

The development of a new measurement instrument to assess health and functioning among tobacco and nicotine product users: the preparatory phase

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Introduction

- Measuring self-reported experience of changes in health and functioning is crucial to assess changes in the health status of individuals who switch from cigarettes to potentially less harmful tobacco- and nicotine-containing products (TNP).
- To date, there are no established smoking-related quality of life (QoL) measures that have proved to be sensitive enough to detect changes in health and functioning in otherwise healthy smokers who switch to potentially less harmful TNPs.
- As part of the **ABOUT** Toolbox (Assessment of Behavioral **OU**tcomes related to Tobacco and nicotine products) initiative [1], we are developing a new fit-for-purpose instrument to assess the impact of potentially less harmful TNPs on health and functioning and possibly related constructs, such as health-related QoL (HRQoL) or generalized perceptions of health.
- The goal of this project is to develop a sensitive measure that will detect changes in health and functioning among healthy smokers who switch to potentially less harmful TNPs.

Methods

- This measurement instrument development project incorporates three major phases, namely preparatory phase, phase I and phase II, as recommended in the U.S. Food and Drug Administration's guidance on patient-reported outcome (PRO) measures [2]. This poster presents the results of the recently finalized preparatory phase.
- The objectives of the preparatory phase were to:
 - Identify and evaluate publications relevant to the positive and negative impacts of potentially less harmful TNP use across a range of product users
 - Identify concepts related to switching to potentially less harmful TNPs
 - Identify and engage with an expert panel
 - Establish a preliminary conceptual model to support the new instrument development.

The preparatory phase spanned 3 methods that are described below:

1. Scoping literature review

A two-fold literature review focused on (1) qualitative information related to the health and functioning of tobacco users and (2) quantitative information focused on existing self-report measurement instruments.

The approach of the scoping review [3] encompassed two main components: (1) a database search in PubMed and the application of Sciome's Rapid Evidence Mapping, followed by manual screening and selection, and (2) the identification of relevant literature through other known sources.

Exclusion and inclusion criteria of literature review for the Rapid Evidence Mapping:

Inclusion criteria	Exclusion criteria
<ul style="list-style-type: none">Human subjectsOriginal sources of new dataInvestigating oral exposure to tobacco or nicotine productsReporting of at least one qualitative or quantitative positive or negative health impact resulting from exposureEnglish language publications	<ul style="list-style-type: none">Animal or <i>in vitro</i> cell studiesNon-original sources of dataSystematic reviews and meta-analysesStudies involving non-oral exposures to tobacco or nicotine productsStudies conducted in populations involving patients with terminal diseaseNon-English-language publications

2. Re-analysis of existing qualitative data

- Focus groups** to support the development of the ABOUT-Perceived Risk instrument (N=29) [4]
- Concept elicitation and cognitive debriefing interviews** to support the development of the ABOUT-Dependence instrument (N=40) [5]
- A coding scheme created for re-analysis within the context of health, functioning, and impact on perceived health and QoL

