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INTRODUCTION

In recent years, electronic cigarettes (E-vapor) and tobacco vapor products (T-vapor) have been increasingly used worldwide by adult consumers, as there is a growing interest in the potential of these products to reduce the health risks of smoking. In the US, ENDS manufacturers can submit Modified Risk Tobacco Product (MRTP) Applications to the FDA for the potential reduced risks of their products to be assessed. The Draft Guidance for Industry on MRTP Applications contains recommendations on phrasing proposed modified risk claims and testing with consumers to ascertain their perception and understanding of such claims. With reference to this Draft Guidance, JTI developed five fictional reduced risk statements for both E-vapor and T-vapor and quantitatively assessed consumers' perceptions and understanding of them.

METHOD

An online survey was performed in 2019 in the UK where English is the native language. 5,064 adults (>20-years-old) including smokers with intention to quit (CY, n = 1268), smokers without intention to quit (CN, 1273), former smokers (FS, n = 1254) and never smokers (n = 1269).

Five fictional statements (combining claim and warning) were prepared for both E-vapor and Tvapor (ten patterns of messages in total). The fictional statements included Reduced Risk (RR-A and RR-B), Reduced Harm (RH-A and RH-B) and Reduced Exposure (RE) messages (Table 1). The messages were combined with product description of E-vapor or T-vapor (Figure 1).

To remove any biases, participants were randomly exposed to one of the ten messages, and subsequently answered questions regarding their intention to quit (smokers only) and their intention to try/use the products etc.

Figure 1 Product descriptions





Tobacco Vaping (T-vapor)

Tobacco vapor products create a vapor without burning tobacco. The vapor contains significantly fewer toxic substances than cigarette smoke.

Table 1 Claim and warning

Message	Message A (RR-A)	Message B (RR-B)	Message A (RH-A)	Message B (RH-B)	Message (RE)
Claim	Research shows that switching completely from cigarettes to [product] can reduce the risks of developing tobaccorelated diseases such as lung cancer, respiratory and heart disease.	Research shows that switching completely from cigarettes to [product] may reduce the risks of developing tobaccorelated diseases such as lung cancer, respiratory and heart disease.	Research shows that switching completely from cigarettes to [product] can reduce the harm that can cause tobacco-related diseases such as lung cancer, respiratory and heart disease.	Research shows switching completely from cigarettes to [product] can reduce the harm that can cause tobacco-related diseases.	Research shows that switching completely from cigarettes to [product] significantly reduces your body's exposure to toxic substances.
Message specific warning	Reduced risk of developing tobacco-related disease does not mean risk free.	Reduced risk of developing tobacco-related disease does not mean risk free.	Reduced harm does not mean [product] are harmless.	Reduced harm does not mean [product] are harmless.	Reducing your body's exposure to toxic substances does not eliminate the risk of developing tobacco related diseases.
General warning	 ✓ [Product] contain nicotine. Nicotine is addictive. ✓ [Product] are meant for adult smokers. ✓ [Product] are not meant for non-smokers or smokers who intend to quit. ✓ The best way to reduce your risk of tobacco-related diseases is to completely quit tobacco use. 				

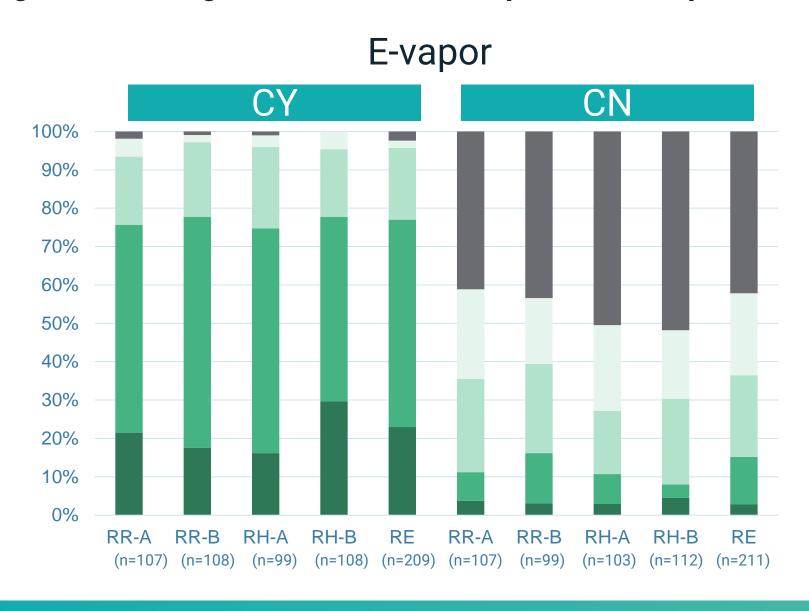
^{*} In the original messages, [product] was replaced with 'electronic cigarettes' or 'tobacco vapor products' for E-vapor or T-vapor statements, respectively.

