

Institution: London South Bank University		
Unit of Assessment: 4 – Psychology, Psychiatry and Neuroscience		
Title of case study: Informing government policy and promoting smoking cessation through quantifying and communicating the effects of e-cigarettes		
Period when the underpinning research was undertaken: 2016 – 2018		
Details of staff conducting the underpinning research from the submitting unit:		
Name(s):	Role(s) (e.g. job title):	Period(s) employed by submitting HEI
Lynne Dawkins	Professor of Nicotine and Tobacco Studies	January 2016 – present
Catherine Kimber	Research Fellow	April 2018 – present
Sharon Cox	Research Fellow	March 2016 – August 2020
Period when the claimed impact occurred: October 2017 – December 2020		
Is this case study continued from a case study submitted in 2014? N		
<p>1. Summary of the impact (indicative maximum 100 words)</p> <p>Research at the Centre for Addictive Behaviours Research (CABR) at London South Bank University (LSBU) has demonstrated unintended negative consequences of EU legislation around nicotine levels in e-liquid and the benefits of electronic cigarettes (EC) over existing treatments for quitting smoking.</p> <p>A submission to the House of Commons' Science and Technology Committee's inquiry resulted in a recommendation from the UK Government to review levels of nicotine in EC liquids.</p> <p>Research on the efficacy of EC for smoking cessation has been used by Stop Smoking Services across England to secure external funding and improve evidence-based information resources. This has led to significant improvements in quit rates (> 20% in some areas) and cost-savings (of GBP80 (£80) per quitter using an EC) to local authorities.</p> <p>The research has also been pivotal to the decision to recommend EC use in a stop smoking app that has been downloaded more than 5,000,000 times across the world.</p>		
<p>2. Underpinning research (indicative maximum 500 words)</p> <p>LSBU is an international leader in Electronic Cigarette research which translates into impact. Smoking kills more than 200 people in the UK every day. Given that it is accepted that vaping (e-cigarette use) is 95% safer than smoking, helping smokers to switch to e-cigarettes (EC) and use them in the safest and most effective way could save thousands of lives. Brexit provided the opportunity for the UK Parliament to review guidelines around the use of EC and the research described in this case study a) highlights some of the negative consequences of current EU legislation and b) presents the first UK evidence of the value of EC for smoking cessation.</p> <p>The research underpinning the impact described stems from work by the CABR at LSBU. It was conducted by Lynne Dawkins (Professor of Nicotine and Tobacco Studies, at LSBU since 2016), Dr Catherine Kimber (Research Fellow, at LSBU since 2018) and Dr Sharon Cox (Research Fellow, at LSBU from 2016 to August 2020). Research collaborators were Professor Peter Hajeck (QMUL) and Hayden McRobbie (Visiting Professor and UNSW) for work on the randomised trial; Professor Caitlin Notely (UEA and CABR Visiting Fellow) for work using EC to sustain smoking cessation.</p> <p>Since joining LSBU, Dawkins has led work focused on EC, particularly in relation to behavioural and health-related consequences of the EU's Tobacco Products Directive (TPD), which was</p>		

transposed into UK legislation through the Tobacco and Related Products Regulation 2016 (TRPR). Other research was on EC use (vaping) for quitting smoking and preventing relapse.

LSBU research showed that legislation intended to minimise harm through reducing EC nicotine levels may have had the opposite effect. In a 2016 study, 11 experienced vapers completed 60 minutes of *ad libitum* vaping under low (6 mg/mL) and high (24 mg/mL) nicotine e-liquid conditions in two separate sessions in a laboratory setting. Puff number and puff duration were measured using an inbuilt puff counter on the EC and volume of liquid consumed was estimated by weighing the device before and after use. Number of puffs was significantly higher, and puff duration significantly longer, in the low compared with the high nicotine concentration condition, resulting in a doubling of e-liquid consumed [R1] This effect of compensatory puffing with a lower nicotine e-liquid concentration was subsequently replicated in a group of 20 vapers in a real-world setting (allowing them to take the device home and use as normal for 4-weeks) [R2] (2018). It was also found that the more intensive puffing resulting from lower nicotine levels was associated with higher levels of carcinogen exposure as measured by levels in users' saliva and urine [R2] (2018). When the puffing patterns obtained from participants in [R1] (2016) were mimicked using a smoking machine to generate e-cigarette aerosol in the lab, carcinogen levels were significantly higher in aerosols from the 6mg/mL compared with the 24mg/mL puffing regimen [R3] (2018). The findings suggested that the 20 mg/mL limit on nicotine levels imposed by the TPD may have had the unintended consequence of encouraging use of lower nicotine e-liquid, which could increase exposure to carcinogenic compounds through compensatory puffing.

