

Promises and Pitfalls of Policy:

The EU Tobacco Products Directive as Applied to E-Cigarettes

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University**

Disclosures

- Pharmaceutical industry: consultancy (2014; 2017)
- Law/Litigation: expert witness/consultant (2014)
- E-cigarette companies: research grants, honorarium (2010-2013)
- Tobacco Industry: no funding



Talk Overview

- Background
- The EU Tobacco Products Directive (TPD (2014) Article 20
- Promises & concerns/pitfalls
- The research
 - Vapers' responses & experiences
 - Nicotine concentration upper limit in e-liquid
 - Nicotine warning messages
- Summary / conclusions



Background

- E-cigarettes appeared on the European & US markets in 2006
- How to regulate?

Medicines?

Drug delivery
devices?

Tobacco
Products?

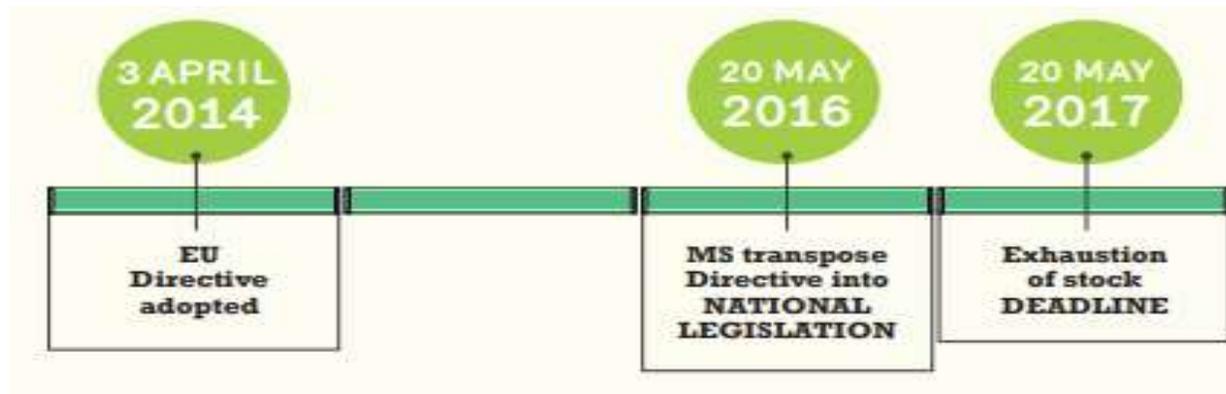
Consumer
Products?



The Tobacco Products Directive (TPD)

- “A directive of the European Union which places limits on the sale and merchandising of tobacco and tobacco related products in the EU”
- Originally created in 2001 and revised in 2014 to include e-cigarettes (under Article 20 as consumer products)
- TPD aim “To improve the functioning of the internal market for tobacco and related products while ensuring a high level of health protection for European citizens”

Implementation Timeline



https://ec.europa.eu/health/tobacco/products_en

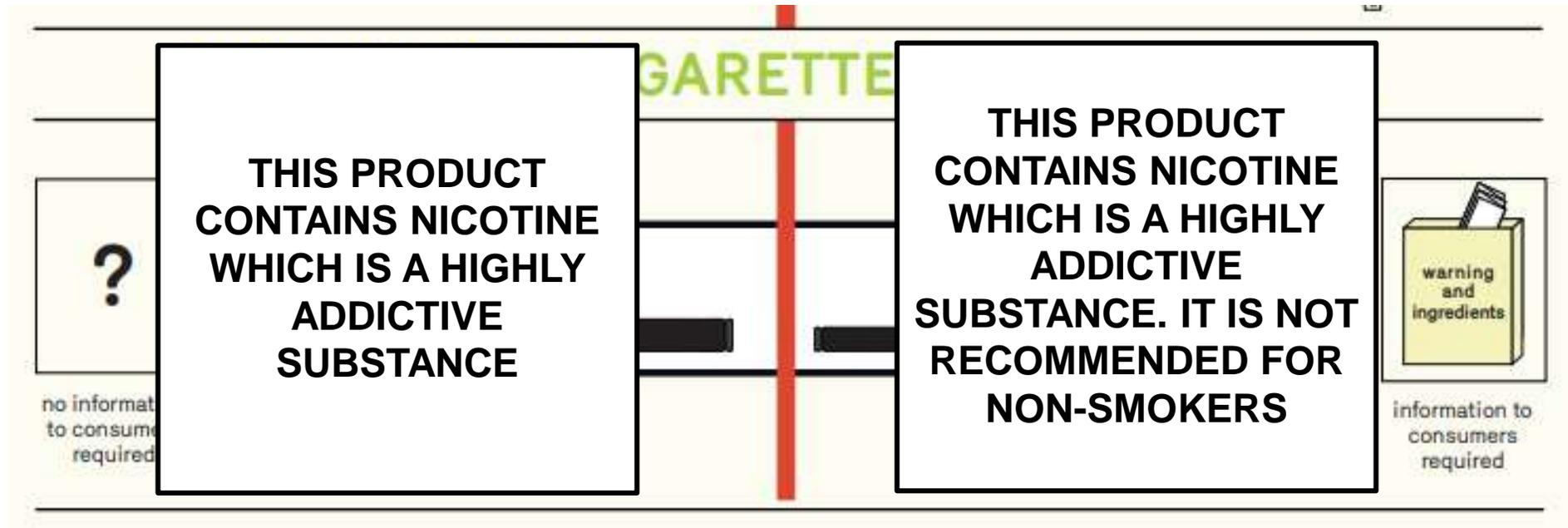
https://ec.europa.eu/health/tobacco/products/revision_en

