

Youth Underestimate the Health and Addiction Risks of Tobacco Products

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Abstract

Perception and intention studies are required by the FDA to assess new tobacco products. These studies are generally conducted as surveys of smokers, former smokers and non-smokers across the United States. A group of 21 up to 25 year olds is over sampled to more accurately estimate the impact the product might have on young never smokers. Approximately 4500 subjects are routinely included in the study. An attempt is made to match the U. S. Census to make sure that all potential users are represented. Study participants are shown labels of the new products and asked about their perceptions of the health and addiction risks using validated questionnaires. In our approach we first show participants different types of tobacco products including cigarettes, smokeless tobacco, e-cigarettes, and nicotine replacement therapy products and assess where on the health and addiction continuum the participants place the products. When compared to the never users in the general population, young participants (legal age up to 25 years of age) consistently underestimate the health and addiction risks associated with the various tobacco products. Current smokers also underestimate the risks while former smokers perceive the risks consistent with the general population. The overall general population order of perceived health risks is cigarettes > e-cigarette = smokeless tobacco > NRT. Depending on the study populations, vapor users tend to perceive e-cigarettes to have less health risks than smokeless tobacco. Smokeless tobacco users generally perceive the health risk of smokeless to be less than e-cigarettes. The new modern oral nicotine pouch products are perceived to have health risk equivalent to NRT.

Background

The PMTA rule requires new product applicants to provide information on the perceptions of products. The FDA requires that applicants include perception and use intention studies as part of its interpretation of the requirements of section 910(b)(1)(A) and under its authority of 910(b)(1)(G) of the FD&C Act because perception of the risk of the product may influence decisions to use the product and the resultant exposure to the health risks presented by the product.

Methods

This study is conducted as an internet-based cross-sectional survey of a representative sample of the general population. Potential respondents were recruited into the study from an online non-probability based opt-in panel. They received an invitation to participate in a research study or self-selected a new survey opportunity from the panel website or an external referring partner via a panel-specific app. After screening for eligibility and establishment of smoking status, respondents provide informed consent prior to moving on to the remainder of the survey. Respondents are assigned to one of the two cells (test and control – Marlboro Gold Cigarettes) following a least-filled method to ensure representative distribution of at least 2,250 respondents per cell across tobacco usage and demographic criteria. **Figure 1** shows the overall study design. The subjects are presented a 3-D version of the product packaging. The purpose of this study is to measure perceptions (defined in terms of perceived health and addiction risks, intent to use, and substitutability) of test products within populations of (1) Adult Smokers, (2) Adult Former Smokers, (3) Adult Never Users and (4) Adult New Product Form Users. **Figure 2** shows the different analytic groups in the study and their definitions. There is an approximate equal number of males and females and the study covered all geographic areas of the U.S. as defined by the Census Bureau. **Table 1** shows the target sampling plan for the study. The estimated error for each group ranged from 3.5 to 5%.

Addiction risks are assessed by a series of questions about the product where the respondent rates the product on a scale of 1 to 5 of no risk to very high risks. Health risks are assessed by a series of questions on tobacco related diseases such as lung cancer and heart disease, harm to others, and reproductive risks. The same 1 to 5 rating scale is used. Only critical health risks (lung cancer, mouth and throat cancer, emphysema and heart disease) are shown.

