Tobacco Product Experience: Which Consumer Reported Outcome Measures for Real World Evidence Studies?

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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 must inform on individuals' product experience of NTP, and Consumer Reported Outcome Measures (CROMs) are central in generating this evidence-base. Originally referred to as the Smoking Effects Inventory (SEI), the modified Cigarette Evaluation Questionnaire (mCEQ) assesses reinforcing effects of smoking cigarettes^[1,2] and was adapted to evaluate subjective effects of NTP use. The study objective was to evaluate product experience CROMs adapted from the mCEQ for use in real-world evidence (RWE) generation for regulatory engagement.

METHODS

We reviewed the literature on development and validation of the mCEQ along with measurement properties of CROM adaptations: the Product Evaluation Scale (PES), the Tobacco and Nicotine Product Experience Questionnaire (ToNiPEQ; aka the ABOUT-Product Experience), the mCEQ-C, mCEQ-E, and | Figure 3. 12 items and five domains of the mCEQ^[5]. mCEQ-N, and the Modified E-Cigarette Evaluation Questionnaire (MECEQ)

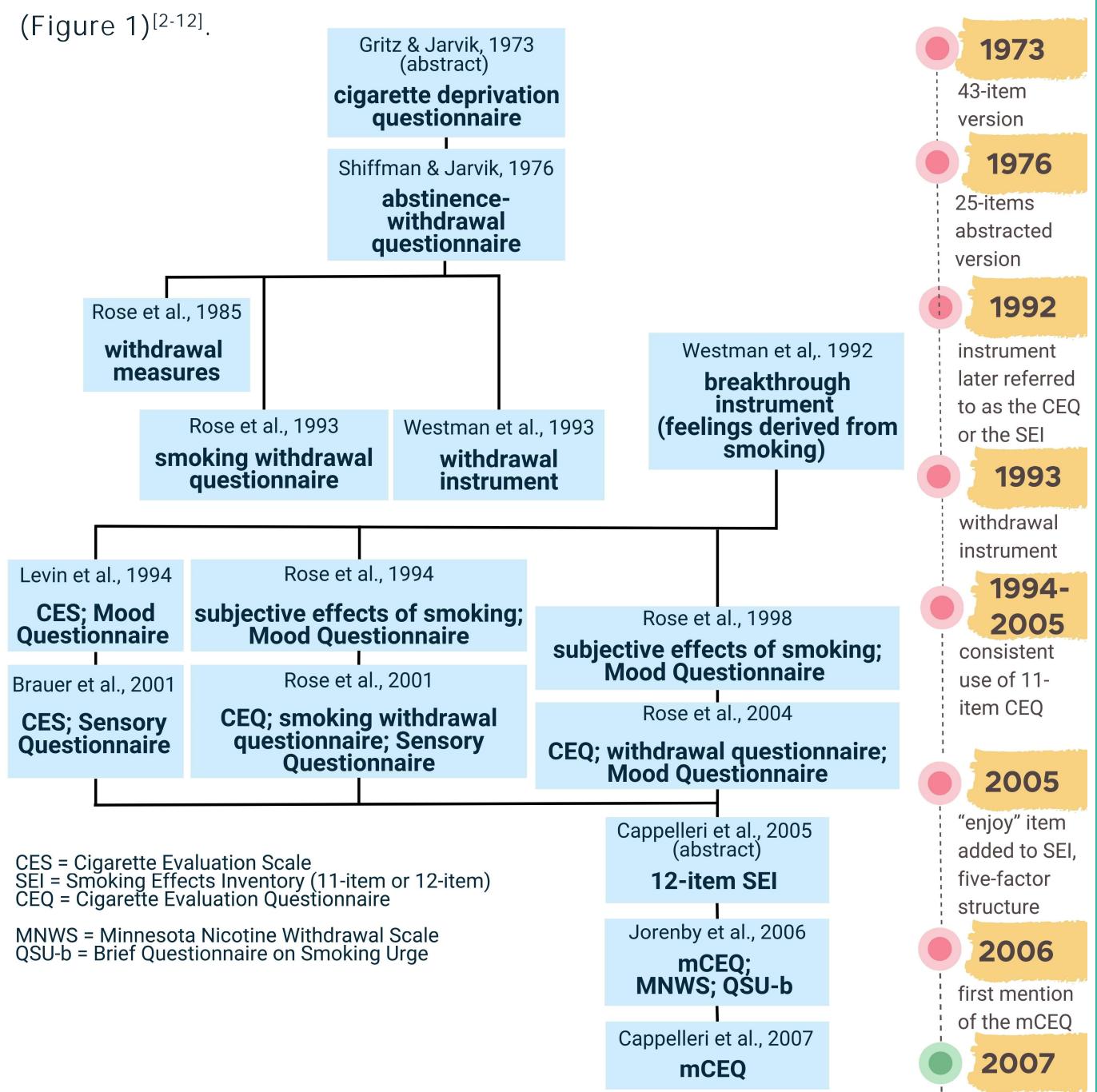
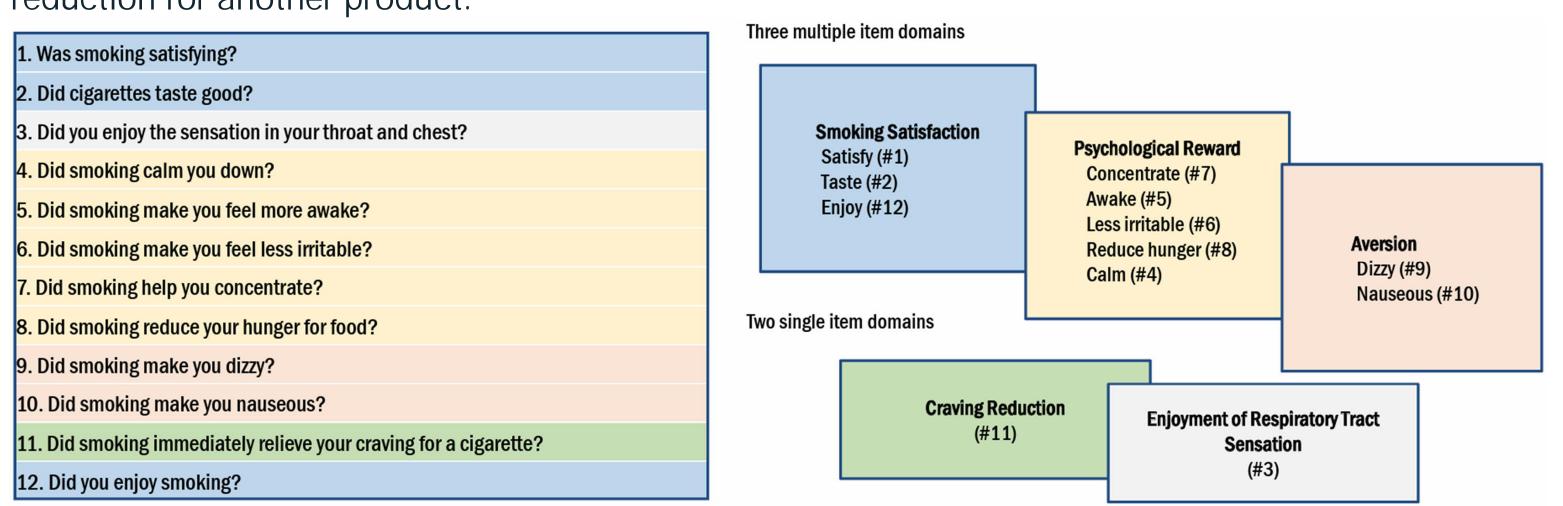


Figure 2. Subjective effects instruments towards the mCEQ.

