



METHOD ARTICLE

Developing fit-for-purpose self-report instruments for assessing consumer responses to tobacco and nicotine products: the ABOUT™ Toolbox initiative [version 1; peer review: 2 approved]

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Abstract

Background. Determining the public health impact of tobacco harm reduction strategies requires the assessment of consumer perception and behavior associated with tobacco and nicotine products (TNPs) with different exposure and risk profiles. In this context, rigorous methods to develop and validate psychometrically sound self-report instruments to measure consumers' responses to TNPs are needed.

Methods. Consistent with best practice guidelines, including the U.S. Food and Drug Administration's "Guidance for Industry Patient-Reported Outcome Measures: Use in Medical Product Development to Support Labeling Claims," scientifically designed, fit-for-purpose, reliable, and valid instruments are now being applied to tobacco regulatory research.

Results. This brief report presents the ABOUT™ Toolbox (Assessment of Behavioral Outcomes related to Tobacco and nicotine products) initiative. This communication: (1) describes the methodological steps followed for the development and validation of the measurement instruments included in the ABOUT™ Toolbox, (2) presents a summary of the high-priority tobacco-related domains that are currently covered in the ABOUT™ Toolbox (i.e., risk perception, dependence, product experience, health and functioning, and use history), and (3) details how the measurement instruments are made accessible to

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Any reports and responses or comments on the article can be found at the end of the article.

the scientific community.

Conclusions. By making the ABOUT™ Toolbox available to the tobacco research and public health community, we envision a rapidly expanding knowledge base, with the goals of (1) supporting consumer perception and behavior research to allow comparisons across a wide spectrum of TNPs, (2) enabling public health and regulatory communities to make better-informed decisions for future regulation of TNPs, and (3) enhancing surveillance activities associated with the impact of TNPs on population health.

Keywords

Modified risk tobacco products, Reduced risk products, Self-report instruments, Behavior, Consumer perception, Best measurement practices

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List of abbreviations

ABOUT: Assessment of Behavioral Outcomes related to Tobacco and nicotine products;

FDA: U.S. Food and Drug Administration; ICF: International Classification of Functioning, Disability, and Health; mCEQ: Modified Cigarette Evaluation Questionnaire MRTP: Modified risk tobacco product; PRO: Patient-reported outcomes; PROQOLID: Patient-Reported Outcome and Quality of Life Instruments Database; RMM: Rasch measurement methods; TA: Translatability assessment; TNP: Tobacco and nicotine product; WHO: World Health Organization.

Introduction

Many stakeholders have recognized that there is a risk continuum for tobacco and nicotine products (TNPs)^{1,2}. On this continuum, combustible products, cigarettes in particular, present the most risk, because burning tobacco creates the vast majority of the harmful and potentially harmful constituents implicated in the development of smoking-related diseases³. Cessation is at the lower end of the continuum, as it is the best way for smokers to lower their risk⁴. Alternative noncombustible TNPs (sometimes referred to as alternative nicotine delivery systems) that avoid combustion lie somewhere between these anchoring points of the continuum¹. Tobacco harm reduction is an approach recognized by the U.S. Food and Drug Administration (FDA), the Institute of Medicine, and the World Health Organization (WHO) as part of a solution to more rapidly reduce the burden of preventable deaths and smoking-related diseases^{3,5-7}. In the U.S., this has given rise to a regulatory framework for manufacturers to market modified-risk tobacco products (MRTPs), defined by the FDA as “any tobacco product that is sold or distributed for use to reduce harm or the risk of tobacco-related disease associated with commercially marketed tobacco products”⁸. However, to implement this approach successfully, consistent, transparent, and evidence-based science on the reduced risk potential of alternative products is paramount².

