

BMJ Open Survey of community pharmacists' perception of electronic cigarettes in London

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ABSTRACT

Objectives: To seek community pharmacists' perception on use, safety and possible effectiveness of e-cigarettes as quit smoking tools, and their future regulation.

Setting: A survey of a sample of 154 community pharmacies across London, UK.

Context: E-cigarettes have exclusively established themselves in the market through consumers-led demand. To date, e-cigarettes still remain unregulated and can be easily purchased in shops, over the internet, but more controversially also in pharmacies in the UK. Pharmacists find themselves with a shortage of information on their safety and efficacy, and may experience an ethical dilemma when consulted by patients/customers.

Key findings: Response rate: 60% (n=92). Independent pharmacies accounted for 90% of the sample. The majority of participants (73%) sell e-cigarettes. A minority of participants (20%) have been presented with adverse effects such as cough and dry mouth. As possible reasons for their use, pharmacists ranked 'aid in stop smoking' as the most important (56%), with 'cheaper alternative' (43%) and 'social/recreational use' (31%) being the least important ones. Safety issues were raised as statements such as 'e-liquid in cartridges may be toxic' were agreed by 52% of respondents. The majority of pharmacists (97%) were supportive of e-cigarettes being regulated, expressing current concerns regarding excipients (42%) and nicotine content (34%). Participants indicated that they would require training in the form of information packs (88%), online tutorials (67%), continuous professional development (CPD) workshops (43%) to cover safety, counselling, dosage instructions, adverse effects and role in the smoking cessation care pathway in the future.

Conclusions: Pharmacists expressed concerns about the safety of e-cigarettes, especially regarding the amounts of excipients and nicotine as these still remain unregulated. Currently, there are no guidelines for pharmacists regarding e-cigarettes. Community pharmacists look forward to regulations so to conduct their duties in a more confident and legislated fashion.

INTRODUCTION

The e-cigarettes market has drastically increased with an estimated 1.3 million users

Strengths and limitations of this study

- This is the first study investigating the community pharmacists' perception on the use, safety and possible effectiveness of e-cigarettes as quit smoking tools, and their future regulation.
- Community pharmacists play an important role in the UK healthcare system as they work at the direct interface with patients and members of the public and due to their accessibility are often the first port of call for smoking cessation. Therefore, their perceptions about e-cigarettes may influence uptake and support.
- Despite having a substantial number of respondents, this study is limited to pharmacies in the Greater London area.
- Follow-up studies seeking community pharmacists' perception on a national scale may be needed to gauge concerns and to better inform regulators.

in the UK only: estimated to be worth £340 million by 2015.¹ E-cigarettes have exclusively established themselves in the market through consumers-led demand. Their tar-free technology enlists their status as being 'safer' than conventional cigarettes, hence their evident peaking popularity. To date, e-cigarettes have ducked the advertising bans imposed on all tobacco products, even though broadcasts have in some occasions been perceived as 'glamorizing smoking and promoting e-cigarettes as a safe new lifestyle choice to young people'.² E-cigarettes may in fact constitute a 'gateway' to smoking for nonusers of tobacco, especially adolescents.³⁻⁵ Coupled with the controversy regarding safety of the additives and flavours, healthcare professionals are still undecided regarding their use.

In 2013, the Medicines and Healthcare products Regulatory Agency (MHRA) announced that e-cigarettes will be regulated by 2016;⁶ this was then followed by the European parliament voting for a dual-supply route: they could be regulated as

either medicinal products (if marketed as quitting aids) or tobacco products.² In the meanwhile, e-cigarettes remain unregulated products that can be easily purchased not only in shops, supermarkets and over the internet, but more controversially also in big chain⁷ and independent community pharmacies. Chief pharmaceutical officers in the UK unanimously expressed concern over pharmacies selling e-cigarettes⁸ warning pharmacy staff not to present e-cigarettes as having any therapeutic benefit until the MHRA licences individual e-cigarettes products. In the meanwhile, pharmacists shall continue advising patients on the benefits of using evidence-based products such as nicotine replacement therapies (NRTs), which have been tested and proved safe. In August 2015, a report commissioned by Public Health England indicated that e-cigarettes are around 95% safer than tobacco smoking as many chemicals present in smoke are absent in the e-cigarettes' vapours.⁹ In November of the same year, the MHRA in the UK licenced British American Tobacco's first-generation e-Voke.