RESULTS

The SEI/mCEQ was validated to evaluate clinical interventions towards smoking cessation by characterizing subjective effects of smoking (e.g., Liking/Satisfaction; Taste/Sensory effects; Reinforcing Effects; Craving; Withdrawal symptoms) (Figure 2 and 3)[1,2,13-26]. CROMs adapted from the mCEQ assess reinforcing effects of product use in adult population of tobacco and nicotine product users. The mCEQ was adapted with changes relating to NTP ("using"/"vaping"; "it"/"<Product>"; respiratory tract sensation), and a modified frame of reference for the MECEQ (Table 1). The PES extended the concepts measured, and the Adapted mCEQ captures craving reduction for another product.



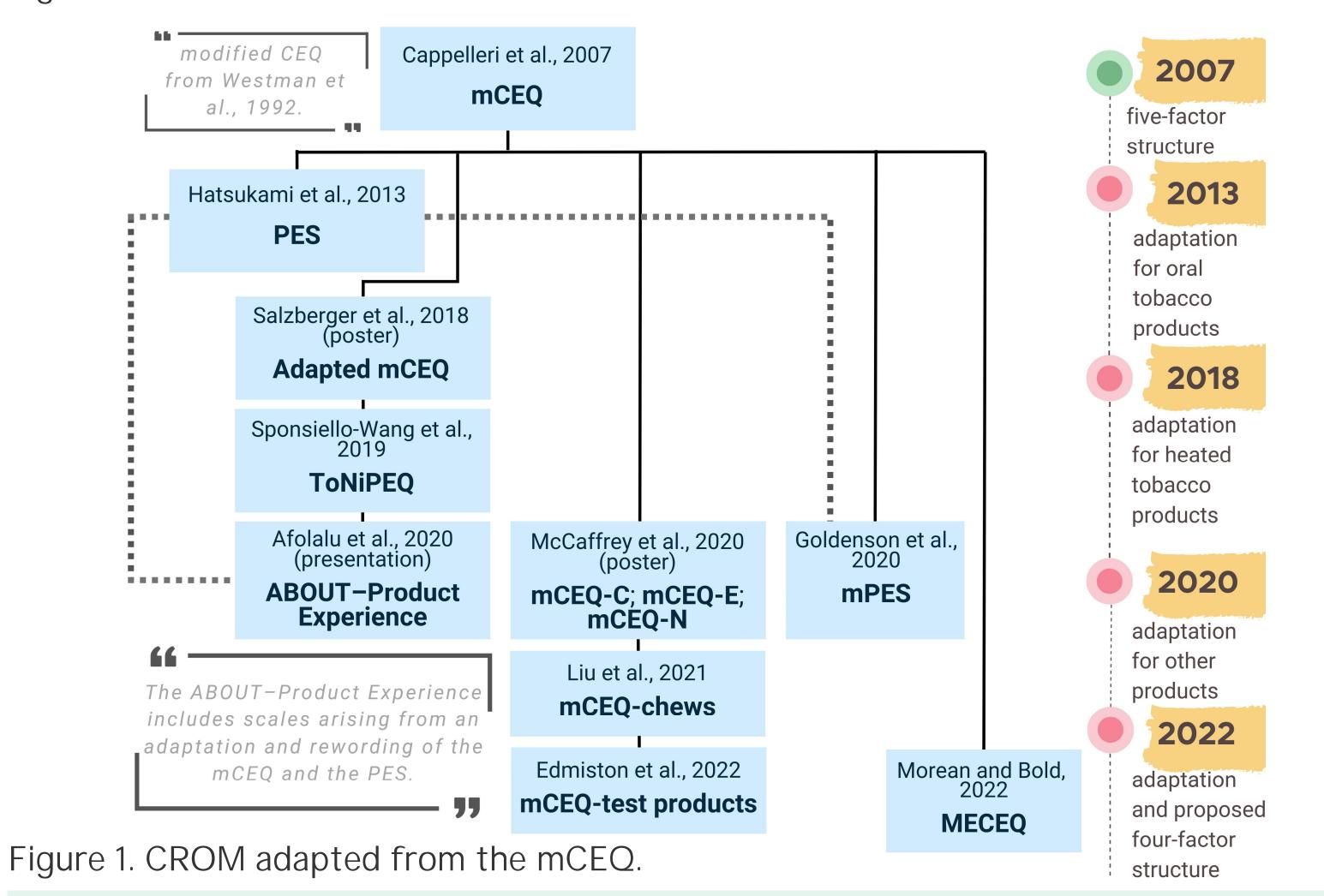


Table 1. Adaptations of the mCEQ for NTP.

