

OVERVIEW OF THE ABOUT™ — PERCEIVED RISK DEVELOPMENT AND EVOLUTION

CORESTA workshop, 29 September 2022

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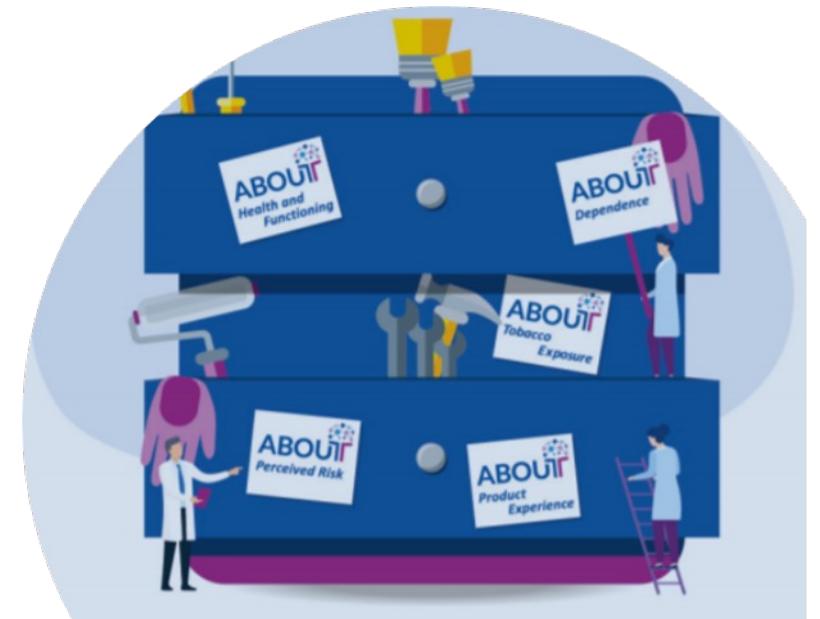


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The ABOUT™ Toolbox Initiative

- A portfolio of **consumer-reported outcome measures (CROM)** to support perception and behavior assessment related to the use of tobacco and nicotine products (TNPs)
- *Developed in collaboration* with scientific experts in the fields of measurement science, tobacco/nicotine research, and consumer perception
- By using best measurement and development practices, these measures are to be made fit-for-purpose to accurately assess both combustible and smoke-free TNPs
- Development and validation follows the FDA guidance on Patient-Reported Outcome measures (2009) and the MRTP draft guidance (2012)



The ABOUT™ – Perceived Risk

- **Measures respondents' perceptions of the risks associated with the use of a wide range of TNPs** (e.g., combustible products, e-vapor products, heated tobacco products, smokeless tobacco products) and Nicotine Replacement Therapy (NRT) products.
- Intended population: adult current, former, and never TNP users.
- Ensures stability of the measurement across:
 - Different TNPs
 - Different user status
 - Different cultural backgrounds and languages
- Cognitive orientation
 - Perceived risk for the individual respondent -> personal version
 - Perceived risk for the population in general -> general version

