

1 **Title: A qualitative exploration of consumers' perceived impacts, behavioural reactions,**
2 **and future reflections of the EU Tobacco Products Directive (2017) as applied to**
3 **electronic cigarettes**

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5 Short title: E-Cigarette Users' experiences of the Tobacco Products Directive

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33 **ABSTRACT**

34 **Background:** Electronic cigarette regulations included in the Tobacco Products Directive
35 (TPD), Article 20, implemented in Europe by May 2017, aimed to improve safety for e-
36 cigarette consumers, and prevent uptake among non-smokers, particularly young people.
37 Before implementation, there were significant concerns from consumers, industry, and some
38 in the scientific community about the potential negative impact of the TPD on people using e-
39 cigarettes to stay stopped from smoking. To date, there is limited evidence on how the TPD
40 has affected consumers. This study aimed to add insight into how consumers perceived and
41 experienced the regulations.

42 **Methods:** Qualitative data, collected between March 2018 and March 2019, relating to
43 participant views of the TPD were extracted from 160 interviews/extended surveys of e-
44 cigarette consumers as part of a wider study into e-cigarette use trajectories (ECtra study).
45 Data were thematically analysed.

46 **Results:** Awareness of the TPD amongst consumers was not universal. Participants' smoking
47 behaviour did not appear to be influenced by the legislation. Participants were reassured by
48 manufacturing regulations and requirements for ingredients labels. Participants responded
49 negatively to changes perceived to cause inconvenience and extra plastic waste. The product
50 restrictions prompted some participants to purchase noncompliant products illegally,
51 potentially putting their safety at risk.

52 **Conclusions:** E-cigarette regulation should focus on ensuring product safety. Raising
53 awareness of the TPD amongst consumers and smokers could be beneficial.

54

55 **KEYWORDS**

56 Electronic cigarettes, vaping, ENDS, tobacco regulation, tobacco policy, Tobacco Products
57 Directive, qualitative research, consumer views, nicotine

58 INTRODUCTION

59 E-cigarettes are now the most popular smoking cessation aid chosen by UK smokers (1) and
60 have been shown to be an effective aid for smoking cessation (2, 3). However, although they
61 are recognised as being much less harmful than tobacco smoking (4), the long-term health
62 effects are not yet known (5) and there is concern, particularly in the US, about the potential
63 for youth uptake, and subsequent nicotine addiction amongst never smokers (6). A number
64 of studies have demonstrated that e-cigarette liquid and aerosol does contain harmful and
65 potentially harmful compounds (e.g. carbonyl compounds with carcinogenic potential, heavy
66 metals, respiratory irritants (7, 8); the levels of which can vary depending on the nature of the
67 device and usage conditions (9, 10, 11). Although these levels are typically far lower than
68 those found in tobacco smoke (7, 11), the effects of repeated inhalation on health are yet to be
69 quantified. Encouragingly, studies of respiratory health have demonstrated fewer respiratory
70 symptoms in exclusive e-cigarette users (vapers) compared with smokers (12) and smokers
71 with asthma or COPD report symptom improvement when switching to e-cigarettes (13, 14).
72 Similarly, studies measuring urinary biomarkers of exposure to cancer, cardiovascular and
73 respiratory disease typically record far lower levels of these markers in e-cigarette users
74 compared with smokers (15-19). Nevertheless, the absolute risk of long-term e-cigarette use
75 (vaping) is yet to be determined, and there have been reported outbreaks of adverse reactions
76 related to the misuse of e- cigarettes; (e.g. by vaping adulterated or unregulated e-liquids)
77 (20). Ensuring that e-cigarette devices and e-liquids are as safe as they can be, falls partly
78 under the remit of legislation and regulation.

79

80 Regulation of e-cigarettes varies considerably around the world, from no legalisation in
81 around half of countries to a complete ban on sales in twenty-nine countries (21). In the
82 European Union (EU), the revised Tobacco Products Directive (TPD) was implemented

83 between May 2016 and May 2017. The TPD included e-cigarettes (Article 20), introducing
84 regulations including refill liquid containers limited to a maximum volume of 10ml with no
85 higher than 20mg/ml nicotine concentration; refillable tanks and cartridges (the reservoir
86 included in the e-cigarette which holds the e-liquid) were not to exceed a capacity of 2ml; all
87 vaping products to include a health warning label stating that “this product contains nicotine
88 which is a highly addictive substance”; and liquid packaging to list ingredients. In addition,
89 the TPD prohibits specific hazardous ingredients and requires producers to notify their
90 country’s relevant regulatory authority before launching a product to market (22).

