Tobacco Product Experience: Which Consumer Reported Outcome Measures for Real World Evidence Studies? N. Mainy¹; M. Bajec²; M. Alves Favaro³; T. Salzberger⁴; J. Rose⁵

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OBJECTIVES

The SEI/mCEQ was validated to evaluate clinical interventions towards smoking cessation by US Food & Drug Administration Center for Tobacco Products' Premarket characterizing subjective effects of smoking (e.g., Liking/Satisfaction; Taste/Sensory effects; Tobacco Product Applications (FDA CTP PMTA) require assessment of Reinforcing Effects; Craving; Withdrawal symptoms) (Figure 2 and 3)^[1,2,13-26]. CROMs adapted from the public health impact of New Tobacco Products (NTP) to gain approval the mCEQ assess reinforcing effects of product use in adult population of tobacco and nicotine via Marketing Granted Orders. PMTA assessment must inform on product users. The mCEQ was adapted with changes relating to NTP ("using"/"vaping"; individuals' product experience of NTP, and Consumer Reported Outcome "it"/"<Product>"; respiratory tract sensation), and a modified frame of reference for the MECEQ Measures (CROMs) are central in generating this evidence-base. (Table 1). The PES extended the concepts measured, and the Adapted mCEQ captures craving Originally referred to as the Smoking Effects Inventory (SEI), the modified reduction for another product. Cigarette Evaluation Questionnaire (mCEQ) assesses reinforcing effects 1. Was smoking satisfying? 2. Did cigarettes taste good? **Smoking Satisfaction** 3. Did you enjoy the sensation in your throat and chest? **Psychological Reward** Satisfy (#1) 4. Did smoking calm you down? Concentrate (#7) Taste (#2) Awake (#5) Enjoy (#12) 5. Did smoking make you feel more awake? Less irritable (#6)



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RESULTS





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.



| Substantial* changes Product category Cigarette HTP ENDS ONP Interchangeability Generic Verb tenses Past Present Present Present Sensorial location | | | | • ** | | chews | products | • | |
|--|---|------------------------|---------------|---------------|---------------------|---------------------|---------------|-----------------------|---------|
| Cigarette HTP ENDS ONP Interchangeability Specific Generic Verb tenses Past Present Present "you" | | | | | | | | • | |
| HTP ENDS ONP Interchangeability Specific Generic Verb tenses Past Present Present "you" | | | | | | | | • | |
| ENDS ONP Interchangeability Specific Generic Verb tenses Past Present Personal pronoun "you" | Image: state of the state o | | | | | | | • | |
| ONP Interchangeability Specific Generic Verb tenses Past Present Personal pronoun "you" | Image: state | | | | | | | • | |
| Interchangeability Specific Generic Verb tenses Past Present Personal pronoun "you" | | | | | | | • | • | |
| Specific Generic Verb tenses Past Present Personal pronoun "you" | t t t | | | | | | • | • | |
| Generic Verb tenses Past Present Personal pronoun "you" | t t t | | | | | | • | • | |
| Verb tenses Past Present Personal pronoun "you" | | | | | | | • | | |
| Past Present Personal pronoun "you" "I" | t ' • | • | | | • | • | | | |
| Personal pronoun "you" "I" | | | | | | | | | 1 |
| "you" "I" | | | | | | | | | |
| | | | | | | | | | |
| 1 | ' | | | | | | | • | |
| Sensorial location | | | | | | | | | |
| | | | | | | | | | |
| "throat and chest" | | | | | | | | | |
| "mouth" | 1 | • | | | | •^^ | •^^ | • | • |
| Feeling sick/nausea | | | | | | | | | |
| "nauseous" | | • | •** | | • | | | • | • |
| "nauseated" | | | | | | | | | |
| Craving reduction "for a cigarette" | ' | | | | | | | | |
| "for <product>"</product> | | | | | • | | • | • | |
| ‡Adapted mCEQ / ToNiPE | | Draduat | Evporiopoo | * A according | L a to ploopific | l otiono portoji | ning to the o | vtont of CI | |
| modifications ^[27] – potential clarified; **Minor modificati ^^Assumption based on pu | l modificati | on of parti | cipant instru | uctions or re | sponse opti | ons was not | systematical | ly reported | d or |
| These CROM ad | laptatio | ns inh | erited | strength | s and | limitatio | ns from | the | origina |
| instrument. While | the orig | ginal st | ructure | of the th | nree mul | ti-item de | omains N | vas co | nfirme |
| using the Rasch | mode | el ^[5] , st | udies u | using fa | actor a | nalysis | suggeste | ed alte | ernativ |
| structures ^[8,12,13] , ir | ncluding | in a p | opulatio | n of add | lescent | s and you | ung adul | ts ^[41] (T | able 2 |
| Empirical confirma | ation of | the mu | ultidimer | nsional c | conceptu | ial mode | l is comp | licatec | l by tw |
| single-item domair | าร ^[5] . | | | | | | | | |
| Fable 2. Reporte | ed psyc | chome | tric pro | opertie | s of ad | apted C | ROM. | | |
| • | | | | | ĺ | nCEQ-E; | mCEQ- | | |

| Metrics | | CEQ | mCEQ | PES | Adapted mCEQ [‡] | mCEQ-E; mCEQ-N; mCEQ-C | mCEQ- chews; mCEQ-test products | mPES | MECEG |
|--------------------------------|-------------|-----------|------|-----|------------------------------|------------------------------|--|------|-------|
| Reliability | | | | | | | | | |
| Internal consistency* | | \bullet | | | | | | | |
| 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 |

"Factor-analysis / iniuititrait analysis / Floor-Celling effect; """" Product and/or People; §^[5,28-38]: §§^[39,40]; 'Based on expert consensus; 'Assumption based on publications detect change; §¹



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