Promises: The Tobacco Products Directive (TPD) Article 20: E-cigarettes

- E-cigarette controls introduced to ensure:
- Minimum standards for the **safety and quality** of all e-cigarettes and refill containers;
- That **information** is provided to consumers so that they can **make informed choices**;
- An environment that **protects children** from starting to use these products

The Tobacco Products Directive (TPD) Article 20: E-cigarettes

- Safety and Quality
- Packaging and Labelling



The Tobacco Products Directive (TPD)

Article 20: E-cigarettes

- Notification - manufacturers & importers must notify Member States before introducing products on the market. Notifications must include info on product composition, emissions, and marketing.
- Monitoring and Reporting - Member States must ensure there is a system for reporting & information about adverse effects/safety concerns.
- Advertising - Advertising or promotion permitted on e-cigarette packaging & containers. Cross-border advertising (e.g. on media print, television, radio, newspapers/magazines) is prohibited.

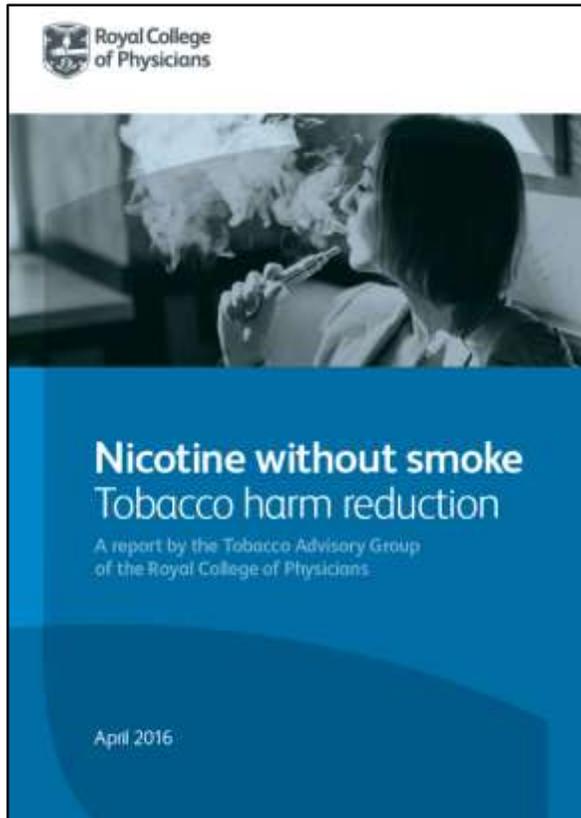
Differences in interpretation and implementation across EU member states

Concerns / possible pitfalls

- Notification regime
 - Costly and burdensome - force smaller companies to...? stifle innovation?
- Severe advertising and promotion restrictions
 - Excessive? Make EC less available &...?
- Restriction on nicotine concentration (mg/mL):
 - Reduce satisfaction and...?
 - Increase chance of relapse...?
 - Sends a misleading message: nicotine is harmful?
- Limiting e-liquid volume to 10mL and tank capacity to 2mL
 - More frequent refills, more chance of spillage, higher cost to user, more waste...
- Nicotine Advertisements Warnings
 - Excessive? Accurate? Increase misperceptions about nicotine & vaping?

