National Assembly for Wales / Cynulliad Cenedlaethol Cymru
Health and Social Care Committee / Y Pwyllgor Iechyd a Gofal Cymdeithasol
Public Health (Wales) Bill / Bil Iechyd y Cyhoedd (Cymru)
Evidence from the British Lung Foundation - PHB 26 / Tystiolaeth gan Sefydliad Prydeinig yr Ysgyfaint - PHB 26

Consultation on the Public Health (Wales) Bill – response from the British Lung Foundation

About us

The British Lung Foundation campaigns for service improvements for people with lung conditions across all forms of health and social care. We deliver direct support to people living with a lung condition and their carers through our helpline, online forums, health information, and through a network of Breathe Easy groups – whose purpose is to improve the lives of people living with a lung condition by enabling people to better self-manage, reduce isolation, and improve wellbeing.

Chronic lung conditions present a huge challenge for Wales, and one which requires SMART solutions, from prevention and early interventions, to caring for people at the end of their lives. Wales has some of the highest incidence of lung disease in Europe; it affects around one in five people here. Where someone lives, their lifestyle, diet, activity, employment, and education all have a cumulative affect on shaping, for better or worse, overall health and wellbeing. Respiratory disease manifests itself in our most deprived communities and poor lung health is at the epicentre of these economic and social determinants of health.

We are the only UK charity that represents people with any lung condition.

Smoking prevalence in Wales

Based on 2014 Welsh Health Survey data the percentage of the adult (age 16 and over) population in Wales categorised as a smoker is 20%, with this figure greater for males (22%) than females (19%).[1] We are delighted by the reduction in the number of people that smoke in Wales as smoking is the biggest contributor to Chronic Obstructive Pulmonary Disease (COPD). However, weare concerned by the huge variation in the number of people smoking which exists between different local authorities. Smoking prevalence rates are a lot higher in areas such as Blaenau Gwent and Torfaen in comparison with authorities such as Monmouthshire.

Consultation questions

Part 2: Tobacco and Nicotine Products

- Do you agree that the use of e-cigarettes should be banned in enclosed public and work places in Wales, as is currently the case for smoking tobacco?

The British Lung Foundation accept that there is a lot we do not know about e-cigarettes at this time, but the national and international evidence does not

[1] Welsh Government (2015). Welsh Health Survey 2014.

appear strong enough to support a ban at this stage. The below points outline our rationale for taking this position.

A. Efficacy as an aid to smoking cessation/use by current smokers

The harm-reduction potential of e-cigarettes as a lower risk alternative to smoking has been widely reported. E-cigarettes have been described by some as "one of the biggest public health innovations of the last three decades that could potentially save millions of lives".[2] A UK-based survey by ASH suggests that the desire to quit, cut down or avoid smoking is the main reason for ongoing e-cigarette use.

Although it has been suggested that e-cigarettes may also satisfy "hand to mouth" behaviour not sufficiently addressed in most Nicotine Replacement Products (NRPs)[3], research has found varying degrees of efficacy for the use of e-cigarettes as an aid to smoking cessation. For instance, a 2014 cross-sectional survey of nearly 6,000 adults, published in the journal Addiction, found that people attempting to quit smoking without professional help are approximately 60% more likely to report succeeding if they use e-cigarettes than if they use willpower alone or over-the-counter NRPs such as patches or gum.[4]

However, other research has delivered more modest results. For instance, a 2013 randomised control trial of 650 people, published in the Lancet, did not find the same degree of efficacy, reporting e-cigarettes to be "modestly effective at helping smokers to quit". Similarly, a 2014 longitudinal study published in the Journal of the American Medical Association (JAMA) found that "when used by a broad sample of smokers under 'real world' conditions, e-cigarette use did not significantly increase the chances of successfully quitting cigarette smoking".[5] There is no indication that e-cigarettes are nearly as effective as methods such as smoking cessation services in helping people quit.

Reviewing all available data on the efficacy of e-cigarettes as an aid to smoking cessation, the Cochrane collaboration published a review in December 2014, concluding that e-cigarettes were more effective that nicotine replacement patches at helping smokers cut down.[6] It also concluded that there was no evidence that dual use of e-cigarettes and cigarettes made smokers any less likely to quit. However, the review also concluded that the quality of evidence in many

[2] Nicotine Science and Policy website http://nicotinepolicy.net/n-s-p/1753-who-needs-to-see-ecigs-as-part-of-a-solution

[3] 'Electronic cigarettes' - Action on Smoking and Health (ASH) briefing, March 2014: http://ash.org.uk/files/documents/ASH_715.pdf

[4] Brown, J. et al. Real-world effectiveness of e-cigarettes when used to aid smoking cessation: a cross-sectional population study. Addiction DOI: 10.1111/add.12623. http://onlinelibrary.wiley.com/doi/10.1111/add.12623/abstract

[5] Grana R et al. A Longitudinal Analysis of Electronic Cigarette Use and Smoking Cessation *AMA Intern Med.* 2014;174(5):812-813. doi:10.1001/jamainternmed.2014.187. http://archinte.jamanetwork.com/article.aspx?articleid=1846627

[6] McRobbie H et al. Can electronic cigarettes help people stop smoking or reduce the amount they smoke, and are they safe to use for this purpose? The Cochrane Collaboration 2014 http://summaries.cochrane.org/CD010216/TOBACCO_can-electronic-cigarettes-help-people-stop-smoking-or-reduce-the-amount-they-smoke-and-are-they-safe-to-use-for-this-purpose#sthash.nWXsbMQj.dpuf

of the areas was low, and that more studies were recommended (many of which have been started).

It has been suggested that e-cigarettes might even prolong smoking habits. For instance, concerns have been raised that e-cigarettes counter-act the "de-normalisation" impact of the ban on smoking in public places by bringing about a "re-normalisation" smoking-related behaviour.[7] Similarly, it has been suggested the use of e-cigarettes in public places where smoking is banned might allow smokers to maintain their nicotine addiction when they might otherwise be encouraged to cut back on their consumption. Although an evidence review by the Cochrane Collaboraion concluded that these fears are currently unfounded, the review authors did recommend further investigation, due to the weakness of current data. The Cochrane review also concluded that nicotine containing e-cigarettes were more effective as cessation aids that those without nicotine.[8]

B. Variation in smoking cessation efficacy between brands

It has been theorised that data in this area has been adversely affected by the difference between brands, particularly with regard to the efficiency of the device in nicotine delivery.[9] There is some evidence indicating that e-cigarettes are gradually becoming more reliable in this regard.[10] Some research has indicated that e-cigarettes are more effective as smoking cessation aids when used by more experienced smoking cessation users.[11] There is little research comparing different brands or efficiencies of nicotine delivery with their efficacy as a smoking cessation aid.