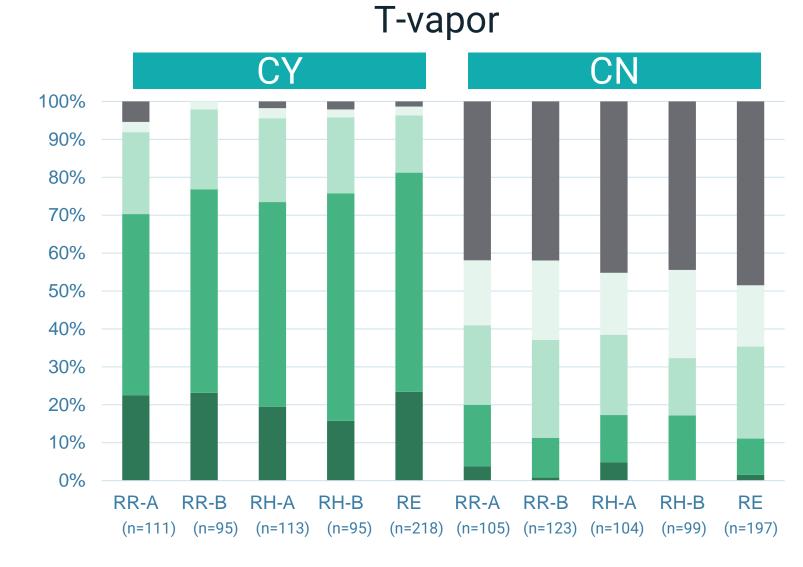
REFERENCES

Food and Drug Administration. Guidance for Industry: Modified Risk Tobacco Product Applications. Draft Guidance. Rockville, MD: Guidance for Industry, U.S. Department of Health and Human Services Food and Drug Administration Center for Tobacco Products; 2012.

RESULTS

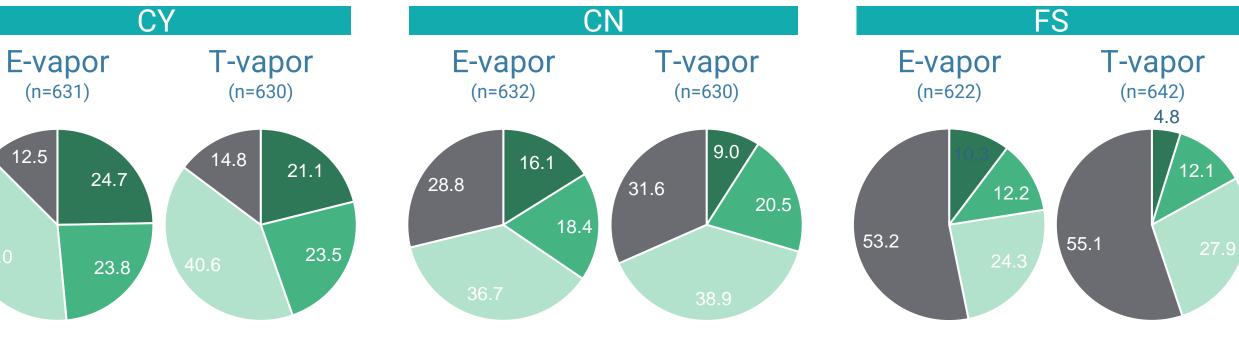
Figure 2 Changes in intention to quit after exposure to statements (smokers only)