May decrease the number of smokers switching to a reduced risk product

Royal College of Physicians (2016)



A risk-averse, precautionary approach to e-cigarette regulation can be proposed as a means of minimising the risk of avoidable harm, eg exposure to toxins in e-cigarette vapour, renormalisation, gateway progression to smoking, or other real or potential risks.

*However, if this approach also makes e-cigarettes less easily accessible, less palatable or acceptable, more expensive, less consumer friendly or pharmacologically less effective, or inhibits innovation and development of new and improved products, **then it causes harm by perpetuating smoking.** Getting this balance right is difficult. (Section 12.10 page 187)*

Have these concerns been borne out?

The Evidence

Notification process

- Number of notifications:
 - UK – 40k
 - France – 37k
 - Germany – 132k
- Variation in guidance, notification fee and waiting time across member states
- Vape shop workers in the UK reported no major problems (Ward et al. 2018, IJEERPH)

Vapers' perceptions & experiences of the TPD: E-Cigarettes Trajectories Study



Ward et al. *in prep*



162 EU vapers interviewed between March 2018 and March 2019

Positives	Negatives
Low awareness/impact for many	Limits consumer choice – makes vaping more expensive, less accessibility to effective products
Ingredients reassurance from liquid bottles provided	Inconveniences consumer – makes vaping more complicated
None reported the 20mg/mL limit had caused them to relapse	Concern that the 20mg/mL limit may prevent smokers from converting to vaping
	10ml bottle limits mean more plastic waste
	Stock-piling non-compliant e-liquid and large quantities of nicotine for home mixing
	Buying illegally from outside the EU
	Market reactions – nicotine shots/shake & vape



Notley, C, Dawkins, L & Holland, R. Real world experiences of using e-cigarettes for avoiding relapse to smoking: success or failure. A qualitative study funded by CRUK.

Young adult dual combusted cigarette and e-cigarette users' anticipated responses to hypothetical e-cigarette market restrictions

Lauren R. Pacek^a, Olga Rass^b, Maggie M. Sweitzer^a, Jason A. Oliver^a, and F. Joseph McClernon^a

^aDepartment of Psychiatry and Behavioral Sciences, Duke University School of Medicine, Durham, North Carolina, USA; ^bOffice of Science, Center for Tobacco Products, U.S. Food and Drug Administration, Silver Spring, Maryland, USA

- 240 young adult dual EC and cigarette users resident in the US.
- Hypothetical regulations around restricting nicotine e-liquid content resulted in **reported intentions to reduce EC use and increase cigarette smoking.**
- Ditto for regulations regarding restrictions on flavours and ability to modify EC devices.



An exploration into “do-it-yourself” (DIY) e-liquid mixing: Users' motivations, practices and product laboratory analysis



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^b Department of Health Behavior, Roswell Park Comprehensive Cancer Center, Buffalo, USA

- 41 vapers who mixed their own e-liquid interviewed in Feb/March 2017
- Common reason: “to achieve a nicotine concentration above the TPD cut-off”
- 85% expressed concern that TPD changes would affect availability of 72mg/mL nicotine and 83% said they stockpiled ingredients
- However, two thirds were currently using e-liquid nicotine concentrations < 10 mg/mL and 85% reported sub-ohming

Nicotine E-liquid Concentration

Tobacco Cigarettes	E-Liquid Nicotine
Unfiltered / Extra strong	30mg
Full strength	24mg
Regular strength	18mg
Mild / Light	12mg
Extra mild / Extra light	6mg

- Trend over time for vapers to use lower nicotine concentration e-liquids
- Possible reasons:
 - Improved sophistication of devices
 - Concern over addictiveness of nicotine; weaning off
 - Reduced availability of higher nicotine concentration liquids (e.g. TPD in Europe)

What happens when vapers switch to lower nicotine concentration e-liquids?

Dawkins et al. (2016)

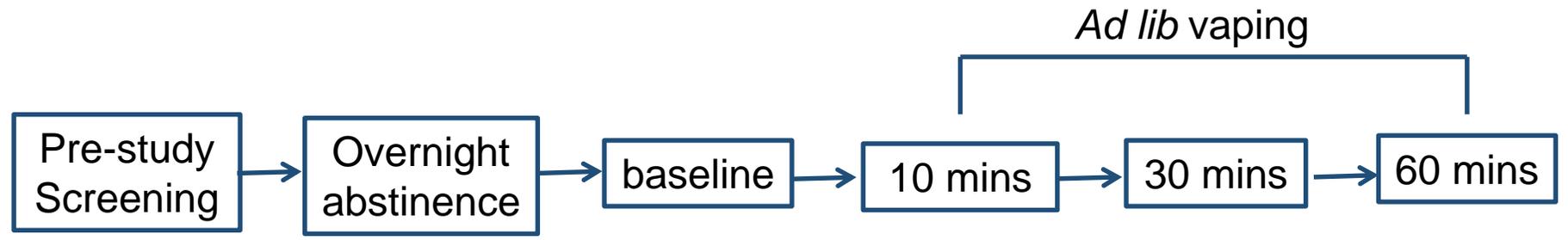
- 11 experienced vapers
- Used eVic Supreme (Joyetech) with Aspire tank (Nautilus) under 2 conditions in the lab
- With 6 & 24mg/mL tobacco flavour e-liquid
- Within-subject, double-blind, counterbalanced