D. Associated health risks

Nicotine in general is associated with a variety of side effects: other NRPs have been shown to increase the users risk of heart palpitations and chest pains, skin irritation, nausea, and mouth and throat soreness.[12] There is anecdotal evidence that people who were not previously heavy smokers have upped their nicotine in-take considerably since they took up e-cigarettes instead of or in addition to smoking, due to the greater ease and lower health risks of consuming nicotine

[7] 'The Renormalization of Smoking? E-Cigarettes and the Tobacco "Endgame"' - Amy L. Fairchild, Ph.D., M.P.H., Ronald Bayer, Ph.D., and James Colgrove, Ph.D., M.P.H. N Engl J Med 2014; 370:293-295, January 2014

[8] Goniewicz ML. and Zielinska-Danch W. (2012): "Electronic cigarette use among teenagers and young adults in Poland", Pediatrics, 130 e879; doi:10.1542/peds.2011-3448.

[9] Vansickel AR, Cobb CO, Weaver MF, Eissenberg TE. A clinical laboratory model for evaluating the acute effects of electronic 'cigarettes': nicotine delivery profile and cardiovascular and subjective effects. Cancer Epidemiol Biomarkers Prev 2010; 19: 1945–53

[10] Robertson OH, Loosli CG, Puck TT et al. Tests for the chronic toxicity of propylene glycol and triethylene glycol on monkeys and rats by vapour inhalation and oral administration. J Pharmacol Exp Ther 1947; 91: 52–76.

[11] Bullen C, McRobie H, Thornley S, et al. Effect of an electronic cigarette on desire to smoke and withdrawal, user preferences and nicotine delivery: randomized cross-over trial. Tobacco Control 2010; 19: 98–103

[12] Mills E et al. Adverse events associated with nicotine replacement therapy for smoking cessation A systematic review and meta-analysis of 120 studies involving 177,390 individuals. Tobacco Induced Diseases 2010; **8**: 8 http://www.ncbi.nlm.nih.gov/pubmed/20626883

through an e-cigarette. However, this has not been supported by any research findings.

Early research into e-cigarette use has indicated a range of short-term health impacts in addition to those associated predominantly with nicotine. For instance, in one study, e-cigarette use for only five minutes by otherwise healthy smokers was found to temporarily increase airway resistance (blocking the air getting into and out of the lungs) and local oxidative stress (a natural response by the lungs for dealing with unwanted inhaled material, which causes inflammation).[13] There is a possibility that the latter might lead to long term obstructive lung damage – this is an area in need of further research.

A recent study also found that e-cigarette use among young people may 'worsen acute respiratory diseases, including asthma and bronchitis'.[14] There is little other research into the health risks of e-cigarettes for people with lung disease, despite smoking cessation being recognised as one of the most effective treatments for respiratory conditions – this is another area in need of research.

Concerns have been raised over the safety of the e-cigarette vapour. The US Food & Drug Administration (FDA) reported detectable levels of known carcinogens and toxic chemicals including diethylene glycol (a toxic constituent of anti-freeze) and nitrosamines (known cancer-causing tobacco constituents) in two different brands of e-cigarettes.[15] A range of studies found various toxins in e-cigarette vapour.[16,17,18,19] Although research has suggested the quantity of toxins are unlikely to represent a significant health risk[20,21,22], with the combination of ingredients having been found to vary so significantly (even between supposedly identical liquids)[23,24], concerns persist over the safety controls around production of vaporising liquids. It has been argued that greater regulatory oversight, as recommended in section 1, would help ease those concerns.

[13] Vardavas C et al. Short-term pulmonary effects of using an electronic cigarette. Chest 2012; **141**: 1400-06
[14] 'Electronic cigarettes may cause, worsen respiratory diseases, among youth, study finds', RTI International, April 2014
[15] US Food & Drug Administration. Summary of results: laboratory analysis of electronic cigarettes conducted by FDA. www.fda.gov/NewsEvents/PublicHealthFocus/ucm173146.htm
[16] Laugesen M. Safety report on the Ruyan® e-cigarette and cartridge. 2008
[17] Williams M, Villarreal A, Bozhilov K, Lin S, Talbot P. Metal and silicate particles including nanoparticles are present in ECcartomizer fluid and aerosol. PloS one 2013;8(3):e57987.
[18] Goniewicz ML, Knysak J, Gawron M, et al. Levels of selected carcinogens and toxicants in vapour from electronic cigarettes. Tob Control 2013;23(2):133–9.
[19] Kim HJ, Shin HS. Determination of tobacco-specific nitrosamines in replacement liquids of electronic cigarettes by liquid chromatography-tandem mass spectrometry. Journal of Chromatography A 2013;1291:48–55
[20] Siegel M. Metals in ECVapor are Below USP Standards for Metals in Inhalation Medications.
[21] Burstyn I. Peering through the mist: systematic review of what the chemistry of contaminants in electronic cigarettes tells us about health risks. BMC Public Health 2014;14(1):18.
[22] Cahn Z, Siegel M. Electronic cigarettes as a harm reduction strategy for tobacco control: a step forward or a repeat of past mistakes? J Public Health Policy 2011;32(1):16–31.
[23] 'Electronic cigarettes' - Action on Smoking and Health (ASH) briefing, March 2014: http://ash.org.uk/files/documents/ASH_715.pdf
[24] 'Electronic cigarettes' - Action on Smoking and Health (ASH) briefing, March 2014: http://ash.org.uk/files/documents/ASH_715.pdf

There have been several reported incidents of e-cigarettes over-heating and exploding or starting fires. Although occurrences remain very rare compared to the breadth of e-cigarette use, they have been a source of considerable concern within the media. Little research has been conducted into the relative safety of various brands when subjected to real life conditions, and their use simultaneous to use of therapies such as oxygen.

Although early research suggests a potential link with the long-term development of obstructive respiratory diseases[26], there is no indication that the risks are anywhere near those of smoking, and have yet to be conclusively substantiated. Overall, there is little research published into the long-term health impact of e-cigarettes, although research in this area is underway and is expected to be published within the next year. E-cigarette use is not advised during pregnancy.

E. Health impact of second-hand exposure to e-cigarette vapour

Research suggests second-hand exposure to e-cigarette vapour may result in involuntary inhalation of nicotine, but not of toxic tobacco-specific combustion products common in second-hand smoke.[25] Testing on animals suggests any health risks associated with second-hand vapour exposure are unlikely to extend beyond irritation of the throat, if at all.[26] The impact of second-hand nicotine exposure is not fully understood.

