Psychometric Evaluation of the mCEQ Applied to Cigarettes and Heat-not-Burn Products in the US and Japan

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Introduction and Objectives

The modified Cigarette Evaluation Questionnaire (mCEQ) is a self-report measurement instrument that assesses the reinforcing effects of smoking cigarettes[1]. Conceptually, the mCEQ consists of three multi-item and two single-item domains (**Figure 1**). The original instruction reads as follows: "*If you have smoked since you last completed this questionnaire, please mark what best represents how smoking made you feel.*"

The increasing availability of alternative products to cigarettes raises the question whether the mCEQ can also be used to assess the reinforcing effects of other nicotine or tobacco-containing products.

This study aimed at a psychometric evaluation of the mCEQ applied to cigarettes and a heat-not-burn tobacco product, the candidate Modified Risk Tobacco Product (MRTP) Tobacco Heating System (THS). In addition, considerations for the inclusion of a special instruction to remove the ambiguity of the wording 'smoking' and 'cigarettes', which do not apply to the use of other products, were discussed with experts, as well as the possibility of rewording items as initially designed in the Cigarette Evaluation Questionnaire (CEQ) by Rose et al.[2,3] and proposed by Hatsukami et al.[4] with the Product Evaluation Scale (PES): e.g., item #1, *Was it satisfying?* instead of *Was smoking satisfying?*

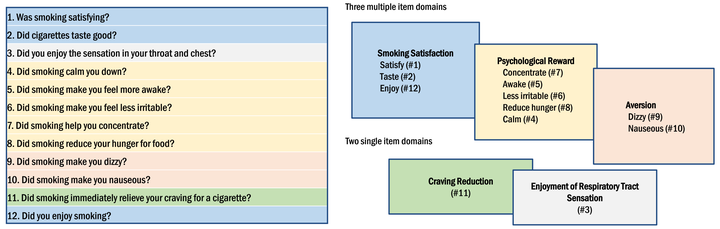

Figure 1. Twelve Items and Five Domains of the mCEQ.

Methods

The mCEQ was administered at various time-points (**Table 1**) in two 3-month reduced-exposure studies (**Figure 2**), one conducted in the US (ZRHM-REXA-08-US - NCT01989156) and one in Japan (ZRHM-REXA-07-JP - NCT01970995)[5,6].

The analysis was based on traditional Classical Test Theory (CTT) and Rasch Measurement Theory (RMT) (**Table 1** and **Figure 3**).

An expert consensus meeting was held to review the results of this evaluation and to consider the potential need for modification or adaptation such as rewording of items and instructions.

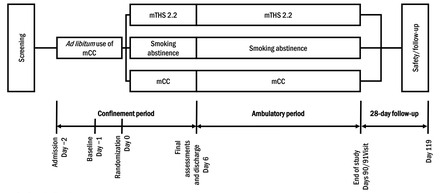

Figure 2. Study Design.
mCC = menthol Conventional Cigarette; mTHS = Tobacco Heating System 2.2 menthol.

Table 1. Overview of the Data Set.

Study Code	ZRHM-REXA-08-US	ZRHM-REXA-07-JP
Time-points	Day 0, 1, 2, 3, 4, 5, 30, 60, 90	
Outcome Measure	mCEQ	
mCC (CC)	n=303 responses	n=371 responses
mTHS 2.2 (THS)	n=575 responses	n=670 responses
Smoking abstinence	Disregarded	Disregarded
Total	n=1919 considered responses across the two studies n=1904 complete response patterns (excluding missing responses)	

mCC: menthol Conventional Cigarette;
mTHS: Tobacco Heating System 2.2 menthol.

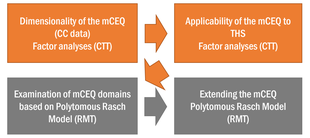

Figure 3. Sequence of Analyses.
CC: Conventional Cigarette; CTT: Classical Test Theory; RMT: Rasch Measurement Theory; THS: Tobacco Heating System.

