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Evaluating the utility of subjective effects measures for predicting product sampling, enrollment, and retention in a clinical trial of a smokeless tobacco product

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HIGHLIGHTS

- Subjective effects predict product use in the short-term, but not enrollment in a clinical trial.
- Initial responses to a product might be associated with the extent of short-term use, but not necessarily continued use.
- Initial subjective measures may have limited implications for longer-term use behavior.

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ABSTRACT

Introduction: Subjective effects of drugs, representing pharmacological and non-pharmacological effects, have been shown to be associated with future use and abuse. This also is the case for tobacco products and so measuring subjective effects, such as liking, satisfaction, and aversion, is crucial to gaining an understanding of consumer perception leading to increased use. This study examined the predictive validity of subjective drug and product effects with respect to product adoption.

Methods: Smokers (N = 151) were enrolled in Minneapolis, Columbus, and Buffalo. Participants were shown two snus products (Camel Snus Winterchill and Robust), asked to try each of the products for 5 min and to rate them using the Product Evaluation Scale (PES) and Drug Effects Questionnaire (DEQ). This was followed by a one-week use period of their preferred product and those who used at least 1 unit of Camel Snus per day (or at least 7 pouches total) were eligible to enroll in the Clinical Trial Phase assessing the impact of complete switching or dual use with smoking. Key outcomes for this study were product evaluation, extent of product use, and Clinical Trial enrollment.

Results: We noted no relationships between participant characteristics such as gender, age, prior smokeless use, baseline cigarettes per day (CPD), or PES and DEQ scores with any of these outcome variables. Subjective effects were weak predictors of product use, which totaled approximately 3 units of snus per day.

Conclusions: Regardless of product, it appears that PES and DEQ ratings were uniformly poor predictors of trial enrollment and retention, though they do predict the amount of snus used during the sampling phase. Findings indicate that while subjective effects predict product preference in the short-term, they did not consistently predict extent of use or enrollment in the trial, suggesting that these initial measures have limited implications for long-term behavior.

1. Introduction

Two broad, inter-related domains of consumer perception are central to trial and adoption of new tobacco products: 1) reactions to messaging (broadly encompassing knowledge, attitudes, beliefs, and risk perceptions), and 2) responses to product use (including behavioral, sensory, and other subjective effects) (Rees et al., 2009). Subjective effects of nicotine, such as sensory factors, enjoyment, liking,

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and hedonics, have been shown to be associated with future use and abuse (de Wit & Phillips, 2012; Hanson, O'Connor, & Hatsukami, 2009). Measuring these sensory, affective, and cognitive elements is crucial to gaining an understanding of consumer perception of tobacco products. This is especially important in the evaluation of novel tobacco products, including those that may be marketed for reduced exposure to toxicants (e.g., modified risk tobacco products; MRTP). In allowing an MRTP claim, the Food and Drug Administration (FDA) must evaluate the generalizability of clinical trial and other findings reporting reduced exposure to toxicants and/or risk of disease from using an MRTP. Indeed, for an MRTP marketing order to be given, the manufacturer must demonstrate not only that the product reduces exposure or risk in individuals, but also that its availability would benefit the population as a whole (U.S. Department of Health and Human Services, Food and Drug Administration, & Center for Tobacco Products, 2012). Part of this 'population health' standard entails projecting the rate of product uptake among current smokers – a product only used by a small subset of smokers, or one used only as an occasional substitute, is unlikely to have dramatic public health benefit (Institute of Medicine, 2012). Product uptake is often inferred from studies of stated preference (Biener & Bogen, 2009; Biener et al., 2016; Zhu et al., 2013), revealed preference (Rousu, O'Connor, Bansal-Travers, Pitcavage, & Thrasher, 2015; Rousu et al., 2014), simulated demand (O'Connor et al., 2014; Quisenberry, Koffarnus, Hatz, Epstein, & Bickel, 2016; Stein, Wilson, Koffarnus, Judd, & Bickel, 2017), or from short-term clinical studies (Blank & Eissenberg, 2010; Cobb, Weaver, & Eissenberg, 2010; Hatsukami et al., 2011; Hatsukami & Severson et al., 2016; Hatsukami, Vogel, Severson, Jensen, & O'Connor, 2016), each of which has strengths and limitations with respect to internal and external validity (Institute of Medicine, 2012). A key question in such short-term studies is whether subjective responses to initial exposures to novel products (e.g., a single sample in the laboratory) are reflective of potential product uptake. If initial impressions were predictive of the extent of use over a longer period, this would suggest that short-term laboratory studies could serve as important screeners for a product's likelihood of adoption, a key consideration of public health impact. If initial ratings were poor predictors of product use, this would suggest that short-term study results could be misleading, and longer-term studies would be required to make an informed judgment.