91

92 The TPD regulations were introduced with the intention to increase e-cigarette safety by
93 setting minimum standards and providing information to consumers to allow them to make
94 informed choices, whilst also protecting children and deterring never-smokers from trying e-
95 cigarettes by limiting marketing and including nicotine warning labels. The vaping
96 community and some scientists raised concerns that a reduction in nicotine strength might
97 stop smokers from quitting using e-cigarettes, or cause users to relapse to smoking, as the
98 lower strength may not satisfy cravings (23-25). However, cross-sectional survey evidence
99 suggests that the limits on nicotine strength do not appear to have influenced consumers
100 previously using non-compliant high strengths to be more susceptible to returning to
101 smoking, as feared (26). UK policy makers were worried that price increases would drive
102 consumers to the black market, potentially putting their health at risk (27). It is not clear to
103 what extent this concern is warranted, but consumers and retailers have found legal methods
104 to overcome the restrictions resulting from the TPD. For example, some consumers
105 stockpiled high nicotine concentrations of e-liquid for use in mixing their own liquids (28),
106 and many retailers embraced product innovation, such as selling ‘nicotine shots’ (29). These
107 are TDP compliant 10ml bottles containing unflavoured nicotine of the maximum legally

108 permitted strength of 20mg/ml; users dilute the nicotine in larger bottles of 0mg/ml liquid,
109 enabling them to legally possess a large bottle of e-liquid tailored to their desired nicotine
110 strength.

111

112 Evidence investigating how the TPD is experienced by consumers is limited, but is vital for
113 policy makers to consider when developing e-cigarette policy. Indeed, the UK Government
114 has recently made a commitment to review the TPD restrictions relating to nicotine strength
115 limits, tank restrictions, advertising, and ingredient notifications, in light of the UK's exit
116 from the EU (30). This is the first study to our knowledge using in-depth qualitative
117 exploration of consumers' views and experiences of the TPD regulation since its
118 implementation.

119

120 **METHODS**

121 The data drawn upon to answer the research question 'How do vapers perceive and
122 experience the EU Tobacco Products Directive (2017) as applied to e-cigarettes (Article
123 20)?' are taken from Phase 2 of a wider longitudinal study, the 'E-Cigarettes Trajectories
124 Study' (ECtra), exploring patterns of e-cigarette use in relation to preventing smoking relapse
125 through longitudinal mixed methods data collection [31, 32]. The study received ethical
126 approval from the UEA Faculty of Medicine and Health Sciences Research Ethics Committee
127 (project reference: 2017/18 – 106).

128

129

130 **Recruitment and sampling**

131 Between March 2018 and March 2019, 184 participants took part in Phase 2 of the study, 12-
132 18 months after they initially participated in Phase 1 of the study (2016- 2017). The

133 eligibility criteria included people aged 18 years or above, who had attempted to use an e-
134 cigarette for smoking cessation. Participants were originally recruited into Phase 1 of the
135 study through word of mouth, local press articles, university bulletins, vape shops, and social
136 media. The ECtra study was initially designed to be an interview study, but due to over
137 recruitment, the research team devised an alternative survey version of the interview which
138 was shared with project enquirers who were unable to participate in an interview, and on
139 social media.

140

141 Forty interview participants were recruited for Phase 1 and thirty-seven participants were
142 interviewed for Phase 2 (one participant declined Phase 2 participation due to personal
143 reasons and two did not respond to contact attempts). With regards to the survey, 371
144 participants were recruited for Phase 1 and 147 participated in Phase 2 (seventy-seven did not
145 provide an email address at Phase 1, fifty-seven started the Phase 2 survey but did not
146 complete, and ninety did not respond to emailed requests to complete the Phase 2 survey). At
147 Phase 2, only participants who identified themselves as being resident in the EU were asked
148 about the TPD; this included all interview participants and 125/147 survey participants. Two
149 EU based survey participants did not provide an answer to the TPD question resulting in a
150 final sample of n=160.

151

152 **Procedure**

153 The Phase 2 online survey and interview topic guide were developed in consultation with lay
154 consultants. Both data collection tools asked similar questions. The questions were derived
155 from findings illuminated from Phase 1 of the ECtra study (29, 31, 33), and related to relapse
156 pathways (34) and partnership working between healthcare professionals and the vaping
157 industry (35). In addition, a question about the perceived impact of the TPD was included to

158 explore experiences of the legislation which had come into full effect in May 2017, just after
159 Phase 1 of the study had completed. Only data generated from that one question were
160 analysed for this paper. Both data collection instruments included the same question phrasing
161 (Appendix 1).