While most of the works currently in the literature focus on the effectiveness of e-cigarettes, little can be found regarding how healthcare professionals perceive the current use, status and effectiveness of these devices. In an effort to assess the extent to which health professionals perceive e-cigarettes as a positive or negative development and needs for guidance, Hiscock *et al*¹⁰ surveyed 587 practitioners in 2011 and 705 in 2013. Despite the majority of respondents increasingly indicated e-cigarettes as a 'good thing', they found no clear evidence they viewed e-cigarettes having an important place in smoking cessation services. Practitioners still expressed concerns in terms of safety or efficacy of e-cigarettes for smoking cessation. Also, this study suggests that patients ask important questions about these products and practitioners felt that the guidance for staff and patients was not satisfactory.¹⁰ It is therefore unclear whether guidance currently provided to healthcare professional is satisfactory. To further feed this uncertainty, a survey¹¹ of members of The British Thoracic Oncology Group showed that only a minority of respondents (21.0%) were confident in providing advice to patients with lung cancer over the use of e-cigarettes, with nurses reporting lower levels of confidence.

In the literature, there is mixed evidence regarding the potential of e-cigarettes to serve as quit smoking aids. Etter *et al*¹² reported that e-cigarettes may contribute to prevention of relapse in former smokers and smoking cessation in current smokers, and they also showed that 81% of those vaping (ie, using e-cigarettes) daily were still vaping after 1 year. The latter datum indicates that people may end up replacing tobacco with e-cigarettes, with still unclear, potential long-term exposure consequences.¹³ Siegel *et al*¹⁴ analysed abstinence rates via an online-based survey and reported that 48.8% of e-cigarette users achieved abstinence for a certain length of time and 34.3% reached complete abstinence at 6 months. More recently, Brown *et al*¹⁵ surveyed 5863

adults who had smoked within the previous 12 months and made at least one quit attempt during that period with either an e-cigarette only (7.9%), over-the-counter NRT (32.8%) or no aid (59.3%). When measuring self-reported abstinence, they observed that the odds of non-smoking in users of e-cigarettes were 1.63 times higher compared with users of NRT and 1.61 times higher compared with those using no aid. These results are remarkable because considering the large sample size of the study, it indicates that e-cigarettes may constitute a viable option for smokers to quit without the support of health professionals. Conversely, Bullen *et al*¹⁶ conducted a randomised controlled trial to evaluate e-cigarettes for smoking cessation against placebo e-cigarettes and patches and found that e-cigarettes were only 'modestly effective' at helping smokers to quit, with similar achievement of abstinence as with nicotine patches. In a 12-month randomised controlled trial on 300 smokers not intending to quit, Caponnetto *et al*¹⁷ documented smoking reduction in 22.3% and 10.3%, and complete abstinence from tobacco smoking in 10.7% and 8.7% of participants at weeks 12 and 52, respectively. Additionally, Ling *et al*¹⁸ followed 949 people who reported their smoking habits through an online survey and 'found that there was no difference in the rate of quitting between smokers who used an e-cigarette and those who did not'.

The current General Pharmaceutical Council's position on the sale of e-cigarettes in registered pharmacies¹⁹ and the Royal Pharmaceutical Society recommend that e-cigarettes should not be sold or advertised by pharmacies.²⁰ There have been reports of pharmacists not adhering to this recommendation.²¹ The current lack of guidance on e-cigarettes for pharmacists and the mixed evidence regarding their efficacy may result in pharmacists having limited confidence in advising patients over the safety and efficacy of e-cigarettes. This work aims at exploring community pharmacists' perception on the use, safety and possible effectiveness of e-cigarettes as quit smoking tools, and their future regulation. We hypothesised that pharmacists have concerns regarding the safety of e-cigarettes and are in favour of future regulations, which will ensure patients' safety.