LSBU research provided gold standard evidence for the effectiveness of EC for quitting smoking. In 2019, the research team published the first randomised trial of e-cigarettes in the UK [R4]. In 886 smokers, EC were shown to be almost twice as effective as the current gold standard (nicotine-replacement therapy (NRT) when accompanied by behavioural support delivered by English Stop Smoking Services (SSS)) in assisting smokers to quit. It was also shown that, compared to NRT, vaping was associated with improvements to respiratory functioning (reduced cough and phlegm production). Between 2016 and 2018 the team explored if and how EC could help people to stay stopped from smoking [R5]. Interviews with 40 vapers suggested that a lapse to smoking was perceived as qualitatively different in the context of vaping and did not necessarily result in full-blown relapse as previously theorised and demonstrated in relation to smoking.

3. References to the research (indicative maximum of six references)

All outputs are peer-reviewed, published in journals with Impact Factors exceeding 1.6 (mean = 18.13; range: 1.6 – 74.70) and SNIPS ranging from 0.98 to 13.21. Collectively, they have been cited over 900 times (Google, November 2020). R1, R2, R3 and R4 are submitted as outputs for REF2021 in UoA 04.

[R1] Dawkins, L., Kimber, C., Doig, M., Feyerabend, C. & Corcoran, O. Self-titration by experienced e-cigarette users: blood nicotine delivery and subjective effects. (2016). *Psychopharmacology*, 233 (15-16), 2933-2941. Doi: <https://doi.org/10.1007/s00213-016-4338-2>

[R2] Dawkins, L. Cox, S., Goniewicz, M., McRobbie, H., Kimber, C., Doig, M. & Kosmider, L. (2018). 'Real-world' compensatory behaviour with low nicotine concentration e-liquid: subjective effects and nicotine, acrolein and formaldehyde exposure. *Addiction*, 113: 1874-1882. Doi: <https://doi.org/10.1111/add.14271>; Linked database also available: Doi: <https://doi.org/10.18744/LSBU.002952> (<https://openresearch.lsbu.ac.uk/item/86z7w>)

[R3] Kosmider, L., Kimber, CF., Kurek, J., Corcoran, O. & Dawkins, LE (2018). Compensatory puffing with lower nicotine concentration e-liquids increases carbonyl exposure in e-cigarette aerosols. *Nicotine and Tobacco Research*, 20 (8): 998-1003. Doi: <https://doi.org/10.1093/ntr/ntx162>

[R4] Hajek, P., Phillips, A., Przulj, D., Pesola, F., Myers Smith, K., Bisal, N., Li, J., Parrott, S., Sasieni, P., Dawkins, L., Ross, L., Goniewicz, M., Wu, Q. & McRobbie, H. (2019). A randomized trial of e-cigarettes versus nicotine-replacement therapy. *New England Journal of Medicine*, Jan 30. Doi: <https://doi.org/10.1056/NEJMoal808779>
<https://www.nejm.org/doi/full/10.1056/NEJMoa1808779>

Dawkins was a co-applicant on the original funding application, contributed to the design and planning of the study and made a substantial contribution to the study write up.

[R5] Notley, C., Ward, E., Dawkins, L & Holland, R. (2018). The unique contribution of e-cigarettes for tobacco harm reduction in supporting smoking relapse prevention. *Harm Reduction Journal*, Jun 20: 15(1): 31. <https://doi.org/10.1186/s12954-018-0237-7>

The outputs were enabled by the following funded projects:

1) E-cigarette puffing patterns associated with high and low strength nicotine e-liquid: Effects on toxicant and carcinogen exposure. Cancer Research UK (CRUK) Population Research Award. GBP77,261; May 16 – Apr 17. PI: Lynne Dawkins. Award no.: C50878/A21130 **[R2]**.

2) A randomised controlled non-inferiority trial to examine the efficacy of e-cigarettes compared with standard pharmacotherapy, used within the UK SSS. National Institute of Health Research (NIHR). GBP739,000; Oct. 14 – Sept.17. PI: Peter Hajek, CI: Lynne Dawkins. Award no.: HTA12/167/135. Registered on ISRCTN registry (60477608) **[R4]**.

3) Real world experiences of using e-cigarettes for smoking cessation: success or failure: A qualitative study. CRUK, Tobacco Advisory Group. GBP40,000. Sept. 16 – Feb 18 PI: Caitlin Notley, CI: Lynne Dawkins. Award no.: C54889/A22732 **[R5]**.

