

Risk Perception of Tobacco and Nicotine Products: Which Consumer Reported Outcome Measures for Evidence Generation in Support of Regulatory Engagement?



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OBJECTIVES

US Food & Drug Administration Center for Tobacco Products' Premarket Tobacco Product Applications (FDA CTP PMTA) require assessment of the public health impact of New Tobacco Products (NTP) to gain approval via Marketing Granted Orders. PMTA assessment should inform on individuals' risk perception of NTP^[1,2]. Consumer Reported Outcome Measures (CROMs) are central in generating this evidence-base^[3-6,14-16]. The study objective was to evaluate risk perception CROMs for use in real-world evidence (RWE) generation in support of regulatory engagement.

RESULTS

The risk perception CROMs assess absolute or relative risk perception, with the PBI and FDA CTP instruments capturing both (Table 1). With different conceptual coverage, the reviewed CROMs measure domains such as perceived health (Table S1), addiction, social, practical, and risk to others, in adult population of tobacco products users as well as non-users (Table 2). CROMs' item/generation and psychometric validation are presented in Table 3 and Table 4, respectively. Measurement properties in multiple countries/languages, using both modern and classic psychometric validation, were only evaluated for the ABOUT – Perceived Risk instrument^[7,13] (Tables S3-S5).

Table 3. Summary of Risk Perception CROMs item generation/refinement.

Risk Perception CROM	Item Generation				Conceptual Framework	Item Refinement / Reduction		
	Participants	Expert Opinion	Literature Review	Pre-existing Instrument		Participants	Expert Opinion	Psychometrics (Quantitative)
ABOUT – Perceived Risk ^[7]	•	•	•		•			•
PBI Survey ^[8]		•	•		•	??		•
FDA CTP instrument ^[9,10]		•	•	(•)*				•

* The FDA CTP instrument for smokeless tobacco products^[10] was adapted from the FDA CTP instrument for e-cigarettes^[9].

** Unclear from the PBI Survey Validation Study Report^[8].

Table 4. Summary of Risk Perception CROMs psychometric validation.

Risk Perception CROM	Data completeness (missing data)	Scaling assumptions (corrected item-total correlations)	Structural validity (factor analysis)	Targeting (floor/ceiling effects)	Reliability (Cronbach's alpha & test-retest)	Construct validity (correlations with scales measuring similar constructs)	Known groups validity (different scores between groups of PPs)	Sensitivity to change
ABOUT – Perceived Risk ^[7]	•	•	(•)*	•	•	•	•	
PBI Survey ^[8]					•	•		•
FDA CTP instrument ^[9,10]			•		•			

* Structural validity tested based on modern test theory; See psychometric validation output for each Risk Perception CROM in Tables S3-S5.

METHODS

Building upon existing literature review^[7], we investigated the development and validation of three risk perception CROMs, (i) the ABOUT – Perceived Risk instrument^[6,7]; (ii) the Perception and Behavioral Intentions (PBI) survey^[8]; and (iii) the brief measures of tobacco product health risk perceptions (FDA CTP instrument)^[9,10]. We reviewed the reported conceptualization, intended population, item-level matrix, scoring structure, and psychometric performance revealed in empirical studies.

Table 1. Overview of Risk Perception CROMs.