METHOD

This is a quantitative study involving a survey of community pharmacists in Greater London. Ethics approval was sought and obtained by the Kingston University Ethics Committee.

Participants and recruitment

Pharmacies were selected by convenience sampling to include small independent pharmacies and big chains. The selection of pharmacies was carried out without knowing whether e-cigarettes were sold on the premises. Pharmacists were approached in person or surveyed via mail. A maximum of two attempts were made to contact each pharmacy. Questionnaires delivered to pharmacies

via mail services included a prepaid envelope for returning the questionnaire. When visiting pharmacies in person by a member of the research team, the options of 'wait and collect' and 'collect at later date' were offered to all pharmacists. Only fully completed questionnaires were considered for the study. Consent was obtained by means of an information letter accompanying the questionnaire outlining its aims and content, confidentiality, right to not participate or withdraw, as well as contacts of a minimum of three members of the research team. All respondents agreed to participate by returning a fully complete questionnaire. Only one response was received by each pharmacy.

Questionnaire

Data collection was performed using a paper-based questionnaire, consisting of 26 questions (4 of which on demographics). Question styles including closed, multiple response and open-ended questions were employed. In questions using a Likert scale, participants were asked to score statements on a five points scale, that is, ranging from 'very effective' to 'totally ineffective' or from 'strongly agree' to 'strongly disagree'. The questions contained in this research tool were developed by the authors in collaboration with undergraduate students. The themes were identified following a previous survey conducted by the same team (unpublished) aimed at establishing the aspects of e-cigarettes which members of the public hoped to find out more about. As a consequence, the questionnaire was structured in six sections. Section A aimed at surveying the current use of any smoking cessation programme and NRTs available on premises. Section B questioned respondents on the current experience with e-cigarettes (eg, whether e-cigarettes were sold on premises and adverse effects presented by users). Questions in Sections C and D aimed at gauging the pharmacists' perception of use, safety and effectiveness, and of regulations of e-cigarettes, respectively. Section E was regarding the type and content of potential training on e-cigarettes for pharmacists. Section F contained questions on demographics.

Pilot study

After ethics approval, a pilot study was conducted with five pharmacists for content and face validation. The outcomes of the pilot indicated that the questionnaire was suitable for pharmacy professional, presented a sensible number of questions which could be completed within a reasonable time, and required some minor amendments of questions. The pharmacists involved in the pilot were then excluded from the study to avoid any type of bias.

Data analysis

Analysis of data was performed using Microsoft Excel. Descriptive statistics were used to describe and summarise the data highlighting the basic features of the study. When analysing the responses, in questions regarding

the perception of safety and effectiveness of e-cigarettes which were based on a Likert scale, the options 'strongly agree' and 'agree' as well as 'disagree' and 'strongly disagree' were, respectively, grouped together. Open-ended questions were not analysed as these were not compulsory and only a minority of respondents added comments.

RESULTS

Response rate and demographics

A total of 154 questionnaires were distributed across all areas of London. From these, 92 questionnaires were fully completed and returned. This resulted in an overall 60% response rate. The demographics of the population are summarised in table 1. On analysis of results, no statistically relevant variation in responses was observed when considering demographic data.

