University of BRISTOL

Informing Policy on Electronic Cigarette E-Liquid Flavour Regulation

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1. Executive Summary

This multi-methods project was a collaboration between the University of Bristol, the University of East Anglia, and Public Health England. It comprised four studies and the development of a tool to aid policy decisions on e-liquid flavour regulation.

E-liquids are available in a wide variety of flavours, including but not limited to tobacco flavourings. Electronic cigarettes (e-cigarettes) are widely accepted as being less harmful than combustible cigarettes, making them a good alternative to smoking and a useful smoking cessation aid.

While the wide variety of e-liquid flavours may be important in engaging people to quit or reduce smoking, there is also concern that flavours may entice never smokers, including adolescents and young people, to "vape".

With support from Public Health England, we completed a programme of work exploring the possible benefits and costs of e-liquid flavour restrictions, which could inform policy decisions on e-liquid flavour availability.

This work included: 1) a systematic review of studies reporting use of flavoured e-liquids among young people; 2) a field trial investigating effects of flavoured* (versus unflavoured**) e-liquids on cigarette craving; 3) an online observational study comparing flavoured and unflavoured e-liquid packaging on appeal among adolescents; 4) a qualitative study exploring opinions of unflavoured e-liquid following a trial of unflavoured products and 5) a decision making aid to inform policy about potential impacts of flavoured-liquid regulation.

At the time of conducting this research, there was relatively little published research on this topic. This is a policy relevant area and unsurprisingly the body of literature in this area is steadily increasing. Our systematic review (Project 1) identified that flavours were considered important for initiation and maintenance of vaping, but the review was limited by a lack of high-quality evidence at the time of reporting.

As expected, flavoured packaging was rated more positively across a range of measures by young people who did not smoke, but both flavoured and unflavoured packaging were rated negatively overall (Project 3). However, among current smokers we found little evidence that flavoured (compared to unflavoured) e-liquids impacted cigarette craving, suggesting that unflavoured liquids may be effective in supporting cessation attempts (Project 2). Qualitatively, current smokers and vapers who tried an unflavoured e-liquid varied in their opinions, with some reporting a flavour restriction (to only unflavoured and/or tobacco or menthol flavours) would increase the likelihood of a return to smoking or not switching to e-cigarettes (Project 4).

Using our policy decision making aid, we have also found that restricting e-liquid flavours may have a net negative impact on the health of people in the UK (Project 5). If flavours were restricted, we estimated that the number of people who would continue or return to smoking would outweigh the number of young people who would be protected from smoking and vaping.

Collectively, our work identifies evidence for and against flavour restriction. The issue remains extremely complex. Changes to flavour availability is likely to have a range of impacts that differ across groups, which are both intended and unintended. Future research should consider other factors such as branding and advertising of e-cigarette products, and the increasing popularity of disposable vaping products.

* Non-tobacco flavours, e.g., strawberry; ** Devoid of any flavour.

2. Background

E-cigarettes are battery-operated devices that allow users to inhale nicotine in the form of a vapour. There are a variety of models available including cigalikes, vape pens, pod systems and mods. E-cigarettes heat a liquid (known as e-liquid) that typically contains nicotine, propylene glycol and/or vegetable glycerine, and they can contain flavourings.

Globally in 2020, there were an estimated 68 million e-cigarette users or "vapers" (Jerzynski, Stimson, Shapiro, & Krol, 2021), including an estimated 3 million vapers in England (McNeill, Brose, Calder, Simonavicius, & Robson, 2021). Among adult e-cigarette users in Great Britain, the four main reasons reported for use are to aid quitting smoking (22%), to prevent smoking relapse (16%), because the experience is enjoyable (13%), and to save money compared with smoking tobacco (13%) (Action on Smoking and Health, 2022b).

Among 11-17-year-olds in Great Britain, 16% had tried vaping and 7% were current users in 2022, a rise from 11% and 3%, respectively, in 2021 (Action on Smoking and Health, 2022a). Although use of e-cigarettes among 11-17-year-olds who have never smoked remains low (only 2% report at least monthly use) (Action on Smoking and Health, 2022a). The most frequent reason for ever use of e-cigarettes among adolescents was 'Just to give it a try' (46%). However, among current adolescent smokers who had tried e-cigarettes, the most common reason was 'I like the flavours' (21%) (Action on Smoking and Health, 2022a).

