Development of Consumer-Reported Outcome Measure (CROM) Best Practices and Guidelines for the Tobacco Industry with Respect to Psychometric CROM Using a Consortium-Based Approach: Methodology and Scope

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SIGNIFICANCE

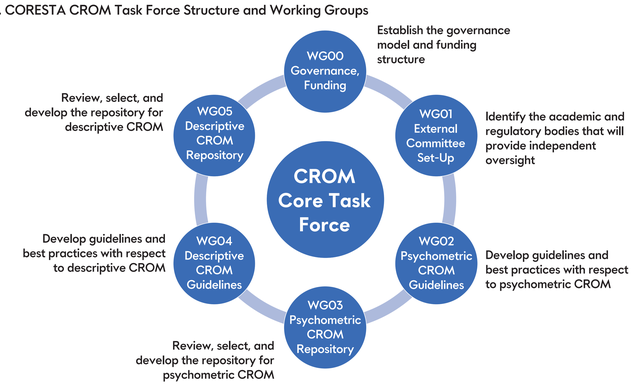
The Need for Consumer Reported Outcome Measures (CROM) Best Practices and Guidelines for Tobacco Regulatory Research

- In tobacco regulatory research, CROMs are a critical component of premarket tobacco product application and modified risk tobacco product (MRTP) application studies.
- The need for guidelines pertaining to CROMs has been articulated in recent published literature (e.g., Kaufman et al., 2020) [1] and has been addressed in part by the October 2020 United States Food & Drug Administration's draft guidance for industry "Tobacco Products: Principles for Designing and Conducting Tobacco Product Perception and Intention Studies" (FDA TPPIS draft guidance) [2].
- This draft guidance may reflect an important first step toward building the foundation for consensual standards for measurement across the tobacco industry as well as consensus regarding optimal measures pertaining to the measurement of tobacco product perceptions, behavioral intentions, and consumer understanding.
- While the FDA TPPIS draft guidance provides general recommendations pertaining to the development, adaptation, and use of quantitative survey measures specifically within the context of tobacco product perception studies, given the critical role of CROMs in tobacco regulatory research, additional guidelines and best practices which more broadly encompass (1) other CROM used in application research (e.g., dependence, craving) as well as (2) CROM used in other areas of tobacco regulatory research (e.g., clinical studies, postmarket studies) are needed.

The CORESTA CROM Initiative

- The Cooperation Centre for Scientific Research Relative to Tobacco (CORESTA) is an organization developed with the purpose of promoting international cooperation in scientific research relative to tobacco and its derived products. Its vision is "to be recognized by our members and relevant external bodies as an authoritative source of publicly available, credible science and best practices related to tobacco and its derived products." (https://www.coresta.org/who-we-are29290.html)
- In November 2018, CORESTA approved the formation of a new Task Force (TF) to establish best practices and guidelines for the integration of CROMs in tobacco regulatory research.
- This TF defined CROM as: data collected by self-report from the subject of research, whether it concerns perceived states, reports of behavior, or the combination of both, and understanding of messages.
- The primary objective of the CROM TF is to provide guidelines on how to identify, develop, and validate CROM, and to provide access to CROMs to evaluate tobacco and nicotine-containing products for pre-market and post-market product assessment purposes.
- To achieve this primary objective, the CROM TF created 6 working groups (WG) (**Figure 1**).

Figure 1. CORESTA CROM Task Force Structure and Working Groups



- Here, we describe the research completed by one of the working groups, WG02. The objective of WG02 is to develop best practices and guidelines for tobacco regulatory research with respect to "psychometric CROM," i.e., CROM intended to measure underlying individual psychological attributes[1].
- Examples of psychometric CROM include, but are not limited to product perceptions (risk perceptions, awareness, ease of use), behavioral intentions, responses to the product (craving, withdrawal symptoms, reinforcing effects, taste/sensory effects, liking/satisfaction), self-reported dependence, consumer understanding (comprehension) of the MRTP claim, believability of an MRTP claim, and impact on health and functioning (quality of life).