Psychopharmacology
DOI 10.1007/s00213-016-4338-2

ORIGINAL INVESTIGATION

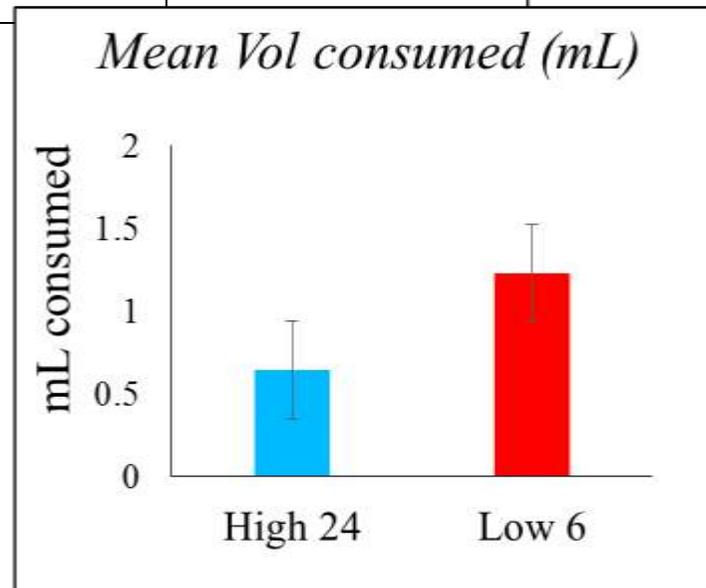
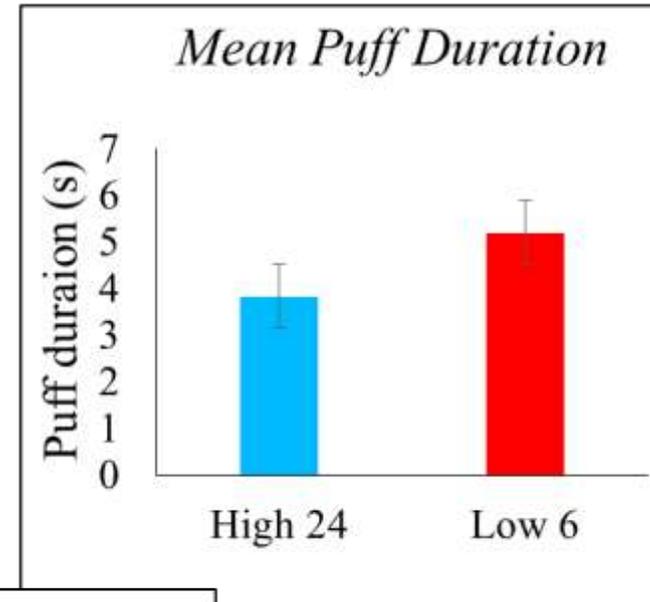
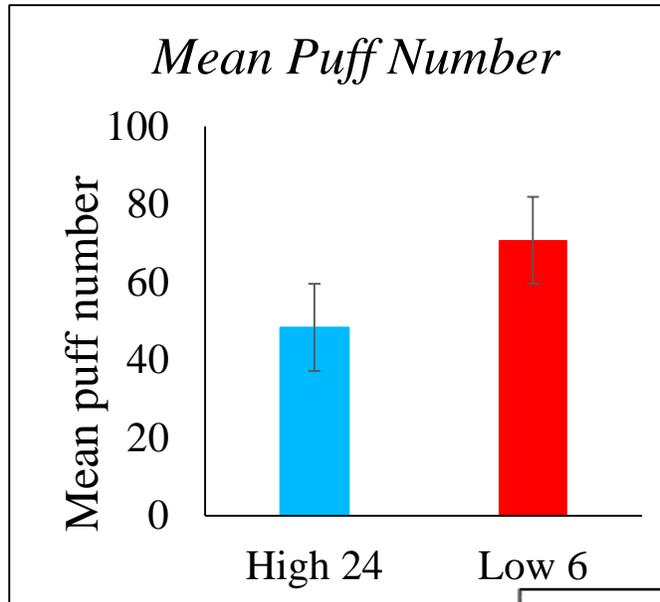
Self-titration by experienced e-cigarette users: blood nicotine delivery and subjective effects