Conclusion

The harm reduction potential of cigarettes as an alternative to smoking is widely acknowledged as immense, and there is no evidence that e-cigarette use represents anywhere near the same health risk as smoking. Although evidence varies as to the value of e-cigarettes as an aid to smoking cessation – some studies observing considerable improvements over over-the-counter NRP, some observing no noticeable affect - it has been speculated that this may relate to the huge variation between brands, particularly with regard to nicotine delivery. Although the Cochrane review of evidence concluded that e-cigarettes were more effective than patches as a smoking cessation aid, the authors commented that the quality of the evidence currently available to support this is relatively low. This is therefore an area in need of urgent research.

The main reason to still recommend NRPs over e-cigarettes relates to certainty over the safety profile. In the short term, there is some evidence that e-cigarette use can cause adverse side-effects in some people: continued use of the same brand by these people would not be recommended. Greater testing of various products with regard to their propensity for combustion would also be useful, although the relatively low incidence of e-cigarette explosions makes this less

[25] Czogala J et al. econdhand Exposure to Vapors From Electronic Cigarettes. Nicotine Tob Res (2013) doi: 10.1093/ntr/ntt203 http://ntr.oxfordjournals.org/content/early/2013/12/10/ntr.ntt203.short

[26] Bauld L., Angus K. and de Andrade M. (2014). E-cigarette uptake and marketing: A report commissioned by Public Health England.

urgent. More wide-spread concerns arise from uncertainty over the long-term health impact, and the use of e-cigarettes by people with pre-existing lung conditions (for whom smoking cessation represents one of the most cost-effective interventions). In both these applications, more research is urgently required (only in the former is it currently being widely conducted). The establishment of long-term patient cohorts will facilitate research into these areas, though it may take many years to confirm their results.

Overall, current smokers should be advised that while there is uncertainty over the long-term health implications of e-cigarette use, vaping can help with smoking cessation if they have not enjoyed success with NRPs or smoking cessation services alone. They should also be advised that there is considerable variation between brands, and that if one brand doesn't work for them, another might prove successful. As with NRPs, however, they should be advised that e-cigarettes, of any single brand or combination thereof, should not be considered a long-term substitute for smoking.

Due to the uncertainty over the long-term health risks and the more general inadvisability of nicotine consumption, e-cigarette use is not recommended for non-smokers. For this reason, e-cigarettes are not recommended for children. Further research would be useful into the gateway effect of vaping: although this it is expected that such research would currently confirm the risk to be relatively low, this may change over time as e-cigarette use becomes more widespread.

- What are your views on extending restrictions on smoking and e-cigarettes to some non-enclosed spaces (examples might include hospital grounds and children's playgrounds)?

We are in favour of extending the current restrictions on tobacco smoking to include some non-enclosed spaces, such as hospital grounds, mental health units, playgrounds, school gates and beaches. We consider this to be an important development that will serve to further de-normalise smoking as an activity in communities across Wales as well as protect members of the public from the damage to their health caused by inhaling second-hand smoke. The current smoke-free legislation, introduced in the UK in 2007, bans smoking in virtually all enclosed and substantially enclosed public and work places. These regulations have been shown to be effective in terms of initiating health benefits for smokers/non-smokers and changes in smoking related attitudes and behaviour.[27]

As per our answer above, we do not believe sufficient evidence currently exists to warrant blanket banning the use of e-cigarettes in enclosed public and work places, but we would support the right of organisations to introduce local bans and for these to be enforced. This idea is explored further in the consultation document.

[27] Bauld, L. (2011). The impact of smokefree legislation in England: Evidence review.

- Do you believe the provisions in the Bill will achieve a balance between the potential benefits to smokers wishing to quit with any potential disbenefits related to the use of e-cigarettes?

We feel at present that the provisions in the Bill are weighted too heavily in favour of protecting the public from the potential hazards associated with the use of e-cigarettes, to the detriment of the potential benefits accrued by smokers resulting from the use of e-cigarettes as a smoking cessation tool.

The Bill could have gone further and the explanatory memorandum could have gone further in providing support for smoking cessation services and supporting individuals to quit. It could have set statutory targets for numbers of adults smoking and required Welsh Ministers to invest money in smoking cessation services to deliver this target – this was not present and was a missed opportunity.

- Do you have any views on whether the use of e-cigarettes re-normalises smoking behaviours in smoke-free areas, and whether, given their appearances in replicating cigarettes, inadvertently promote smoking?

We believe that there is too little evidence to make determine whether smoking behaviours are being re-normalised or not at stage. However in terms of changing the habits of individuals we do have some concerns that life style changes could be undermined by e-cigarettes.

If someone is diagnosed with COPD one of the most important things to do is to stop smoking as soon as possible. This is an incredibly difficult thing to do and typically it would come as part of a lifestyle change. Through pulmonary rehabilitation and/or the exercise referral scheme, the importance of breathing techniques and exercise are introduced, and the hope is that an individual will change their lifestyle, get more active and not fall back into smoking. E-cigarettes do not change life style behaviours and in fact one of the perceived benefits to younger smokers if the ability to 'vape' inside or in a workplace. Studies have shown a significant number of e-cigarette users continue to smoke at a reduced level[28], and we are concerned that they leave the former in the life style they were previously in, reducing the chance that they will quit completely.

[28] Chapman S. (2014). E-cigarettes: the best and the worst case scenarios for public health. British Medical Journal http://www.bmj.com/content/349/bmj.g5512

- Do you have any views on whether e-cigarettes are particularly appealing to young people and could lead to a greater uptake of their use among this age group, and which may ultimately lead to smoking tobacco products?

We believe that the existing evidence does not support this position and that it is too soon to tell.

A 2014 US study found that adolescents who used the devices were more likely to smoke tobacco and less likely to abstain from smoking, adding to pre-existing fears that e-cigarettes may provide a route into conventional smoking and nicotine addiction.[29] However, other researchers, assessing the same source data, have commented that the study authors did not give due allowance to experimental use, pointing out that there is no indication that the e-cigarette use came first.

A widely-quoted 2014 study found that between 2010 and 2014, a rise in the rates of e-cigarette use among 15-19 years old Polish students corresponded with an increase in the use of tobacco products.[30] Yet it has been pointed out that the study findings did not methodically trace the same students and (in many) took data from different schools. It was concluded by the study's critics that, as a result, the study as published cannot be considered evidence of a gateway effect (instead merely shows different rates of e-cigarette and tobacco use among different student populations). The study authors are currently analysing the data available to see if more accurate conclusions regarding the gateway effect can be drawn.

UK-based research indicates that general e-cigarette use among children is very low and consists almost entirely of those self-defining as current or former smokers, suggesting no gateway affect.[31] Similar data has arisen from in US jurisdictions and in Europe.[32] More targeted research is being conducted and will shed further light on this issue.