162

163 **Analysis**

164 Participants gave informed consent before taking part in a confidential online survey or
165 telephone (25)/face-to-face (12) interview. Interviews were recorded, transcribed verbatim,
166 and anonymised. Surveys were administered via the Qualtrics online survey platform (36)
167 using a hyperlink and data were downloaded once the survey closed. Participant responses to
168 the TPD question were extracted from interview transcripts and downloaded survey data,
169 then were uploaded to NVivo 12 qualitative analysis software (37). The extracts were coded
170 using a standardised thematic analysis method (38): CA coded data for latent and semantic
171 content within the interview sample data, with EW coding a subset of approximately 10% of
172 interview data to check for coding consistency. Codes were iteratively reviewed and sorted
173 into subthemes and overarching themes by CA in discussion with EW until data analysis
174 saturation was achieved with no new codes being generated. This coding structure was
175 applied deductively to coding of the survey sample by CA and EW, allowing for inductive
176 coding and iterative sorting of themes as needed. Following this, the themes were written up
177 with illustrative quotes for each identified theme by CA and EW. As is typical in in
178 qualitative research, this sometimes resulted in the recoding and categorising of the data. The
179 final analytical write up was critically reviewed by EW resulting in a comprehensive
180 interpretation of the data in relation to the research question and the final thematic structure
181 agreed by CA, EW, and CN.

182

183 **RESULTS**

184 Profile of participant characteristics is reported in Table 1. Just over a quarter of all
 185 participants were female (41, 27.3%), ages ranged from 22 to 79 years (mean 49, SD 12.37),
 186 three participants were from Black, Asian, and minority ethnicities (BAME), and 45.9% (67)
 187 were employed in managerial, professional or technical occupations (39). Most (133, 89.9%)
 188 participants identified as being resident in the UK due to this being where the UK based
 189 research team recruited, and that English language was used. The vast majority of
 190 participants were vaping and abstinent from tobacco (139, 86.9%), 10 participants had
 191 relapsed (4 dual using both tobacco and vaping), and 11 were no longer using either e-
 192 cigarettes or tobacco. Of those using e-cigarettes at the time of Phase 2 data collection, the
 193 median length of use was four years (range 1-9) and the vast majority did not plan to quit
 194 using e-cigarettes (124, 86.7%). The survey and interview samples differed mainly on gender
 195 and vaping status. No participants reported regular use of smokeless ‘heat-not-burn’ tobacco
 196 products.

197

198

	Interview sample n=37	Survey sample* n=123	Combined int/survey sample n=160
Gender:			
Male	51.4% (19)	79.6% (90)	72.7% (109)
Female	48.6% (18)	20.4% (23)	27.3% (41)
Age (n=150):			
Range (years)	49: 22-71	53: 26-79	57: 22-79
Mean (years)	42 (SD 14.32)	52 (SD 10.71)	49 (SD 12.37)
Ethnicity:			
White	100% (37)	97.3% (108)	98% (145)
BAME		2.7% (3)	2% (3)
Managerial, professional, or technical occupation:	37.8% (14)	48.6% (53)	45.9% (67)
Resident location:			
UK	97.3% (36)	87.4% (97)	89.9% (133)
Other EU	2.7% (1)	12.6% (14)	10.1% (15)
T2 vaping status:			
Vaping and abstinent from tobacco	62.2% (23)	97.3% (116)	86.9% (139)
Abstinent from both vaping and tobacco	16.2% (6)	4.1% (5)	6.9% (11)

Relapsed to tobacco (dual using)	5.4% (2)	1.6% (2)	2.5% (4)
Relapsed to tobacco (not vaping)	16.2% (6)		3.8% (6)
Approx. years using e-cig at T2 (for vaping participants only, n=79)			
Range	8: 1 -8	9: 1-10	9: 1-9
Median	4	4	4
T2 future intentions to continue/discontinue vaping (for vaping participants only, n-143)			
No plans to quit vaping	96% (24)	87.7% (100)	86.7% (124)
Plans to quit vaping	4% (1)	15.3% (18)	13.3% (19)

199 *Only included participants identifying as resident in EU who answered the TPD question

200 Table 1: Profile of participant characteristics (n=160)

201

202 Overarching themes relating to participants' perceptions of the TPD regulation were

203 identified (Table 2) and are discussed in turn using illustrative quotes from both survey and

204 interview data. Numbers of participants discussing each individual theme are not provided in

205 line with common qualitative practices (40), as the aim of the analysis was to identify

206 possible perspectives and experiences of the TPD, rather than infer prevalence of experience.