Results

Expert Consensus Meeting and Follow-up Discussions

- Adaptation of the mCEQ was agreed with (i) rewording of items as per the original design by Rose et al.[2,3], and (ii) use of the word 'nauseated' instead of 'nauseous' (item #10, nauseous) to better reflect the concept of interest (nauseous means "causing nausea" while nauseated means "feeling sick") (**Figure 5**).
- Discussion with the experts also confirmed the relevance of the initial 12 items for the conceptual framework of product reinforcement and further suggested to apply the item #11 on Craving Reduction to any nicotine or tobacco-containing products instead of restricting to cigarettes.
- New instructions were developed to reflect various recall periods considered to differentiate immediate *vs.* retrospective use of the product, as well as particular instances of product use.

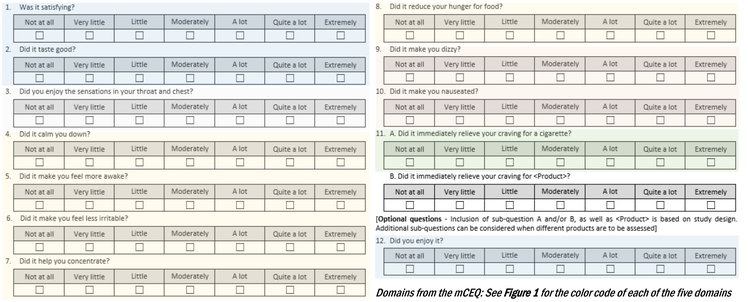

Figure 5. Wording of the Adapted mCEQ (Version AU0.5)

*Domains from the mCEQ: See **Figure 1** for the color code of each of the five domains together with original items.*

Results

Classical Test Theory (CTT) - Factor analyses

- Factor analyses confirmed the three multi-item domains of the mCEQ for both cigarette and THS, showing that the mCEQ is applicable to THS (**Tables 2 and 3**).

Table 2. Factor Loadings (Rotated) of a Three-Factor Solution of the mCEQ Applied to CC in the US and Japan Combined.

Pattern Matrix[a]	Factor		
	1	2	3
Item #1, *satisfaction*	.959	-.033	.045
Item #2, *taste*	.941	-.010	.031
Item #12, *enjoy*	.897	.022	.023
Item #3, *enjoyment of respiratory tract sensation*	.779	-.002	-.071
Item #11, *craving reduction*	.677	.005	-.055
Item #4, *calm*	.511	.038	-.428
Item #9, *dizzy*	.031	.874	.024
Item #10, *nauseous*	-.033	.812	-.020
Item #7, *concentrate*	-.134	.011	-1.025
Item #5, *awake*	.061	-.036	-.861
Item #6, *less irritable*	.227	-.020	-.715
Item #8, *reduce hunger*	.048	.060	-.697

[a] *Oblique rotation converged in 6 iterations.*
CC: Conventional Cigarette.
n=668 complete response patterns.

Table 3. Factor Loadings (Rotated) of a Three-Factor Solution of the mCEQ Applied to THS in the US and Japan Combined.

Pattern Matrix[a]	Factor		
	1	2	3
Item #2, *taste*	.949	.033	.083
Item #1, *satisfaction*	.916	-.047	.039
Item #12, *enjoy*	.816	.003	-.030
Item #3, *enjoyment of respiratory tract sensation*	.699	.047	-.113
Item #11, *craving reduction*	.556	-.058	-.104
Item #10, *nauseous*	-.035	.800	.008
Item #9, *dizzy*	.023	.798	-.016
Item #7, *concentrate*	-.073	-.022	-.965
Item #6, *less irritable*	-.021	-.025	-.856
Item #5, *awake*	.040	-.014	-.844
Item #4, *calm*	.302	-.056	-.585
Item #8, *reduce hunger*	.070	.121	-.499

[a] *Oblique rotation converged in 9 iterations.*
THS: Tobacco Heating System.
n=1236 complete response patterns.