There are thousands of e-liquid flavours available in some markets, including tobacco, menthol/mint, fruit, candy/sweet, dessert, and soft drink flavours (Krusemann, Boesveldt, de Graaf, & Talhout, 2019; Zhu et al., 2014). Because of the appeal of these e-liquid flavours among youth (World Health Organisation, 2021), and concerns about a possible gateway effect into smoking combustible cigarettes (Soneji et al., 2017), several countries have implemented policies restricting flavoured e-cigarette products (World Health Organisation, 2021; Zhang, Wang, Shen, Gu, & Shao, 2022). However, the impact on smokers is unknown, and there may be unintended consequences by reducing the appeal and effectiveness of e-cigarettes for smoking reduction and cessation (McNeill, Brose, Calder, Bauld, & Robson, 2020). Flavoured e-liquids appear to be important for smoking cessation. Therefore, it is possible that due to a reduction in smoking cessation, the net effect of a ban could be poorer population health.

With support from Public Health England, we completed a programme of work exploring the possible benefits and costs of e-liquid flavour restrictions, which could inform policy decisions on e-liquid flavour availability.

The research projects presented in this report were conducted by the Tobacco and Alcohol Research Group at the University of Bristol, in collaboration with, and funded by, Public Health England. One project was led by collaborators at the University of East Anglia. This program of work comprised five research projects using a variety of methods, which are detailed below.

3. Projects

Project Overview	Research Aims	Study Design	Sample
Project 1: Systematic Review	To review the use of e-liquid flavours by young people and describe associations with uptake or cessation of vaping and tobacco smoking.	Systematic review of interventional, observational and qualitative studies reporting on the use of e-cigarette flavours by young people.	58 studies of young people and their carers (including participants aged <18 years), published in English language from any country or cultural setting.
Project 2: Experimental Field Trial	To investigate the effects of using e-cigarettes with flavoured versus unflavoured nicotine-containing e-liquid for 1 week on general and cue-elicited cigarette craving.	An experimental study with a parallel groups design. Participants were randomised to use unflavoured or flavoured e-liquid (10 or 18 mg/ml, depending on their typical cigarette consumption per day).	84 healthy daily smokers (≥5 cigarettes per day for ≥3 months), who were ≥18 years, residing in the UK, and willing to replace all cigarettes with an e-cigarette for 1 week.
Project 3: Online Observational Survey	To compare the effect of e-liquid packaging (flavoured versus unflavoured) on packaging appraisal, packaging receptivity, and perceived harm.	Online observational study with a within-subjects design. Participants rated 15 images of e-liquids (5 candy/sweet-flavoured, 5 fruit-flavoured, and 5 unflavoured).	120 UK 11–17-year-olds who did not currently smoke/vape and had never regularly smoked/vaped.
Project 4: Qualitative Study	To explore current smokers' and vapers' opinions of unflavoured e-liquid after a brief trial, and how participants believe e-liquid flavour restrictions may impact their future smoking and vaping.	A qualitative study data using semi-structured interviews to explore perceptions of unflavoured e-liquid after use and the impact of an e-liquid flavour ban.	24 healthy UK residents (12 adult daily smokers and 12 adult daily vapers who stopped smoking within the 12 months prior to the study session).
Project 5: Policy Decision Making Aid	To develop a decision making aid that integrates evidence on the impact of e-cigarette flavour availability, enabling policymakers to make evidence-based decisions to increase the likelihood of net population health gain.	n/a	n/a