E-cigarettes users profile

E-cigarettes were shown to be sold on the premises of 73% (n=67) of community pharmacies responding to the study. The majority of pharmacists identified the most common form was nicotine-containing e-cigarettes (97%, n=65). The most common age group to be identified as purchasing e-cigarettes according to community pharmacists was the '25–40 years old' (90%, n=60), with equal popularity among '18–24' and '41–55 years old' (each 4%, n=3). Adverse effects were presented to only 20% (n=19) of community pharmacists. Of these, 17% (n=16) were 'rarely' presented with side effects and 3% (n=3) of respondents described the frequency as 'sometimes'. Side effects reported to pharmacists included

Table 1 Demographics of population

	Number (n)	Percentage (%)
Job type		
Full time	45	48.9
Part time	5	5.5
Locum	34	36.9
Superintendents	3	3.2
Managers	5	5.5
Location		
North	17	18.5
South	17	18.5
East	40	43.5
West	18	19.5
Years of practice (since registration)		
0–5	27	29.3
6–10	36	39.1
11–15	15	16.3
16–20	5	5.5
>20	9	9.8
Gender		
Male	61	66.3
Female	31	33.7
Total N=92.		

Table 2 Community pharmacists' perception of reasons behind the use of e-cigarettes

	Aid in stop smoking		Use in public places		Prevent relapse		Cheaper alternative		Social/recreational use	
	n	%	n	%	n	%	n	%	n	%
Ranked 1 (most important)	47	55.9	5	6.0	28	33.3	2	2.4	2	2.4
Ranked 2	25	29.8	8	9.5	33	39.3	5	6.0	13	15.5
Ranked 3	10	11.9	24	28.6	9	10.7	16	19.0	25	29.8
Ranked 4	1	1.2	30	35.7	11	13.1	25	29.8	18	21.4
Ranked 5 (least important)	1	1.2	17	20.2	3	3.6	36	42.8	26	30.9
Total	84	100	84	100	84	100	84	100	84	100

cough (n=10), dry mouth (n=7), sore throat (n=3) and headache (n=1).

Respondents were required to rank '1' (the most important) to '5' (the least important) the reasons why users choose e-cigarettes. Some respondents (9%, n=8) could not answer the question, due to lack of awareness of the subject. From the remaining pharmacists (n=84), its use as an 'aid in stop smoking' was ranked as the most important ('1') by 56% (n=47). The use in 'prevent relapsing' was ranked as '2' (39%, n=33), whereas being a 'cheaper alternative' was ranked as '5' (43%, n=36), thus deemed as the least important. Results are summarised in [table 2](#).

Pharmacists' perception of effectiveness and safety

Participants were asked to rate the effectiveness of e-cigarettes as a smoking cessation tool as compared to NRTs and other support. Results are summarised in [table 3](#).

In regard to 'e-cigarettes are safe to inhale', most community pharmacists showed no opinion (52%, n=47). The majority of pharmacists (60%, n=65) disagreed with the statement 'e-cigarettes do not cause any adverse effects'. With regard to 'manufacturing of e-cigarettes is unreliable', half of the participants (51%, n=46) were found to agree. Similarly, the following two statements 'e-cigarette encourages smoking in non-smokers' and 'e-liquid in cartridges may be toxic' found respondents in agreement with 58% (n=52) and 61% (n=55), respectively. For 'the design of e-cigarettes encourage smokers to

give up smoking', a significant majority (81%, n=73) agreed with it. Responses are summarised in [figure 1](#).

Pharmacists' perception of regulations

Overall, 97% (n=89) of respondents were in support of future regulations of e-cigarettes. For the 97% who were supportive, further potential benefits were rated. The main benefits (rated '5, extremely beneficial') were 'reassured safety for e-cigarette users' and 'regulated as an established NRT for smoking cessation', with 72% (n=64) and 55% (n=49), respectively. With regard to 'preventing the misuse of illegal substances' and 'increased profit for retail pharmacy', responses were more normally distributed as summarised in [figure 2](#).

All community pharmacists were required to choose one aspect of e-cigarettes which they perceive should be more tightly regulated. Excipients were selected by 42% (n=37) of participants, nicotine concentration by 34% (n=30), followed by eligibility and accessibility at 10% (n=9) and 9% (n=8), respectively. Also, results from the survey show that 63% (n=58) of pharmacists think that the main disadvantages arising from the new regulation will be the generation of a 'black market'.