Lynne E. Dawkins¹ · Catherine F. Kimber² · Mira Doig³ · Colin Feyerabend³ · Olivia Corcoran⁴



Repeated under high and low nicotine concentration conditions

Puffing topography



More puffs, longer puffs and more liquid consumed in the low (6mg/mL condition ($p < 0.05$))

Original investigation

Compensatory Puffing With Lower Nicotine Concentration E-liquids Increases Carbonyl Exposure in E-cigarette Aerosols

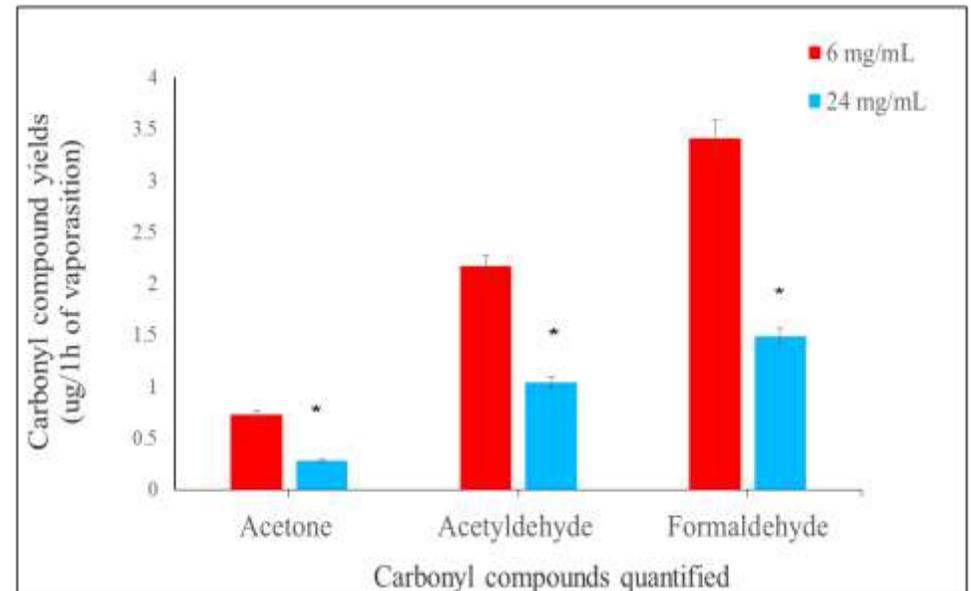
Leon Kośmider PhD¹, Catherine F. Kimber MBPsS², Jolanta Kurek MSc³,
Olivia Corcoran PhD⁴, Lynne E. Dawkins PhD⁵

Vaping machine used to generate aerosol using the mean puffing patterns recorded under 6mg/mL and 24mg/mL nicotine conditions

- Puffing pattern associated with the 6mg/mL e-liquid resulted in:

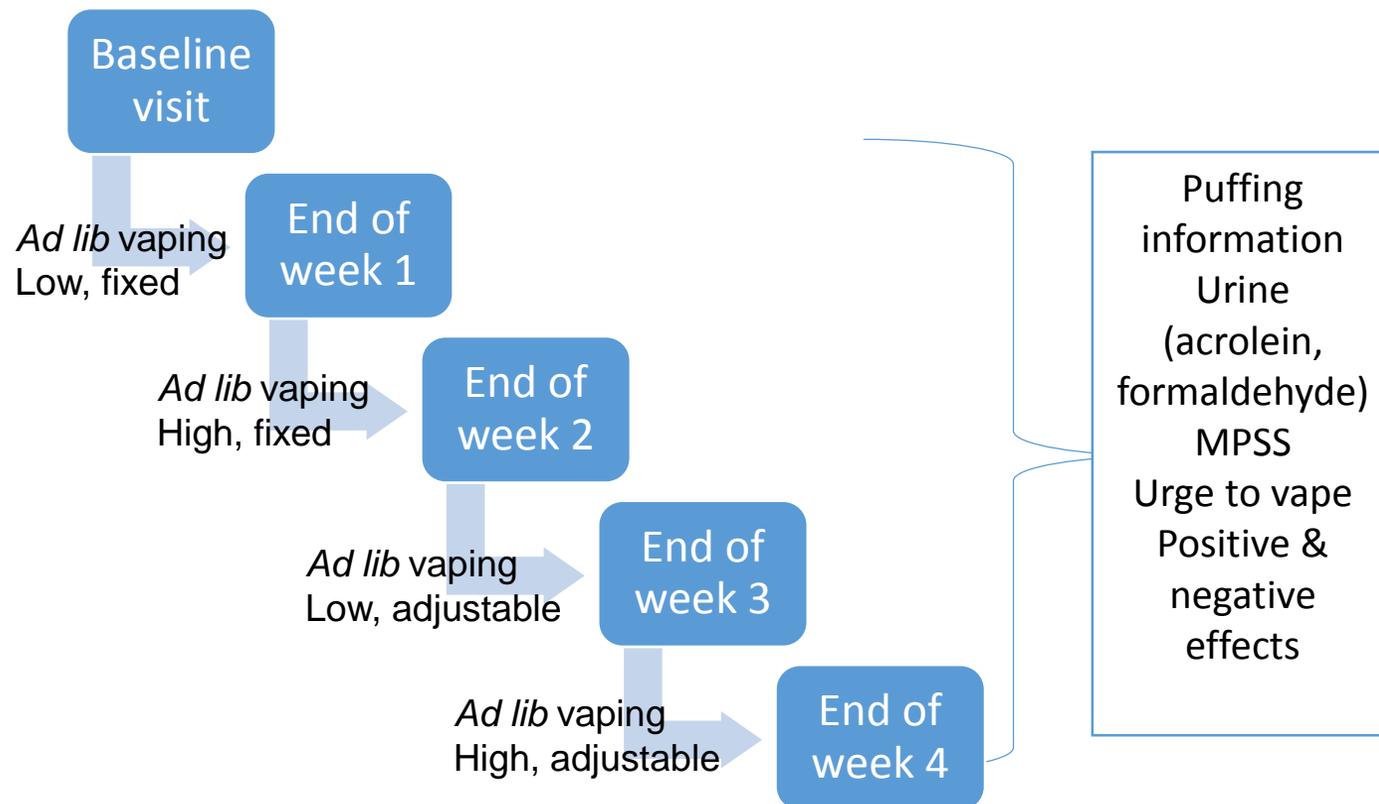
- 52% increase in aerosol production
- 45% more formaldehyde
- 33% more acetaldehyde
- 65% from acetone

($p < 0.05$ in all cases)



'Real-world' compensatory behaviour with low nicotine concentration e-liquid: subjective effects and nicotine, acrolein and formaldehyde exposure

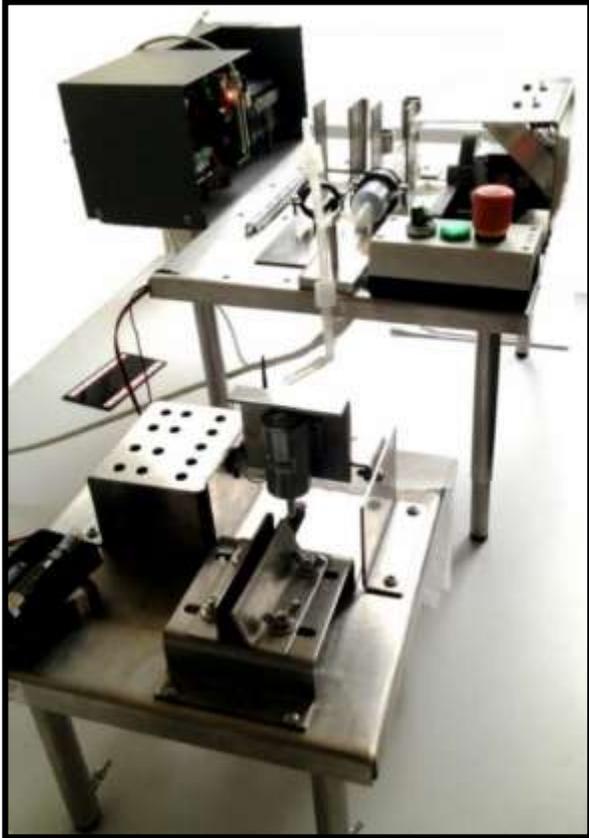
Lynne Dawkins¹ , Sharon Cox¹, Maciej Goniewicz², Hayden McRobbie³, Catherine Kimber⁴, Mira Doig⁵ & Leon Košmider⁶