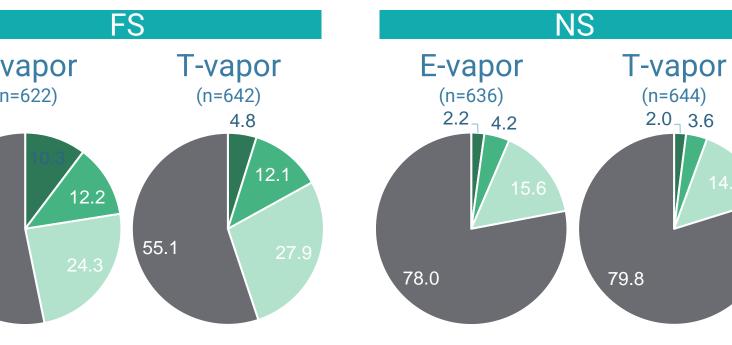


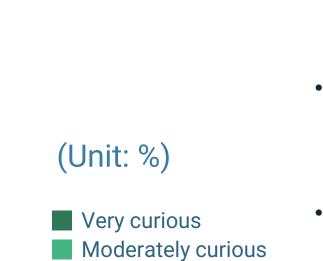


- After exposure to the statements, no change in intention to quit was observed for 97.6 - 100% and 94.6 - 100% of CY who saw the statements of E- and T-vapor, respectively.
- Approximately 50 60% of smokers without intention to quit (CN) thought about quitting after exposure to the statements (48.2 - 58.9% and 51.8 - 58.5% of CN who saw the statements of E- and T-vapor, respectively). Such impact was relatively lower in CN who were exposed to RH statements of E-vapor.
- Not thinking about guitting
- Thinking about quit, but not during the next 12 months
- During the next 12 months During the next 6 months
- During the next 30 days