207 Forty-six (28.7%) participants reported no awareness of the TPD or any personal behavioural

208 reactions/ negative impacts. In these instances, participants' opinions about the TPD

209 regulations were elicited. Within the sample, males were four times more likely to report a

210 behavioural reaction or negative impact compared to women ($X^2(2, N=150)=13.04, p<.01,$

211 $OR=3.93$).

212

THEME	EXAMPLE QUOTATION
Perceived Impacts – how consumers perceive the TPD has affected them	
Low awareness and no perceived impact	<i>"It has not affected me." (SurveyNo.48)</i>
Reassurance about e-liquid ingredients – makes vaping feel safer	<i>"I think the TPD has been good at cleaning up the market from foreign imports which could contain poor ingredients." (SurveyNo.42)</i>
Limits consumer choice - makes vaping more expensive, less accessibility to effective products	<i>"Strength restrictions mean many early stage vapers fail because they can't get the nicotine level needed and those who do stay on are using more eliquid than would otherwise be needed. This means more vapour is produced leading to more complaints." (SurveyNo.60)</i>
Inconveniences consumer – makes vaping more complicated through	<i>"Tank Capacity (2ml) - To me this seems pointless and unnecessary." (SurveyNo.22)</i>

increased refilling and bottle purchasing/carrying
Increases plastic waste

“People have to fill up tanks more often, carry extra bottles of juice and the 10ml bottles greatly increased plastic waste.” (SurveyNo.26)

Behavioural Reactions – how consumers perceive they have responded to the changes

Already using compliant products – no reaction

“The e-liquid I’ve been buying has always only come in 10mils so I guess [the TPD] hasn’t really crossed my consciousness at all.” (InterviewNo.18)

Stocking up on non-compliant products pre-TPD - including large quantities of nicotine

“I home mix and stocked up on 72mg before the deadline.” (SurveyNo.101)

Market reactions such as nicotine shots

“10 mil bottles are ridiculous, suppliers get round this by doing nicotine shots. This needs to change fast.” (SurveyNo.25)

Buying from black market/abroad– concerns about safety

“I have actively defied the TPD, importing directly from china.” (SurveyNo.33)

Future Reflections – what consumers believe regulation should focus on

To avoid confusing switchers, removal of nicotine warning labels on vaping products not containing nicotine should be considered

“Nicotine labels = ridiculous, laughable idiocy.” (SurveyNo.69)

To reduce possible health risks, further regulation of e-liquid ingredients/product safety desired

“Perhaps there’s potential for further regulation because obviously there’s a myriad of people selling vaporising products now.” (InterviewNo.1)

213 **Table 2: Summary of themes identified and example quotations relating to participants’ views and**
214 **experiences of the Tobacco Products Directive regulatory changes**
215

216 **Perceived Impacts**

217 Irrespective of whether or not participants were aware of the legislation, most participants
218 supported some form of regulation designed to promote consumer safety:

219
220 *“You do need regulation in things like this, because it is going into somebody’s body. It’s a*
221 *risk with operational, in the fact that it’s got batteries in it, you definitely need regulation.”*
222 *(InterviewNo.31)*

223
224 The most popular change initiated by the TPD was the requirement for ingredients lists on e-
225 liquid bottles. This reassured most participants to some extent, allowing them to know what
226 they were inhaling and to exert choice over which ingredients they were consuming:

227

228 *“You would expect to find the ingredients on food that you buy, wouldn’t you? So why*
229 *shouldn’t they be on the vaping liquids? So yeah, I think they should have them, and I*
230 *suppose as well, that can help you avoid certain things.”(InterviewNo.30)*

231

232 Some participants were using compliant products prior to the TPD implementation and,
233 therefore, did not feel that their purchasing was negatively restricted:

234

235 *“Not worried about strength as I use a fairly low strength anyway.”(SurveyNo.126)*

236

237 Although a small number of participants had noticed a decrease in price due to competition
238 between shops, many participants had noted an increase in price:

239

240 *“The legislation has made it difficult for me to cost-effectively buy consumables for vaping*
241 *(coils, e-liquid). In a large number of cases, hardware has also increased in price.”*