[29] 'Electronic Cigarettes and Conventional Cigarette Use Among US Adolescents: A Cross-sectional Study', UCSF Center for Tobacco Control Research and Education. Lauren M. Dutra, ScD; Stanton A. Glantz, PhD, JAMA Pediatrics (March 2014)
[30] Goniewicz M et al. Rise in Electronic Cigarette Use Among Adolescents in Poland. Journal of Adolescent Health, 2014. DOI: http://dx.doi.org/10.1016/j.jadohealth.2014.07.015
[31] YouGov for ASH Wales. Total sample size was 1,002 adults. Fieldwork was undertaken between 26th February to 12th March 2015. (in press).
[32] CDC. National Youth Tobacco Survey. Atlanta, GA: US Department of Health and Human Services, CDC; 2013.

- Do you have any views on whether restricting the use of e-cigarettes in current smoke-free areas will aid managers of premises to enforce the current non-smoking regime?

We sympathise with the view that it may be different for managers of premises to enforce the existing Smoke-free premises regulations, but do not believe that this constitutes a justification for a Wales-wide ban on using e-cigarettes in public spaces. We support the right of individual organisations to ban e-cigarettes and have set out proposals in the 'Other comments' section of this document to strengthen the rights of these organisations.

- Do you agree with the proposal to establish a national register of retailors of tobacco and nicotine products.

We agree with the proposal for a national retail register of retailors of tobacco and nicotine products. We welcome the measure as an important step towards reducing the number of young people in Wales who become smokers or start using e-cigarettes, and consider it to be both workable and proportionate. Whilst the evidence on the long term effect of e-cigarettes is limited, nicotine is recognised to be a highly addictive substance, and we are concerned that at present seemingly anyone can sell e-cigarettes or other nicotine products. We believe that the introduction of a registration scheme will help to crack down on underage sales and sales of illegal tobacco/nicotine products.

- Do you believe the establishment of a register will help protect under 18s from accessing tobacco and nicotine products?

Yes. The establishment of a national register of retailors of tobacco and nicotine products will hold retailors more accountable for their actions if caught partaking in underage sales and will make it easier for them to be monitored and tracked over time.

- Do you believe a strengthened Restricted Premises Order regime, with a national register, will aid local authorities in enforcing tobacco and nicotine offences?

Yes. This will act as a greater deterrent to any retailors tempted to breach the new requirements. It is important however that following any changes the regime is easy to enforce plus there should be clear guidance for enforcement officers and magistrates on how to implement the changed regime.

- What are your views on creating a new offence for knowingly handing over tobacco and nicotine products to a person under 18, which is the legal age of sale in Wales?

We support the measure and believe that it would serve as a deterrent to prevent tobacco or nicotine products falling into the hands of children.

- Do you believe the proposals relating to tobacco and nicotine products contained in the Bill will contribute to improving public health in Wales?

We believe the proposals to establish a national register of retailors of tobacco and nicotine products, strengthening the Restricted Premises Order regime and prohibiting the handing over of tobacco and/or nicotine products to a person under the age of 18 will each contribute to improving public health in Wales.

However, we are concerned that the proposal to place restrictions on the use of nicotine inhaling devices such as e-cigarettes in enclosed public and work places may serve to damage public health in Wales. There is a clear risk that this regulation will reduce uptake of e-cigarettes among current adult smokers who may otherwise have sought to use the device in an attempt to quit tobacco smoking or harm reduce. The British Lung Foundation therefore recommends that any decision to on the wholescale ban the use of e-cigarettes in enclosed public and work places in Wales should be delayed until additional evidence is forthcoming.

Other comments
As stated throughout this document, the British Lung Foundation supports the Welsh Government's efforts to reduce the number of people smoking and sections of the Bill that increase the number of places where people can smoke. We have been shocked by the rapid increase in the popularity of e-cigarettes and remain unclear on the long term effect that they will have on smoking cessation. However there is not enough evidence to prove that second hand vapour from e-cigarettes are harmful or that they are a gateway product.

We would like to see a greater focus on tobacco control from than e-cigarettes in the Bill and would urge the committee to consider the following proposals.

1. Chapter 1 – removal of nicotine inhaling devices from the substantial ban
We would propose that chapter 1 is amended so that the ban is focussed solely on tobacco products an organisation/company wants to introduce a ban in its premises. This would require the following amendments

Chapter 2 title	No change
Section 2	No change
Section 3	No change
Section 4	Remove 'or using a nicotine inhaling device' in title Remove 4(2)
Section 5	Remove 'or using a nicotine inhaling device' in title Remove 5(1)(b) Remove 'or using a nicotine inhaling device' in 5(4)

Section 10	Remove 'or using a nicotine inhaling device' in 10(4) Delete all from 'in relation to' in 10(5)

2. Voluntary bans on the use of e-cigarettes or nicotine inhaler devices

We do not believe that there is sufficient evidence at this time to ban the use of e-cigarettes in every location where smoking tobacco is banned, but we do support organisations having the power to ban the devices if they feel it is appropriate. This might be a community centre due to the high number of children using it. It could be a nightclub where there is concern that staff can't distinguish e-cigarettes and cigarettes in poor lighting. There are countless reasons why an organisation or company might wish to introduce a voluntary ban.

At present there are companies across Wales already that already operate a ban on e-cigarette use,[33] but this relies on the good will of staff or customers, and is not legally enforceable.

We propose inserting a new section into Chapter 2 that gives organisations the ability to apply to a local authority to register that e-cigarettes are banned in their premise. This new provision would allow sections 6,7,9 and 11 to apply to the organisation or company, allowing them to be supported by local authority enforcement officers if needed. This new section would need to be an enabling power so that Welsh Ministers could introduce guidance setting out how the voluntary registration would operate, but we believe that this is more measured response rather than the complete ban across Wales envisaged by the Welsh Government.

3. Statutory target on smoking prevalence

Another additional measure that we would like the committee to consider is a statutory target on the numbers of adults smoking. The Welsh Government has a target within the Tobacco Control Action Plan to reduce the number of adults smoking to 20% by 2016 and 16% by 2020. The 16% is a bold target for Wales, but at present it is simply a health board and civil service target like many other targets. The British Lung Foundation would like to see the 16% target put on the face of the Bill and for Ministers to be required to report on the smoking prevalence rates annually. Statutory targets are not used very often, but do exist on child poverty and climate change. A statutory target would send a powerful message this target matters allowing money to be released to.

[33] 'Is there a stealth ban on e-cigarettes in Cardiff? Here the public places where you already can't use a e-cigarette' http://www.walesonline.co.uk/news/wales-news/stealth-ban-e-cigarettes-cardiff-here-9444814

4. Physical activity and exercise

Finally we note that there is nothing in the Public Health Bill on physical activity and exercise and we wonder whether this is a missed opportunity. The Bill focusses on the huge public health problem caused by smoking and focusses on public bans, but does not focus on smoking cessation, physical activity or exercise. The British Lung Foundation does see a need to legislate for smoking cessation services (money would hopefully be invested based on the statutory target), but we do see an opportunity to legislate on physical activity and exercise.

