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INTRODUCTION

A pre-market tobacco application in the USA requires information to support the appropriateness of a new product for protection of public health. Important elements of this are the risks and benefits of introducing a new product to the population as a whole. To develop tools to collect such data, a suite of guestionnaires of subjective measures of individuals' motivations for, and use of, tobacco and nicotine products was collated from the published literature.

OBJECTIVES

- · To test subject burden and understanding of a selection of questionnaires and to assess their effectiveness for use in premarket assessment.
- · To determine changes in responses following a short period of electronic cigarette (e-cig) use.

STUDY PRODUCT

Vype estick (blended tobacco flavour, e-liquid, 3.5% v/v nicotine).

SUBJECTS

- 37 smokers who had been smoking for at least six months, with a self-reported consumption of at least ten cigarettes per day.
- Approximately equal numbers of males and females, aged between 19 and 64 years.
- · Females who reported to be pregnant or breastfeeding were excluded.
- · Subjects were aware of but had never used e-cigs, but were willing to use an e-cig for a period one week.
- Subjects signed Informed Consent Form.

METHODS

- Study was conducted by CDMR in Glasgow, UK.
- Subjects completed a web-based questionnaire (pre e-cig). Each subject was provided with an e-cig and cartridges to use for a week and asked to record their daily e-cig use and cigarette consumption (CPD).
- · After a week the subjects completed a follow-up questionnaire (post e-cig) assessing their experiences of using the e-cig.

Week 1 Questionnaire

Socio-demographic information

- Smoking history
- · Environmental influences to smoke
- Smoking motives
- Smoking dependence
- Quit motivations / attempts
- Worries / barriers about e-cig use
- · Perception of risks for different behaviours

Week 2 Questionnaire

e-cia use

- · Quit smoking motivation
- · Nicotine/cigarette dependence modified for use with e-cias
- Subjective effects
- · Positive / negative experiences of e-cig use
- Reasons for using / not using e-cig •
- Likelihood of future e-cig use
- · Perception of risks for different behaviours
- · Attractiveness of design and packaging

RESULTS

- Most subjects reduced their CPD during the week of e-cig use (Figure 1). Urge to vape post e-cig use was lower than urge to smoke post e-cig use, which was in turn lower than urge to smoke pree-cia use (Figure 2).
- 78% of the subjects perceived e-cigs to be less risky than cigarettes, while only 22% thought ecigs to be less risky than nicotine patches (Figures 3 and 4).
- · Subjects' perceived risk to health associated with e-cigs was generally lower than cigarettes both pre and post e-cig use (Figure 5).
- More than half of the subjects expressed a future intention to take up e-cios and smoke fewer cigarettes (Figure 6).



Figure 1: Change in average CPD (pre and post e-cig)



Figure 2: Urge to Smoke / Vape (pre and post e-cig)

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Figure 3: Perceived risk e-cig vs cigarettes



Figure 4: Perceived risk of e-cig vs nicotine patches

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Study Time Take 20 puffs of an e Take 40 puffs of an e-si ake 60 puffs of an e-ci Drink three clarger red win moke 10 cigarett Mean Perceived Risk Figure 5: Perceived risk to health (pre and post e-cig)



Figure 6: Self-reported future intentions

CONCLUSIONS

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- Questionnaires successfully collected useful pre-market and follow-up data from this small sample size
- · Demonstrated that they could be used to investigate effects of the introduction of a novel product.
- · Follow-up six months later would give better insight into whether subjects' perceptions have changed or not.
- · Further exploratory work with larger subject numbers and different populations, and with additional items to collect data from never and former smokers is planned.

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