Training needs

Out of all responses, 83% (n=76) of community pharmacists stated that they were ready to stock and supply e-cigarettes in their pharmacy, under new regulations. To evaluate the perception of required training to meet

Table 3 Perception of the effectiveness of e-cigarettes in smoking cessation

	Classic NRTs (eg patch)		Newer NRTs (eg Quickmist)		E-cigarettes		GP and pharmacist counselling		Family and support group	
	n	%	n	%	n	%	n	%	n	%
Very effective	34	36.9	42	45.6	18	19.6	41	44.6	30	32.6
Effective	45	48.9	41	44.6	39	42.4	31	33.7	26	28.3
Slightly effective	12	13.1	8	8.7	22	23.9	18	19.5	24	26.1
Somewhat ineffective	1	1.1	1	1.1	8	8.7	2	2.2	11	11.9
Totally ineffective	–	–	–	–	2	2.2	–	–	1	1.1
Unsure	–	–	–	–	3	3.2	–	–	–	–
Total	92	100	92	100	92	100	92	100	92	100

GP, general practitioner; NRT, nicotine replacement therapy.

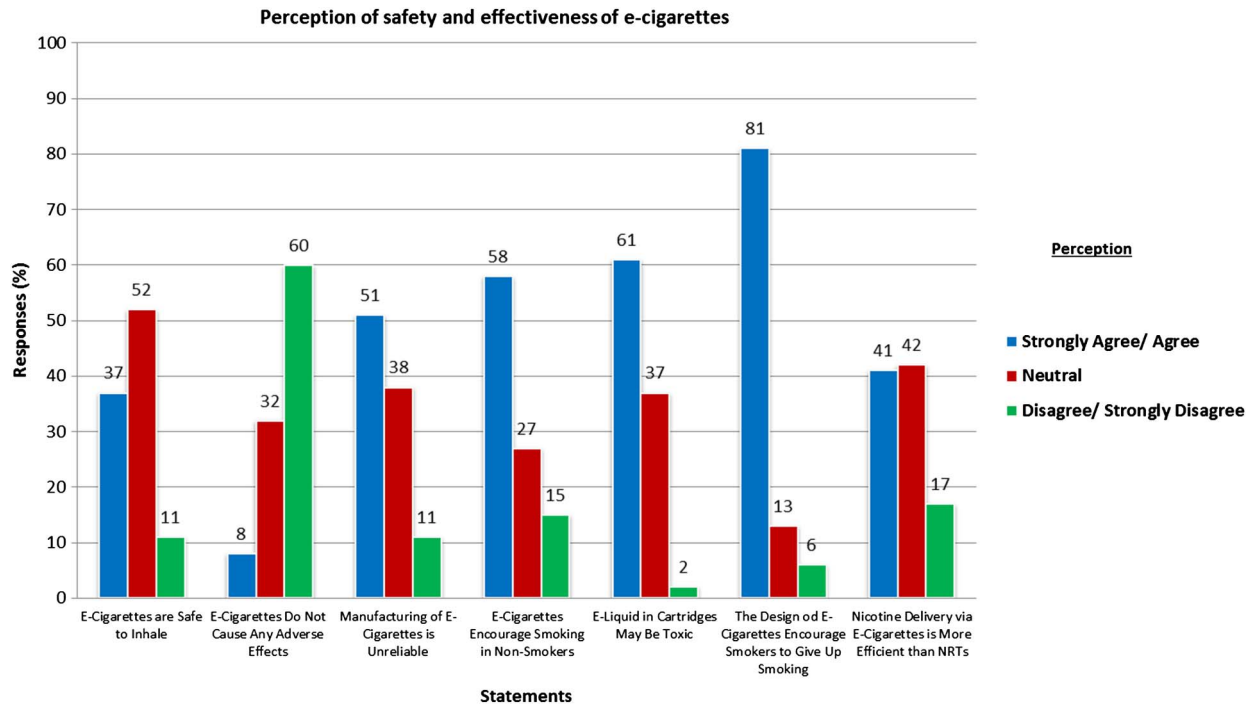


Figure 1 Perception of the safety and effectiveness of e-cigarettes.