We would propose an additional section that amends the Well-being of Future Generations Act 2015 to ensure that local plans NHS, local authority and third sector exercise provision from specialised rehabilitation, to the exercise referral scheme through to mainstream leisure.

We believe that access to condition specific exercise is important in improving the health of an ex-smoker, someone with a chronic condition and the general population. We therefore call on Assembly Members to consider this and other proposed amendments.

Appendix to Public Health Bill submission from the British Lung Foundation

Policy Position Statement
E-cigarettes

The BLF believes that:

- More, targeted research is urgently needed into the long-term safety of e-cigarettes and their efficacy as a smoking cessation aid, if we are to unlock their immense harm-reduction potential as an alternative to the much more harmful practice of smoking
- Ongoing research in a number of areas is required, including their safety for use by people affected by lung disease, the relative safety and efficacy of different brands, the appeal of certain flavours to children, and their potential role in the re-normalisation of tobacco
- E-cigarettes should be recommended as an optional smoking cessation aid for people who have not achieved success through other nicotine replacement therapies and local cessation services
- Until there is greater clarity on their long-term safety, e-cigarettes should not be recommended for non-smokers, especially children
- Guidance is needed for healthcare professionals on offering patients e-cigarette advice
- Current regulations on e-cigarette sale and promotion in the UK strike the right balance between maintaining safety without discouraging product development
- The EU Tobacco Products Directive is an important piece of tobacco control legislation that could also help improve e-cigarette safety and labelling accuracy. However, some e-cigarette clauses (such as the nicotine concentration permitted before an product is regulated as medical) lack a sufficiently robust evidence base, and should be considered for updating
- Only products delivering particularly high concentrations of nicotine, or those marketed as medical devices, should be regulated as such
- E-cigarettes should not be banned in enclosed public spaces as smoking is, although bars, restaurants, shops and attractions – particularly those with a high child footfall – should retain their right to ban e-cigarette use on their premises if they see fit

BLF policy position summary

Smoking is the single biggest cause of premature mortality in the UK, killing over 100,000 annually. It is also the single most common cause of respiratory disease in the UK. As such, the harm-reduction potential of e-cigarettes, as an alternative mode of nicotine consumption and smoking cessation aid, is immense.

However, opinion among individuals and organisations with an interest in tobacco control has been divided on e-cigarettes. Many healthcare professionals and tobacco control experts are particularly concerned about tobacco industry involvement in a product that – if successful in the way it is hoped – would result in the collapse of the market for their primary product. That said, while the BLF understands these concerns, we believe that those with an interest in public health should not be deterred from seeking to maximise the potential benefits of e-cigarettes in the fight against tobacco-related illness by the presence of such undesirable parties.

Another reason for the schism of opinion is the lack of conclusive evidence in a number of key areas. The BLF recommends that research into these areas be urgently conducted, in order to unlock any harm reduction potential of e-cigarettes as soon as possible.

Research into the long-term health impact of e-cigarettes should be considered amongst these urgent research needs. Although there is no indication that e-cigarettes pose anywhere near the same risks as smoking, greater certainty over what the health impacts are (if any) would inspire greater confidence in their use among smokers, healthcare professionals and regulators. Long-term user cohorts should be established now to enable this research into the future.

Although there is growing evidence of the efficacy of e-cigarettes as an aid to smoking cessation, the picture here is not yet clear cut, and would also benefit from urgent research. Particular attention should be paid to variation between brands and differing nicotine delivery efficiencies, in both long-term safety and smoking cessation efficacy.
Research is also urgently needed into the health impact of e-cigarette use among people living with respiratory diseases. With up to 60,000 people a year dying of smoking-related respiratory disease, and smoking cessation identified as the most cost-effective intervention for respiratory disease patients, any role e-cigarettes can safely play in minimising smoking rates in respiratory patients will prove invaluable.

Until all of the above research it is carried out, it is advised that e-cigarette use be recommended to smokers with caution. Healthcare professionals should make it clear that while the long-term safety profile is uncertain, e-cigarettes may help with smoking cessation, if an individual has not achieved success through use of other nicotine replacement products (NRPs) and smoking cessation services alone. Additionally, they should be advised that differing brands of e-cigarette may offer differing chances of success, but that as with NRPs, long-term use of e-cigarettes is not advised. Healthcare professionals should be provided with guidelines on how to speak to patients about e-cigarettes, as many have called for.

Given the uncertainties over the long-term health impact of e-cigarette use, the BLF does not recommend their use by non-smokers, particularly children. Current use amongst these groups appears to be low, but this is something that could change as e-cigarette use becomes more commonplace, and should therefore be monitored closely through regular, well-designed surveys. Although there is currently little evidence suggesting any 'gateway' relationship between trying e-cigarettes and smoking uptake among children, this is another area that will need continued, regular monitoring. We also recommend more research in to whether supposedly child-friendly sweet flavours increase the likelihood of children using e-cigarettes.

The BLF welcomes the forthcoming ban on e-cigarette sale to under-18s, and support the 2014 Committee on Advertising Practices restrictions on e-cigarette advertising (particularly that targeted at children or which could be construed as accepting of tobacco use). More research into the effectiveness of advertising regulations is needed, however, given the availability of unregulated content on the internet and through social media.

Although the BLF does not recommend inclusion of e-cigarettes in the ban on smoking in public places, we recommend that their potential role in re-normalising tobacco use be researched. We also support the existing right of individual premises – particularly those with a high child footfall - to prohibit e-cigarette use if they see fit, until more research into long-term safety and renormalisation impact has been conducted.

The BLF generally supports the 2016 EU Tobacco Products Directive as an important piece of tobacco control legislation. If the provisions are more tightly enforced than existing consumer protection regulations, they will help minimise the inclusion of potentially harmful ingredients in e-liquids, and give users greater confidence in the accuracy of labelling relating to ingredients and nicotine content. By making manufacturers and importers responsible for the quality and safety of the product, it will also increase incentives to guard against malfunction, fire hazard and tampering by children. Labelling regulations would help guard against poisoning in children. However, the BLF does have concerns that some of the e-cigarette clauses currently lack an evidence-base. In particular, the clause limiting e-liquid nicotine concentration to 20mg/ml before the product should be regulated as a medicine, seems overly restrictive: a higher limit, that would deliver nicotine at a rate similar to a regular cigarette, should be considered.

On the whole, the BLF believes that regulating e-cigarettes as a medicinal product isn't generally necessary, and could stifle product development and use by smokers in this country. Exceptions to this rule would apply to products that explicitly market themselves as medicinal products, or which contain ingredients or quantities of ingredients that can be considered to have a medicinal (rather than recreational) level impact. However, as e-cigarettes are still an emerging technology, all regulations should be regularly reviewed and updated as new evidence emerges.

