

Development of a fit-for-purpose tobacco and nicotine product dependence instrument

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Introduction and Objectives

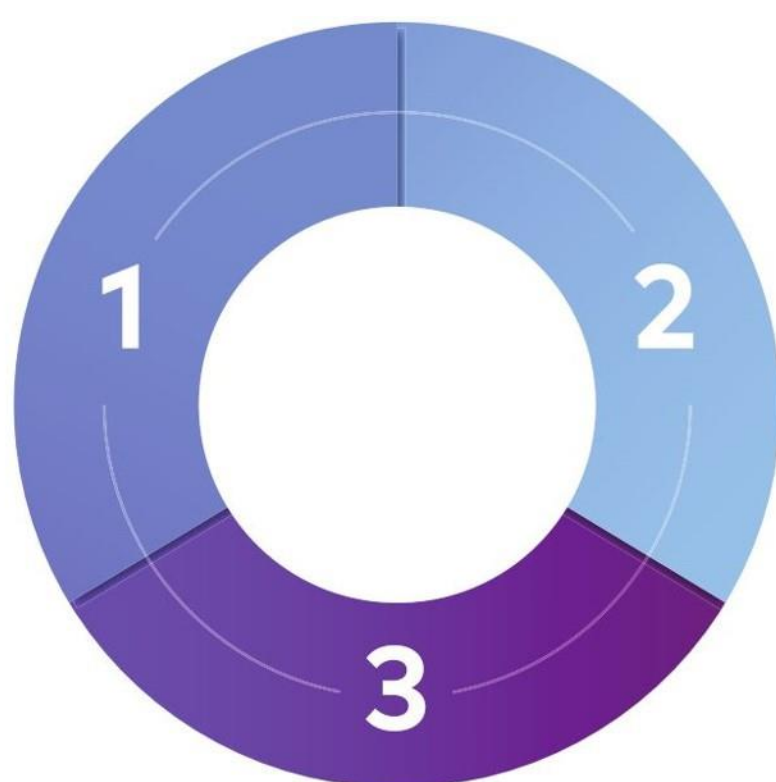
- Nicotine dependence is a primary driver of tobacco-use behavior, a fact supported primarily by research historically focused on cigarette smokers.
- Currently, there are no generally accepted self-report instruments available to measure dependence in a directly comparable way across different tobacco- and nicotine-containing products (TNP).
- As part of the ABOUT™ Toolbox (Assessment of Behavioral Outcomes related to Tobacco and nicotine products) initiative [1], we developed a new fit-for-purpose instrument named ABOUT–*Dependence*.

Methods

A stepwise approach was used in line with the guidelines for the development and validation of self-report instruments [2].

Development of the conceptual framework and item generation

- Define concepts of interests, context of use and intended population
- Generate conceptual model based on expert opinion, literature review, and concept elicitation/cognitive interviews with TNP users (n=40)
- Generate draft instrument with items best representing concepts of interest, appropriate response options, format, and recall period
- Evaluate content validity with cognitive debriefing interviews with TNP users (n=40)



Cultural adaptation, expert consensus meeting, scoring rule

- Ensure cross-cultural equivalence (translatability assessment)
- Consolidate psychometric and conceptual considerations to finalize the instrument
- Establish scoring rule and user manual
- Make the instrument publicly available

Confirmation of the conceptual framework and item reduction

- Field-test the draft instrument in a large representative cross-sectional survey of TNP users (n=2434)
- Identify items that best work together to form a scale, ensure items are well targeted, and ensure response options work as intended based on Rasch Measurement Methods (data completeness, scaling assumptions, targeting)
- Ensure stability of the instrument across different population groups and different TNPs based on differential item functioning (DIF)
- Assess other measurement properties of the reduced-item instrument (construct validity, score reliability)

Figure 1: Overview of research methods for the development and validation of the ABOUT–Dependence Instrument.

Results

For both qualitative and quantitative studies, the sample was recruited in order to have an equal number of single tobacco product users (e.g., balanced across cigarettes, cigar/cigarillos, e-cigarettes, smokeless tobacco, and other TNPs) and poly-users (Table 1).