Figure 1. Study Design

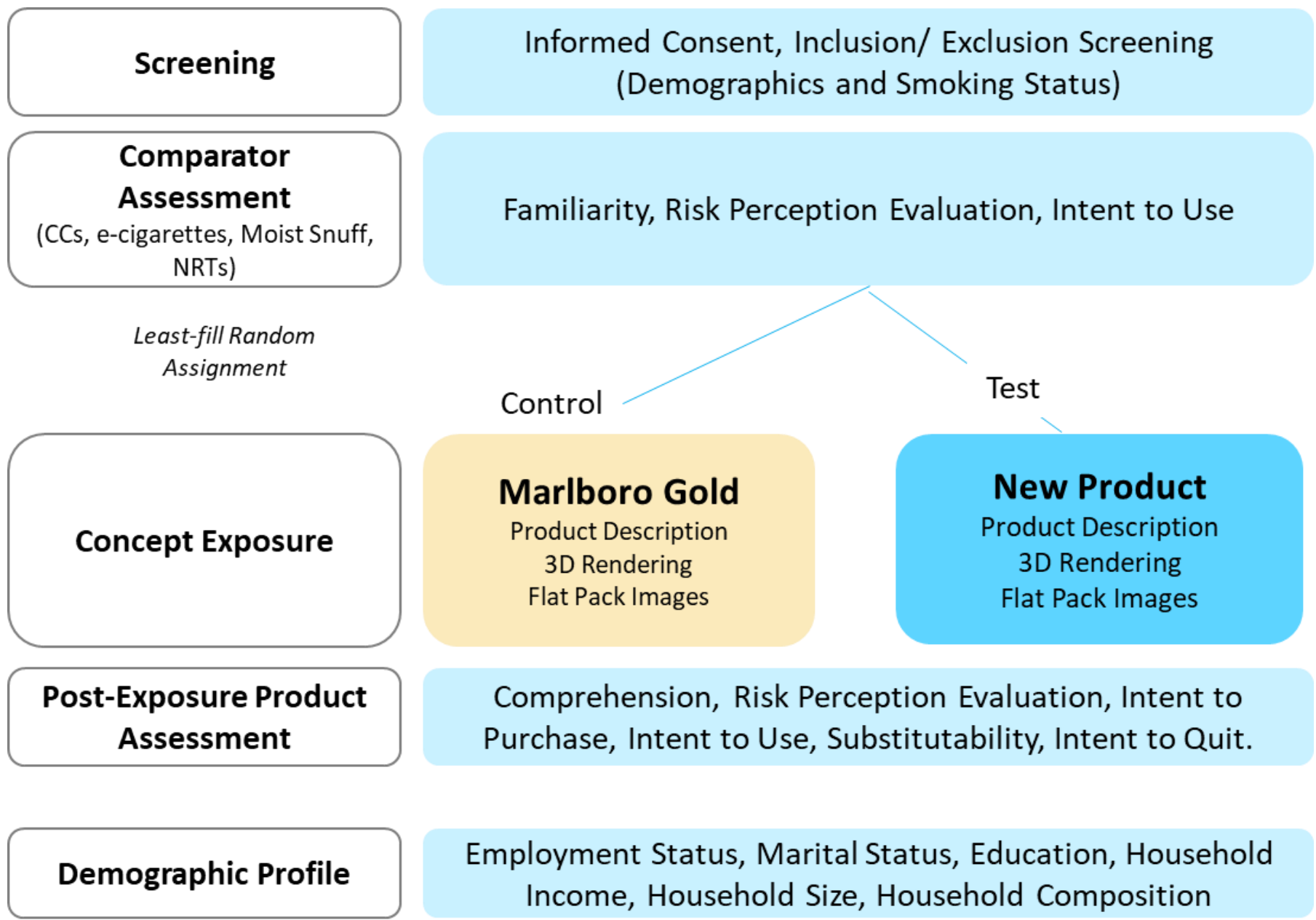


Figure 2. Analytic Groups in the Study

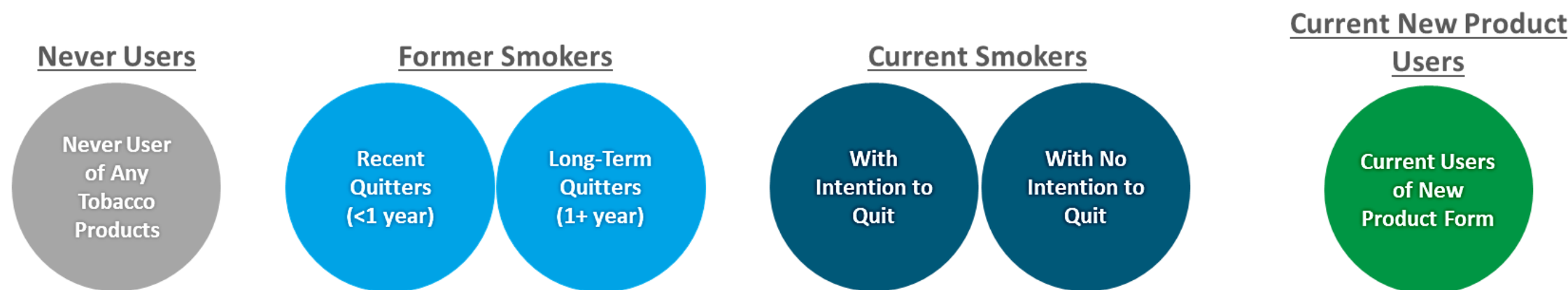


Table 1. Study Target Sampling Plan

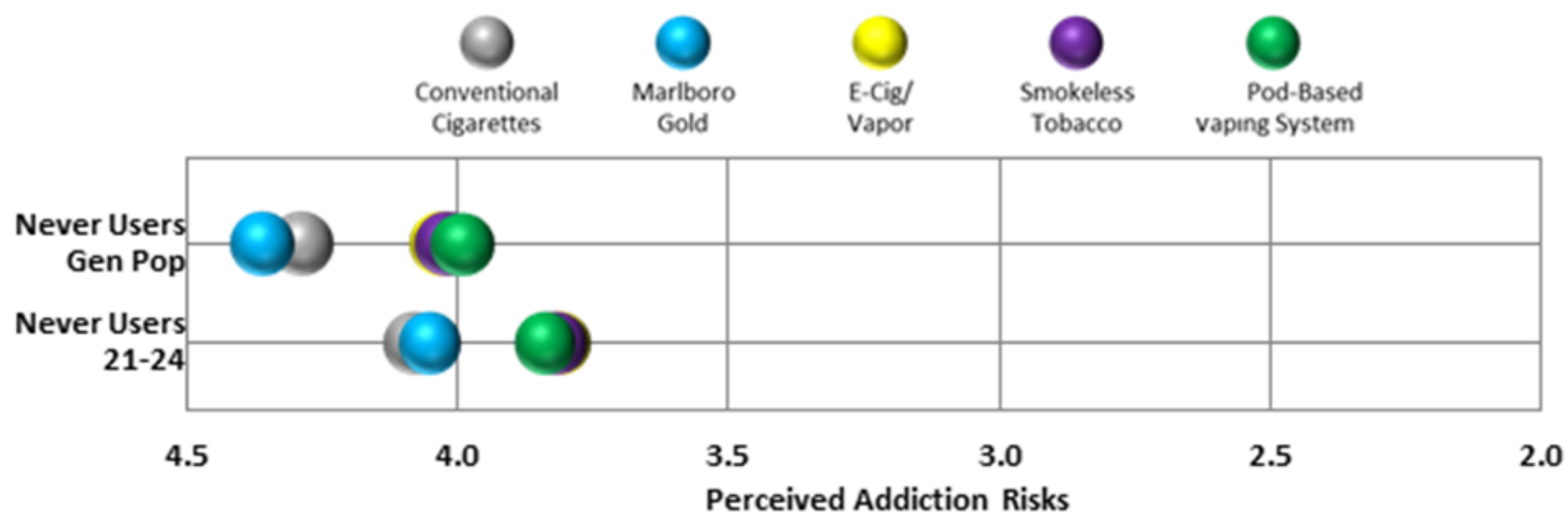
Population	Control (Marlboro)	Test Cell	Total Overall
Never Users	750	750	1500
Adult Consumers	375	375	750
Legal Age to 25 (Oversample)	375	375	750
Former Smokers	500	500	1000
Long-Term Quitter	250	250	500
Recent Quitters	250	250	500
Current Smokers	750	750	1500
With Intention to Quit	375	375	750
With No Intention to Quit	375	375	750
Current New Product Form Users	250	250	500
TOTAL	2250	2250	4500