In order to remain a fully independent source of information and advice on e-cigarettes, and due to the involvement in the e-cigarette industry of tobacco manufacturers (whose work stands in direct contrast to the desire of the BLF to *reduce* the impact of respiratory disease in the UK), the BLF does not accept any funding from any e-cigarette manufacturers or specialist retailers.

Supporting information

Contents

Section 1: About e-cigarettes

1.1: Definition

E-cigarettes (electronic cigarettes), are hand-held battery-operated products designed to facilitate the absorption of nicotine and replicate smoking behaviour, without the need to inhale harmful combusted tobacco. They are also known as 'e-cigs', 'ENDS' (electronic nicotine delivery systems), or personal vaporisers (PVs).

1.2: Construction and function

An e-cigarette will typically consist of a cartridge or tank/reservoir of nicotine-containing liquid, an 'atomiser' (heating element), a battery, and connecting electronics.[1] They function by heating the nicotine-containing liquid into a vapour, which is then inhaled by the user, delivering the nicotine into the lungs to be absorbed into the blood stream. Some of the vapour is released into the air as a visible gas (not dissimilar to tobacco smoke in appearance) when the user exhales.[2] The process of using an e-cigarette is commonly known as 'vaping' (as distinguishable from 'smoking').

Many devices feature a rechargeable battery, and cartridge that can be replaced or a tank/reservoir that can be refilled once the liquid with has all been vaporised and inhaled. Other devices are designed to be disposed of once the liquid or battery has been used up. Surveys by the charity ASH suggests that reusable devices are around 11 times more commonly used than disposable models.[3]

1.3: Ingredients

The nicotine-containing liquid vaporised by when an e-cigarette is used usually comprises a mixture of propylene glycol, glycerine and water, with flavourings sometimes added[4]. The exact mix of ingredients and the concentration of nicotine within can vary considerably from brand to brand, and even between supposedly identical cartridges.[5,6]

Most brands list the nicotine concentration of their vaporising liquid on the packaging. However, although some research has found this labelling to be broadly accurate, other papers have called the accuracy into question: one study from the US in particular found that nicotine concentration differed from the amounts advertised by more than 20% in one in four products tested.[7] Research has indicated no reliable correlation between the descriptor of a brand and the amount of nicotine it contained.[8]

Further detail on flavour-related additives is covered in section 1.5.

1.4: Appearance

The appearance of e-cigarettes can vary considerably between brands. Many brands of e-cigarette are designed to look like conventional cigarettes, often featuring red LEDs (light emitting diodes) at the end of the device that glow when vapour is inhaled (resembling the glow of burning tobacco at the end of a cigarette when the smoker is inhaling). Some devices resemble cigarettes, but have a blue or other coloured LED light at the end to distinguish them from cigarettes when in use. These e-cigarettes are sometimes referred to as 'cigalikes', and were common amongst older brands of e-cigarette.

'EGos', more common among newer brands and increasingly preferred to cigalikes by consumers[8], are those characterised by refillable tanks and are larger than cigalikes. 'Mods' are larger still versions of eGos, and offer more opportunity for customisation.

EGos and mods frequently only resemble an e-cigarette in its most practical form, but can be customised to resemble pens, make-up containers (such as nail-varnish, lipstick or mascara), or other pocket-size electronic devices such as USB sticks or Dictaphones. Some are brightly coloured, resembling sweets or crayons/colouring pens when displayed next to each other, while others are designed to look unlike any other product of that size.

1.5: Taste

As of January 2014 (the last time a review was conducted) there were over 7,700 flavours of e-cigarette available across over 460 brands[8]. At the time of research, the availability of flavours was increasing by 242 new flavours a month.

Such flavouring vary from those commonly associated with smoking (tobacco, menthol), to fruits, sweets and deserts, drinks and alcohol, spices such as cinnamon, and other food substances. Some flavours are sold as inherent ('normal') or as deliberately indefinable ('mystery'). It has been widely speculated that sweet and fruit flavours, including some relating to specific sweet brands, act as a draw to children. However, insufficient research has been conducted to substantiate or disprove this claim.[9]

Online searches reveal companies producing flavourings that can be added to the e-cigarette liquid to make the vapour taste of cannabis. No major e-cigarette manufacturer themselves have been found to produce such a product. Again, there is little data regarding who such flavours appeal to, and whether they are being used by cannabis smokers as part of quit attempts.

There have been reports of some flavourings leading to lung ill-health. In particular, butterscotch-flavoured refill, manufactured by the VIP brand, contained diacetyl – a flavouring often found in foods (particularly popcorn and dairy-based spreads), but linked to the development of obliterative bronchiolitis when inhaled. Similar concerns have been raised over some coffee-flavoured vapour. Given the range of flavours available, the link between flavouring additives and ill-health is not consistent or widespread.

1.6: Manufacture

E-cigarettes are manufactured throughout the world, with China the biggest producer globally. Concerns have been expressed that differences in manufacturing safety regulations between the EU and other parts of the world may lead to less safe products being manufactured outside of Europe and imported for use. However, there has been no research substantiating this claim.

Some e-cigarette manufacturers have begun making reference to user uncertainty regarding where their e-cigarettes and e-liquids are manufacturers in their marketing. For example, in January 2015, Intellicig issued a press release highlighting that, compared to users of other brands, the majority of consumers of their ECOpure brand knew that their e-liquid was manufactured in the UK, and that the majority of its ingredients were sourced within the EU.[10] The release questioned whether e-cigarette users could be confident of their product's safety if this they did not have such certainty over their device's origins.

All major tobacco manufacturers have e-cigarette divisions, either acquired, developed in-house, or a combination of both. See section 1.8 for further detail on the association with the tobacco industry.

Office staff from one e-cigarette manufacturer (Blu) have held a fundraising event for the BLF, but funds were not accepted due to that company's association with tobacco manufacturer Lorillard.

1.7: Price and sale

In early 2014, the e-cigarette market was valued at £193m a year in the UK. Based on growing rates of use, it was estimated then that it would be worth around £340m by the end of 2015.

The prices of e-cigarettes can vary considerably, from under £5 to in excess of £80. They are sold widely throughout the UK, and are available to order online. Increasingly, this is leading to a tiering of the e-cigarette market according to alleged price and quality: for example, the VIP brand markets its e-liquids as 'premium' grade, while Vype is marketed as 'pharmaceutical-grade'.[11]

There has been little research into whether the health impact of quality of these brands can be genuinely distinguished.

Anecdotal reports suggest that they are not routinely available where smoking tobacco is sold (particular amongst vendors with longer opening hours), but there has been no research conducted to verify this.