In alignment with the FDA’s draft guidance on MRTPs, consumer perception and behavior assessments are key components of assessing the full public health impact of tobacco harm reduction⁸. Valid and reliable self-report measures are needed to assess consumer responses to MRTPs in comparison with other commercially available TNPs⁹⁻¹¹. Although this has been acknowledged for quite some time¹⁰, the field of tobacco regulatory research falls short of specifically developed measures due to the lack of adherence to measurement best practices and specific guidelines that would facilitate standardization and harmonization of measures across studies (e.g., see a recent review on risk perception measurement in tobacco control research¹¹). Some measurement and standardization initiatives have recently been proposed, the most predominant ones being the Patient-Reported Outcomes Measurement Information System Smoking Initiative¹²⁻¹⁷ and PhenX measures for Tobacco Regulatory Research (<https://www.phenxtoolkit.org/collections/trr>). It is worth noting that both initiatives focus primarily on combustible tobacco products, with their development based on legacy measures developed solely for cigarettes¹⁵. It is crucial, however,

to attempt further efforts to develop new measurement instruments that would be “fit-for-purpose” to compare combustible and noncombustible products on the same risk continuum in order to better inform the public health decisions.

We present an ongoing collaborative effort to develop fit-for-purpose measurement instruments (i.e., concept-driven instruments providing interpretable outcomes for the purpose intended) to enhance the scientific framework of harm reduction. This new initiative has resulted in the creation of the ABOUT™ Toolbox (Assessment of Behavioral Outcomes related to Tobacco and nicotine products).

The objectives of this communication are (1) to describe the methodological steps followed for the development and validation of the measurement instruments included in the ABOUT™ Toolbox, (2) to present a summary of the high-priority tobacco-related domains that are to be covered in the ABOUT™ Toolbox, and (3) to detail how the measurement instruments are to be made accessible to the scientific community.

Methods

Development and management of the ABOUT™ Toolbox

The ABOUT™ Toolbox has been developed using best measurement development practices and as the manifest of an underpinning behavioral conceptual model for TNPs.

Several guidelines, including the FDA’s “Guidance for Industry Patient-Reported Outcome Measures: Use in Medical Product Development to Support Labeling Claims”¹⁸, have been used as the foundation for the creation of the ABOUT™ Toolbox initiative^{19,20}. These guidelines provide the scientific basis for the development, modification, and validation of patient-reported outcome (PRO) measures in support of medical care research. Although not specifically designed for the tobacco regulatory research field, these recommendations are essential in outlining a wide range of development considerations, such as (1) defining the context of use and identifying the concept(s) of interest, (2) generating items that best capture the concept(s) of interest as expressed by the population of interest, (3) choosing the right response options and recall period, (4) evaluating the content validity of the instrument, and (5) assessing psychometric measurement properties for construct validity. These recommendations also cover the considerations around the adaptation of a self-report measure (e.g., for a different context of use, target population, or cultural group [see below the paragraph “cross-cultural equivalence”]).

The application of these best practices requires the use of mixed-methods research, which can be defined as “research in which the investigator collects and analyzes data, integrates the findings, and draws inferences using both qualitative and quantitative approaches, and methods in a single study or program of inquiry”²¹. As noted in a recent paper on rare disease patients²², qualitative methods alone are unable to inform us about the extent to which concepts are measurable. Conversely, quantitative methods alone cannot inform us about which concepts should be measured.

By applying these best measurement practices for the development of the ABOUT™ Toolbox (see Figure 1), the initiative further enhances tobacco regulatory research by combining five major components (described in the paragraphs below) that are paramount for rigorous instrument development.

1. Generation of a conceptual framework

The development of each instrument starts with the generation of a conceptual framework, which is grounded in theory and supported by the triangulation of evidence data from literature reviews, consumer input, and expert opinions. Furthermore, the development of each measurement instrument in the ABOUT™ Toolbox has been or is being conducted in close partnership with scientific experts from academic and commercial organizations with expertise in the fields of nicotine addiction, motivational aspects of consumer perception, and relevant areas on approaches to measurement (e.g., PROs, cross-cultural adaptation, psychometrics, regulatory submissions). The role of these experts is pivotal not only to provide input during the development of the conceptual framework but also to assist in the objective consensus-building process throughout the entire development of the instrument.