3.1 Systematic Review

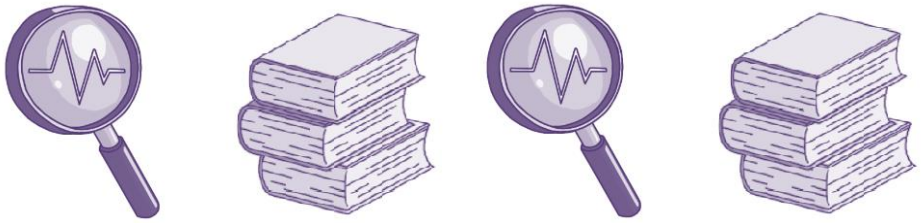
Title: *Youth use of e-liquid flavours - a systematic review exploring patterns of use of e-liquid flavours and associations with continued vaping, tobacco smoking uptake or cessation*

Protocol: https://osf.io/hcbyu/

Publication: Notley et al. (2022) *Addiction* 117(5): 1185-1505; doi: 10.1111/add.15723

Aims: To complete a systematic review of the use of e-liquid flavours by young people.

Review questions focussed on six primary areas: 1) the incidence, prevalence and patterns of use of flavoured e-cigarette e-liquids, 2) association of use of flavoured e-liquids and vaping uptake, 3) association of use of flavoured e-liquids and smoking uptake, 4) association of use of flavoured e-liquids and smoking cessation, 5) reports and experiences of adverse effects of flavoured e-liquids, and 6) perspectives on, and experiences of, flavoured e-liquids (young people and their carers) and implications for policy.



Methods: Systematic review conducting in accordance with PRISMA guidance including studies reporting on population (young people and their carers), interventions (flavoured e-liquid in electronic cigarettes) and study design. Electronic databases used in the search included: MEDLINE, EMBASE, PsychINFO, CINAHL, Applied Social Sciences Index and Abstracts, Cochrane database, ProQuest Dissertation and Theses Database, and Open Grey. To address questions 5 and 6, both quantitative and qualitative study designs were included. For full methodology including search teams, see open access publication (via DOI provided above).

Results: A total of 1,289 papers were screened after removal of duplicates. 58 studies were included in the analysis. The quality of evidence was low with the majority (n = 39) being cross-sectional surveys. There was consensus across studies that flavours were important for vaping initiation and continuation. The role of flavours in smoking uptake was unclear due to a paucity of good quality evidence. We found no reports on adverse effects.

3.2 Experimental Field Trial

Title: *Effects of electronic cigarette e-liquid flavouring on cigarette craving*

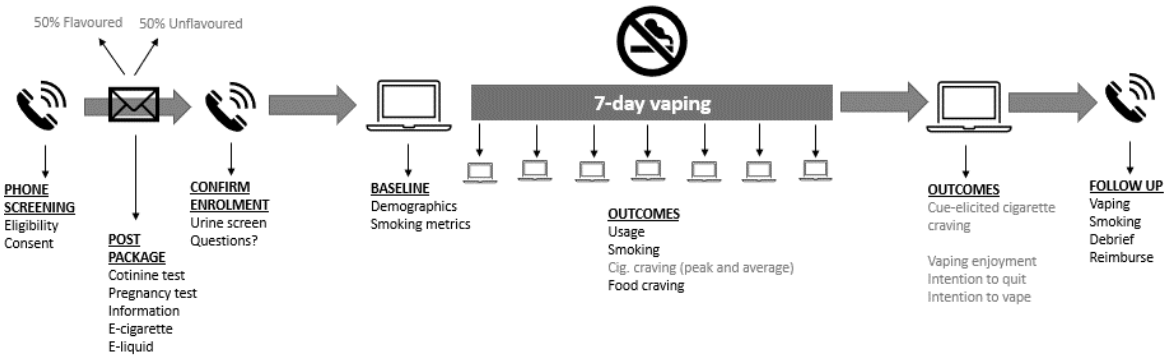
Protocol: https://osf.io/jtgxc/

Publication: Dyer et al. (2021) *Tobacco Control* 32: e3-e9; doi: 10.1136/tobaccocontrol-2021-056769

Aims: To investigate the effects of using e-cigarettes with nicotine-containing flavoured (fruit or sweet) e-liquid for one week, compared with unflavoured (no flavour) e-liquid, on: 1) average cigarette craving during the week, 2) peak cigarette craving during the week, and 3) cue-elicited cigarette craving in response to smoking-related cues.