Table 1: Overview of the sample demographics for both qualitative and quantitative studies

Characteristics	Qualitative Study			Cross-sectional survey		
	Exclusive Users n = 19	Poly users n = 21	Total sample n = 40	Exclusive Users n = 1181	Poly users n = 1253	Total sample n = 2434
Age						
Mean (SD)	38.0 (14.95)	46.0 (11.06)	40.0 (27.0)	52.1 (13.9)	45.9 (13.0)	48.9 (13.8)
18–34 years, n (%)	7 (36.8)	7 (33.3)	14 (35.0)	155 (13.1)	305 (24.3)	460 (18.9)
35–49 years, n (%)	8 (42.1)	10 (47.6)	18 (45.0)	352 (29.8)	462 (36.9)	814 (33.4)
50 years and more, n (%)	4 (21.1)	4 (19.1)	8 (20.0)	674 (57.1)	486 (38.8)	1160 (47.7)
Gender, n (%)						
Female	7 (36.8)	8 (38.1)	15 (37.5)	442 (37.4)	532 (42.5)	974 (40.0)
Male	12 (63.2)	13 (61.9)	25 (62.5)	739 (62.6)	721 (57.5)	1460 (60.0)
Race/ethnicity, n (%)						
Black	4 (21.1)	8 (38.1)	12 (30.0)	66 (5.6)	148 (11.8)	214 (8.8)
White	12 (63.1)	8 (38.1)	20 (50.0)	1011 (85.6)	961 (76.7)	1972 (81.0)
Other	3 (15.8)	5 (23.8)	8 (20.0)	104 (8.8)	144 (11.5)	248 (10.2)
Education level						
High school and below	6 (31.6)	8 (38.1)	14 (35.0)	189 (16.0)	141 (11.3)	330 (13.6)
Some college or college degree	5 (26.3)	7 (33.3)	12 (30.0)	459 (38.9)	507 (40.5)	966 (39.7)
Bachelor's degree and beyond	8 (42.1)	6 (23.8)	14 (25.0)	533 (45.1)	605 (48.3)	1138 (46.8)
TNP currently used, n (%)						
Cigarette	5 (12.5)	17 (81.0)	22 (55.5)	250 (21.2)	932 (74.4)	1182 (48.6)
Cigars/cigarillos	4 (10.0)	9 (42.9)	13 (32.5)	250 (21.2)	529 (42.2)	779 (32.0)
E-cigarettes	5 (12.5)	13 (61.9)	18 (45.0)	252 (21.3)	775 (61.9)	1027 (42.2)
Smokeless tobacco	5 (12.5)	10 (47.6)	15 (37.5)	250 (21.2)	265 (21.1)	515 (21.2)
Others (pipe, waterpipe, NRT)	0 (0.0)	4 (19.0)	4 (10.0)	179 (15.2)	481 (38.4)	660 (27.1)
TNP use history						
Age start TNP use, mean (SD)	N/A	N/A	N/A	20.7 (9.1)	19.2 (6.0)	19.9 (7.7)
Current TNP/day, mean (SD)						
Cigarettes	14.6 (7.1)	8.6 (12.7)	10.0 (9.9)	12.5 (8.8)	9.9 (9.2)	10.5 (9.2)
Cigars/cigarillos	1.0 (1.3)	2.3 (3.0)	1.9 (1.5)	2.6 (5.5)	1.6 (3.1)	1.9 (4.1)
E-cigarettes (10 puffs)	1.77 (3.3)	3.9 (0.30)	3.5 (4.6)	11.7 (22.2)	4.2 (7.5)	6.0 (13.2)
Smokeless tobacco	3.6 (1.9)	1.1 (0.4)	2.0 (1.9)	4.4 (3.6)	2.6 (3.6)	3.5 (3.7)
Pipe	0.0 (0.0)	0.0 (0.0)	0.0 (0.0)	3.5 (4.1)	1.4 (3.0)	1.9 (3.4)
Waterpipe	0.0 (0.0)	0.3 (0.1)	0.1 (0.0)	0.8 (0.9)	1.3 (2.4)	1.2 (2.2)
NRT	0.0 (0.0)	0.0 (0.0)	0.0 (0.0)	6.3 (6.3)	2.3 (3.1)	3.3 (4.4)
Previous quit attempts, n (%)						
Less than 1 year	N/A	N/A	N/A	54 (4.6)	75 (6.0)	129 (5.3)
1 to 9 years	N/A	N/A	N/A	408 (34.5)	557 (44.5)	965 (39.6)
10 years and more	N/A	N/A	N/A	253 (21.4)	254 (20.3)	507 (20.8)
Missing	N/A	N/A	N/A	2 (0.2)	1 (0.1)	3 (0.1)
FTND score*, n (%)						
Mild (score 0 to 3)	N/A	N/A	N/A	113 (45.2)	345 (37.0)	458 (38.7)
Moderate (score 4 to 6)	N/A	N/A	N/A	103 (41.2)	387 (41.5)	490 (41.5)
Severe (score 7 to 9)	N/A	N/A	N/A	34 (13.6)	200 (21.5)	234 (19.8)

