox is comprised of a core set of measurement instruments that assess key domains associated with TNP use, including perceived risks, dependence, product experience, health and functioning, and use history.
- By making the ABOUT™ Toolbox available to the tobacco research and public health community, we envision a rapidly expanding knowledge base, aiming at:
 - Supporting consumer perception research to allow comparisons across a wide spectrum of TNPs,
 - Enabling public health and regulatory communities to make better-informed decisions for future regulation of TNPs, and
 - Enhancing surveillance activities associated with smoking-related disease.
- The ABOUT™ Toolbox launches a dialogue on new perspectives required to develop standards and best practices in the spirit of current guidance for self-reported measures and may facilitate the creation of a consortium to work on standard practices across the industry.

References (cont)

- U.S. Department of Health and Human Services, Food and Drug Administration. Guidance for industry - Patient-reported outcome measures: use in medical product development to support labeling claims; 2009.
- Andrich D: *Rasch models for measurement*. Beverly Hills: Sage Publications; 1988
- Wild et al. *Value Health*. 2005;8(2):94-104.
- Wild D et al. *Value Health*. 2009;12(4):430-440.