

Development of a Post Market Surveillance Questionnaire on Reduced Risk Tobacco and Nicotine Products

Prasad K, Shetty M, Hart R, Caraway J, Fiebelkorn S, Rogers L, Battista D, Shane R, Miera M, Schwartz E, Barlow K, Montelongo M

Introduction

Post-market surveillance (PMS) enables the evaluation of potentially reduced risk tobacco and nicotine products (RRPs) at a population level. A two-phase study was designed to develop and pilot a robust PMS questionnaire. The questionnaire will be used in epidemiological cross-sectional and longitudinal studies to describe prevalence rates, risk perception and assess usage patterns of RRP and other tobacco and nicotine products as well as self-reported chronic and acute smoking-related health conditions.

Methodology

This study was conducted in two phases:

- **Phase 1** - Development of the questionnaire
- Test Launch – Review of initial responses by subset of participants
- **Phase 2** - Fielding of the questionnaire via a pilot study

Phase 1 involved a non-interventional, prospective, qualitative, interviewer led research study consisting of concept elicitation/cognitive interviews (CE/CIs) with Swiss adult consumers of tobacco and nicotine products.

Phase 2 will involve testing of the developed and finalised questionnaire and the envisaged approach in various markets.

Concept Elicitation (CE)

CE aimed to identify concepts important to consumers of each tobacco and nicotine product (Heated Tobacco Product (HTP), Electronic Nicotine Delivery Systems (ENDS), Oral Nicotine Pouch (ONP) Users and Combustible Cigarette (CC) Users), with a primary focus on current tobacco use patterns and preferences, health and risk perceptions, and reasons for initiation and current use.

Cognitive Interviewing (CI)

The CI portion involved a 30 minute semi-structured interview led by moderators and assessed the questionnaires in terms of the following parameters; Relevance, Clarity, Comprehensiveness and Ease-of-completion.

Thirty participants were recruited in Switzerland for the combined CE/CI phase of the study. Participants were approximately evenly distributed across the three study products of interest, HTP (n=11), ENDS (n=9), and ONP (n=10).

Once transcribed in English and pseudonymised, MAXQDA analysis output (qualitative coding software) was used to determine key themes discussed through an induction-abduction approach. Induction inference relates to findings that emerge directly from the data and abductive inference related to application of data from prior knowledge.

Results (Phase 1)

The content of the surveys was generally interpreted in line with the intended meaning, considered easy to understand and answer, and response options were seen as relevant and appropriate. Below are examples of findings from the qualitative interviews.

- The product descriptions received minor revisions to improve clarity, e.g. the German translations were updated to correct the translation of “gum”.
- Response options for ‘use in contextual situations’ questions (i.e. time of day and situation used) were informed by participant responses and included in the final versions of the survey.
- “I don’t use this product,” was removed from the question that asks participants to compare the health risks of various products to cigarettes to elicit product perceptions from all TNP users who may be knowledgeable about a product even if they do not use it themselves.

Strengths and Limitations

- A diverse range of participants were recruited to collect feedback and determine relevant, clarity, comprehensiveness and ease-of-completion for all three product categories.
- Future studies and questionnaire development would benefit from incorporating the format of administration (i.e. Computer-Assisted Web Interview)

Conclusion

Overall, these surveys performed well within this population of Swiss TNP users. From the data collected from these qualitative interviews and with the survey revisions that followed, we can be confident that the finalised surveys are fit-for-purpose and ready for launch into the next step of the pilot study in Switzerland. The content of the surveys was generally interpreted in line with the intended meaning, considered easy to understand and answer, and response options were seen as relevant and appropriate.

As these surveys have demonstrated their effectiveness with TNP users in Switzerland, it is likely that they will perform similarly well within the same consumer group in regions that are geographically and culturally similar to Switzerland. However, it is still recommended to do pre-testing of the surveys to conduct additional qualitative work to identify the potential need for region-specific survey revisions and provide evidence that the surveys are appropriate and well-understood in the target population.

Adaptation of (existing) Questionnaires

Combined Concept Elicitation/Cognitive Interviewing

Questionnaire Finalisation

Pilot Study in Switzerland

Phase 1

Phase 2



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