The intention of this study was to examine the predictive validity of subjective drug and product effects with respect to product adoption, measured by use in a 2 month clinical trial. To model this, we built an initial "Sampling" phase into the clinical trial to assess whether sensory, drug effects, and experiential measures can predict who enrolls in a clinical trial of Camel Snus. The current study examines whether ratings of appeal, particularly sensory and subjective effects, are associated with degree of product use, and clinical trial enrollment and retention among current smokers.

2. Method

Data from this study come from a randomized, multi-site open-label trial examining clinical trail methods for assessing toxicity of a tobacco product (in this case snus) based on its substitution for cigarettes (NCT 01867242). The primary outcomes of the trial will be reported elsewhere. Our focus here is on the sampling phase, which was determinative of eligibility for the larger trial.

2.1. Eligibility criteria

Participants were initially eligible if they were at least 18 years of age, currently smoked at least 10 cigarettes per day (CPD), had not used smokeless tobacco for at least 3 months, were able to provide consent and read and understand study documents, and had no medical contraindications such as pregnancy, breastfeeding, uncontrolled hypertension, uncontrolled diabetes, recent myocardial infarction, or cancer. Recruitment ads targeted smokers who were interested in using oral tobacco, but not necessarily quitting: "Smokers who want to try a new oral tobacco product developed for smokers are needed for a research study that may reduce their exposure to harmful tobacco smoke." A total of 159 individuals was enrolled in the study across 3 sites: University of Minnesota (UMN; Minneapolis, MN), Ohio State University (OSU; Columbus, OH), and Roswell Park Cancer Institute (RPCI; Buffalo, NY).

2.2. Sampling phase procedure

At an initial orientation visit, eligible participants completed a core questionnaire on smoking and tobacco use behaviors. Participants were then shown the two snus products (Camel Snus Winterchill and Camel Snus Robust), and were asked to smell then try each of the products for 5 min and rate the sensory effects, taste and appeal of each product immediately afterward. Participants then indicated a flavor preference (Winterchill vs. Robust), and were provided 4 tins (15 pouches per tin) of Camel Snus to use at home. Factors associated with flavor preference are reported in a separate manuscript (Schneller et al., under review). Participants were instructed to use as much or as little of the product as they wished over the next 7 days, and to record amount of daily use of both the Camel Snus and other nicotine-containing products using Interactive Voice Response (IVR). Participants were allowed to smoke during this sampling period. Participants could request and receive additional snus if more was needed. Upon return to the clinic one week later, those who used at least 1 unit of Camel Snus per day[1] were eligible to enroll in the Clinical Trial Phase. Participants were then randomized to one of five treatment arms differing in degree of intended substitution level for cigarettes (full vs. partial) crossed with instructions for use (specific vs. ad libitum), versus continued smoking (waitlist control).

2.3. Subjective effects

For each product, participants completed a Product Evaluation Scale (PES) (Cappelleri et al., 2007; Hatsukami, Zhang, O'Connor, & Severson, 2013), and Drug Effects Questionnaire (DEQ) (de Wit & Phillips, 2012; Morean et al., 2013) in the laboratory immediately after the five minute trial of each flavor of snus. The PES resolves to four subscales: Relief, Aversion, Psychological Reward, and Satisfaction (0–6 scales). The DEQ consists of six individual items assessing the overall desirability of the product and intentions to use in the future (0–10 scales). These items were assessed again one week later on return to the laboratory, prior to enrollment in the clinical trial phase.

Frequencies, cross-tabulations, and distributions initially characterized the data. Statistical methods included Fisher's exact test, Chi-square test, and the non-parametric Spearman correlations and Wilcoxon rank-sum tests given non-normal distributions. Multiple regression and logistic regression models identified factors related to amount of product used and randomization status, respectively. p-Values < 0.05 were considered statistically significant. All analyses was carried out using SAS version 9.3 (SAS Institute, Inc., Cary NC).

3. Results

3.1. Participant demographics

Participants were recruited predominately from OSU (72.9%), followed by UMN (19.9%) and RPCI (7.3%). Eight participants who switched flavors during the study period were excluded from all analyses, leaving a final total of 151 participants. Males comprised 62.3%

[1] Initially the criterion was at least 14 pouches total, but was later reduced to at least 7 pouches total because so few people met the initial criterion.