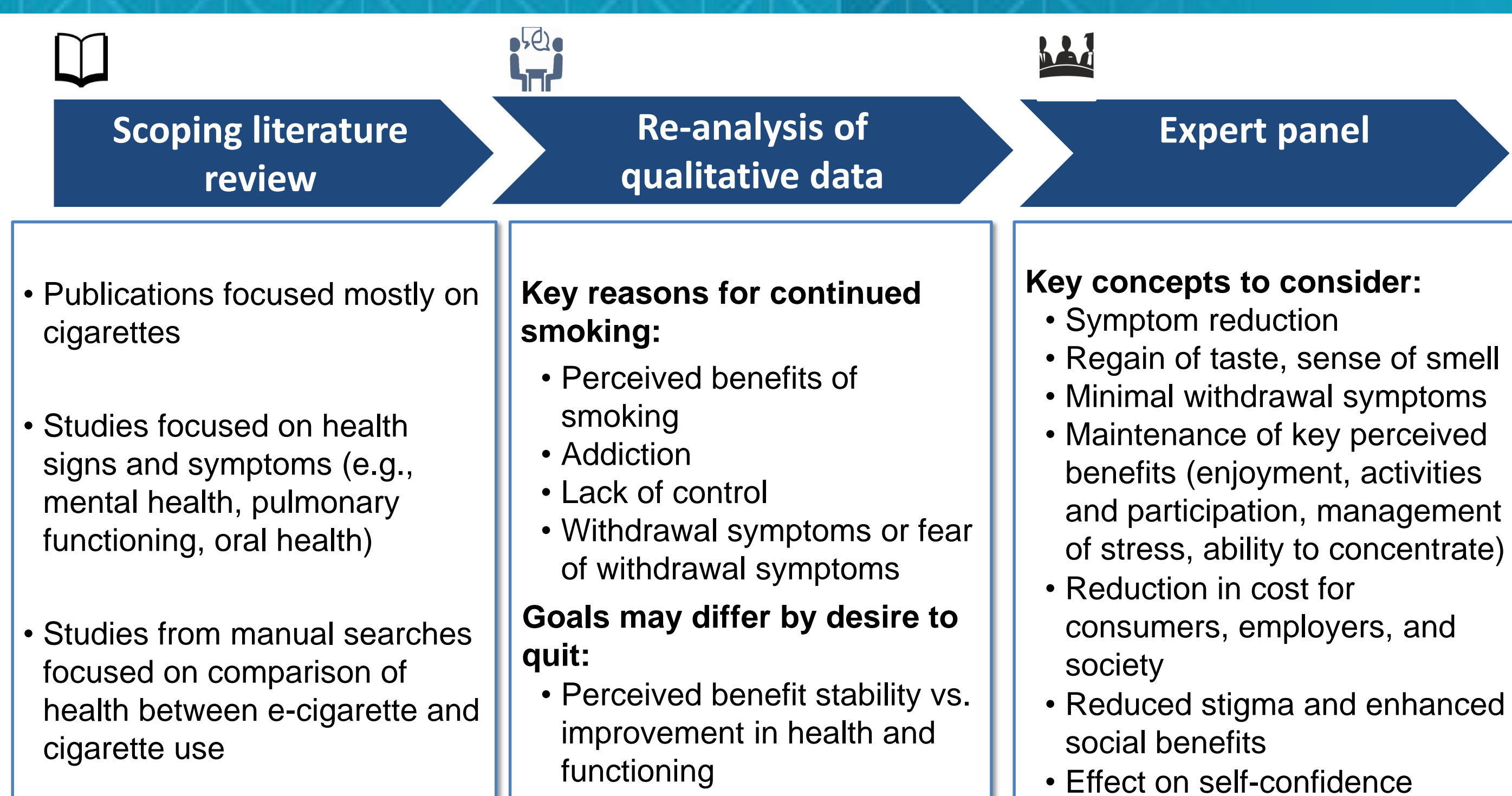
3. Expert panel discussion

- Experts in smoking cessation (#1), PRO scale development (#2), PRO regulatory matters (#1), health economics (#1)
- Additional technical consultants in tobacco addiction, smoking-related diseases, and PROs
- Four experts in the practical application of the development and validation of PROs

The model content has been structured by leveraging two frameworks that define concepts associated with health status:

- World Health Organization's (WHO) International Classification of Functioning, Disability and Health (ICF) [6]
- Revised Wilson Cleary model for HRQoL [7].

Results



Results – cont.

The preliminary health and functioning conceptual model derived from the literature review, the qualitative research re-analysis, and the expert panel discussion is presented in Figure 1.