4. Details of the impact (indicative maximum 750 words)

The research findings have influenced UK regulators, provided guidance to health professionals and improved outcomes for patients.

The impacts can be summarised under three headings:

1. Shaped UK Government policy and regulatory decision-making
2. Improved information for health professionals and outcomes for clients
3. Raised awareness of researchers, lobbyists, media and the public

Shaped UK Government policy and regulatory decision making: The findings **[R1,2,3]** shaped the recommendation by the Department of Health and Social Care (DHSC) to re-appraise current regulation around nicotine concentrations in EC liquids. CABR submitted written evidence to the House of Commons Science and Technology Committee's (STC) enquiry into EC regulation **[S1]** (2017). Dawkins then provided oral evidence at the STC's second hearing in Parliament **[S1]** (February 2018). Its report on EC **[S1]** (August 2018) directly quoted the CABR submission stating "[the research] told us that the 20mg/mL nicotine limit for e-cigarette refills was not evidence-based and was actually counter-productive" and "This upper limit is arbitrary and is not based on empirical evidence. In fact, it may increase harm". It concluded that "the limit on the strength of refills means that some users have to puff harder to get the nicotine they seek" **[S1]**. The resulting recommendation to the UK Government directly reflected the research findings and the CABR submission, that "the limit on nicotine e-liquid concentrations and other regulatory anomalies should be reviewed" **[S1]**. The written response from the DHSC (December 2018) accepted the recommendation and stated that, with the UK's exit from the EU: "The Government will explore those areas identified by the Committee, such as the 20mg/ml maximum nicotine refill limit, [...] etc." **[S1]**.

The research also informed policies on smoking and vaping in Parliament itself. The work on e-cigarette self-titration **[R1]** and a report on EC for behaviour change, published by the British Psychological Society (BPS), led to an invitation to join the panel for a roundtable discussion on vaping in public places and workplaces by the All Party Parliamentary Group (APPG) on Vaping

(December 2017). As a result, a new smoking and vaping policy for Parliament, was developed which Dawkins helped to draft. It was launched in November 2018 [S2].

Improved information for health professionals and outcomes for clients: In the UK, the NHS stop smoking webpages use the findings [R4] to support their headline advice to smokers - *"E-cigarettes are far less harmful than smoking and can help you quit smoking for good"*. Stop Smoking Services (SSS) have become more *"e-cigarette friendly"* as a result of the findings. Staff report greater confidence in supporting smokers to quit using e-cigarettes', quit rates have significantly improved and services have used the findings to secure external funding (e.g. Southwark, Northamptonshire). Barnet SSS wrote, *"We refer to [the] findings in our training package for advisors; in turn confidence in using e-cigarettes among clients, and supporting use among staff, has increased.[...] in 2019/20 we saw a 1.5% increase in successful quits in our clients who also use e-cigarettes"* [S3] (10 November 2020). Northamptonshire SSS reported, *"Our policies, practices and funding have been greatly influenced by your published research [...]. In quarter 1 of 2019 my team achieved an overall quit rate of just 48%, [...] in quarter 1 of 2020 this figure rose to 69%."* It also identified that the research had led to a cost saving of GBP80 (£80) for every client that chose vape over NRT and that *"the evidence [...] was absolutely pivotal in helping us to build a case around the effectiveness and safety of vapes (to secure external funding)"* [S3]. The National Centre for Smoking Cessation and Training (NCSCT), a social enterprise, published a briefing for practitioners based on the study. It wrote, *"Prior to the publication of your 'Trial of E-Cigarette' (TEC) in 2019, the NCSCT were unable to make any specific recommendations about the effectiveness of e-cigarettes within SSS as research in this area was lacking. [After it] we were able to recommend that SSS should include e-cigarettes among their treatment options"* [S4] (9 February 2021). The developer of the popular "Smoke Free" stop smoking app stated that, *"[...] your research [...] has been pivotal in our decision to recommend and support [EC] use in our app. [...] the research [...] has helped to reassure our users that e-cigarettes are a valid choice of cessation product"* [S3] (28 October 2020). The app has been downloaded over 5,000,000 times across the world.

The work on how EC helps prevent relapse to smoking [R5] led the NCSCT to co-produce a leaflet with the research team ("Staying Switched"). This provided advice about devices, flavours, dealing with cravings, and addressed concerns about addiction taken from quotes and themes drawn from interviews with vapers [R5]. Since 2018, NCSCT has sent out 2,000 leaflets to SSS and related organisations [S4]. The research team have since sent out a further 8,000+ leaflets nationwide to over 100 SSS, pharmacies, medical practices, dentists, vape shops and NHS colleagues (mostly as a result of direct requests). The leaflet is available on many NGO and charity websites including ASH Wales and QuitRight [S5]. Recipients of the leaflets stated that they are *"extremely useful"* in helping them to stay stopped because they offered strategies for avoiding relapse and reassured them about EC safety. A healthcare provider stated, *"With the recent scaremongering that has enveloped the vaping industry [...], the leaflet gave some customers reassurance from an independent organisation"* (28 August 2020). Another wrote, *"Your leaflets are a fantastic resource for our service users"* [S5] (27 November 2018).