Two brands, Puritane and Vype (both made by tobacco companies) are available in pharmacy chains (Boots and Lloyds respectively).[12] Many other brands are available widely, including in supermarkets such as Sainsbury's and Tesco.

Several small, independent specialist e-cigarette vendors have contacted the BLF in order to fundraise or enter into a corporate fundraising arrangement. These advances have been rejected on grounds that the BLF wanted to remain independent in the debate, and on grounds that a variety of products sold by the retailers were made by tobacco manufacturers.

For details on the **marketing** of e-cigarettes, see section 4.3.

1.8: Ownership

All major tobacco manufacturers have e-cigarette divisions, either acquired, developed in-house, or a combination of both. In Britain, British American Tobacco was the first major tobacco group to buy a domestic e-cigarette manufacturer buying CN Creative (makers of Intellicig) in December 2012, merging it with its pre-existing e-cigarette subsidiary, Nicoventures, to launch the new brand Vype.

Amongst other major tobacco companies, Imperial Tobacco owns Fontem Ventures (manufacturers of Puritane), Lorillard owns Blu and the originally-independent Scottish brand Skycig, and Phillip Morris is part of the same company (Altria) that owns MarkTen and Green Smoke.

NJOY are the highest profile e-cigarette brand to maintain no tobacco industry affiliation. The brand has launched major advertising campaigns in the United States commenting on the advantages of e-cigarettes over smoking. Other still-independent e-cigarette manufactures include Ten Motives, and Victory (makers of Vapestick).

1.9: Conclusion and policy recommendations

There is conflicting data regarding whether the list of ingredients most brands display is accurate, particularly with regard to nicotine content. This suggests consumer regulations are not being enforced as tightly as they should be: the BLF recommends that the appropriate government agencies ensure this happens.

In particular, the use of flavourings should be monitored more closely, given the link between some flavouring ingredients and the development of lung disease. Closer monitoring would ensure that ingredients for which an association with lung disease has previously been highlighted, such as diacetyl, are not used.

In addition, the link between supposedly child-friendly flavourings (such as particular sweet varieties) and uptake amongst non-smoking children should be subjected to further research, if only to corroborate the conclusions drawn from research into other areas that there is no correlation between the two.

Although the pricing of various e-cigarette brands has created a tiered market place, there is little evidence looking at whether there is any association between price and safety/quality. This is an area that the BLF recommends be researched so that, as evidence emerges regarding the safety of e-cigarettes and their efficacy as an aid to smoking cessation, price is not a determining factor in the choice of brand by smokers: were higher prices found to be associated with safer or more effective smoking cessation products, this could lead to an exacerbation of tobacco-related health inequalities.

Although all tobacco companies have e-cigarettes subsidiaries, the BLF's evidence-based approach and person/patient-centred focus means that the issue of industry ownership will not impact on the BLF's policy regarding the regulation of e-cigarettes and their role in smoking cessation (discussed in sections 4 and 3 respectively). However, the BLF refute that any involvement of tobacco companies in the manufacture and sale of e-cigarettes should qualify them to be considered public health stakeholders, and as such believe that they should not be consulted and be able to influence policy as such. The BLF will continue to highlight the unethical business practices of the tobacco industry, in line with its tobacco control policy The BLF will also refuse any funding from manufacturers and specialist retailers of e-cigarettes, both tobacco-owner and independent. This is not only to guarantee compliance with the BLF's policy of refusing tobacco industry donations, but to maintain the charity's independence in the ongoing debates around e-cigarette use.

Summary of policy recommendations:

- Regulations on ingredients, particularly flavourings, should be more rigorously enforced
- The link between supposedly child-friendly flavours (sweets, etc) and uptake among non-smoking children should be subjected to further research
- The link between the price of a brand and both its safety and effectiveness as a smoking cessation aid should be subjected to further research
- The presence of the tobacco industry in the e-cigarette market should not impact on the BLF's recommendations on the use of e-cigarettes. However, it should not allow them the opportunity to influence health policy under the guise of being a public health stakeholder
- The BLF will maintain its independence in e-cigarette debates by refusing any money from e-cigarette manufacturers or specialist retailers

Section 2: Awareness and use

2.1: Awareness

Based on ONS population data and a representative survey of over 12,000 adults, the third sector tobacco control lobby group ASH estimate that 95% of smokers and 90% of non-smokers had heard of e-cigarettes, suggesting wide-spread awareness.[12] The correlation between internet searches for e-cigarettes and tobacco control measures, suggests e-cigarette awareness may have been in part driven by tighter tobacco control.[13]

2.2: Extent of use

Based on ONS population data and representative surveys of over 12,000 adults, the charity ASH estimate that there are currently around 2.1 million adult e-cigarette users in Great Britain, of which 700,000 are ex-smokers and 1.3 million are current smokers[13]. This represents a threefold increase in total e-cigarette use since 2011. Research also suggests that fewer than 1% of people who had never smoked had tried an e-cigarette, and continued use in this cohort was negligible (on a par with continuous users of nicotine replacement therapies).[12,14] Continued use amongst people who self-identify as former smokers stands at around 4.7%. Amongst current smokers, rates are 17.6%, suggesting substantial dual use.[12] The prevalence of e-cigarette users in different age groups broadly follows smoking patterns (highest rates among 25-34 year olds, followed closely by 16-24 year olds, and then decreasing use with each age group over 35 years old).[13]

Based on a representative survey of over 2,000 children aged 11-18, ASH have also estimated that around 2% of children within this age bracket have used an e-cigarette within the last month, with around 1% expecting to use an e-cigarette soon. As with adults, ASH estimate that children who smoke are significantly more likely to have tried an e-cigarette and to be a regular user. It should be noted that the method of investigation employed by ASH in this research was to ask children via parent-facilitated online self-reporting, a process with the potential to distort results.

In November 2014, a survey by the Welsh Assembly found a cohort of children in Wales (aged 10-11) were experimenting more with e-cigarettes than smoking (6% vs 4% respectively).[15] This was the

first time such a result had been seen in the UK. Although data was collected that would have allowed for greater analysis of a potental gateway affect, this data was not released. The BLF requested the full dataset to enable this analysis, but this has not yet been provided.

2.3: Reasons for use

UK-based research suggests that the vast majority of current e-cigarette users give smoking-related reasons for the reasons they started using e-cigarettes[12] The main reasons reported in the survey were to help quit, cut down or avoid smoking, although only 40% of users state that they are doing so as part of a current quit attempt.[12,13] E-cigarettes overtook over-the-counter nicotine replacement products (OTC NRPs) as the most popular smoking cessation aid in late 2013.[13] A substantial decline in OTC NRPs, coinciding with the rise of e-cigarettes (and coupled with no change or a minor decline in the use of prescription NRPs) suggests that e-cigarettes are being widely used as a direct alternative to OTC NRPs. The efficacy of e-cigarettes as a smoking cessation aid is looked at in section 3.1.