2. Evaluation of content validity

The main goal is to evaluate whether the instrument represents the concepts of interest, and the instructions and item content are appropriate, relevant, comprehensive, and understandable to the target population. This evaluation is performed in accordance with current good research practices^{23,24}. The content validity of the instruments included in the ABOUT™ Toolbox is supported by the execution of qualitative research with consumers (e.g., 25–27).

3. Use of an appropriate psychometric model

The psychometric assessment of most of the ABOUT™ instruments is based on the use of Rasch measurement

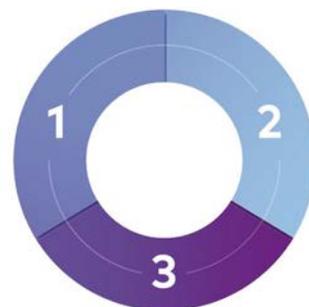
methods (RMM)²⁸, supplemented by diagnostic evidence of the dimensionality and reliability properties rooted in classical test theory^{29,30}. RMM particularly investigate to what extent (1) the items are targeted for the type and range of issues to be measured³¹, (2) the items work well together as a set forming a unidimensional scale^{31–33}, (3) the response options are working as intended³⁴, and (4) the items do not show differential item functioning across various population groups or TNPs³⁵. This evaluation provides the necessary evidence that the conceptual framework has been converted successfully into a list of items, the responses to which can be summed to form a statistically sufficient total score (i.e., comprising all available information). The score can then be transformed into a linear measure that is comparable across population groups or TNPs, conceptually meaningful and substantively interpretable (e.g., 36,37). The final outcome of the application of RMM is the development of a calibrated scoring table that transfers sum scores to logit measures, which are mapped to a 0–100 scale for ease of interpretability. The conversion is a simple, linear transformation that changes the logit mean of 0 to 50 and converts most extreme measures to 0 and 100, respectively (e.g., 37). The purpose, description, administration, and scoring (including the calibrated scoring table) of the final validated version of an instrument is documented in a user manual that accompanies all the instruments of the ABOUT™ Toolbox.

4. Cross-cultural equivalence of the ABOUT™ instruments

In the context of the globalization of tobacco regulatory research, measures appropriate for use in different cultures are crucial. The demonstration of cross-cultural equivalence requires investigating that the instrument measures the same concepts in a comparable way across different languages and cultures^{38–40}. The first step toward cross-cultural equivalence is to ensure that rigorous translation procedures are followed. In the field of health outcomes research, recommendations to support the use

Development of the conceptual framework and item generation

- ① Define concepts of interests, context of use and intended population
- ② Generate conceptual model based on literature review, qualitative study, expert opinion
- ③ Generate draft instrument with items best representing concepts of interest, appropriate response options, format, and recall period
- ④ Evaluate content validity with cognitive debriefing interviews



Cross-validation of the psychometric properties, scoring rule and cultural adaptation

- ① Test cross-cultural equivalence (linguistic validation, psychometric properties, scoring)
- ② Finalize instrument (document content, formats, psychometric properties, and scoring rule in a user manual)
- ③ Document instrument development and validation in publications
- ④ Make the instrument publically available

Confirmation of the conceptual framework and item reduction

- ① Identify items that best work together to form a scale and ensure items are well targeted
- ② Ensure response options work as intended
- ③ Ensure stability of the instrument across different population groups
- ④ Assess other measurement properties of the reduced-item instrument (construct validity, ability to detect change, score reliability)

Figure 1. Iterative process for the development of an ABOUT™ instrument.

of self-reported measures in multinational contexts have been provided^{41,42}. These recommendations apply to measures developed in one language and subsequently translated for use in other countries and cultures. In line with this guidance, the instruments included in the ABOUT™ Toolbox follow a thorough linguistic validation process consisting of two forward translations to the targeted new language, one back translation to the source language, and qualitative cognitive debriefing interviews with participants in the targeted language to ensure that the translations are understood (e.g., 43 and Figure 2)⁴⁴.

The investigation and demonstration of the cross-cultural equivalence of the ABOUT™ instruments are completed by quantitative steps (e.g., 37,45), such as the evaluation of the psychometric properties of the translations and differential item functioning⁴⁶.