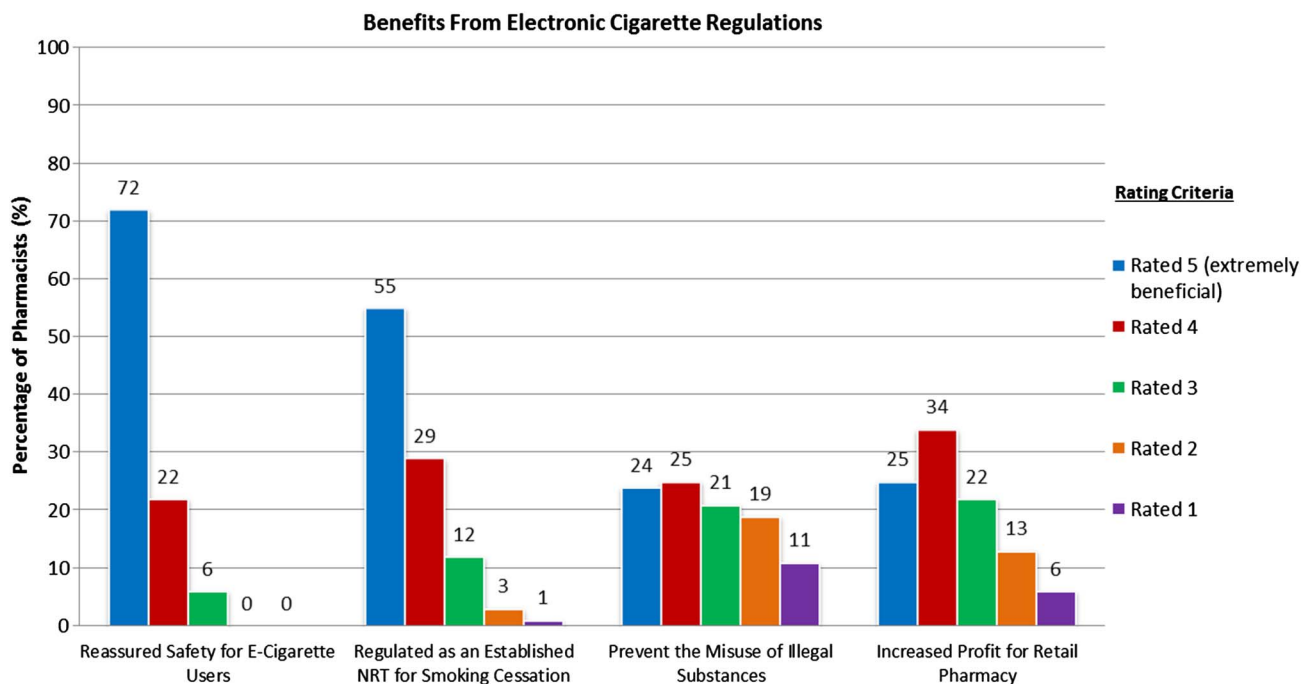


Figure 2 Perception of potential benefits stemming from e-cigarettes regulations.

potential future MHRA regulations on e-cigarettes, all participants were asked to indicate the likely form and content of training packages. Considering that each participant could tick as many options as appropriate, information packs were the most popular (88%, n=67), followed by online tutorials at 67% (n=51), and professional developments workshops and video tutorials at 43% (n=33) and 33% (n=25), respectively. Participants

were also asked to score (1 to 10, with 10 being the most important) the likely content of training packages. A median grading analysis showed that safety was scored in all cases as the most important (10 out of 10). Counselling information, dosage instructions and dealing with adverse effects had an average of 9 out of 10, whereas implementation into cessation programmes scored 8 out of 10.

