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Translatability assessment and linguistic validation of the ABOUT™–Dependence instrument into German, Italian, Japanese, and Russian

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VIRTUAL ISOQOL 2020
2020 THE FUTURE IS NOW:
A Vision for the Future of Outcomes Measurement and Quality of Life Research

ABOUTToolbox
Assessment of Behavioral OUtcomes related to Tobacco and nicotine products

Background

✓ ABOUT–Perceived Risk	Measures respondents' perceptions of the individual and general risks associated with a range of tobacco and nicotine-containing products.
2019 ABOUT–Product Experience	Measures respondents' sensorial experience associated with a range of tobacco and nicotine-containing products.
In development (2021) ABOUT–Tobacco Exposure	Measures respondents' self-reported use of a range of tobacco and nicotine-containing products.
2019 ABOUT–Dependence	Measures respondents' perceived level of dependence associated with the use of a range of tobacco and nicotine-containing products.
In development (2021) ABOUT–Health & Functioning	Measures respondents' perception of health and functioning status associated with the use of a range of tobacco and nicotine-containing products.

Chrea, Acquadro, Afolalu et al. Developing fit-for-purpose self-report instruments for assessing consumer responses to tobacco and nicotine products: the ABOUT™ Toolbox initiative. F1000Research 2018, 7:1878 doi: 10.12688/f1000research.16810.1

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Assessment of Dependence

1978

Fagerström Test for Nicotine Dependence (FTND)

Created by chappara from Noun Project

2020

Assessment of perceived dependence a priority research area in evaluating the potential public health impact of reduced risk products (RRPs)* and to enable comprehensive assessment of the likelihood of initiation, maintenance, or persistence of use.

Created by Andrew Nielsen from Noun Project

Fagerström K. O. (1978). Measuring Degree of Physical Dependence to Tobacco Smoking with Reference to Individualization of Treatment. *Addictive behaviors*, *3*(3-4), 235–241. https://doi.org/10.1016/0306-4603(78)90024-2

Heatherton, T. F., Kozlowski, L. T., Frecker, R. C., & Fagerström, K. O. (1991). The Fagerström Test for Nicotine Dependence: a revision of the Fagerström Tolerance Questionnaire. *British Journal of Addiction*, *86*(9), 1119–1127. https://doi.org/10.1111/j.1360-0443.1991.tb01879.x

FDA (2012) Modified Risk Tobacco Product Applications Draft Guidance https://www.fda.gov/regulatory-information/search-fda-guidance-documents/modified-risk-tobacco-product-applications

Cigarette by chappara from the Noun Project

E-Cigarette by Andrew Nielsen from the Noun Project

*Reduced-risk products ("RRP") is the term Philip Morris International uses 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.

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ABOUT–Dependence Development Overview

Development of the conceptual model

- EMBASE literature review
- Expert panel (nicotine addiction experts, patient reported outcome experts, psychometricians)
- 11-item draft instrument

Qualitative research to assess content validity of draft instrument

- Interviews in Charlotte, North Carolina, USA
- N = 40 (20 single users and 20 poly users across different products)
- Concept elicitation interviews and cognitive debriefing of draft instrument

Expert consensus meeting and feedback from qualitative research

- Review of the conceptual model, modifications to wordings, removal of 3 items and addition of new 11 items
- Revised 19-item draft instrument

Psychometric validation

- Web survey in US adults (N = 2434); a subsection (n = 1421) for test–retest assessment
- Single and poly users across different products (cigarette, cigars/cigarillos, e-cigarettes, smokeless tobacco, pipe, waterpipe, NRTs)
- Psychometric assessment (Rasch measurement methods and classical test theory)

Final instrument in US English**:**
12 items and **3 domains**

- Extent of use (two items)
- Signs and symptoms (five items)
- Behavioral impact (five items)

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Translatability Assessment

- **Translatability Assessment (TA)** defined as “evaluation of the extent to which a measure can be meaningfully translated into another language”.

- **Objectives**:
  - Identify possible linguistic, conceptual, or cultural difficulties
  - Optimize source instrument for future conceptually and culturally appropriate translations

- **Process:**
  - Performed on a draft version of the instrument during the development stage
  - Preparation, review, recommendations, and documentation (report)
  - Recommendations implemented or considered for future translations

Acquadro et al. Translation and Cultural Adaptation Special Interest Group (TCA-SIG) (2017). Emerging good practices for Translatability Assessment (TA) of Patient-Reported Outcome (PRO) measures. Journal of patient-reported outcomes, 2(1), 8.