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Modifications	mCEQ	PES	Adapted mCEQ [‡]	mCEQ-C	mCEQ-E	mCEQ-N; mCEQ- chews	mCEQ- test products	mPES	MECEQ
Substantial* changes							•		
Product category									
Cigarette	•		•	●**			•		
HTP			•				•		
ENDS			•		•		•	•	•
ONP		•				•	•	•	
Interchangeability									
Specific	•			•	•	•	•		•
Generic		•	•					•	
Verb tenses									
Past	•	•	•	•	•	•	•	•	
Present									•
Personal pronoun									
"you"	•	•	•	•	•	•	•	•	
" "									•
Sensorial location									
"throat and chest"	•		•	•	•		•~		
"mouth"		•				•^	•~	•	•
Feeling sick/nausea									
"nauseous"	•	•		•	•	•	•	•	•
"nauseated"			•**						
Craving reduction									
"for a cigarette"	•	•	•	•	•	•	•	•~	•
"for <product>"</product>			•						

‡Adapted mCEQ / ToNiPEQ / ABOUT-Product Experience. *According to classifications pertaining to the extent of CROM modifications^[27] – potential modification of participant instructions or response options was not systematically reported or clarified; **Minor modifications: "smoking cigarettes" vs. "smoking", and "nauseated" to better reflect the concept of interest [5,24]. ^Assumption based on publications for mCEQ-chews^[9], mCEQ-test products^[8,10], and mPES^[11]

These CROM adaptations inherited strengths and limitations from the original instrument. While the original structure of the three multi-item domains was confirmed using the Rasch model^[5], studies using factor analysis suggested alternative structures^[8,12,13], including in a population of adolescents and young adults^[41] (Table 2). Empirical confirmation of the multidimensional conceptual model is complicated by two single-item domains^[5].

Table 2. Reported psychometric properties of adapted CROM.

Metrics		CEQ	mCEQ	PES	Adapted mCEQ [‡]	mCEQ-E; mCEQ-N; mCEQ-C	I CHAWS' I	mPES	MECEO
Reliability									
Internal consistency*		•	•						•
Test-retest reliability**		•	•						
Construct Validity									
Item-scale relationships***		•	•§	•	(●)^	•			•
Concurrent/Convergent validity			•§	● §§					
Known group validity****			•§	● §§					•
Responsiveness****			•§	•					
Number of Items		11	12	21	12	12	12	20	12
Number of	Multi-item	3	3	4	3	3	3^^	4	4
Domains	Single-item	2	2	3	2	1	2^^	2	0

‡Adapted mCEQ / ToNiPEQ / ABOUT-Product Experience; *Based on Cronbach's alpha coefficient; **Based on Pearson's correlation coefficient; *** Factor-analysis / Multitrait analysis / Floor-Ceiling effect; **** Product and/or People; ***** Ability to detect change; §^[5,28-38]; §§^[39,40]; Based on expert consensus; Massumption based on publications.

CONCLUSIONS

Selecting optimal product experience CROMs for use in assessment studies requires considerations of instruments characteristics. Ensuring rationale-based changes and systematic reporting (items, response scale, participant instructions, scoring) would further contribute to data comparability and potential bridging. Instruments to measure NTP use experience would benefit from the addition of items to single-items domains, coupled with further empirical research on the dimensionality in support of a meaningful conceptual model for sound data interpretation. Together with novel study design elements, appropriate psychometric CROMs have the potential to capture RWE insights concerning one individual's journey (stages, moments). Characterizing product experience elements contributing to a desired behavioral change could further support tobacco harm reduction.