METHODS

Consumer-Reported Outcome Measures Working Group 02 (WG02)

- CORESTA approved the formation of WG02 in June 2020.
- WG02 includes 11 researchers from the CROM TF. WG02 members have diverse expertise and backgrounds, with experience in psychometrics, patient-reported outcomes, survey methodology, and tobacco product use behavior.
- Since its inception in June 2020, WG02 has met regularly (two times every month).

Approach for Developing the Guidelines

- WG02 adopted a consensus-based approach for drafting the guidelines, inspired by approaches taken by prominent outcomes research organizations, such as ISPOR (The Professional Society for Health Economics and Outcomes Research).
- Development of the guidelines is a collaborative, iterative process, with peer-review as an integral factor driving each iteration of guideline development. That is, WG02 is actively seeking collaboration from individuals (subject matter experts; "SMEs") with diverse perspectives and expertise representing public health, academia, and the tobacco industry throughout the guideline development process.
- WG02 members, in conjunction with external SMEs, are collaboratively drafting the initial guidelines based on their review of relevant literature and expertise.
- WG02 members are reviewing ~50 different documents, including peer-reviewed publications and publicly available guidelines and best practices published by other prominent organizations from related fields. These include but are not limited to guidance and best practices authored by FDA, CONSORT PRO Group, ISOQOL, COSMIN, SISAQOL Consortium, ISPOR, PRO Harmonization Group, PROMIS, ERIQA, SPIRIT-PRO Group, and AERA/APA/NCME[2].
- Initial draft content is being disseminated at conferences to generate feedback and to obtain informal peer-review. Simultaneously, feedback is also being obtained through a more formal peer-review process, whereby WG02 members are reaching out to request feedback on the draft guidelines from SMEs.

CONCLUSIONS

The CORESTA CROM TF WG02 is currently in the process of drafting best practices and guidelines for tobacco regulatory research with respect to psychometric CROM. We are actively seeking collaboration from individuals with diverse perspectives and expertise representing public health, academia, and the tobacco industry throughout the guideline development process.

Contact Information: WG02 welcomes anyone interested in assisting with guideline development or providing feedback on draft content to contact the WG02 coordinators, Stacey McCaffrey (**Stacey.McCaffrey@juul.com**) and Esther Afolalu (**Esther.Afolalu@pmi.com**).

Footnotes:

[1]Psychometric CROM differ from descriptive CROM, which are items that measure behavior directly, such as the number of days a product was used in the past 7 days. Behavior captured by descriptive CROM is observable.

[2]FDA (US Food and Drug Administration), CONSORT (Consolidated Standards of Reporting Trials) PRO Group, ISOQOL (International Society for Quality of Life Research), COSMIN (COnsensus-based Standards for the selection of health Measurement INstruments), SISAQOL (Setting International Standards in Analyzing Patient-Reported Outcomes and Quality of Life Endpoints Data) Consortium, ISPOR (The Professional Society for Health Economics and Outcomes Research), PRO (Patient Reported Outcomes) Harmonization Group, PROMIS (Patient-Reported Outcomes Measurement Information System), ERIQA (European Regulatory Issues on Quality of Life Assessment Group), SPIRIT-PRO (Standard Protocol Items: Recommendations for Interventional Trials – Patient Reported Outcomes) Group, and AERA (American Educational Research Association)/APA (American Psychological Association)/NCME (National Council on Measurement in Education)

[3]Even if the researcher decides to use an existing psychometric CROM for their study, the researcher may still conclude that additional testing would be beneficial to evaluate a critical psychometric property (e.g., sensitivity to detecting change over time).

References

1. Kaufman AR, Persoskie A, Twesten J, et al. Tob Control 2020;29:s50–s58

2. U.S. Food & Drug Administration (FDA). Tobacco Products: Principles for Designing and Conducting Tobacco Product Perception and Intention Studies Guidance for Industry. Draft Guidance. October 2020.

