CROM Workshop

Risk Perception of Tobacco and Nicotine-Containing Products: From Measurement Challenges to Unique Opportunities for Strengthening CROM-Related Science

29 September 2022 | 2:00 to 4:30 pm CET

PROGRAMME

AGENDA

2:00 p.m. - 2:05 p.m.	Introduction	**Stacey McCAFFREY**, PhD JUUL Labs Inc.
2:05 p.m. - 2:20 p.m.	The Perceived Risk Continuum for Tobacco and Nicotine-Containing Products – Does Measurement Matter?	**Christelle CHREA**, PhD Philip Morris Products S.A. & CROM Consortium Coordinator
2:20 p.m.- 2:40 p.m.	Overview of the ABOUT™—Perceived Risk Development and Evolution	**Emilie CLERC**, MA Philip Morris Products S.A.
2:40 p.m.- 3:00 p.m.	Understanding of the Mechanisms Underlying Perception of Risk	**Thomas SALZBERGER**, PhD University of Vienna (WU Wien)
3:00 p.m.-3:15 p.m.	**Break**	
3:15 p.m.-3:35 p.m.	Evolution of Risk Perception of IQOS Over Time: Evidence from PMI's Post-Market Cross-Sectional (PMX) Surveys	**Suzana AL MOOSAWI** Philip Morris Products S.A.
3:35 p.m. - 4:25 p.m.	Audience Q&A following speakers presentations	Moderated by **Stacey McCAFFREY**, PhD JUUL Labs Inc.
4:25 p.m. - 4:30 p.m.	Closing remarks	**Stacey McCAFFREY**, PhD JUUL Labs Inc.

WORKSHOP ABSTRACT

Risk Perception of Tobacco and Nicotine-Containing Products: From Measurement Challenges to Unique Opportunities for Strengthening CROM-Related Science

In tobacco regulatory research, risk perceptions are defined as the subjective judgments about the potential harms to health from using tobacco and nicotine-containing products. It is an important construct that can predict future use behaviour such as experimentation, cessation, as well as switching to other tobacco- and nicotine-containing products. In the context of tobacco harm reduction strategies, risk perceptions are often evaluated prior to product commercialization, to ensure that the product risk communication materials are an accurate, non-misleading, and scientifically substantiated reflection of the product characteristics. This allows current adult smokers to understand the risks and benefits of the product compared to other tobacco products, without encouraging non-smokers and ex-smokers to initiate or reinitiate tobacco use. Risk perception is also evaluated in a post-market setting to evaluate the trends of risk perception and thus potentially use behaviour over time.

Risk perception assessments rely exclusively on consumer-reported outcome measures (CROM), and this requires reliable and valid measures that ensure legitimate comparison (from a measurement standpoint) between different tobacco and nicotine products and different user (and non-user) groups. In the last few years, there have been numerous advances in the measurement of risk perception, including methodological considerations in using such measures in regulatory applications. In this workshop, we will use the case study of the specific development of the ABOUT™—Perceived Risk to illustrate some of the key measurement challenges and unique opportunities this domain of perception offers to strengthen CROM-related science.

The Perceived Risk Continuum for Tobacco and Nicotine-Containing Products – Does Measurement Matter?

Many stakeholders have recognized that there is a risk continuum for tobacco and nicotine-containing products (TNPs), which denotes the impact of tobacco use on human health at the individual and population levels. On this continuum, combustible products, cigarettes in particular, present the highest risk, because burning tobacco creates high levels of the harmful and potentially harmful constituents implicated in the development of smoking-related diseases. Cessation is at the lowest and other end of the continuum, as quitting is the best way for smokers to reduce their risk. Alternative non-combustible TNPs that avoid combustion lie somewhere between these anchoring points of the continuum. While this risk continuum is mainly built on objective health-related outcomes, risks of TNP use as perceived by users and non-users are also of high importance to understand the public health impact of a non-combustible product as it can predict future use behaviour. In this presentation we will summarize the current thinking on the important considerations for assessing risk perceptions in applied contexts, and will describe some measurement criteria derived from modern psychometrics that may be important to consider to establish a perceived risk continuum for tobacco and nicotine products.

Overview of the ABOUT™—Perceived Risk Development and Evolution

The ABOUT™—Perceived Risk is a self-report instrument, developed by Philip Morris Products S.A., designed to assess perceived risks associated with the use of a wide range of tobacco- and/or nicotine-containing products (TNP), such as cigarettes, e-cigarettes, smokeless tobacco, and heated tobacco products, as well as perceived risk associated with the use of nicotine replacement therapies (NRT) or remaining risks after

smoking cessation. In this presentation a brief history of the development and evaluation of the ABOUT™—Perceived Risk will be presented, starting with the original conceptual framework developed on the basis of qualitative studies, literature review, and input from experts to the initial psychometric validation of two multi-item scales for Perceived Health Risk and Addiction Risk, respectively, and three single items for "harm to others." To keep the instrument fit-for-purpose and to adapt to a growing population of dual and poly TNP users, further cognitive debriefing interviews and quantitative studies were conducted to validate 1) additional scales (Social and Practical Risk), 2) new versions of products to be assessed (current use of two or more TNPs; remaining risk after quitting all tobacco use), and 3) a short form (9-items) of the Perceived Health Risk scale. As for the original instrument edition, the new edition including all the updates to the instrument will be made available through PROQOLID™.