* Cross-sectional survey, cigarette smokers only (n=250 for exclusive users; n=932 for poly-users; n=1182 for total sample)

N/A: Not collected in qualitative study; FTND: Fagerström Test for Nicotine Dependence; NRT: nicotine replacement therapy product; TNPs: Tobacco and nicotine-containing products

Results

Development of the conceptual framework and item generation

- Literature review provided evidence that there is no validated instrument to measure dependence in a directly comparable way across different TNPs. In total, 28 tobacco dependence instruments (25 self-reported and three interview-administered) were identified, the majority of which focused solely on cigarette dependence.
- Based on this and discussions with the expert panel, a preliminary conceptual framework was proposed, with lack of control as the core concept of dependence (Figure 2).
- A pilot version of the instrument was developed to include nine items that characterized the “severity” of dependence on three different response scales (intensity, frequency, duration) adapted to the characteristics of the individual symptoms.
- Qualitative thematic analysis of the concept elicitation part of the interviews largely confirmed the draft conceptual framework, and no differences in concepts between poly and single TNP users were identified. This led to the addition of 11 items to specific concepts.
- Based on cognitive debriefing, revisions to some of the items and response options were made to enhance comprehension.
- The expert panel reviewed and finalized the conceptual framework and a 19-item draft TNP dependence instrument.

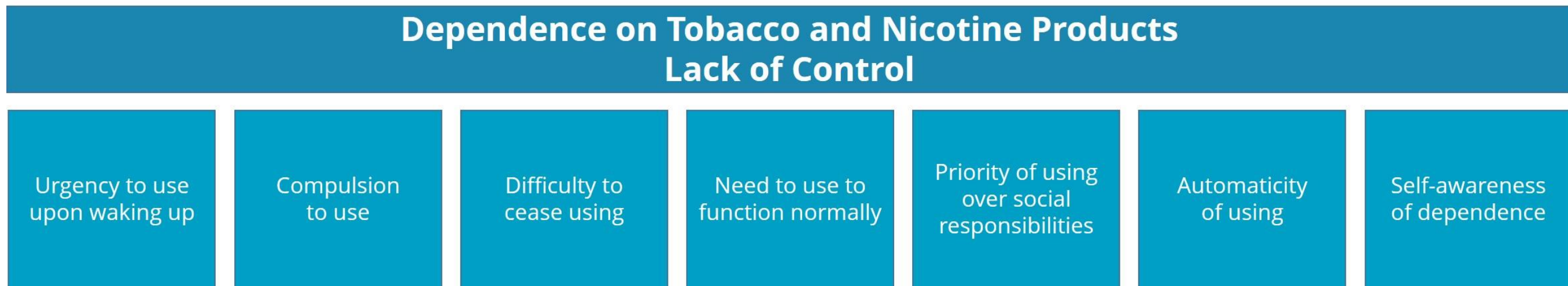


Figure 2: Preliminary conceptual framework for the TNP Dependence Instrument based on a review of existing instruments and expert opinions.