242 *(SurveyNo.102)*

243

244 The restriction on e-liquid strength to 20mg/ml was considered too low by many participants.

245 Although no participants mentioned lapsing themselves as a result of the changes, several

246 commented that it may prevent smokers from converting to vaping as they needed over

247 20mg/ml of nicotine when they initially stopped smoking:

248

249 *“20mg is useless for heavy smokers wanting to switch, I needed 36mg to start 5 years ago,*
250 *so more will fail and go back to smoking”(SurveyNo.41)*

251

252 Some participants commented that products they normally used were no longer sold as they
253 did not comply with the new regulations, resulting in having to buy new parts which, in
254 addition to increasing the cost, was also inconvenient:

255

256 *“It was more annoying, basically I had to buy a new tank because the coils didn’t fit in the*
257 *same tank anymore, or like stuff was discontinued.”(InterviewNo.27)*

258

259 One participant, however, did comment that, although inconvenient, the restrictions on tanks
260 had improved functionality and safety:

261

262 *The pro is that they don’t leak, and that is a real plus and no vaper wants a leaky tank and*
263 *they never bothered before about making sure they were all leak proof, so that’s a good*
264 *thing. (InterviewNo.31)*

265

266 The reduction in tank size to 2ml and refill bottles to 10ml was an unpopular change amongst
267 the participants who reported having to refill the tank more frequently and carry several
268 smaller refill bottles around with them. In addition, they reported that it made the vaping
269 process more difficult as everything is now smaller.

270

271 *“TPD restrictions are well meaning but misguided. It is completely pointless to restrict the*
272 *size of bottles and tanks, in fact it may even add to the problem. If you need to constantly*
273 *keep topping up a small tank, you need to carry bottles of liquid, and restricting bottle size*
274 *does not make people carry less liquid.”(SurveyNo.49)*

275

276 Some participants commented that reduced tank size could discourage smokers to switch due
277 to the added inconvenience:

278

279 *“Convenience is a big factor in helping smokers transition to vaping so I think it's a big*
280 *shame. Specifically: It's a [pain] to keep filling up your tank every few hours.” (SurveyNo.88)*

281

282 In addition to finding the smaller bottles inconvenient, many participants were uncomfortable
283 with the extra plastic waste that was being generated as a result of using far more plastic
284 bottles of e-liquid than before the legislation:

285

286 *“I'm more concerned about the environmental impact of many, many more tiny plastic bottles*
287 *being produced. This is a backward step for the environment.” (SurveyNo.78)*

288

289 **Behavioural Reactions**

290 Many participants did not discuss any behavioural reactions, because they were not aware of
291 the TPD and/or they were using compliant products pre-regulation. Reported reactions
292 included participants who had pre-empted the TPD and began home mixing e-liquid enabling
293 them to create higher nicotine strength liquid and/or keep the price of e-liquid low rather than
294 buying expensive 10ml bottles. They had bought the nicotine base before the legislation came
295 into force:

296

297 *“I stocked up on high strength nicotine solution (72mg/ml) before the TPD came into force -*
298 *I have about 4 years supply left.”(SurveyNo.24)*

299

300 Participants reported benefitting from retailers stocking nicotine shots which could be added
301 to larger bottles of 0mg e-liquids:

302

303 *“The bottle size doesn't stop people purchasing the same amount of e-juice, and of course*
304 *there are ways (legal ways) around the legislation which suppliers provide, such as shake*
305 *and mix type purchasing (purchasing nicotine shots to add to a larger flavour bottle).”*

306 *(SurveyNo.2)*

307

308 Many participants had bought non-compliant products from the black market via countries
309 where the regulations did not apply, with China, USA, and the Isle of Man being the most
310 commonly mentioned countries:

311

312 *“If you order it from outside the UK, they will send out the bigger tank glasses without a*
313 *second thought.”(InterviewNo.36)*

314

315 *“Since I continue to use 24mg/ml, which is prohibited under the TPD, I have no alternative*
316 *but to source products from the black market.”(SurveyNo.136)*

317

318 These participants believed that this was the only way they could purchase higher strength
319 nicotine and larger tanks that contributed to the vaping set up which worked well for them. A
320 couple acknowledged the impact on domestic business and commented that they would have
321 preferred to support local shops if the products were available:

322

323 *“Small businesses in the UK are throttled and for little need.” (SurveyNo.139)*

324

325 Some also had concerns that purchasing in this way put their safety at further risk because
326 they did not trust the quality of black market foreign products:

327

328 *“Making my own liquid is more of a problem. Getting nicotine concentrate isn't as easy,*
329 *sourcing it nowadays means getting what could be dodgy stuff[...] I still have some nicotine*
330 *base in the freezer. When that runs out, I'll have a problem, but I'll just have to use the black*
331 *market and risk getting "bad" ingredients.” (SurveyNo.111)*

332

333

334 **Future Reflections**

335 Many vapers, although pleased with the ingredients' listings/restrictions as outlined above,
336 wanted further regulation on the content of liquids and safety of devices. They felt that this
337 would give them much needed reassurance that the products they were using were as safe as
338 possible:

339

340 *“I think that's a good thing[...] It's alluding to a degree of quality control, you know, the*
341 *actual chemicals that they do put in the liquid, but I think they could have probably gone a bit*
342 *further and you know just made that any chemicals or flavouring, they know are safe or not*
343 *known to be carcinogenic”(InterviewNo.2)*

344

345 Some participants who wanted further regulation for product safety were not aware that e-
346 liquid ingredients had already been regulated as part of the TPD legislation:

347

348 *“I'd be happy to see more regulations. I don't know how much has been done in this area*
349 *already, on the liquids, on the additives and the alcohols and the sort of diacetyl and things*

350 *like this, the extra things that could be harmful in it. I mean I know there is a lot of choice out*
351 *there now [...] I don't know how strict they are in what chemicals go into the product [...]*
352 *And I actually don't know if that is being regulated enough yet.” (InterviewNo.8)*

353

354 In contrast to inclusion of ingredients lists, the vast majority of participants thought that the
355 inclusion of the ‘contains nicotine’ warning label, including hardware and 0mg liquids, was
356 nonsensical and confusing:

357

358 *“Mandatory warning labels on mods or empty atomizers saying they contain nicotine are, in*
359 *my opinion, plain ridiculous and serve no purpose” (SurveyNo.114)*

360

361 *“I think it's misinformation in terms of all the kit have got to have it marked “this product*
362 *contains nicotine” which as we well know a lot of them don't.” (InterviewNo.6)*

363

364 Many participants felt that the warning label may deter people switching from smoking,
365 although no participant reported that the warning label making them think twice about
366 vaping. A couple proposed that warning labels should instead focus on communicating
367 reduced harm messages to smokers on tobacco cigarette packets in an attempt to nudge them
368 into switching to less harmful vaping.

369

370 *“[Tobacco packaging] is all standardized in terms of the colour and you know big health*
371 *warnings on there and pictures of you know people with their throats falling out and stuff!*
372 *[...] I think if they, rather than it all just being you know pictures of, all the horrible things*
373 *they put on there[...] is to actually maybe actually have some information about alternatives*
374 *like vaping, you know, vaping is 95% safer. I think those kind of nudging ways of*

375 *encouraging people, you know as well as the health warnings would be helpful.”*

376 *(InterviewNo.2)*

377

378 **DISCUSSION**

379 To the best of our knowledge, this is the first study of consumers’ views and reported
380 experiences of the EU-TPD. Mixed reported experiences of TPD were illuminated, ranging
381 from no impact or awareness, to illegal purchasing of non-compliant products. Aspects of
382 the TPD that participants agreed with, irrespective of whether or not they were previously
383 aware of the regulations, were greater manufacturing regulations and full ingredients
384 labelling. Participants wanted reassurance about the safety of the products they were using
385 and would welcome further regulations addressing this, mirroring the UK Government’s
386 commitment to fund research into product toxicity (30). A previous UK survey of smokers,
387 ex-smokers, and vapers, showed that awareness for most of the TPD regulations was less
388 than 10% (26). It can be inferred that, like many participants in this study, the vast majority
389 of e-cigarette users are not familiar with the legislation. It is reassuring that this participant
390 group did not knowingly experience any negative impacts. However, these participants
391 perceived vaping products to be currently unregulated and, in some cases, wanted regulations
392 that were already in place. It may be helpful to raise awareness of the TPD among
393 consumers, as smokers may be put off switching if they think products are not subject to any
394 regulation or control.