Perceived Addiction Risks

The results presented are derived from studies conducted over the last seven years. The study products included cigarettes, e-liquids, e-cigarettes, nicotine pouches, and a novel smokeless tobacco free product. The results presented here are not on the products themselves but are on perceptions to the general categories of products. The results are consistent across studies and categories. In the studies, the respondents are shown marketed sample products in different categories (conventional cigarettes, smokeless, ENDS, and NRT) asked about their perceptions of the addiction and health risks.

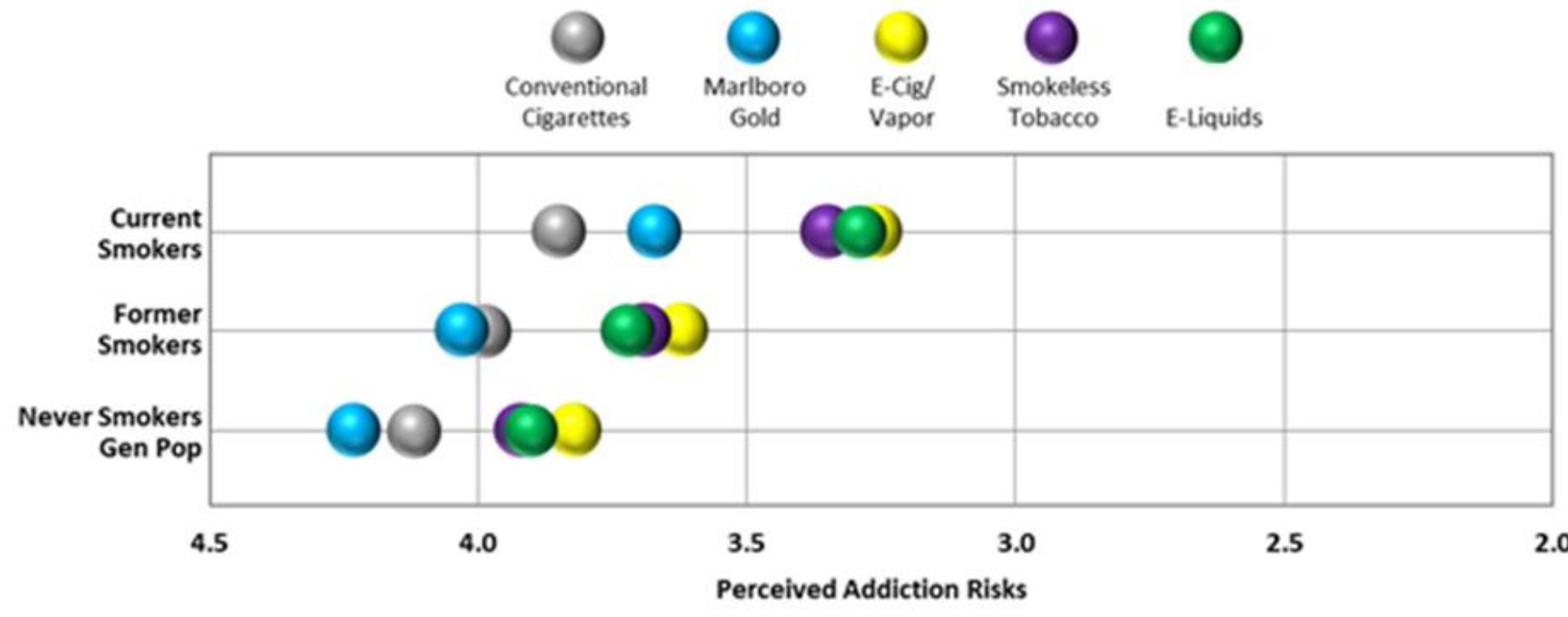
Young never users (aged 21 to 24) underestimate the addiction risk of all tobacco products when compared to the general population (Figure 5).