Translatability assessment (TA) is a technique that will be applied to all future ABOUT™ instruments. It is defined as the review of an original measure, preferably during the development stage, prior to its use, in order to determine its suitability for future translations in multilingual studies⁴⁷. TA can be viewed as the very first step toward ensuring measurement equivalence between the original measure and its future translations.

5. Appropriate access and use of the validated instruments (original and translations)

Easy, centralized, and appropriate access to original instruments and their translations is often a prerequisite to efficient research. With a unique point of access endorsed by the developers

of instruments, researchers are able to access and use the original instrument and its translations⁴⁸. The centralization and control of access also enables the integrity of the each measurement instrument (original and translations) to be respected⁴⁹. Once the instruments are fully developed and validated (Steps 1 and 2 on Figure 1), they are made publicly available through the Patient-Reported Outcome and Quality of Life Instruments Database (PROQOLID™)⁵⁰, managed by Mapi Research Trust and part of the ePROVIDE™ web platform (<https://eprovide.mapi-trust.org/>).

To get access to the instruments distributed on ePROVIDE™, each new user has to complete a free registration form at <https://eprovide.mapi-trust.org/login> (click to the Free Registration button). The following link leads to a tutorial to help navigating through the whole registration process: <https://eprovide.mapi-trust.org/tutorials/registering-for-free>. Once the registration is completed, the register button will lead the user to his/her free ePROVIDE™ account. From there, any retrieval of instruments can be performed.

Instruments and their respective user manuals can be retrieved through the main search engine of the database by using either the full name or parts of the name (e.g., ABOUT™–Perceived Risk, Perceived, or Risk) or within the “Our Catalog” section of ePROVIDE™ (<https://eprovide.mapi-trust.org/catalog>) by filtering through the Behavior and Behavior Mechanisms category.

To be able to use any of the ABOUT™ Toolbox instruments, all users (whether they are commercial or non-commercial



Figure 2. Linguistic validation process for the development of an ABOUT™ instrument.

users) will have to accept the conditions of a license/user agreement and complete the appropriate form. This license, issued by Mapi Research Trust, which is the official distributor of the instruments, specifies the terms under which each instrument should be used: Special terms, i.e., specific to each instrument, and General terms: <https://eprovide.mapi-trust.org/user-agreement-general-terms>.

Tutorials are available on how to submit requests (commercial users) or download copies directly (non-commercial users) (see <https://eprovide.mapi-trust.org/faq>). All requests are handled by the PROVIDE team of Mapi Research Trust.

Results

Inventory of the ABOUT™ Toolbox

The ABOUT™ Toolbox currently comprises five measurement instruments, which are at various stages of development and validation. Table 1 presents a summary of the relevant domains, concepts of interest, and context of use to be covered by the instruments. The initiative is to be expanded by additional domains as they are identified. The initial inclusion of these current instruments were informed extensively by existing research and domains that have been prioritized based on public health impact and issues of key importance to tobacco regulatory research.

Fully developed and validated instruments

1. ABOUT™–Perceived Risk

Assessment of risk perception is an important domain of tobacco-related behaviors and influences any tobacco harm reduction strategies aimed at getting individuals to switch to less harmful alternatives to cigarette smoking^{1,11}.

The Perceived Risk Instrument was developed as a multi-scale instrument intended to assess the perceived risks associated with use across a range of different of TNPs, relative to other products, cessation aids, and quitting all tobacco products. The health risk and addiction risk scales have been calibrated in three countries (U.S., Italy, and Japan) for two perception types: risk to the individual respondent (personal risk) and risk to users of the product in general (general risk)^{25,37}. The validation of further scales for perceived social and practical risk is currently under development.

2. ABOUT™–Use History

One of the key aims underlying tobacco control and harm reduction is to reduce the burden of smoking-related diseases through the implementation of monitoring strategies for tobacco consumption and characterization of key patterns and trends in tobacco use³. The Smoking Questionnaire, included in the ABOUT™ Toolbox, was developed to provide a core set of questions that cover the major dimensions of TNP use and is consistent with criteria used for defining smoking history and status⁵¹. It assesses frequency and intensity of current and past TNP use behavior, initiation, and cessation and demonstrates good test-retest reliability^{52,53}.