Figure 3 Interest to E/T-vapor before exposure to statements







A little curious

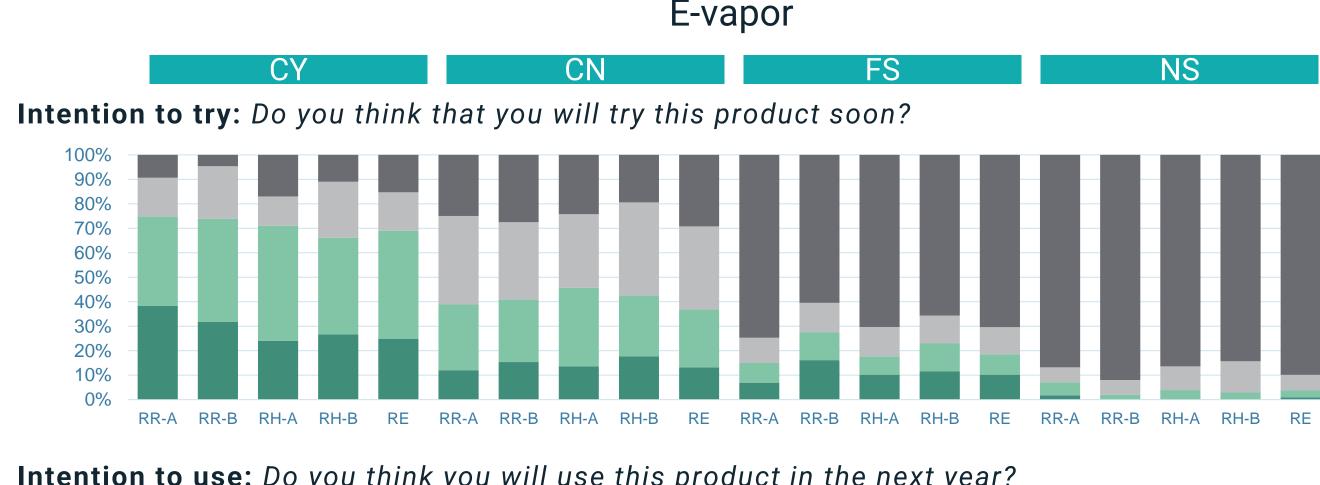
Not at all curious

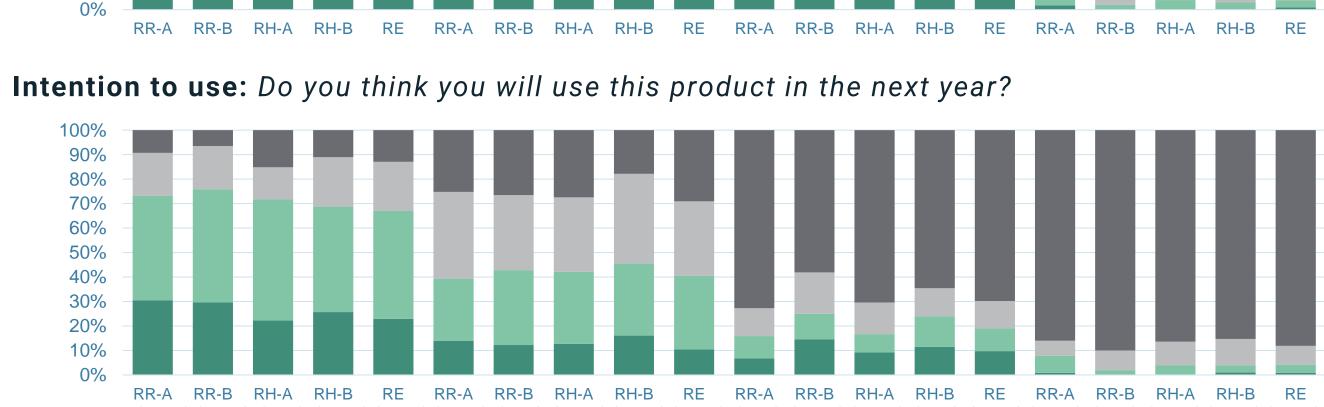
have ever been curious about using E/Tvapor products. • 85.2 - 87.5% of CY and 68.4 - 71.2% of