Confirmation of the conceptual framework and item reduction

- All respondents but one completed all items in the questionnaire, supporting the acceptability of the instrument.
- Initial Rasch measurement methods analyses did not support unidimensionality of the conceptual model. Dependence was thus reconceptualized as a multidimensional construct including three dimensions: attitudinal (*feeling*), behavioral (*doing*), and time to first and last TNP use (*frequency of use*).
- From the 19-item draft instrument, seven items were removed based on psychometric and conceptual considerations (Table 2).
- The 12-item multidimensional instrument showed acceptable psychometric performance:
 - Targeting:** Person measurements well covered
 - Suitability:** Response option thresholds ordered correctly
 - Reliability:** Satisfactory person separation indices (0.73 to 0.89)
 - Item invariance:** No differential item functioning (DIF) by type of users (exclusive vs. poly), but DIF noticeable for products used occasionally, such as pipe and waterpipe
 - Convergent validity:** Moderate to good correlation with existing dependence measures (e.g., FTND, Cigarette Dependence Scale-short version, brief Wisconsin Inventory of Smoking Dependence Motives)

Table 2: Summary of the ABOUT–Dependence Instrument item reduction

ID	Item description	Decision for reduction	ID	Item description	Decision for reduction
I01	how soon after you woke up	ITEM RETAINED in <i>FREQUENCY OF USE</i> domain (underdiscriminating in the context of all <i>DOING</i> items)	I03	need to function “normally”?	ITEM RETAINED
I02	how long before going to sleep	ITEM RETAINED in <i>FREQUENCY OF USE</i> domain (underdiscriminating in the context of all <i>DOING</i> items)	I04	difficult to cut down	eliminated due to redundancy with item I06 (Yen's Q3 statistic)
I09	use more than intended	ITEM RETAINED	I05	how addicted	eliminated due to overdiscrimination (suggesting I05 being a summary item), misfit (χ^2 statistic) and local dependence with item I06 (Yen's Q3 statistic)
I11	use in a situation not supposed to	ITEM RETAINED	I06	difficult to completely quit	ITEM RETAINED
I12	use an excuse	eliminated due to conceptual redundancy with I16 and misfit (χ^2 statistic ^a)	I07	part of who you are?	eliminated due to misfit (χ^2 statistic)
I14	use in secret	eliminated due to redundancy with I16 (Yen's Q3 statistic ^a)	I08	strong desire to use	ITEM RETAINED
I15	interrupt what you were doing	eliminated due to redundancy with I18 (Yen's Q3 statistic) and misfit (χ^2 statistic)	I10	HAD to have one	ITEM RETAINED
I16	sneak off to use	ITEM RETAINED	I13	hard to control the need or urge	ITEM RETAINED
I17	avoid an activity	ITEM RETAINED			
I18	stop what you were doing	ITEM RETAINED			
I19	using automatically	eliminated due to conceptual redundancy with I09 and misfit (χ^2 statistic)			

^a Yen's Q3 statistic assessing local dependence based on item residual correlation

^b χ^2 fit statistic based on observed responses versus expected responses

Cultural adaptation, expert consensus, scoring

- Translatability assessment was conducted in five languages on a draft version of the instrument (Italian, German, Japanese, Russian, and French), leading to the conclusion that the way instructions, items, and response options were worded would be suitable to ensure cultural equivalence in future translation.
- An expert consensus meeting will take place before the end of 2018 to discuss the best set of recommendations for the implementation and interpretation of the instrument.

Conclusions

- As no validated instrument applicable across the spectrum of TNPs currently exists, the present development fills an important gap.
- This approach was designed to adhere to best research practices to generate evidence from a range of qualitative and quantitative research steps.
- The findings extend previous conceptualizations of dependence on cigarettes and suggest that a standardized approach to measure dependence, in a directly comparable way, across a wide range of TNPs, is achievable.
- The ABOUT–*Dependence* instrument will be made available to the scientific community in PROQOLID™ upon the finalization of the scoring rule and user manual.

References

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