Instruments under development

1. ABOUT™–Product Experience

Product experience encompasses a range of self-reported expressions of an individual's experience using a TNP and is a key

predictive measure of short-term preference and long-term TNP use⁵⁴. The modified Cigarette Evaluation Questionnaire (mCEQ) has been endorsed by regulatory and public health bodies to use in the context of MRTP assessment^{9,55}. The ABOUT™ Toolbox includes a measure consisting of two multi-item scales and three single-item scales arising from an adaptation and rewording of the mCEQ⁵⁶ and the Product Evaluation Scale⁵⁷. The scales focus on satisfaction, psychological reward, craving reduction, aversion, and enjoyment of respiratory tract sensation. Psychometric testing and validation have been carried out for the use of the measure to assess cigarettes and heat-not-burn products⁴⁵, and further validation is ongoing for a variety of TNPs (e.g., e-cigarettes, cigars/cigarillos, smokeless products) and different recall periods.

2. ABOUT™–Dependence

Nicotine dependence has been shown to be a primary driver of smoking and TNP use behaviors⁵⁸. However, dependence on nicotine has generally focused on cigarette smoking. Evidence suggests that measuring dependence with a common set of symptoms across different TNP use groups is feasible and may better reflect the dynamics of dependence across a range of products⁵⁹⁻⁶¹. Work is ongoing to develop such a fit-for-purpose dependence instrument for inclusion in the ABOUT™ Toolbox. The proposed instrument is rooted in a conceptual framework of dependence that identifies lack of control (e.g., urgency to use upon waking up, difficulty to cease using, self-awareness of dependence) as the core construct. Recommended practices in PRO development have been used to generate a draft instrument from a range of qualitative research steps, including literature review, concept elicitation, and cognitive debriefing interviews with different groups of adult tobacco users²⁷. The draft instrument is currently undergoing quantitative field testing to assess psychometric properties and produce a final validated measure.

3. ABOUT™–Health and Functioning

Health and functioning is a relevant dimension for the evaluation of TNP impact on public health and requires further investigation^{8,9,58}. There are no established measures specific to tobacco-related health outcomes to date. In addition, existing generic health and functioning instruments do not capture the small, but potentially important, concepts that may change when a smoker switches to an MRTP. Currently, efforts are ongoing to develop a new outcome measure for inclusion in the ABOUT™ Toolbox that would accurately reflect the health and functioning status of individuals who use TNPs, with a particular focus on healthy adult smokers who switch to MRTPs. The measure's development will be underpinned by conceptual frameworks including, but not limited to, the WHO's International Classification of Functioning, Disability, and Health (ICF)⁶² and the Revised Wilson and Cleary Model for Health-Related Quality of Life⁶³. The ICF is particularly well suited to serve as a guiding framework, as it conceptualizes a person's level of functioning as a dynamic interaction between body structure and functions, health conditions, social participation, personal factors, and environmental factors. The Wilson and Cleary Model is included to address subjective dimensions of health and functioning, such as well-being and health-related quality of life. Literature review, an expert panel, and qualitative research

Table 1. Information on the ABOUT™ Toolbox and access to the instruments.