Figure 5. Perceived Addiction Risks (Pod Based Vaping System Study)



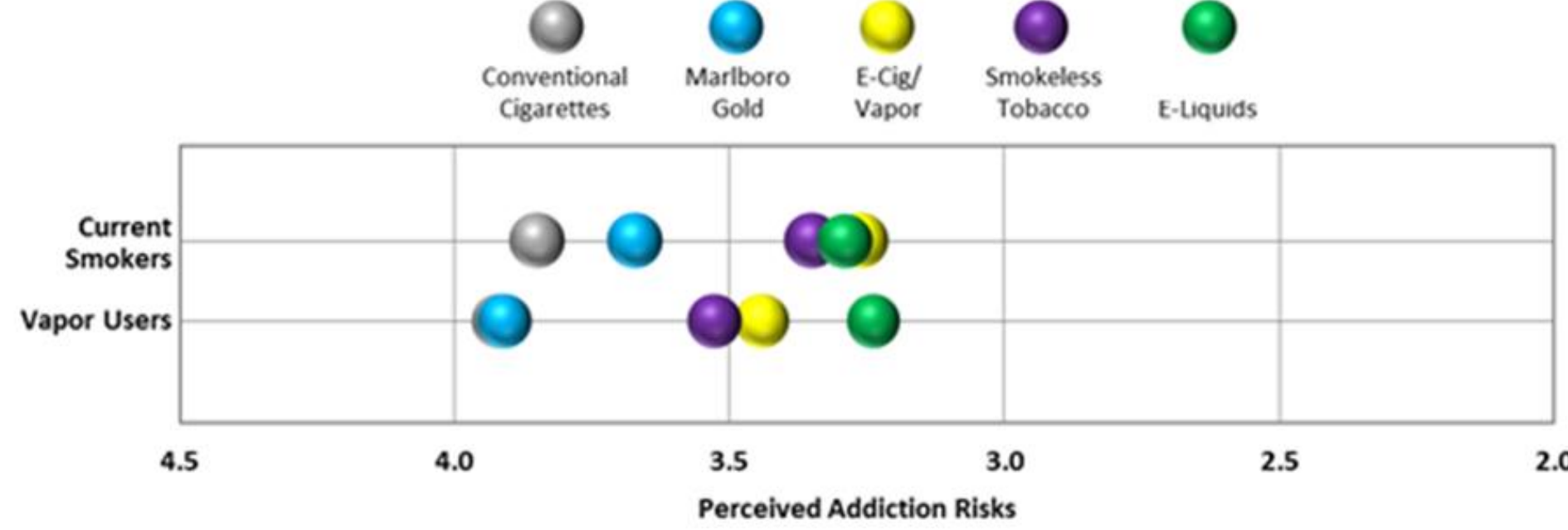
Current smokers underestimate the risks of addiction compared to former smokers and never users (Figure 6).

Figure 6. Perceived Addiction Risks (E-Liquid Study)



Smokers think ENDS are about as addictive as smokeless, whereas Vapers think they are less addictive (Figure 7).