395

396 It is encouraging that no participants commented that they had relapsed as a direct result of
397 the restrictions, as most had adapted to the changes or were already using compliant products,
398 but some participants had decided to purchase illegal products, such as nicotine strength over
399 20mg/ml. For some participants, the nicotine strength liquid they originally used to quit

400 smoking was no longer available. However, most tobacco quitters using e-cigarettes today
401 may not need to use illegal strengths, because technology has advanced alongside the TPD
402 implementation, meaning that devices are more powerful and effective at delivering nicotine
403 and that lower strength e-liquids can be satisfying (41). It is worth noting though that many
404 new users lack vaping experience and may initially use less sophisticated devices which may
405 require higher strength liquid to be effective or satisfying (42, 43). In addition, using
406 advanced devices with high power alongside lower nicotine results in compensatory puffing
407 causing vapers to use more e-liquid which can increase exposure to potential toxicants and
408 carcinogens (44, 45). The nicotine strength limit, however, has been suggested as a possible
409 reason for the UK having comparatively lower rates of youth vaping compared to North
410 America (46), which, if evidenced, should be carefully considered when reviewing the
411 legislation. Stricter marketing restrictions have also been suggested as a possible reason for
412 comparatively lower rates of youth vaping. Interestingly, advertising was not discussed by
413 any of the participants, indicating established e-cigarette users may not be expressively
414 concerned with that part of the legislation.

415

416 Many participants in this study reported experiencing an increase in the price of vaping
417 products, less product choice, and added inconvenience. Factors in the success of using e-
418 cigarettes to stay stopped from smoking are not limited to e-liquid nicotine strength, but also
419 include having a satisfying functioning vaping set-up which is affordable and convenient
420 (31). Therefore, although not demonstrated in this study of mostly exclusive e-cigarette users,
421 it is possible that the TPD regulations may have had the unintended consequence of making it
422 more difficult for some smokers to quit using an e-cigarette, and warrants further
423 investigation. These potential barriers to switching may be further compounded by TPD
424 warning labels which have been found to deter smokers from using e-cigarettes (47),

425 although similar messages have been shown to have the potential to deter never smokers
426 from trying e-cigarettes (48, 49). Harm reduction messages comparing e-cigarettes to
427 tobacco, such as “Use of this product is much less harmful than smoking” (50), have been
428 explored in relation to *e-cigarette* packaging and advertising (47, 50, 51), but future research
429 could focus on their inclusion on *tobacco* packaging as suggested by participants in this study
430 as a way of nudging smokers to switch to less harmful vaping.

431

432 Paradoxically, the TPD restrictions prompted some vapers to buy much higher concentrates
433 and amounts of nicotine than they would have otherwise, through stocking up on large
434 quantities of nicotine before the TPD came into force or purchasing nicotine shots to add to
435 larger bottles of 0mg/ml liquid. This behaviour, also noted elsewhere (27, 28), contradicts
436 one of the main objectives of the legislation, potentially posing greater safety risks, e.g.
437 accidental poisoning by swallowing. In addition, the TPD restrictions had prompted some
438 participants to buy unregulated illegal products. Black market products may pose risks to
439 consumers (35) and safety was a significant worry for participants who perceived foreign
440 vaping products to be inferior and more hazardous than EU produced products. Although
441 likely to be used by only a minority of e-cigarette users in the UK, these results indicate that
442 there is a black market offering products which are no longer legally available, such as
443 nicotine strengths above 20ml/mg, eliquid bottles larger than 10ml, and prohibited
444 components.

445

446 **Limitations**

447 Although the sample can be considered large for a qualitative study, these findings may not
448 be generalisable to the wider e-cigarette user population, and, therefore, whilst evidencing
449 experiences of the TPD (in line with the study’s aim), they cannot give an indication of how

450 widespread the issues discussed are. Indeed, the sample had disproportionate representation
451 from white males, and the sample consisted mostly of consumers who were exclusive e-
452 cigarette users who reported being impacted by the TPD. In contrast, it is likely that the vast
453 majority of UK e-cigarette users will have not knowingly been affected by the changes.
454 However, it is still important to listen to the views of those consumers that have been affected
455 in order to improve future policy. For example, policy makers are unlikely to want anyone
456 turning to the black market ideally, and ways of limiting this should be considered. In
457 addition, it is also important in reviewing policy to ask consumers what they value in
458 legislation affecting them, irrespective of their awareness of current legislation; fortunately,
459 despite over representation of some groups, the large sample enabled a range of perspectives
460 to be reported, including women who were less likely to report awareness or impacts of the
461 TPD. It would be helpful though to gain more views from minority groups, and those that had
462 relapsed to smoking, to explore the full range of possible views and experiences of the
463 regulations.