Instrument	Concept of interest (# items)	Context of use	Target population	Accessibility/Publications
Fully developed and validated instruments				
Perceived Risk	Health risk (18) Addiction risk (7) Harm to others (2) Social and practical risk scales are currently under development	All TNPs + Cessation	Adult current, former, and never TNP users	Available in PROQOLID™ under ABOUT™–Perceived Risk: https://eprovide.mapi-trust.org/instruments/about-perceived-risk-formally-perceived-risk-instrument-pri ^{25,37}
Use History	Initiation Cessation Intensity of current and past use	All TNPs	Adult current, former, and never TNP users	Available in PROQOLID™ under Smoking Questionnaire (SQ): https://eprovide.mapi-trust.org/instruments/smoking-questionnaire2 ^{52,53}
Instruments in development				
Product Experience	Satisfaction (3) Psychological reward (5) Craving reduction (1) Aversion (2) Enjoyment of respiratory tract sensation (1)	All TNPs Different recall periods	Adult current TNP users	Available in PROQOLID™ in 2019
Dependence	Time to first and last product use (2) Attitudinal evaluation (5) Behavioral evaluation (5)	All TNPs	Adult single or poly-TNP users	Available in PROQOLID™ in 2019
Health and Functioning	Body structure and function Activity Participation Personal factors Environmental factors	All TNPs + Cessation	Adult current and former TNP users	Development initiated in 2018

PROQOLID™, Patient-Reported Outcome and Quality of Life Instruments Database; TNPs, Tobacco and Nicotine Products.

with a wide range of consumers are planned for the initial phase of the project.

Discussion and conclusion

In the present paper, we have presented a new initiative aiming at enhancing the scientific framework of harm reduction and promoting the establishment of consensus and standardized tools to be used across tobacco regulatory research studies. Within the new regulatory MRTP pathway, FDA can issue an order authorizing the marketing of MRTPs. To do so, data must demonstrate that use of the new product (1) would present a significantly lower risk of harm to the individual user and (2) would reduce the incidence of harm in the population as a whole (e.g., with evidence that marketing the new product as a less risky alternative to cigarettes would not increase use of the new product by non-smokers), as described in section 911 of the Federal Food Drug and Cosmetic Act⁶⁴. Since the inception of the MRTP pathway in 2011, FDA has received 35 MRTP applications and granted zero Modified Risk Orders (<https://www.fda.gov/TobaccoProducts/Labeling/TobaccoProductReviewEvaluation/ucm304465.htm#2>). This suggests that (1) no manufacturer

has yet successfully demonstrated the harm reduction potential of any new TNP to the FDA and (2) the FDA and manufacturers have not shared a common understanding of what classifies consistent, transparent, and evidence-based science. Therefore, it is of paramount importance to establish a common, well-defined understanding of the types and volume of research data that would demonstrate a candidate MRTP to be appropriate for the protection of the public health to the FDA and other regulatory authorities. As expressed by the National Institutes of Health Tobacco Regulatory Science Program and the FDA Center for Tobacco Products, “One way to accomplish this is to provide investigators with a common set of tools and resources to facilitate sharing, comparing, replication of findings, and integration of data from multiple sources”⁶⁵.

As part of this effort, the current ABOUT™ Toolbox may facilitate progress toward consensus of domains to be assessed and consensus on how they should be measured and reported. With the development and dissemination of the ABOUT™ Toolbox, researchers will have access to instruments that are (1) developed and validated with state-of-the-science methods

to be psychometrically sound, straightforward to implement in clinical and population-based studies, and easy to interpret; (2) created to be relevant and applicable across the whole spectrum of TNPs and across various population groups; and (3) designed to enhance standardization and comparison of data on perception and behaviors toward MRTPs across academic, industry, and public health research communities.

The current measurement instruments highlighted in the ABOUT™ Toolbox fit within what can be described as a broader behavioral conceptual model, designed to understand TNP switching or transition behaviors, which encompasses several levels of assessment (i.e., individual, product, and environment [Spies *et al.*, manuscript in preparation]). This conceptual model evolved from the review of several existing frameworks that propose explanations of and factors associated with TNP use^{10,66,67} and was complemented by literature on principles of behavioral changes, taking a socio-ecological approach to the conceptualization of TNP switching or transition behaviors⁶⁸. Each of the individual, product, and environment levels includes several categories for which concepts and variables are defined. For instance, the individual level includes individual traits (e.g., dependence), attitudes and beliefs toward products (e.g., perceived risk), response to the product (e.g., satisfaction), self-reported product behavior (e.g., consumption changes), and functional health and quality of life. Instruments within the ABOUT™ Toolbox are intended to be used within this conceptual model to measure each of these concepts of interest in a standardized way.