Secondary outcomes: (a) smoking lapse, (b) e-cigarette enjoyment, (c) ease of transition from smoking to e-cigarette, (d) intention to quit smoking, (e) intention to continue using an e-cigarette, and (f) motivation to quit smoking and (g) return to smoking (h) continuation of e-cigarette use.

Methods: We included 84 UK adult daily smokers (at least 5 cigarettes per day for at least 3 months), in an experimental study with an independent groups design. Participants were randomised to use unflavoured or flavoured (blackcurrant, strawberry, caramel, vanilla) e-liquid (10 or 18 mg/ml). The study was run remotely using the UK postal service, Qualtrics, and phone and video calls. The study procedures took around 3 weeks per participant.



Results: Average, peak, and cue-elicited cigarette craving did not differ between participants using an e-cigarette containing unflavoured versus flavoured e-liquid for 1 week. We did not find evidence of an effect of e-liquid flavouring on smoking lapse occurrence (during the study week), e-cigarette enjoyment, ease of transition from smoking to using an e-cigarette, intentions to continue using an e-cigarette or quit smoking, motivation to quit smoking (after study week), and return to smoking and continuation of e-cigarette use (1-week follow-up).

These findings suggest that, during an initial switch from smoking to using e-cigarettes, there may be little impact of a fruit/sweet-flavoured e-liquid restriction on cigarette craving. However, it is plausible that a lack of flavoured products on the market may discourage smokers from initiating a switch to e-cigarettes and this should be investigated in follow up research.

3.3 Online Observational Survey

Title: *Do flavour descriptions influence subjective ratings of flavoured and unflavoured e-liquids among non-smoking and non-vaping UK adolescents?*

Protocol: original https://osf.io/zrxyw and updated https://osf.io/39u6h

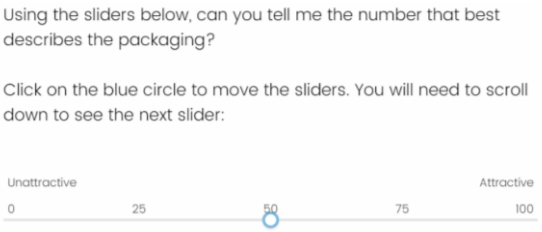
Publication: Preprint available: https://psyarxiv.com/sxvum; doi 10.31234/osf.io/sxvum

Aims: Our primary aim was to compare the effect of e-liquid packaging flavour description (flavoured versus unflavoured) on packaging appraisal and packaging receptivity. Our secondary aim was to compare the effect of e-liquid packaging flavour description (flavoured versus unflavoured) on perceived harm of, and perceived audience for, the product.

In addition, we aimed to compare the effect of candy/sweet flavour descriptions versus fruit flavour descriptions (i.e., flavours which have, versus do not have, strong associations with childhood, respectively) on all four outcomes.

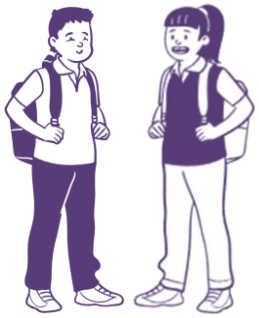
Methods: We conducted an online observational survey study with 120 adolescent participants who were aged 11–17 years and did not currently smoke/vape and had never regularly smoked/vaped. Participants were recruited via schools, academies, and colleges, and later via charities, local authority public health teams, youth and parent organisations, and social media.

We used a within-participant design. Participants rated 15 images of e-liquids (5 candy/sweet-flavoured, 5 fruit-flavoured, and 5 unflavoured) on 11 rating scales. Outcome variables were packaging appraisal, packaging receptivity, perceived harm, and perceived audience.



Results: In support of our hypotheses, packaging appraisal and receptivity ratings were higher (more positive) for e-liquids with flavoured versus unflavoured descriptions. However, packaging appraisal and ratings did not appear to differ for e-liquids with candy/sweet flavour versus fruit flavour descriptions.

As predicted, adolescents perceived e-liquids with flavoured (versus unflavoured) and candy/sweet flavour (versus fruit flavour) descriptions as less grown-up. We did not find evidence for an effect of e-liquid packaging flavour description on perceived harm. However, despite these differences, adolescents generally had low appraisal and receptivity for e-liquids, and they perceived them as being grown-up and harmful.