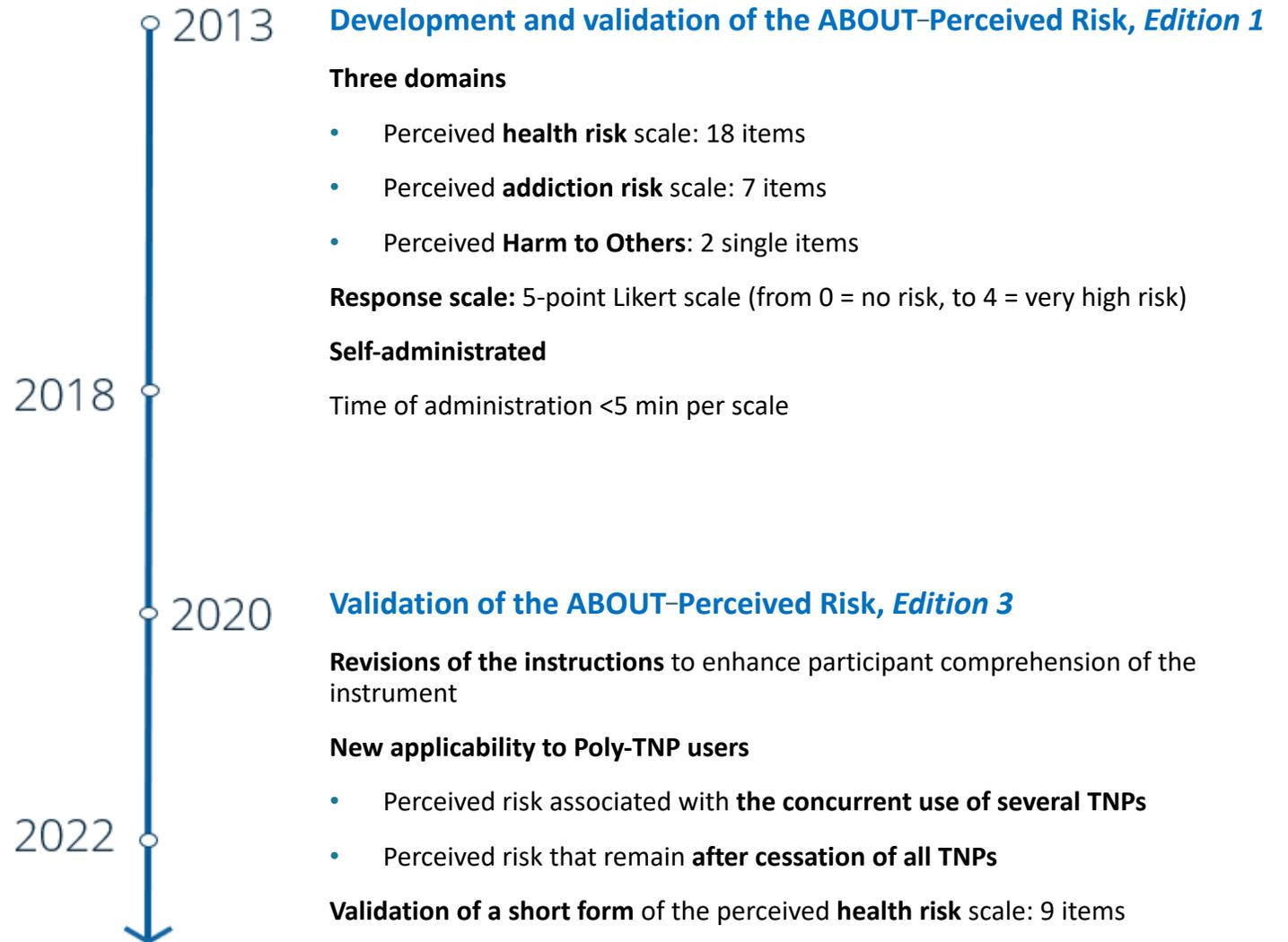


Development and Validation: An Overview

Validation of the ABOUT-Perceived Risk, *Edition 2*

Two additional domains

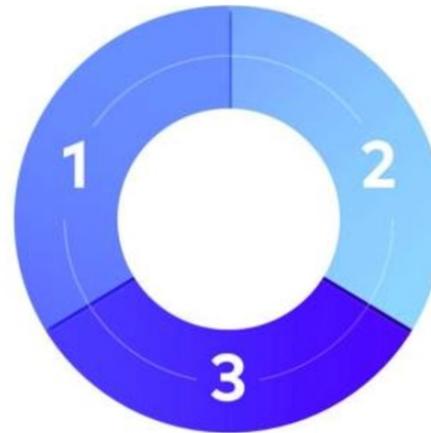
- Perceived **social risk** scale: 7 items
- Perceived **practical risk** scale: 6 items



Development of a CROM: An Iterative Process

Development of the conceptual framework and item generation

- ① Define concepts of interests, 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



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

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)



Development and Validation of the ABOUT–Perceived Risk, Edition 1

2013 – 2018

Phase 1: Development of Conceptual Framework & Item Generation

- **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
- **Cognitive Debriefing Interviews** in UK and US to test comprehension (**n = 98**), and in Italy and Japan for linguistic validation of translated versions (**n = 20**)

Phase 2: Scale Formation & Item Reduction

- **Cross-sectional web-survey** conducted among respondents from the US population (**n = 2020**)
- **Classical Test Theory and Rasch Model Measurement psychometric analyses** to identify items that best perform as a scale for different subpopulations and different tobacco products (**targeting, item fit, reliability, item invariance, construct validity**)

Phase 3: Final psychometric Validation of the Instrument

- **Cross-sectional web-survey** conducted among respondents from the US (**N = 1640**), Italy (**N=1623**), and Japan (**N= 1618**)
- **Classical Test Theory and Rasch Model analyses** to cross-validate results from the first survey, **calibrate final scales, establish the scoring rule, and confirm cross-cultural comparability** of the instrument