DISCUSSION

Three-quarters of participants indicated e-cigarettes to be sold on their premises. This demonstrates that many pharmacies do not adhere with the current General Pharmaceutical Council's and the Royal Pharmaceutical Society's recommendations for pharmacies not to sell and advertise e-cigarettes.^{19 20} The majority of respondents are from small independent pharmacies, which may have been driven to the decision of selling e-cigarettes following major pharmacy chains doing so in the UK.⁷ The most popular form of e-cigarettes is the nicotine-containing one (97%, n=65). This popularity is most probably due to the need to relieve craving and consistent with the outcomes of the trial conducted by Dawkins *et al.*²² which consisted of 86 smokers being randomised to nicotine-containing (18 mg) e-cigarettes, placebo or device given to hold. The outcomes indicated that after 20 min, the use of nicotine-containing e-cigarettes was superior in terms of relieving cravings.

The possibility of adverse effects was highlighted as one of the primary reasons for enforcing e-cigarette regulations for the safety of users. However, respondents reported to be not commonly presented with adverse effects as the vast majority of them chose 'never' when asked about user's reports. Etter *et al.*²³ reported 21% of e-cigarette users who stopped using e-cigarettes due to the fear of e-cigarette-induced side effects, whereas Goniewicz *et al.*²⁴ had only 17 (out of 179) users reporting adverse effects. The most common adverse effect reported by community pharmacists was 'cough'. Polosa *et al.*²⁵ classified this frequent adverse effect as being a result towards secondary exposure to humectants used within e-liquid formulations. The excipient propylene glycol has also been established to cause irritations through inhalation. Headache and cough are also reported as very common side effect of the use of e-Voke.

More than half of the pharmacists perceived users turn to e-cigarettes as an 'aid in stop smoking'. This is supported further by 44% (n=39) of respondents who rated e-cigarettes as being 'effective' in promoting smoking cessation. These views seem to be in line with the perception of users who indicated to be using e-cigarettes because they were safer than tobacco and to quit smoking.²³ Correlations can also be based on perceptions of community pharmacists on the 'design of e-cigarettes encouraging smokers to give up smoking', in which 62% (n=56) chose 'agree', hence concluding that the design of e-cigarettes is an effective characteristic in promoting cessation as this targets the stimulus attachment a smoker has.²⁶

With regard to preventing relapse, the majority of respondents (42%, n=38) chose 'neutral' and 27% (n=25) chose 'agree' for the statement 'nicotine delivery via e-cigarettes is more efficient than NRTs'. In addition to this, e-cigarettes were perceived as effective as classic NRTs (ie, patch, gum) and the newer NRTs (ie, Quicqumist, inhalator). In a 6-month study,¹⁶ abstinence

was compared between a nicotine patch and an e-cigarette. The trial concluded with 7.3% attaining abstinence through optimising an e-cigarette and 5.8% attained abstinence through a NRT patch. Thus, this shows the potential of e-cigarettes to attain increased cessation numbers, which can be based on their ability to provide nicotine through the same route as conventional cigarettes. It is also noted that in comparison to pharmacological tools, psychological support from 'general practitioners and pharmacist counselling' is also perceived as 'very effective' according to 45% (n=41).

In relation to 'social/recreational use', 31% (n=26) of respondents ranked this as the least important for usage of e-cigarettes. However, aspects of social and recreational use can be determinant when non-smokers are attracted to the vaping community. Regarding the statement 'e-cigarettes encourages smoking in non-smokers', almost half of respondents chose 'agree'. According to Bell and Keane,²⁷ this promotes a negative opinion regarding e-cigarettes and furthermore fears of uncontrolled use in non-smokers and in young adolescents.

Safety was a key concern expressed notably by community pharmacists within this study. Participants revealed concerns regarding the verified safety of e-cigarettes. In regard to 'e-cigarettes are safe to inhale', the majority either chose 'neutral' or 'strongly agreed/agreed'. This correlates to perceptions relating to 'e-cigarettes do not cause any adverse effects', in which 60% chose 'disagree/strongly disagree' and for 'e-liquid in cartridges may be toxic', where 61% chose 'strongly agreed/agreed'. This is in line with the concerns expressed by smoking cessation practitioners and reported by Hiscock *et al.*¹⁰ The evidentiary confirmation on negative perceptions on safety can also be linked to requests by respondents of stricter regulations being imposed on excipients. In line with respondents' perception of e-cigarettes on safety, half of the community pharmacists chose 'strongly agree/agree' for the statement 'manufacturing of e-cigarettes is unreliable'. Chen²⁸ and Avdalovic and Murin²⁹ have related these types of perspectives to the unregulated procedures of manufacturing, including being below standards of optimal quality, reduced quality control and insufficient evidence to assure safety.