RESULTS

Scope of the Guidelines: The draft content is currently organized into the following sections, described in Table 1.

Table 1. Psychometric CROM Best Practices and Guidelines Initial Draft Content

Content Area	Overview of Content
Identify ideal characteristics of the psychometric CROM based on the context of the research study	• Determine the optimal characteristics of the psychometric CROM within the context of the specific study - Considerations include: construct to be measured (how is the construct operationally defined?), output of the measure (interpretation of the score), frequency of administration, mode/method of administration, and the psychometric properties of greatest importance. • This step is intended to assist the researcher in determining whether an "off-the-shelf" CROM may be appropriate (with or without any additional testing[3]), whether an existing CROM might be modified to meet the study's demands, or whether it may be necessary to develop a new CROM.
Modification/ adaptation of existing psychometric CROM	• Examples of modifications/adaptations commonly encountered in tobacco regulatory science: - Adaptation of the CROM to a different target population (e.g., former tobacco user) or tobacco product/category - Modifying the instructions - Updating wording within the item/response options - Administering a subset of the items, or adding new items - Changing mode or method (e.g., adapting a paper-based CROM to an electronic platform) (Note, this often results in format changes) - Modifying the format of administration - Changing a rating exercise to a ranking exercise • The type of evidence (qualitative, quantitative) and extent of the evidence which may be useful to support the adaptation/modification depends on various factors, such as: - The extent of the modifications - Way in which the modified instrument will be used and interpreted • The researcher may also conclude that no additional testing is necessary.
Development and validation of new psychometric CROM	**General steps:** **(1)** Conceptual model development (based on data from focus groups, review of the literature, concept mapping, subject matter expert interviews, etc.) **(2)** Item generation and instrument drafting - Consider mode/method of administration and potential formatting challenges on a small screen (smart phone) - Consider replicability across vendors/electronic survey platforms **(3)** Qualitative (e.g., cognitive debriefing interviews) and quantitative (e.g., content validity ratio) research to refine draft instrument and obtain evidence of content validity **(4)** Quantitative methods to evaluate psychometric properties - Psychometric properties to be evaluated depend on the measure and its purpose **(5)** Scoring and interpretation (development of a users' guide) The specific steps that a researcher may choose to take to develop and validate the CROM will vary depend on various factors (e.g., purpose and intended use of the CROM, whether the CROM will address a primary, secondary, tertiary, or exploratory endpoint, etc.)
Application, implementation, and interpretation /scoring of psychometric CROM	• Researchers should be cautious and purposeful in the way in which they apply, score, analyze, and interpret the psychometric CROM within the context of the study. If a well-established and validated psychometric CROM is being applied and interpreted incorrectly, then the validity of the conclusions drawn from that measure could be called into question. • General considerations for implementation: - Mode/method and format of administration should be appropriate for the study and generally should be consistent with the measure's intended mode/method and format of administration - Timing of data collection (ecological momentary assessment to collect data in real-time, administering the measure at the end of each day vs. at the end of the week to collect daily data) - Manipulation checks and other validity assessments - Consistency of administration (across interviewers, across studies, across electronic platforms with different formatting capabilities, etc.) and context of administration • General considerations for scoring, analysis and interpretation - Scoring should follow the developer's initial publication if no user manual is available - Approaches for handling missing data should be stated a priori in the statistical analysis plan - CROM data analysis and reporting should be appropriate in relation to study outcomes
Linguistic /cultural adaptation of CROM	• This may apply to CROMs developed in one language and translated for use in other countries and cultures (modification/adaptation of existing CROM) or the development of CROMs across multiple languages and cultures (proactively planning as part of the CROM development process) • CROMs should measure the same concepts in a comparable way across different languages and cultures • Ensuring CROM cross-cultural equivalence may be conducted qualitatively or quantitatively • Processes related to cross-cultural adaptation and translations should be well-documented and researchers should ensure that information related to the appropriate access and use of translated CROMs is provided.

All authors, including the author presenting this poster, have no conflicts of interest to disclose.

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