464

465 Another limitation was that the vast majority of respondents were from the UK; it is not clear
466 whether the TPD was experienced similarly in other EU countries, although the same themes
467 were identified in data from the small group of participants not residing in the UK. As
468 expected, data generated via verbal interview were generally richer than data generated via
469 the survey, although the same themes were identified through triangulation. It was beyond the
470 scope of the project to obtain the views of smokers, never smokers, and young people,
471 although it would be helpful to explore whether the TPD protects these groups as intended

472

473 **Conclusions**

474 This research indicates that awareness of the TPD was not universal and restrictions do not
475 appear to have influenced participants' smoking relapse behaviour. Consumers valued
476 regulatory changes that supported informed decision making (e.g. ingredients lists) and safety
477 (e.g. regulation of e-liquid contents). They responded negatively to changes that caused
478 inconvenience and plastic waste (e.g. smaller e-liquid refill bottles and tanks/cartridges). This
479 research shows that the TPD legislation has prompted some consumers potentially to put their
480 safety at risk by purchasing noncompliant products from the black market. The cost of these
481 impacts needs to be balanced against the potential benefit of deterring non-smokers and
482 children from vaping, and more research is needed to ascertain to what extent the legislation
483 has achieved this benefit. The implications of our analysis suggest that, from a consumer
484 perspective, future e-cigarette regulation should not further restrict liquid/tank volumes and
485 nicotine concentration, but should focus on ensuring product safety, particularly around
486 ingredients used in e-liquids. Public health bodies, Stop Smoking Services, and healthcare
487 professionals should consider raising awareness of the regulations to smokers to offer
488 reassurance about vaping products and e-liquid ingredients, for example by signposting to
489 educational materials (e.g. 36). Vape retailers also have a responsibility to communicate to
490 customers how aspects of the regulations are designed to protect consumers.

491

492 **CONTRIBUTIONS**

493 EW is the lead researcher for the E-Cigarette Trajectories Study and is the lead author for this
494 article. EW undertook the data collection, led the thematic analysis, and wrote and prepared
495 the manuscript. CA is a medical student assisting with the study. CA contributed significantly
496 to the thematic analysis and writing of the article. SG is Academic Clinical Fellow in Public
497 Health who has been assisting with the quantitative aspects of the study and contributed
498 significantly to the writing of the article. LD and RH are Co-Is for the study. They were

499 involved in conceptualising the study design and funding applications, have assisted in the
500 interpretation of the analysis, and contributed substantially to the drafting of the article for
501 publication. CN is the PI for the study. She led the study design, funding application,
502 undertook data collection and assisted analysis. All authors read and approved the final
503 manuscript.

504

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511

512 **DECLARATION OF CONFLICTING INTERESTS**

513 EW, CA, SG, RH and CN declare that they have no competing interests. LD has provided
514 consultancy for the pharmaceutical industry and acted as an expert witness for an e-cigarette
515 patent infringement case. She has no links with, and has not received any funds from the
516 tobacco industry.

517

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689

690

691 REFERENCES

692 APPENDIX 1: QUESTION PHRASING

693

694 **Survey:**

695

696 Do you live in an EU country (including the UK)?

697 Yes (1)

698 No (2)

699

700

701 *Display This Question:*

702 *If Do you live in an EU country (including the UK)? = Yes*

703

704 The Tobacco Products Directive (TPD) is an EU Directive which restricts liquid bottle sizes to
705 10ml, tank sizes to 2ml, and nicotine strength to 20mg. Liquid has to have its ingredients
706 listed on the label, and vaping products including hardware have to have a warning label on
707 them stating they contain nicotine. How has the legislation affected you?
708 (advantages/disadvantages, change in price, availability or effectiveness, changed you
709 vaping behaviour? E.g. started home mixing, buy on the black market). Please comment in
710 the box below:

711

712

713

714

715

716

717

718 **Interview:**

719

720 'Last time we spoke to you was just before the Tobacco Products Directive legislation came
721 in last May. Are you aware of the legislation?' Give brief description of legislation: 'It
722 restricted the bottle sizes you could buy to 10ml, tank sizes to 2ml, and nicotine strength to
723 20mg. It meant that liquid had to have its ingredients listed on the label and that vaping
724 products, including hardware, had to have a warning label on them stating they contained
725 nicotine.

726 'What are your thoughts on this legislation?' 'Advantages/disadvantages?'

727 'Has this legislation affected you at all?' 'How?' 'Have you noticed a change to the

728 price, availability, or effectiveness of products?' 'Have you changed your purchasing

729 behaviour as a result?' (Prompt for home mixing, online purchasing, black or second

730 hand market, modifying).