Raised awareness of researchers, lobbyists, media and the public: Findings from the studies informed and enhanced broader public and NGO engagement with health and regulatory issues regarding EC and smoking. Dawkins was invited to write an article on e-cigarettes as part of the British Psychological Society's (BPS) Behaviour Change series (2017). It used in the BPS submission to the STC inquiry into e-cigarettes [S6]. The research was used by several consumer organisations in their lobbying activities. The New Nicotine Alliance (NNA), a tobacco harm-reduction organisation, cited the work [R1] in a letter and briefing to the UK Minister of Health in support of its argument to remove the limit on nicotine concentrations in e-liquid [S6] (2020). The Adam Smith Institute and "We Vape" also referenced it [R3, R4]. A political advisor in the UK wrote, *"I present [...] scientific evidence [...] to the public, politicians, civil servants and health professionals. Research like yours [is] incredibly important for my work. I cited the NEJM article [...], in a recent article 'Can Vaping Reduce Inequality' which was read over 50,000 times [...]. I have also referenced this important trial in meetings with [MPs] and when speaking to audiences about the efficacy of vaping as a smoking cessation tool"* [S6] (13 November 2020).

The work [R2] also featured as part of a broader discussion around nicotine concentrations in cigarettes and e-cigarettes by Vaping Post (an independent online publication specialised in e-cigarette and vaping news since 2011) [S6].

The Dutch organisation of retailers of electronic cigarettes (Esigbond) used the research [R3, R4] in the evidence they presented to the Dutch government [S6] as part of the National Prevention Agreement consultation.

Broader public engagement was achieved through a variety of international media outlets and public engagement channels including: The Guardian's Science Weekly podcast (130,000 subscribers; est. readership 570,000) on e-cigarettes (2018) and an interview (2017) on Canadian Regulator Watch (7,650 subscribers on YouTube & 9,580 on Facebook). A public lecture on myths associated with e-cigarettes (2018) [S7] was subsequently put on YouTube and has received 2,969 views. Comments include *"This is a great source of knowledge. Really appreciate it. Vaping helped me from day 1"* and *"These ladies are Angels. We need people like this in America. Real studies done by real people...Not paid studies done by paid off scientists"*.

5. Sources to corroborate the impact (indicative maximum of 10 references)

[S1] For Dawkins' contribution to the House of Commons Science and Technology inquiry in to e-cigarettes [based on R1, R2, R3] [the written submission from CABR can be found here](#). The [video recording of the oral evidence session is available here](#) and the [transcript of the oral evidence session is here](#). See also [The Final Report of the House of Commons Science and Technology Committee on E-cigarettes, Seventh Report of Session 2017-19](#) (see pages 29 & 38), and the [Government Response, Department of Health and Social Care report](#) published December 2018 (see p.10).

[S2] The Vaping in Parliament Policy which Dawkins contributed to [based on R1 and the subsequent BPS report] and the related testimonial from Mark Pawsey, MP for Rugby and Chair of the APPGV.

[S3] Letters from various English (Northampton, Barnet, Southwark) SSS and from David Crane, founder and CEO of the Smoke Free app which have utilised the findings from R4.

[S4] The [NCSCT briefing for practitioners](#) which recommends that SSS offer EC starter kits based on R4. A factual statement from the NCSCT is also available to corroborate the impacts of R4 on their e-cigarette guidance documents and training modules

[S5] Reference to the use of the 'Staying Stopped' leaflets [R5] can be found on the [ASH Wales website](#) and the [QuitRight website](#). Responses from recipients of leaflets will be made available to the REF team.

[S6] The [BPS submission to the Science and Technology Committee E-cigarette Inquiry](#) which cites R1. Letters from Esigbond and We Vape referencing R2,4 in their government lobbying activities are available to the REF team. The [NNA letter](#) and [briefing to the UK Minister of Health](#) which cites R1 (as well as LSBU research on e-cigarette pack warnings). [The discussion about R2 on the Vaping Post](#).

[S7] The [Guardian Science Weekly](#) and the [Regulator watch](#) programs in which Dawkins discusses her work. The [YouTube public lecture is available here](#).