The concern on safety has been prevalent on the support for regulations to be imposed in order to control aspects of e-cigarettes. The support of MHRA regulations to become obligatory was almost a unanimous consent in this study. Expressed opinions by many included 'to fully ensure the content in an e-cigarette do not interact with patient medications', 'if available on NHS then it is more for reaching' and 'gives us as pharmacists the opportunity to engage those purchasing these items, the same we would do with our regular customers'. These perceptions enhance the hopes of community pharmacists to be more proactive in smoking cessation while ensuring patient safety under enforced

regulations. From those in support of regulations, major benefits were significantly rated for 'reassured safety for e-cigarette users' and for e-cigarettes to be 'regulated as an established NRT for smoking cessation'. Conversely, those who were against regulations were primarily due to perceptions on e-cigarettes being a tobacco product, that is, 'e-cigarettes are made by tobacco companies and secondly it does not encourage you to quit at all'. This type of perception can be the direct consequence of the indecisiveness occurring in the EU parliament (and MHRA) on regulations and e-cigarettes as being produced by tobacco companies, hence placing doubts on e-cigarettes being a candidate to meet the criteria of being a 'medicine'.³⁰

Respondents were further asked to choose one aspect of e-cigarettes, which they felt should be more tightly regulated. Excipients were selected by almost half of the respondents, hence hinting the need for regulations to ensure quality assurance and safety by manufacturers. 'Nicotine concentration' was instead selected by 34% (n=30) of the respondents, ensuring that concentrations do not lead to increased dependence or fatal toxicities.

Community pharmacists were also asked if they were ready to stock and supply under future regulations. The vast majority of respondents felt they were ready, hence confirming that community pharmacists are more comfortable to supply under enforced regulations. Despite e-Voke has been licenced as NRT, to date, there has not been an organised statement from the regulators as to the role of e-cigarettes in smoking cessation nor a guidance to the community pharmacists at the forefront of this issue.

CONCLUSIONS

This study was implemented in order to gain an understanding of the community pharmacists' perceptions of e-cigarettes in terms of safety, reason for use, effectiveness and regulations. The concerns outlined include risks of unregulated excipients, faulty manufacturing leading to suboptimal quality, uncontrolled concentrations of nicotine and risks of adverse effects. In contrast, e-cigarettes were distinguished as being an ideal candidate as an effective tool for cessation, distinctively supported by respondents. With the majority wishing to stock and supply e-cigarettes under enforced regulations, it is clear that community pharmacists believe e-cigarettes can play a significant role in affording smoking abstinence and are ready to take new steps into achieving higher quitting rates in smoking cessation. The perceptions of community pharmacists are based prominently on ensuring the upmost care and safety for their patients. For these reasons, it is recommended that regulations, other than on ad hoc basis as it has happened for e-Voke, are introduced in the near future. This study is limited to a relatively small number of pharmacies in the Greater London area; a similar study on national scale is recommendable as its outcomes may

give a more general perception of e-cigarettes by community pharmacists and gather useful information for regulators. With the effects of control in conjunction with implementation of the pharmacist's role in an effective guidance, it is believed by many that e-cigarettes do have a future within the community pharmacy.

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Contributors GC is the principal investigator of the study. He is responsible for the design of the study, and organised and coordinated all aspects of the research including all steps of the manuscript preparation. ACNMG has drafted the publication and co-led the investigation. FB has contributed to the analysis of results. SN-G and RK have actively helped the provision of data collection tool and analysis of results.

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