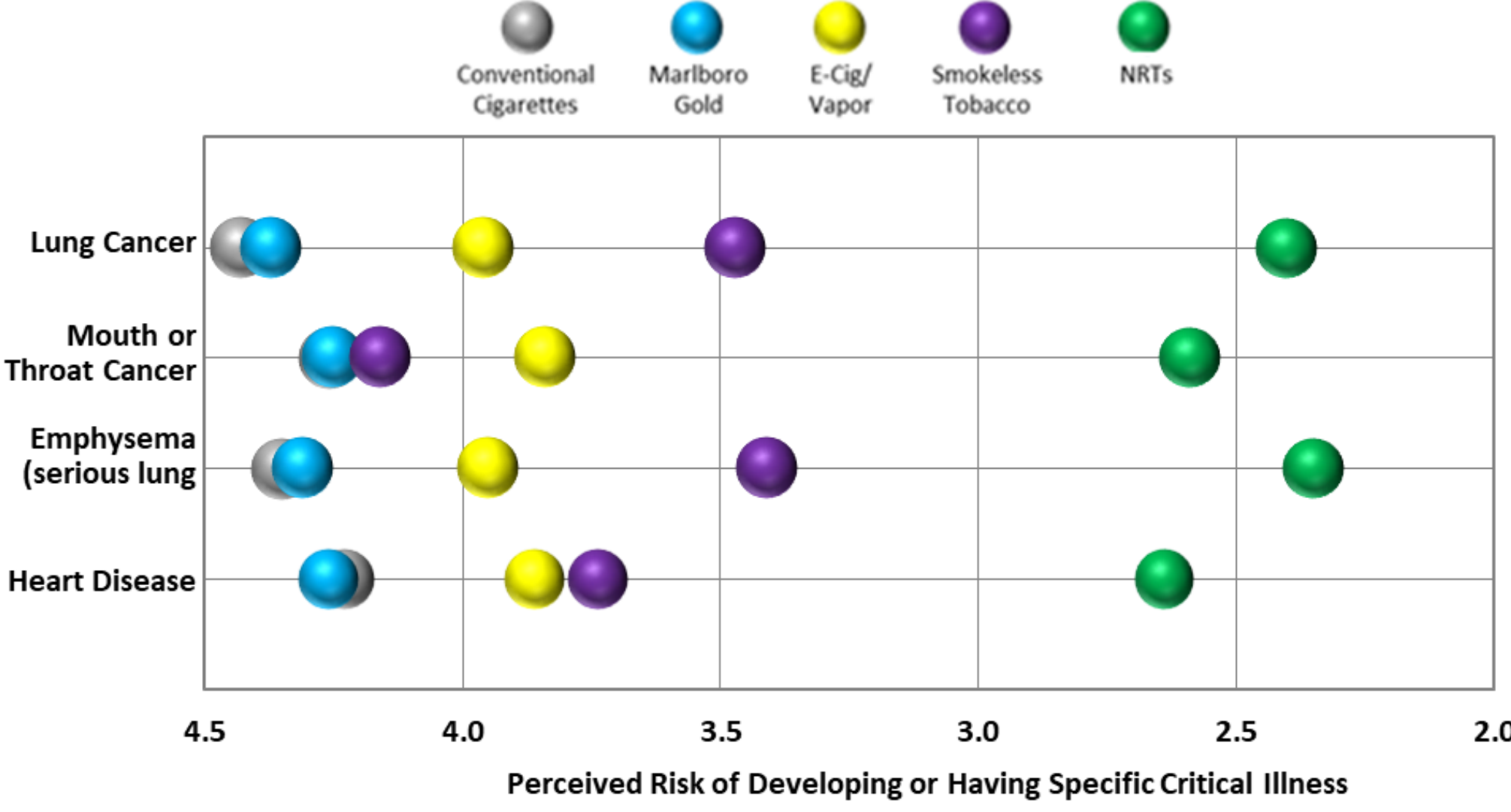
Figure 7. Perceived Addiction Risks (E-Liquid Study)



Perceived Critical Health Risks

The subjects clearly **understood the different products and their health risks**. Smokeless has a high mouth and throat cancer rating whereas the inhalables have lung effects (**Figure 8**).