Risk Perception CROM	Intended construct of measurement	Population developed for	Number of items	Response scale	Item stems**	Recall period	Scoring structure***
ABOUT – Perceived Risk ^[7]	Perceived risk of tobacco and nicotine-containing products.	Adult smokers; Former smokers; Never-smokers.	25 (v1.0) 40 (v3.0)	5-point Likert-like scale (0 = 'no risk'; 4 = 'very high risk') + 'I don't know option'		Your lifetime health risk	Separate score for each domain scale - transformed from 0 (no perceived risk) to 100 (very high perceived risk)
PBI Survey ^{[8]*}	Perceptions of general harm, relative risk perceptions, and risk perceptions for tobacco-related health outcomes.	Adult smokers; Adult e-vapor/ e-cigarette users; Non-tobacco users.	32	General harm: 5-point Likert scale ('Not at all' to 'Extremely') Relative risk (total health): 10-point Likert scale (0 = 'No risk to health' to 9 = 'Great risk to health') Absolute risk of general and specific diseases (% of likelihood): 11-point scale (0% = 'Extremely unlikely' to 100% = 'Extremely likely')		Not specified Using [product] daily To a person who only uses [product] daily	Separate score for each sub-scale
FDA CTP instrument ^[9,10]	Absolute and Relative risk of e-cigarettes.	Adult smokers; Adult e-vapor/ e-cigarette users; Non-tobacco users.	21	Absolute risk scales: 5-point Likert scale ('Not at all likely' to 'Extremely likely') Relative risk scales: 5-point Likert scale ('MUCH more likely with [product]' to 'MUCH more likely with [cigarettes/NRT/quitting tobacco]')		If you were to use [product] every day...	Single items + score for each domain scale
	Absolute and Relative risk of smokeless tobacco products.	Adult smokers; Adult smokeless tobacco users; Non-tobacco users.	35	Absolute risk scales: 5-point Likert scale ('Not at all likely' to 'Extremely likely') Relative risk scales: 5-point Likert scale ('MUCH more likely with [product]' to 'MUCH more likely with [cigarettes/NRT/quitting tobacco]')		If you were to use [product] every day...	Single items + score for each domain scale

* The PBI Survey evaluates behavioral intentions, risk perceptions, and attitudes and beliefs about e-vapor/e-cigarette products and was further adapted for other nicotine and tobacco products and adults who use these products: oral tobacco products^[11] and heated tobacco products (heated tobacco capsule system)^[12]. ** Item stems in Table S2; *** There is no total score for these CROMs. § 7-point Likert scale (1 = 'Not at all risky'; 7 = 'Extremely risky') in^[11,12]; §§ 4-point Likert scale (1 = 'Not at all harmful'; 4 = 'Very harmful') in^[12].

Table 2. Summary of Risk Perception CROMs item content.

Risk Perception CROM	Domain						Total number of items	Product Use Behavior [§]			
	Absolute Risk					Relative Risk (compared to other TNPs)		Single use	Dual use	Poly use	
	Health risk	Addiction risk	Social risk	Practical risk	Risk to others						
ABOUT – Perceived Risk ^[7]	v1.0	18 items	7 item**	N/A	N/A	N/A	N/A	25	•		
	v3.0	18 items*	7 item**	7 items	6 items	2 items	N/A	40	•	• §§	
PBI Survey ^[8,11,12]		9 items (cigarettes) 2 items (e-cigarettes) 11 items ([product name])		N/A	N/A	N/A	10 item scale of different product use behavior ^{\$\$\$}	32	•	•	
FDA CTP instrument ^[9,10]	e-cigarettes	1 item	1 item	N/A	N/A	N/A	17 items (compared to cigarettes) 1 item (compared to NRT)	21	•		
	smokeless tobacco products	5 items	1 item	N/A	N/A	N/A	27 items (compared to cigarettes) 1 item (compared to NRT) 1 item (compared to cessation)	35	•		

* Short version: 9 items (as per user manual); ** 6+1 specific to cessation; § Concurrent use of one (single), two (dual), or more (poly) tobacco products; §§ 'more than one'; \$\$\$ quantity and pattern.

CONCLUSIONS

Selecting and potentially combining risk perception CROMs for use in assessment studies require considerations of instruments' characteristics, including conceptual overlap, as well as prerequisites pertaining to copyright and translation. Health communication strategies should ensure targeted, effective, non-misleading messaging to empower adults who elect to continue to use nicotine and tobacco products to make informed decision when switching to potentially reduced risk alternatives. Appropriate psychometric CROMs have the potential to capture RWE insights concerning one individual's journey (stages, moments). Characterizing elements that promote a desired behavioral change, such as accurate risk perception, could further support tobacco harm reduction.