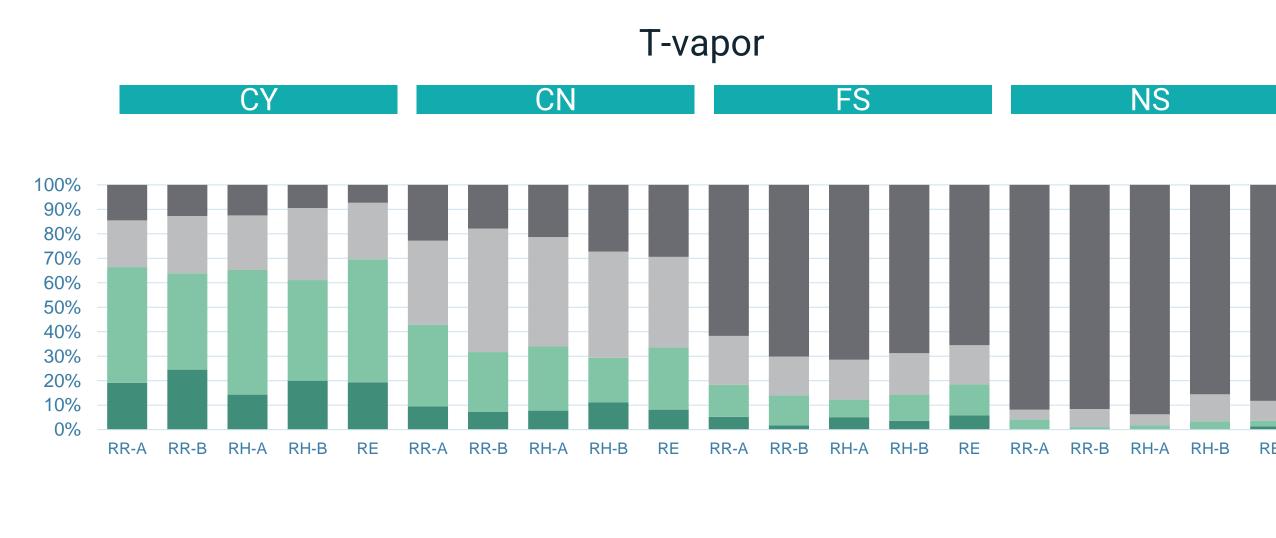
Participants were asked whether they

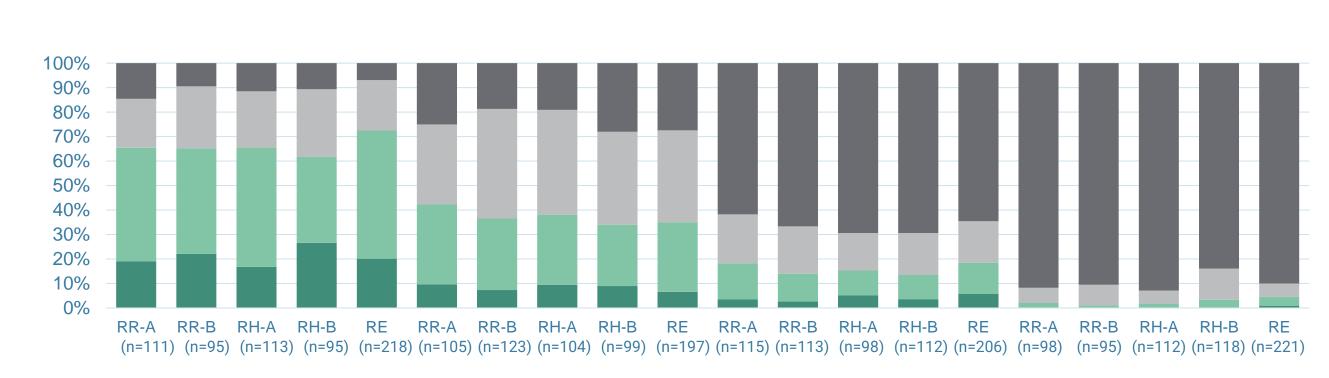
- CN have been curious about E/T-vapor products.
- 44.9 46.8% of former smokers (FS) and 20.2 - 22.0% of never smokers (NS) have been curious about E/T-vapor products.

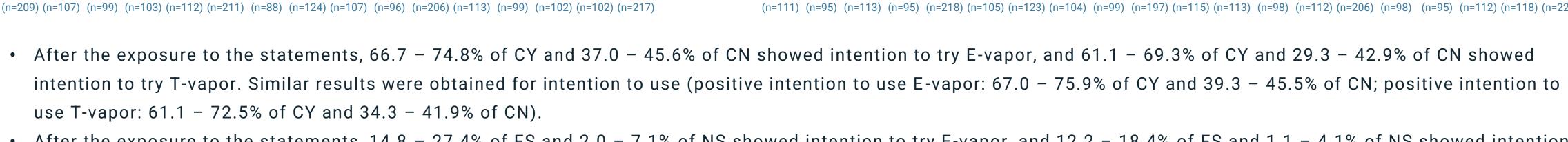
Figure 4 Intention to try/use after exposure to statements











• After the exposure to the statements, 14.8 - 27.4% of FS and 2.0 - 7.1% of NS showed intention to try E-vapor, and 12.2 - 18.4% of FS and 1.1 - 4.1% of NS showed intention to try T-vapor. Similar results were obtained for intention to use (positive intention to use E-vapor: 15.9 – 25.0% of FS and 2.0 – 8.0% of NS; positive intention to use T-vapor: 13.4 - 18.4% of FS and 1.1 - 4.5% of NS).

CONCLUSION

The results overall did not show an increase in the intention to quit of adult smokers who already had such an intention. However, the intention to quit increased among adult smokers who already had such an intention to quit cigarettes. After reading the statements, adult smokers in general showed intention to try the products (66.7 – 74.8% of smokers with intention to quit and 37.0 - 45.6% of smokers without intention to quit), while most of the former smokers and never smokers and 92.9 - 98.0% of never smokers). Similar results were obtained for intention to use. For all groups, certain proportion of participants have been curious about E/T-vapor, and positive intention to try/use after exposure to statements themselves will not excessively induce the readers to use E/T-vapor. In conclusion, existing adult smokers are more likely to use these products as a consequence of product statements communicating their reduced risk potential, but former smokers and never smokers are not likely to start using them.

Definitely not

Probably not

Probably yes

Definitely yes