3.4 Qualitative Study

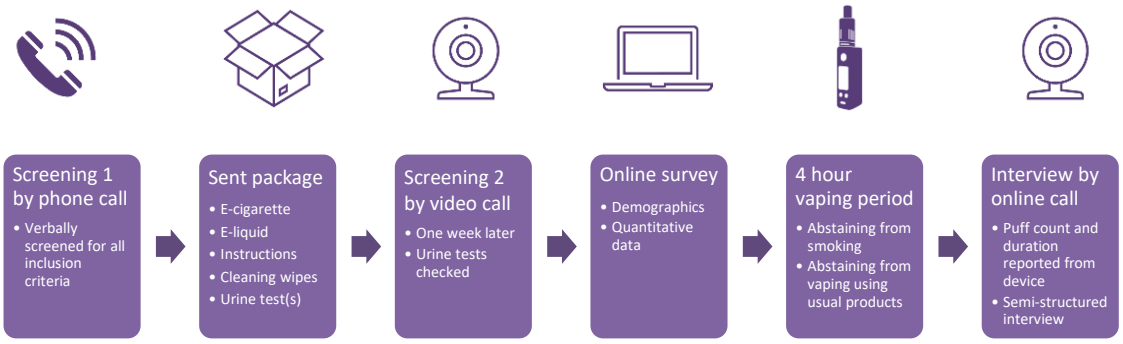
Title: *Exploring the opinions and potential impact of unflavoured e-liquid on smoking cessation among smokers and smoking relapse among e-cigarette users: Findings from a UK-based qualitative study*

Protocol: https://osf.io/snmp9

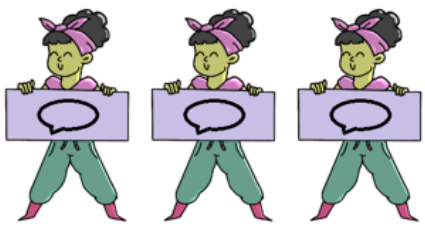
Publication: Preprint available: https://psyarxiv.com/ezrtx; doi.org/10.21203/rs.3.rs-2054093/v1

Aims: Among UK adults who either currently smoked or currently vaped, we aimed to explore: 1) opinions of unflavoured e-liquid after a 4-hour trial of an unflavoured e-liquid, and 2) how a hypothetical e-liquid flavour restriction (i.e., banning non-tobacco and non-menthol flavoured e-liquids) may impact future smoking, vaping, and intentions to vape unflavoured e-liquids.

Methods: 24 semi-structured interviews were conducted (12 smokers and 12 vapers who had quit smoking in the last 12 months). Participants (aged 18+ years) were recruited online via social media, existing participant mailing lists and website. Participant were sent a tank-style e-cigarette and a bottle of unflavoured. On the day of the study, participants completed a short survey and trialled the unflavoured e-liquid for four hours while abstaining from using their usual nicotine products. Participants then engaged in a ~20-minute semi-structured online interview.



Results: Using Interpretive Phenomenological Analysis we found differences in smokers' and vapers' opinions of unflavoured e-liquid. If only unflavoured, tobacco flavoured, and menthol flavoured e-liquids remained on the UK market, some smokers and vapers may be unaffected, but some may be at a greater risk of relapsing to smoking or continuing smoking. Despite wanting to protect children from the harms of vaping, there was disagreement about whether flavour restrictions would be an effective method.



3.5 Policy Decision Making Aid

Title: *A decision making aid for policymakers to estimate the impact of e-cigarette flavour restrictions on population smoking and e-cigarette use prevalence among youth versus smoking prevalence among adults*

Publication: Preprint available**:** https://doi.org/10.1101/2022.11.14.22282288

Aims: Well-considered policy decisions can have substantial impact on the health of the population. However, even effective policies can have unintended consequences that could outweigh the positive impact. Policymakers have to consider a wide range of evidence, which may be conflicting, to try to make the best decision. This can be a time-consuming process for policy makers who have little time to make these decisions. We developed a decision making aid to assist policy makers in making informed decisions with regards to e-liquid flavours.