Understanding of the Mechanisms Underlying Perception of Risk

Typically, the psychometric scale validation is based on various statistical (i.e., quantitative) methods on the one hand and content-related, usually qualitative, considerations on the other. Both approaches are essential but not linked. While statistical relationships between scores determine whether items behave as expected, it is content validity that ultimately provides evidence that we are measuring what we claim to be measuring (i.e., risk perceptions). A measurement mechanism for perceived risk aims at linking qualitative evidence and content validity by specifying an explanatory model of risk. Risk is generally defined as a function of the probability of an outcome and its utility, which is typically negative.

It can be shown that perceptions of probability and negative utility of the health conditions included in the 9-item Perceived Health Risk scale short form of the ABOUT™—Perceived Risk significantly explain psychometric properties of the items and the participants' level of perceived risk. This not only strengthens the validity of the scale by providing evidence that the ABOUT™—Perceived Risk actually measures perceived risk. It also allows insight into how probability and negative utility contribute to the perceived risk of individual health conditions.

Evolution of Risk Perception of IQOS™ Over Time: Evidence from PMI's Post-Market Cross-Sectional (PMX) Surveys

Risk perception (RP) is a key factor influencing adult smokers' decision to transition to smoke-free tobacco and nicotine products (TNP), in addition to being a critical factor that could limit relapse among TNP users who switched away from cigarettes. PMI post-market cross-sectional surveys have been monitoring changes in the health RP of a novel tobacco heating system commercialized under IQOS™), relative to cigarette smoking, among current IQOS™ users in several countries. Our surveys demonstrate that RP is an evolving construct that changes over time and may be influenced by various factors including the availability of information on the product's risks and benefits. Regular surveillance of the RP of novel TNPs is warranted to ensure that adult smokers who would otherwise continue to smoke and adult TNP users who switched away from cigarettes receive adequate communications on the relative risks of novel TNPs.

BIOSKETCHES

Christelle CHREA, PhD
Manager Behavioural Sciences
Philip Morris Products S.A.

Christelle Chrea is a behavioural scientist with extensive technical expertise in the design, development and testing of psychometric instruments and survey questionnaires to address consumer-centric measurement gaps in clinical research or real world setting. She has 15+ years international experience in regulated consumer products industries and she is currently managing the Behavioral Sciences group at Philip Morris Products S.A. (PMP S.A.). In collaboration with international experts in patient-reported outcomes (PRO), Christelle Chrea and her team are advancing the development of well defined, developed and validated consumer-reported outcome measures (CROM) through the ABOUT™ Toolbox initiative, to support smoke-free products' assessment strategies, in line with requirements by regulatory agencies. Since November 2018, she is the coordinator of the CORESTA CROM Taskforce, an inter-industry consortium which goal is to establish best practices and guidelines for the integration of CROM in tobacco regulatory research.

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Emilie CLERC, MA
Behavioural Scientist
Philip Morris Products S.A.

Emilie Clerc works as a Behavioural Scientist in the Behavioural Science team at PMP S.A. She holds a Bachelor of Arts in Social Psychology and Anthropology, and a Master of Arts in Public Opinion and Survey Methodology, from the University of Neuchâtel. After working for 3.5 years as a social educator and being responsible for the accompaniment and education of people with multiple disabilities in daily life activities, she shifted her career aspirations towards social science research. She has been employed by PMP S.A. for the past 5 years. She serves as a key scientific resource in the conduct and evaluation of scientific assessments related to behavioural outcome projects, and in the development and validation phases of self-report instruments, in the roles of project manager and behavioural scientist. She is the key contact in a collaboration with a third-party for the distribution of self-report instruments developed by the Behavioural Science team in PMP S.A. and is responsible for the management of a knowledge repository, compiling self-report instruments and related psychometric information.

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BIOSKETCHES

Thomas SALZBERGER, PhD
Psychometric Consultant, Senior Lecturer at the Institute for Statistics and Mathematics, at the WU Wien, Lecturer at various Universities of Applied Sciences, WU Wien (University of Economics and Business, Vienna, Austria)

Thomas Salzberger has been working as a psychometrician for almost three decades. He received a doctorate in 1998 on the comparison of traditional test theory and Rasch measurement for assessing cross-cultural measurement equivalence in international market research. In 2008, he completed the habilitation on an Alternative Framework for the Measurement of Latent Variables in Marketing Research. He currently teaches courses on quantitative methods and statistics at various levels. He joined the WU Wien in 1993 and has since held different positions at the university. He is a psychometric consulting associate at Modes Outcomes. In collaboration with Philip Morris Products (R&D), Thomas has been involved in the development and validation of the ABOUT−PRI and the ABOUT−Dependence among other projects.

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Suzana AL MOOSAWI, PhD
Manager Regulatory Consumer Research
Philip Morris Products S.A.

Suzana Al Moosawi is a Manager of Regulatory Consumer Research at Philip Morris. She holds a Bachelor of Science in Human Nutrition, and a PhD in Public Health Nutrition from Queen Margaret University, Edinburgh. Suzana Al Moosawi dedicated her initial career to academic and policy research where she led the analysis of national surveys as well as longitudinal cohorts initially for the Medical Research Council in Cambridge and then for Newcastle University. Prior to joining PMI, she held a senior Teaching Fellow position in Public Health at the School of Public Health at Imperial College London. Since joining Philip Morris, Suzana Al Moosawi has been managing regulatory pre- and post-market surveillance studies in several countries focusing specifically on monitoring risk perception of IQOS™.

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