Salzberger, T., Chrea, C. C., Atkison, M., Emilien, G., Mainly, N., Ramazzotti, A., . . . Lüdicke, F. (2017). Perceived risks associated with the use of tobacco and nicotine-containing products: findings from qualitative research. *Tobacco Science & Technology*, 50(13), 32-42

Cano, S., Chrea, C., Salzberger, T. A., Emilien, G. M., Ramazzotti, A., Lüdicke, F., & Rolf, W. (2018). Development and validation of a new instrument to measure perceived risks associated with the use of tobacco and nicotine-containing products. *Health and Quality of Life Outcomes*, 16(1), 192-207.

Validation of the ABOUT-Perceived Risk, Edition 2

2018 – 2020

Expansion of Conceptual Framework & Item Generation

- Development of **conceptual framework and item generation for perceived Social risk and perceived Practical risk** domains was done as part of the initial instrument development (2013-2018), including **Cognitive Debriefing**. However, these were psychometrically untested.

Item reduction and measurement performance of the new scales

- **Cross-sectional web-survey** conducted among N = 2500 respondents from the US: “exclusive TNP users” n = **1250** and “poly-TNP users” n = **1250**
- **Classical Test Theory and Rasch Model analyses** to identify items that best perform as a scale for different subpopulations and different tobacco products (targeting, item fit, reliability, item invariance, construct validity)



Clerc, E., Salzberger, T., Cano, S., Afolalu, E. F., & Chrea, C. (2021). Psychometric Validation of New Scales for Expanding the Conceptual Coverage of ABOUT-Perceived Risk: Perceived Social Risk and Perceived Practical Risk [Conference presentation]. CORESTA SSPT 18-28 October 2021. Virtual Conference.

Validation of the ABOUT-Perceived Risk, Edition 3

2020 – 2022

Content validation of revised instructions and of versions applicable to poly-TNP users

- Several **workshops** with **PRO and psychometric validation experts** for the revision of instrument instructions, and the development of instructions applicable to poly-TNP users
- **Cognitive Debriefing Interviews** in the US (3 waves, n = 28) and in the UK (2 waves, n = 10) to test instrument comprehension.

Measurement performance of the revised instrument

- **Cross-sectional web-survey** conducted among n = 1336 respondents in the UK (current exclusive cigarette, heated tobacco products, e-cigarette users, current poly-TNP users, former poly-TNP users, and never TNP users)
- **Classical Test Theory and Rasch Model analyses** to confirm the psychometric performance of instrument in its revised version, of the perceived health risk short form (9-items), and of the versions applicable to poly-TNP users (targeting, item fit, reliability, item invariance, construct validity)



Overview of the ABOUT–Perceived Risk Measurement Performance

Scale	Rasch Person Separation Index	Cronbach's alpha	Test–retest	Differential item functioning (lack of invariance)	Local dependence (correlation >0.30)
Perceived health risk (18-item long form)	0.97*/#	0.99*/0.98#	-	None*/#	None*/Minimal#
Perceived health risk (9-item short form)	0.94#	0.95#	0.85#	None#	None#
Perceived addiction risk	0.94*/+	0.98*/0.97+	0.81#/0.80+	None*/+	None*/#/+
Perceived social risk	0.92#/0.90+	0.95#/0.96+	0.80#/0.74+	None#/+	None#/+
Perceived practical risk	0.82#/0.81+	0.87#/0.92+	0.77#/0.72+	Minimal#/None+	None#/+

* Psychometric Validation study for Edition 1

+ Psychometric Validation study for Edition 2

Psychometric Validation study for Edition 3



Conclusion

- The ABOUT-Perceived Risk **fills an important gap** by providing a validated psychometric CROM for measuring and comparing the perceived risk of tobacco-related products from *consumers' and non-consumers'* perspectives
- The CROM provides a **comparable measurement** for Personal/General risk; different TNP use status groups; various products; different cultural backgrounds
- Potential to support clinical and population-based studies and an evidence-based product assessment to meet regulatory requirements
- Part of an on-going process to keep the measurement instrument **fit-for-purpose** to different research purposes and to new TNP use behaviors
- The latest edition of the ABOUT-Perceived Risk and its user manual is made publicly available through MAPI Research Trust on the *E-provide platform*.

<https://eprovide.mapi-trust.org/instruments/about-perceived-risk-formally-perceived-risk-instrument-pri>