By making the ABOUT™ Toolbox available to the tobacco research and public health communities through PROQOLID™, we envision a rapidly expanding knowledge base, with the goals of not only advancing further the interpretation of consumer perception data comparing a large spectrum of TNPs but also enabling public health and regulatory communities to make

better-informed decisions for future regulation of MRTPs and to enhance surveillance activities associated with smoking-related disease. The ABOUT™ Toolbox launches a dialogue on new perspectives required to develop standards and best practices in the spirit of current guidance for self-reported measures and may encourage the creation of a consortium to work on standard measures across the industry.

Data availability

Access to the measurement instruments, as well as further information on the original versions and translations is freely available for non-commercial use on ePROVIDE™ (<https://eprovide.mapi-trust.org>).

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This article deals with an important issue facing society today – how to encourage tobacco harm reduction without introducing new and undefinable hazards, and to make possible the perception of risk by individuals using a range of devices. While not wishing to question the integrity of the authors or the value of the thought and effort they have put into developing ABOUT™ Toolbox, we think it essential that wider questions related to the development of safer smoking materials and alternative sources of nicotine are considered, before turning to specific aspects of the ABOUT™ Toolbox proposal itself.

In the Introduction, the authors refer to the continuum between cigarette smoking at one extreme and cessation at the other. However, it is not clear whether “cessation” refers only to tobacco products, including non-combustible TNPs, or to all forms of voluntary uptake of nicotine. Our own position, as toxicologists, is clear. Nicotine is a very toxic and addictive substance, so its use should be actively discouraged. Therefore, the increasing use of electronic cigarettes (ECs) is a matter of great public health concern.

Another continuum is that between heavy cigarette smokers and individuals who have never smoked at all. Encouraging heavy smokers to switch to ECs in order to reduce their risk of tobacco harm can be a helpful strategy, but encouraging non-smokers to use ECs can only be seen as highly undesirable.

Public Health England (PHE), an executive agency of the Department of Health and Social Care, has stated that ECs are 95% safer than tobacco cigarettes. Such a statement is without scientific justification, as there are no compatible quantitative measures of the risks involved in smoking cigarettes or ECs, which would permit such a comparison between them to be made. The statement is based on the conclusions of a small number of experts who advise PHE.

Safety is related to risk, which is the product of hazard and exposure. However, there is no satisfactory body of scientific evidence concerning the hazard represented by the vapours produced by ECs. The effects of exposure to EC vapour must also be highly variable, as they will depend on a variety of factors, including the type of EC used, the sources and levels of its nicotine and other additives, puff volume, puff frequency, the extent of inhalation, and the age, previous smoking history, health conditions affecting the respiratory system, such as asthma, and genetic polymorphism in relation to, for example, nicotine biotransformation enzymes, and nicotinic-acetylcholinergic receptor subunit structures, which affect binding affinity for nicotine. In combination, these and other factors must mean that there is also a continuum of individuals subject to high to low risks from exposure to EC vapour, whatever those risks may be.

An important principle in society is that individuals should have the freedom to make their own decisions about what they do, bearing in mind the risks involved, as they are able to perceive them. However, given the lack of evidence about the safety of alternatives to cigarette smoking, how can members of the general public be expected to make their own decisions about what, if anything, to smoke, and with what limitations?

The article refers to a triangulation of evidence from literature reviews, consumer input and experts opinions, but we would argue that none of these are a satisfactory basis for the self-assessment of risk. Such as it is, the literature is sparse and conflicting, and both consumers and policy makers are strongly influenced by the media, where reporters are easily led by soundbites, such as the PHE "95% safer" slogan. In addition, finding experts without conflicts of interest is not easy. There is a continuum from individuals who lack sufficient expertise to those who have a great deal of expertise, but those at the latter end of the spectrum are likely to have conflicts of interest as a result of the ways in which their experience was gained. We note that the list of experts mentioned in relation to the generation of a conceptual framework did not include toxicologists. Having a sufficient basis for perceiving the potential toxic effects of tobacco and other nicotine products is surely as essential to ABOUTTM Tool as is the use of an appropriate psychometric model.