Rasch Measurement Theory (RMT) - Polytomous Rasch Model

- Items of the multi-item domains Smoking Satisfaction and Psychological Reward (excluding item #8, *hunger*, for reason of misfit) were found to work as scales, meeting the requirements of RMT with good targeting and high reliability (Person-Separation Index/Rasch reliability of 0.90 and 0.89, respectively).
- For Aversion (items #9, *dizzy*, #10, *nauseous*) strong floor effects were identified, implying poor targeting (i.e., low suitability of items to differentiate between respondents and, by implication, different products). Thus, a conclusive psychometric assessment was not possible suggesting they should, for the time being, be interpreted as single items, albeit with very limited discriminatory power.

The scales assessing the domains of Smoking Satisfaction and Psychological Reward (after excluding item #8, *hunger*) qualify for being analyzed and scored using the Rasch model. The items form a meaningful hierarchy in terms of the variables measured (**Figure 4**). Despite their brevity, both scales showed few extreme scores (Smoking Satisfaction 10.9%, Psychological Reward 10.3%) implying satisfactory targeting.

Analyses of differential item functioning (DIF, testing for item equivalence) revealed good comparability across responses to different products. In terms of equivalence across US and Japanese respondents, there was some indication of DIF requiring corrective action (such as item splitting by country).

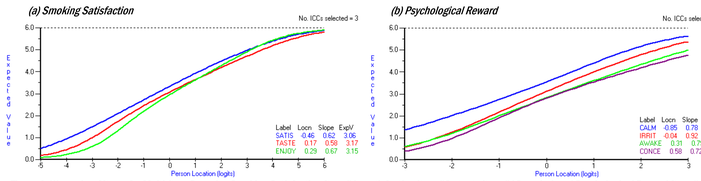

*Figure 4. Hierarchy of Items for Multi-Item Domains Smoking Satisfaction (***item #1,** *satisfaction;* **item #2,** *taste;* **item #12,** *enjoy)* **and Psychological Reward (item #4,** *calm;* **item #6,** *less irritable;* **item #5,** *awake;* **item #7,** *concentrate), mCEQ Applied to CC and THS in the US and Japan Combined.*
CC: Conventional Cigarette; THS: Tobacco Heating System.

Discussion

The mCEQ is, in principle, applicable to cigarettes as well as to THS. From a CTT perspective, all three multi-item domains could be confirmed. The two multi-item domains of Smoking Satisfaction and Psychological Reward, together consisting of eight out of the 12 mCEQ items, also met the requirements of RMT after minimal adaptation (excluding one item from Psychological Reward).

The applicability of the mCEQ to cigarettes and THS was confirmed for respondents from the US and Japan based on RMT analyses.

A possible limitation lies in the pooled analysis of all responses from different time points (**Table 1**) as if they were coming from independent respondents. Since the main goal of the study was to assess the general applicability of the mCEQ, the possible dependency was deemed non-critical.

The two multi-item domains (Smoking Satisfaction and Psychological Reward) can be interpreted at the scale level, whereas the remaining items (one item deleted from Psychological Reward, two items assessing Aversion, one item on Craving Reduction for each product, and one item on Enjoyment of Respiratory Tract Sensation) should be interpreted as single-item measures.

The adaptation of the mCEQ enables the measure of reinforcing effects of nicotine or tobacco-containing products and supports the assessment of candidate MRTPs.

Moving forward, additional psychometric testing is planned with a wider variety of products (e-cigarettes, cigars/cigarillos, smokeless products) to assess the applicability of the measurement instrument to these products. Also, new instructions are to be developed (e.g., product(s) used '*today*', or '*during the past 24h*', or '*during the past 7 days*') and subsequently assessed so as to determine the potential impact of different recall periods on the psychometric properties of the adaptation of the mCEQ.

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Competing Financial Interest

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