Introduction

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.

![Environmental Characteristics](image)

**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, 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 its 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 smoking have been identified by the clinical studies being conducted by PAN [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.

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 [5]. 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 TNP
  - Establish and engage with an expert panel
  - Establish a preliminary conceptual model to support the new instrument development.

The preparatory phase spanned 3 methods described as 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 Scopus’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:

<table>
<thead>
<tr>
<th>Inclusion criteria</th>
<th>Exclusion criteria</th>
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<tbody>
<tr>
<td>Human subjects</td>
<td>Non-English languages</td>
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<tr>
<td>Original sources of new data</td>
<td>English language publications</td>
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<tr>
<td>Investigating oral exposure to tobacco or nicotine products</td>
<td>Animal or in vitro cell studies</td>
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<tr>
<td>Reporting of at least one qualitative or quantitative positive or negative health impact resulting from exposure</td>
<td>Non-original sources of data</td>
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<td>English language publications</td>
<td>Systematic reviews and meta-analyses</td>
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2. **Re-analysis of existing qualitative data**
   - Focus groups to support the development of the ABOUT-Predicted Risk Instrument (N=24) [6]
   - 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:

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

Results

**Environmental Characteristics**

<table>
<thead>
<tr>
<th>Individual Characteristics</th>
<th>Biological and Psychological Variables</th>
<th>Symptom Status</th>
<th>Functional Status</th>
<th>General Health Perceptions</th>
<th>Health-Related Quality of Life</th>
<th>Utility of Use</th>
</tr>
</thead>
<tbody>
<tr>
<td>N=188 cigarette smokers</td>
<td>Respiratory and cardiovascular systems</td>
<td>Physical weight maintenance</td>
<td>Social support, enhanced social functioning</td>
<td>Physical and social improvement</td>
<td>Social support - increased stress, anxiety, depression</td>
<td>Social support - increased stress, anxiety, depression</td>
</tr>
<tr>
<td>A=105 nicotine users</td>
<td>Negative effects on smoke and speech</td>
<td>Cognitive function limitation</td>
<td>Increased social functioning</td>
<td>Economic</td>
<td>Economic</td>
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<tr>
<td>Z=58 participants</td>
<td></td>
<td>Physical symptoms</td>
<td>Emotional/</td>
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<td>Emotional/</td>
<td>Emotional/</td>
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<tr>
<td>C=107 participants</td>
<td></td>
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<tr>
<td>May 2019</td>
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<td>Physical symptoms</td>
<td>distress</td>
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**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:
  - Additional concept elicitation studies in Germany and Japan to identify relevant concepts and assess perception of health and functioning status of consumers of potentially less harmful TNP, with a primary focus on GOOP users.
  - A pilot 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 DAP 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 TNP.

References