The development of systems such as ABOUTTM Toolbox raises many important questions, including how, and by whom, they are designed and managed, the results are analysed and reported, and their outcomes are used in making policy decisions. This must involve high degrees of independence and transparency, and there is also a continuum in terms of motivation. At one end are those responsible for advising on public health, while at the other end are those with commercial interests in developing and maintaining markets and dividends. These various motivations are defensible, and those with one kind of responsibility should recognise the responsibilities of others placed elsewhere in the continuum.

This leads us to other matters of particular concern. First, the move from cigarettes smoking to the use of ECs should only be a stage in a longer process, leading to the avoidance of all forms of nicotine, however, consumed, in order to protect the delicate tissues of the respiratory system, in particular, from avoidable harm resulting from exposure to toxic and addictive substances. There is growing evidence that that is not a scenario that the tobacco industry wants, as the industry appears to be aiming to replace one kind of profitable dependence on addiction to nicotine with another one, on the grounds that it is less harmful. Secondly, tobacco harm results from repeated and long-term exposure to tobacco smoke, but there is no available evidence concerning the long-term effects of repeated exposure to EC vapours. Here, then, the precautionary principle should

apply, and, ideally, the health of cohorts of EC users and non-users should be monitored over several years, before any statements about safety are made. Thirdly, we are all taken in by the tactic of pricing of goods at \$10.99, which seems lower than \$11.00. Similarly, we tend to think that, if something is 95% safer than something else, it is absolutely safe. That is not true for ECs. This tendency may be useful to the short-term ambitions of PHE and to the commercial hopes of the producers of ECs, but cannot possibly be a satisfactory and acceptable basis for a public health policy. Fourthly, there must be a clear distinction between policies aimed and assisting cigarette smokers to switch to something less harmful and those aimed at individuals who have never smoked at all. Regrettably, there are campaigns aimed at attracting young people, including children, to use ECs, and there is evidence that individuals who begin to take in nicotine via ECs, later switch to cigarettes.

We hope that the authors may wish to consider our points and perhaps make some minor modifications to their article.

Is the rationale for developing the new method (or application) clearly explained?

Yes

Is the description of the method technically sound?

Yes

Are sufficient details provided to allow replication of the method development and its use by others?

Yes

If any results are presented, are all the source data underlying the results available to ensure full reproducibility?

No source data required

Are the conclusions about the method and its performance adequately supported by the findings presented in the article?

Yes

Competing Interests: No competing interests were disclosed.

Reviewer Expertise: Our experience as toxicologists is primarily in the development, validation, acceptance and application of non-animal toxicity test procedures and integrated test systems, and in particular, those which involve human cells and tissues.

We confirm that we have read this submission and believe that we have an appropriate level of expertise to confirm that it is of an acceptable scientific standard.

Reviewer Report 12 February 2019

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The authors tackle an important issue in tobacco regulatory science - how to integrate data on the potential impact of the introduction of potentially reduced risk tobacco and nicotine products on the population. It draws on approaches to labelling claims on medical products, and as such may miss some important elements of what may influence behaviours and use of what are in most jurisdictions consumer products. Some of these may become apparent as the tool is used in a multi-national context. For example, the cost of the devices of vaping or 'heat-not-burn' may have a major influence on the likely uptake in countries with low disposable income. Other cultural influences may also become important, and so rather than a translation followed by back translation, additional items may need to be added in some countries.

Is the rationale for developing the new method (or application) clearly explained?

Yes

Is the description of the method technically sound?

Partly

Are sufficient details provided to allow replication of the method development and its use by others?

Yes

If any results are presented, are all the source data underlying the results available to ensure full reproducibility?

No source data required

Are the conclusions about the method and its performance adequately supported by the findings presented in the article?

Partly

Competing Interests: Employed by a competitor in the same industry

Reviewer Expertise: Tobacco regulatory science

I confirm that I have read this submission and believe that I have an appropriate level of expertise to confirm that it is of an acceptable scientific standard.

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