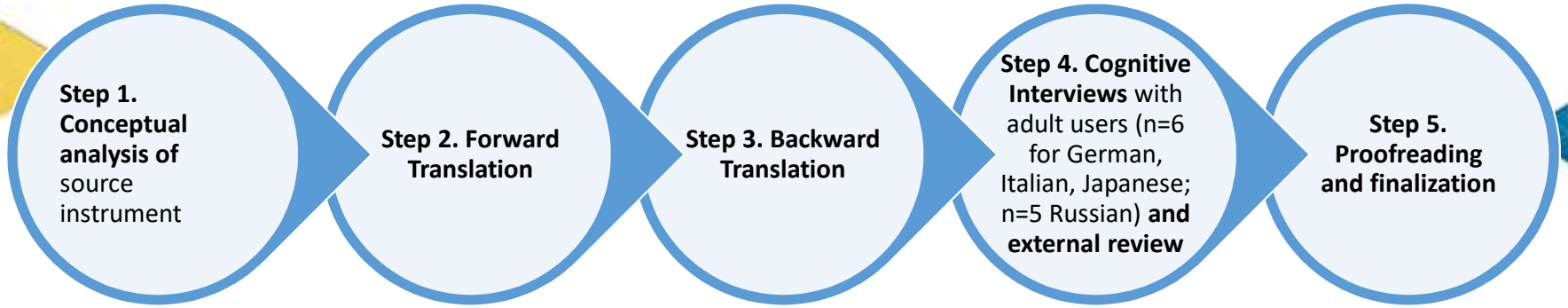
Translatability Assessment - Findings

- Instrument of reasonable length and likely to be **positively accepted** by respondents.

- A few cultural and linguistic issues identified:
  - *How much do you feel you need your product(s) to function "normally"* item: may need **explanation and/or alternative wording and qualifier** in Japanese and Italian to be properly translatable
  - **Interpretation of response scale** of some items (Not at all / A little / Moderately / Very much / Extremely)
  - **Syntactic length and presentation** of translated items

- Adjustments suggested to facilitate comprehension and the translation process.

Linguistic Validation



Translation issues across the 4 languages categorized as:

Cultural
Semantic
Syntactic
Idiomatic

Acquadro C., Jambon B., Ellis D. and Marquis P. Language and translation issues. In Spilker B, ed. Quality of Life and Pharmacoeconomics in Clinical Trials. Philadelphia: Lippincott-Raven Publishers, 1996: 575-585.
Linguistic Validation Manual for Health Outcomes Assessments. Acquadro C, Conway K, Giroudet C, Mear I. Second Edition - MAPI Institute, Lyon, France, January 2012 - ISBN: 2-9522021-0-9.
Wild D, Grove A, Martin M, et al.: Principles of Good Practice for the Translation and Cultural Adaptation Process for Patient-Reported Outcomes (PRO) Measures: report of the ISPOR Task Force for Translation and Cultural Adaptation. Value Health. 2005; 8(2): 94–104. DOI: 10.1111/j.1524-4733.2005.04054.x

Linguistic Validation – Findings

	Issues across all languages			
ABOUT-Dependence Items (*shortened/paraphrased*)	**Semantic**	**Syntactic**	**Idiomatic**	**Total issue with item**
1. On average how soon after woke up used first product	3	1	0	4
2. On average how long before going to sleep used last product	2	0	0	2
3. Need product(s) to function “normally”	0	0	3	3
4. Difficult to completely quit	0	0	0	0
5. Strong desire to use	0	0	0	0
6. Use more than intended	0	0	0	0
7. HAD to have one	0	1	1	2
8. Use in a situation not supposed to	1	0	0	1
9. Hard to control the need or urge to use	1	0	1	2
10. Sneak off to use	0	0	0	0
11. Avoid an activity because couldn’t use	1	0	0	1
12. Stop what doing to use	1	0	0	1
Total issues with items	**9**	**2**	**5**	**16**

Linguistic Validation – Findings

Item #1 and general issue: "Using" tobacco and/or nicotine products (TNPs)

- Semantic issues in *German and Italian*, the literal translation of "*use*" not contextually appropriate for TNPs; replaced by ***"consume"*** in multiple items.

Item #3 How much do you feel you need your product(s) to function "normally"

- Translation of idiomatic expression proved to be challenging
- Leveraged insights from translatability assessment findings
  - *[Italian]* How much…need product(s) to act "in a normal way"?
  - *[Japanese]* How much…need product(s) to carry out your daily living as usual
  - *[Russian]* ***How strong…***feeling that need product(s) to function "normally"

Item #7 How often did you feel that you "HAD to have one"?

- Modified to ***"I must use it"*** in *Japanese* to transfer the syntactic and idiomatic emphasis provided by the capital letters.

Linguistic Validation – Findings

Item #8 How often did you use your product(s) in a situation where you weren't supposed to?

- In Russian, it was recommended to translate ***"not supposed to"*** with a ***place/situation "not allowed to"*** — semantics discrepancy from original concept from a social and regulatory perspective.
  - ✓ *[Japanese]* Use in a situation where, properly speaking, I must not use it
  - ✓ *[German]* Consume in a situation in which it was not appropriate
  - ✓ *[Italian]* Consume in a situation where you should not have done it

- Russian translations modified to match the original concept and item concept definition of this item in English revisited for clarification.

- Finding emphasized importance of clear a priori conceptual definition of items.

Conclusion

- Combination of the Translatability Assessment and Linguistic Validation processes ensured reliable translation of the ABOUT–Dependence and applicability in German, Italian, Japanese, and Russian.

- Ensures validity and conceptual equivalence to assess and evaluate data on the concept of perceived dependence across different TNPs in a comparable way across different languages and cultures.

- Conditions to access and use the ABOUT–Dependence translations on PROQOLID, via the Mapi Research Trust eProvide platform *https://eprovide.mapi-trust.org/instruments/about-dependence*

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Grazie!

ありがとうございました!

Thank you!

Questions: esther.afolalu@pmi.com

Danke!

Спасибо!