Phase 1:

- 20 exclusive e-cig users
- Used eVic Supreme & Aspire tank (BVC 1.6ohm)
- Under 4 counterbalanced conditions:
 - Low (6mg/mL) nicotine, fixed power
 - High (18mg/mL) nicotine, fixed power
 - Low (6mg/mL) nicotine, adjustable power
 - High (18mg/mL) nicotine, adjustable power
- With a choice of 4 flavours (tobacco, menthol, fruit, dessert)

Phase 2: Carbonyls in Aerosol



- EC attached to vaping machine to generate aerosol based on the puffing patterns of each participant under each of the 4 conditions
- Carbonyl compounds in aerosol quantified using AT 1200 liquid chromatograph

Results:

- Power change: Power increase was greater in the low vs. high condition
- Puffing patterns: More puffs & longer puffs in the low condition, especially with fixed power
- Subjective effects: Urge to vape was higher and satisfaction, lower with low nicotine
- Biomarkers in urine: no difference for 3-HPMA (acrolein). Higher formate (formaldehyde) levels in the low nicotine/adjustable power condition
- Carbonyls in aerosol: greater exposure to formaldehyde and acetaldehyde in the low nicotine condition
- Cancer risk: our simulation suggests a 1.27 to 2.06 fold increase in Cancer Risk Index when switching from 18 to 6mg/mL nicotine concentration e-liquid

Dawkins et al. (2018) *Addiction*

Kosmider et al. (under review) *Scientific Reports*

Pitfalls of Policy

- Use of lower nicotine concentration e-liquid results in compensatory behaviour which can increase craving, reduce satisfaction and increase exposure to cancer-causing toxins
- It may be safer to use e-liquids with higher rather than lower nicotine concentration
- Limiting nicotine concentrations in e-liquid as per TPD regulations may do more harm than good
- Needs to be balanced against effects on non-smokers



The image shows two pieces of media related to e-cigarettes. On the left is a screenshot of a news article from 'The Sun' website, dated June 8, 2018. The article is titled 'SMOKE SCREEN Vaping 'stronger e-cigarettes means ex-smokers inhale FEWER cancer-causing toxins''. The sub-headline reads: 'Vapers using low nicotine e-cigarettes puff harder, for longer and more often - so inhale more cancer-causing chemicals'. The author is Lizzie Parry, Digital Health Editor. On the right is a newspaper clipping from 'The Sun' dated June 8, 2018. The headline is 'Quit with big e-cig'. The text states: 'SMOKERS trying to quit should use the strongest e-cigarettes to protect their health, experts say. Vaping low nicotine oils means they will inhale more cancerous toxins by puffing harder and longer to get the same hit. London South Bank University found that exposes vapers to more of the dangerous chemicals produced by the devices. Low nicotine users also had a stronger urge to vape and suffered worse withdrawal symptoms.'

THE Sun THE SUN, A NEWS UK COMPANY

ay, June 8, 2018 **Sun** 31

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SMOKE SCREEN Vaping 'stronger e-cigarettes means ex-smokers inhale FEWER cancer-causing toxins'

Vapers using low nicotine e-cigarettes puff harder, for longer and more often - so inhale more cancer-causing chemicals

By Lizzie Parry, Digital Health Editor
8th June 2018, 12:01 am | Updated: 7th June 2018, 6:55 pm

Quit with big e-cig

SMOKERS trying to quit should use the strongest e-cigarettes to protect their health, experts say. Vaping low nicotine oils means they will inhale more cancerous toxins by puffing harder and longer to get the same hit. London South Bank University found that exposes vapers to more of the dangerous chemicals produced by the devices. Low nicotine users also had a stronger urge to vape and suffered worse withdrawal symptoms.

E-cigarette nicotine addiction warnings

- Scares smokers away from using e-cigarettes?
- Proportion of adults perceiving EC to be as harmful or more harmful than smoking is increasing
- Widespread misperceptions of nicotine: 60% believe nicotine causes cancer (Villanti et al. 2019)
- “I do not want to substitute one addiction for another” – main reason given for not trying EC (ASH, 2017; 2018)
- Evidence: Perceptions of addictiveness and toxicity in smokers and vapers have increased since the implementation of the TPD (van Mourik et al., 2019; *IJERPH*)