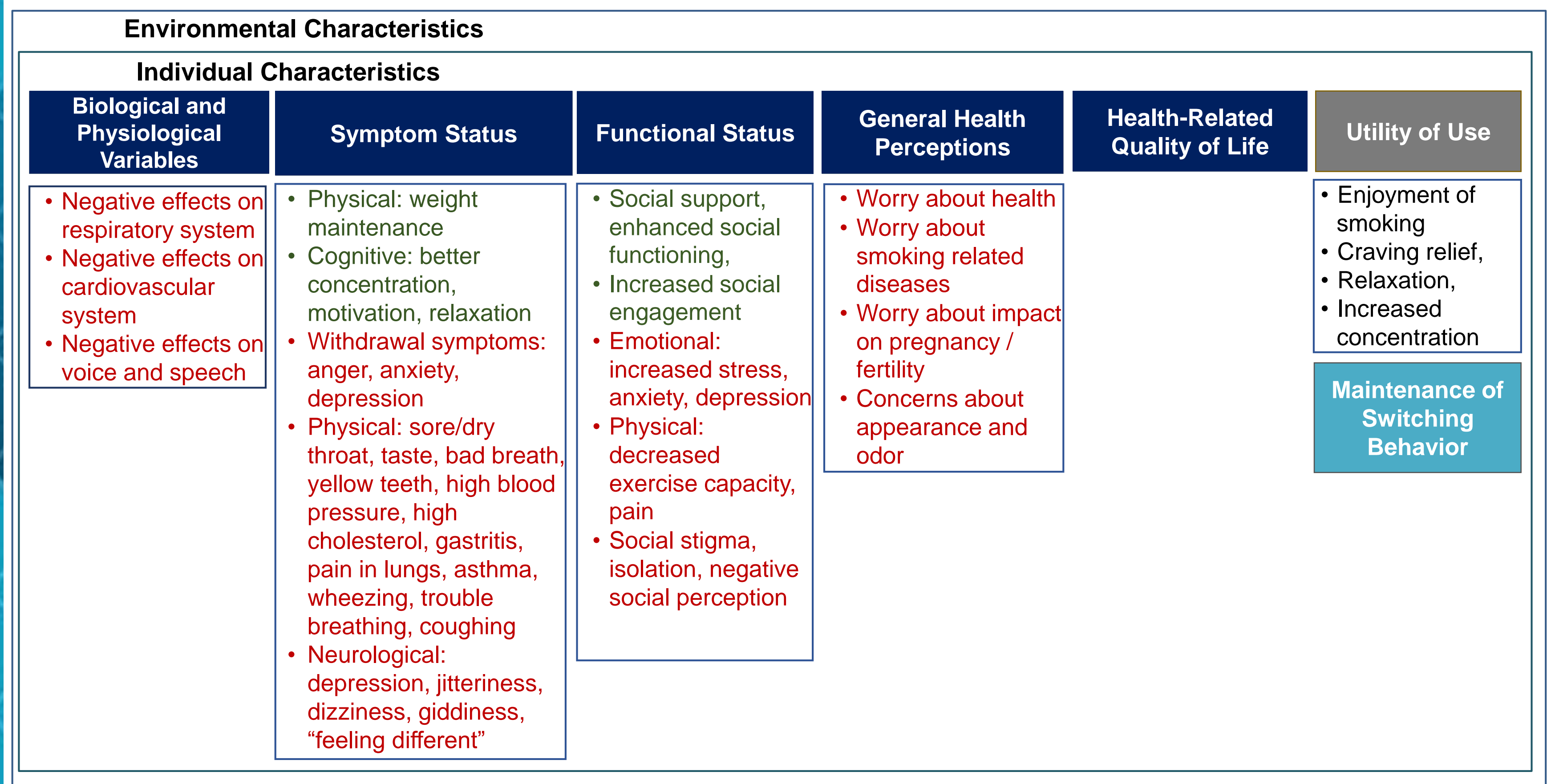


Figure 1: Preliminary conceptual model

The key concepts identified through these three methods and presented in the preliminary conceptual model are:

- Utility of use**, also known as perceived benefits of use, were found to be of great importance by the expert panel, which was also in line with the re-analyzed qualitative research. Utility of use refers to consumers' perceptions of smoking related to the enjoyment of smoking, craving relief, positive effects of smoking, and maintaining benefits, such as relaxation, weight control, and social affiliation.
- Signs and symptoms** refer to both perceived withdrawal symptoms (like depression, anxiety, anger, irritability, stress/tension, and lack of concentration) and relatively immediate (within 3 months) perceived positive effects of quitting smoking (such as better oral hygiene, less coughing, and improved exercise capacity).
- Functioning** includes cognitive, physical, social, emotional, and role functioning.
- General health perceptions** refer to the worry associated with smoking and smoking-related diseases.
- Quality of life** refers to all of the elements of functioning mentioned previously, plus, possibly, sexual functioning and enjoyment of life or life satisfaction.
- Environmental characteristics** refer to the physical, social and attitudinal environment in which people live and conduct their lives. **Individual characteristics** are influenced by larger social and cultural environments.

In addition, biomarkers relevant for switching have been identified by the clinical studies being conducted by PMI [8] were considered by the expert panel as important to include in the conceptual model, even though they would be assessed independently using objective clinical or biological assessments.

Conclusion

- The triangulation of published literature, qualitative data, and expert opinion led to the development of the presented conceptual model for the new health and functioning measurement instrument.
- As the next step, additional conceptual model refinement is expected through the execution of qualitative studies:
 - Qualitative concept elicitation studies are currently ongoing in Germany and Japan to identify relevant concepts and assess perception of health and functioning status of consumers of potentially less harmful TNPs, with a primary focus on IQOS® users.
 - A third qualitative study, with a primary focus on smokeless tobacco and e-cigarette users, will leverage the findings from the two previous qualitative studies to narrow down the concepts to be assessed in the health and functioning instrument.
 - A Delphi panel with international experts will be organized to further ensure the clinical and cross-cultural relevance of the measure by identifying health, functioning, and HRQoL concepts that are consensually rated as clinically important.
- These studies will aid the development of the self-reported measurement instrument on health and functioning, including key concepts that are relevant to a broad range of current users of potentially less harmful TNPs.

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