Methods: The decision making aid uses existing data to estimate the impact of e-liquid flavour restrictions on overall public health and the health of people who are most at risk of smoking (e.g., people with greater social disadvantage).

To use the aid, we enter the most recent data for a range of questions (e.g., to what extent do flavours draw in non-smoking youth?) and a guidance document is automatically created that advises on whether a flavour restriction could have a net postive or negative effect on the health of the population. The guidance is therefore based on current evidence available, and can be updated when new evidence is available. These updates are regularly provided to the office of Health Improvements and Disparities and government officials, enabling guidance to be adapted as new knowledge is generated.

The ability of the aid to effectively assess potential impacts of policy decisions depends on the quality and quantity of available evidence. In the current study, the data inputted into the aid was largely derived from Action on Smoking and Health surveys and Smoking Toolkit Study data.

Results: The first page of the latest output from the decision making aid is shown below. The guidance document states:

"Using the available evidence on 26 April 2023, we estimate that 72,838 non-smoking youth experiment with e-cigarettes as a result of flavoured e-liquid availability and 382,769 smokers and ex-smokers do not smoke due to flavoured e-liquid availability. This output suggests that restricting flavoured e-liquids in the UK could have a negative overall impact on public health.

Using the available evidence on 26 April 2023, we estimate that 26,222 non-smoking youth subsequently smoke as a result of flavoured e-liquid availability and 382,769 smokers and ex-smokers do not smoke due to flavoured e-liquid availability. This output suggests that restricting flavoured e-liquids in the UK could have a negative overall impact on public health."

E-LIQUID POLICY DECISION AID

University of BRISTOL

HEALTH PROTECTION OF FLAVOUR RESTRICTION

A

To what extent do flavours draw in non-smoking youth?

a. 6,423,069 of youth at smoking age

b. 81% of those are non-smokers

c. 10% of those non- smokers have vaped

d. 14% of those state they vape because of flavours

Number of non-smoking youth who could potentially be at risk of initiating vaping because of flavours = a x b x c x d

A = 72,838

B

How many non-smokers who vape subsequently smoke?

a. 72,838 of non-smoking youth may be at risk of vaping because of flavours

b. 36% of non- smoking youth who try vaping later try smoking

Number of youth who could potentially be at higher risk of ever smoking because of the availability of flavoured e-liquids = a x b

B = 26,222

HEALTH COST OF FLAVOUR RESTRICTIONS

C

To what extent do flavours draw in adult smokers who would quit smoking using e-cigarettes as a resource?

a. 6,600,000 smokers

b. 4% of smokers quit smoking because of e-cigarettes

c. 33% of smokers state they would not quit/smoke more if flavours were not available

Number of potential lost additional quit attempts per year = a x b x c

C = 87,120

D

How many current adult vapers would relapse to smoking if flavours were not available?

a. 17,494,002 ex-smokers

b. 13% of ex-smokers vape

c. 13% of ex-smokers state they would relapse to smoking if flavours weren't available

Number of ex-smokers who may relapse to smoking = a x b x c

D = 295,649

POLICY DECISIONS

A-(C+D)

Positive values indicate the number of youth vaping due to flavours outweighs the number of smokers and ex- smokers not smoking due to flavours.

Negative values indicate the number of smokers and ex-smokers who are not smoking due to flavours outweighs the number of youth vaping due to flavours.

B-(C+D)

Positive values indicate the number of youth smoking due to flavours outweighs the number of smokers and ex- smokers not smoking due to flavours.

Negative values indicate the number of smokers and ex-smokers who are not smoking due to flavours outweighs the number of youth smoking due to flavours.

Suggested Resources: ASH surveys (SmokeFree GB); England Smoking Toolkit Study; ONS Adult smoking habits in the UK (Annual Population Survey) E-cigarette use in England, NHS digital Smoking, Drinking and Drugs Survey (SDD); ONS Annual Population Survey (E-cigarette use in England) and Opinions and Lifestyle Survey (OPN)

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Illustrations produced by @paupanimation

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