**THIS PRODUCT
CONTAINS NICOTINE
WHICH IS A HIGHLY
ADDICTIVE
SUBSTANCE. IT IS NOT
RECOMMENDED FOR
NON-SMOKERS**

Alternative 'relative risk' messages

**COMPLETELY
SWITCHING TO E-
CIGARETTES LOWERS
YOUR RISK OF
SMOKING RELATED
DISEASES**

**THE ROYAL COLLEGE
OF PHYSICIANS
REPORT (2016)
CONCLUDED THAT E-
CIGARETTES ARE 95%
LESS HARMFUL THAN
SMOKING**

**USE OF THIS
PRODUCT IS MUCH
LESS HARMFUL THAN
SMOKING**



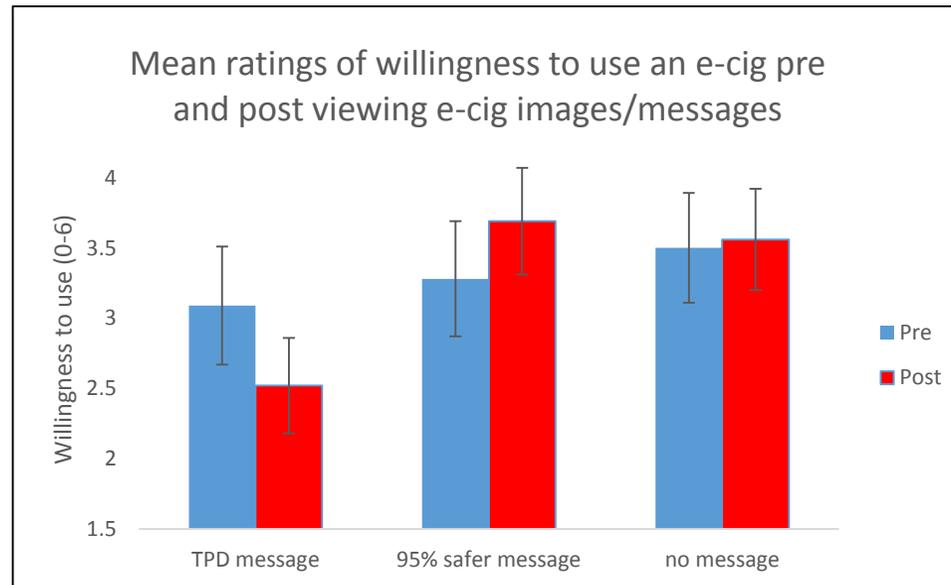
Messages matter: The Tobacco Products Directive nicotine addiction health warning versus an alternative relative risk message on smokers' willingness to use and purchase an electronic cigarette



Sharon Cox*, Daniel Frings, Reeda Ahmed, Lynne Dawkins

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Willingness to use, likelihood of purchase and intention to use as a quit aid were all lower after viewing the TPD message but did not differ between the 95% safer and no message conditions



- 95 smokers rated:
- Willingness to use, likelihood of purchasing and intention to use an EC in a quit attempt
- Before and after viewing either: i) TPD message; ii) the 95% safer message or iii) no message alongside EC images

- 2495 participants (1283 smokers and 1212 non-smokers)
- Self reported perceived EC harm, addictiveness, effectiveness, social acceptability, intentions to purchase & use and (for smokers) quit intentions...
- ...before and after exposure to EC packs with either: TPD message, reduced risk (RR) message, both together or no message



Kimber et al.
(under review)



Main findings

- Harm and addictiveness perceptions were higher with TPD vs. RR message
- TPD vs. no message increased harm perceptions in non-smokers only.
- RR message alone vs. no message reduces harm perceptions in smokers only
- RR (vs. TPD) increased purchase and use intentions in smokers but not in non-smokers

**USE OF THIS
PRODUCT IS MUCH
LESS HARMFUL THAN
SMOKING**

A RR message may potentially act as an effective harm reduction tool for smokers without resulting in increased uptake among non-smokers

The Good



- Notification & monitoring
- Regulation reassuring

To conclude...

The Bad (unintended consequences)



- Restrictions on tanks and liquid refills: more inconvenience, more waste
- Limit on nicotine concentrations: compensatory puffing = increase toxicant exposure
- EC warning labels: may perpetuate concerns re EC harms. RR messages may increase uptake in smokers without attracting non-smokers.

The Ugly (truth)

Smoking kills. Vaping is much less harmful.
Regulations that make vaping more inconvenient, less satisfying or which increase perceptions of harm or addiction may increase harm through continued smoking.



- What is the purpose of regulation?
- TPD promises: to ensure a high level of health protection; specifically - safety & quality, provide information and protect children
- Unclear at this stage if these promises have been fulfilled and if so, at what cost?