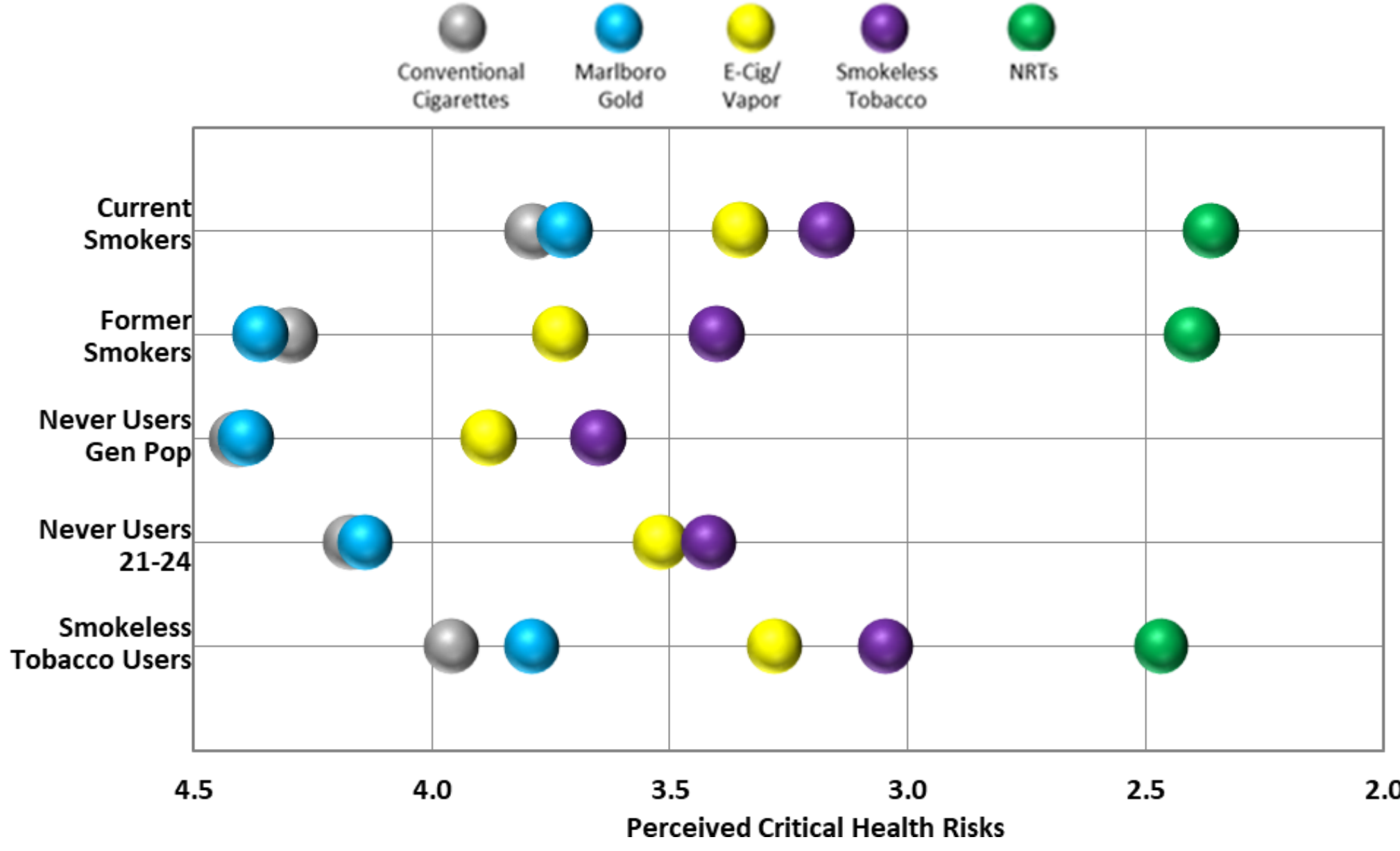
Figure 8. Overall Perceptions of Critical Health Risks



Current smokers underestimate the risks of using tobacco products. Former smokers risk perceptions for cigarettes are similar to the general population. Young never users underestimate the health risks (**Figure 9**).

E-cigarettes are perceived to have a higher risk than smokeless (Figure 9).

Figure 9. Perceptions of Critical Health Risks (Smokeless Study)



Conclusions

The subjects clearly understand the general health and addiction risks of tobacco products. Smokers and young never users underestimate the health and addiction risks. E-cigs are perceived as having a higher risk than smokeless.