Amongst those not using e-cigarettes as a smoking cessation aid considered e-cigarettes as a cheaper method of nicotine consumption than smoking, with a few wishing to avoid the impact that their second-hand smoke has on others.[12] The findings published by ASH are the most widely reported estimates, although the nature and methodology of the survey has not been published. Evidence elsewhere has suggested that tighter tobacco control measures may be driving e-cigarette use[16].

2.4: Vaping behaviour

The BLF is aware of anecdotal reports that e-cigarettes use has resulted in a rise in nicotine consumption, although evidence is inconclusive on this.

A number of specialist vaping cafes have been launched across the UK, particularly in London. No data is yet available on whether this has impacted on vaping behaviour, although there are concerns that it might drive increased use.

2.5: Conclusion and recommendations

E-cigarette use is growing rapidly in the UK, mainly former and especially current smokers. The number of people using e-cigarettes who don't smoke is on a par with NRP use by non-smokers. The same applied to use among children. However, although this has been the situation during these early years of e-cigarette use, the situation should continue to be monitored closely and regularly to check that, as e-cigarette use becomes more widespread, it is not widely taken up amongst non-smokers. It is recommended that questions on e-cigarette use be included in the national Survey of Smoking, Drinking and Drug Use among Young People to help verify existing data.

More research is urgently required into the impact dual (with smoking) and single e-cigarette use has on levels of nicotine consumption: a product that escalates an individual's nicotine appetite would not be recommended.

The impact of specialist vaping cafes on vaping behaviour would also be an interesting area of research, although given the relative uncommonness of vaping cafes, this research is not considered urgent.

Summary of policy recommendations:

- Use of e-cigarettes amongst adults and children, especially those who do not smoke, should continue to be monitored closely: policies and regulations may need updating should significant growth in e-cigarette use by children or non-smokers occur
- Questions on e-cigarette use should be included in the Survey of Smoking, Drinking and Drug Use among Young People
- More research is also needed to confirm the impact of e-cigarette use on overall nicotine appetite

Section 3: Health impact

3.1: Efficacy as an aid to smoking cessation/use by current smokers

The harm-reduction potential of e-cigarettes as a lower risk alternative to smoking has been widely reported. E-cigarettes have been described by some as "one of the biggest public health innovations of the last three decades that could potentially save millions of lives".[17] A UK-based survey by ASH suggests that the desire to quit, cut down or avoid smoking is the main reason for ongoing e-cigarette use.

Although it has been suggested that e-cigarettes may also satisfy "hand to mouth" behaviour not sufficiently addressed in most NRPs[18], research has found varying degrees of efficacy for the use of e-cigarettes as an aid to smoking cessation. For instance, a 2014 cross-sectional survey of nearly 6,000 adults, published in the journal Addiction, found that people attempting to quit smoking without professional help are approximately 60% more likely to report succeeding if they use e-cigarettes than if they use willpower alone or over-the-counter NRPs such as patches or gum.[19]

However, other research has delivered more modest results. For instance, a 2013 randomised control trial of 650 people, published in the Lancet, did not find the same degree of efficacy, reporting e-cigarettes to be "modestly effective at helping smokers to quit". Similarly, a 2014 longitudinal study published in the Journal of the American Medical Association (JAMA) found that "when used by a broad sample of smokers under 'real world' conditions, e-cigarette use did not significantly increase the chances of successfully quitting cigarette smoking".[20] There is no indication that e-cigarettes are nearly as effective as methods such as smoking cessation services in helping people quit.

Reviewing all available data on the efficacy of e-cigarettes as an aid to smoking cessation, the Cochrane collaboration published a review in December 2014, concluding that e-cigarettes were more effective that nicotine replacement patches at helping smokers cut down.[21] It also concluded that there was no evidence that dual use of e-cigarettes and cigarettes made smokers any less likely to quit. However, the review also concluded that the quality of evidence in many of the areas was low, and that more studies were recommended (many of which have been started).

It has been suggested that e-cigarettes might even prolong smoking habits. For instance, concerns have been raised that e-cigarettes counter-act the "de-normalisation" impact of the ban on smoking in public places by bringing about a "re-normalisation" smoking-related behaviour.[22] Similarly, it has been suggested the use of e-cigarettes in public places where smoking is banned might allow smokers to maintain their nicotine addiction when they might otherwise be encouraged to cut back on their consumption. Although an evidence review by the Cochrane Collaboraion concluded that these fears are currently unfounded, the review authors did recommend further investigation, due to the weakness of current data.[21]

The cochrane review also concluded that nicotine containing e-cigarettes were more effective as cessation aids that those without nicotine.[21]

3.2. Variation in smoking cessation efficacy between brands

It has been theorised that data in this area has been adversely affected by the difference between brands, particularly with regard to the efficiency of the device in nicotine delivery.[23] There is some evidence indicating that e-cigarettes are gradually becoming more reliable in this regard.[24] Some research has indicated that e-cigarettes are more effective as smoking cessation aids when used by more experienced smoking cessation users.[25] There is little research comparing different brands or efficiencies of nicotine delivery with their efficacy as a smoking cessation aid.

3.2 As potential gateway to smoking

A 2014 US study also found that adolescents who used the devices were more likely to smoke tobacco and less likely to abstain from smoking, adding to pre-existing fears that e-cigarettes may provide a route into conventional smoking and nicotine addiction.[26] However, other researchers,

assessing the same source data, have commented that the study authors did not give due allowance to experimental use, pointing out that there is no indication that the e-cigarette use came first.

A widely-quoted 2014 study found that between 2010 and 2014, a rise in the rates of e-cigarette use among 15-19 years old Polish students corresponded with an increase in the use of tobacco products.[27] It has been pointed out, however, that the study findings reported did not methodically trace the same students and in many took data from different schools. It was concluded by the study's critics that, as a result, the study as published cannot be considered evidence of a gateway effect (instead merely shows different rates of e-cigarette and tobacco use among different student populations). The study authors are currently analysing the data available to see if more accurate conclusions regarding the gateway effect can be drawn.

UK-based research indicates that general e-cigarette use among children is very low and consists almost entirely of those self-defining as current or former smokers, suggesting no gateway affect.[12] Similar data has arisen from in US jurisdictions and in Europe.[28] More targeted research is being conducted and will shed further light on this issue.

3.3: Associated health risks

Nicotine in general is associated with a variety of side effects: other NRPs have been shown to increase the users risk of heart palpitations and chest pains, skin irritation, nausea, and mouth and throat soreness.[29] There is anecdotal evidence that people who were not previously heavy smokers have upped their nicotine in-take considerably since they took up e-cigarettes instead of or in addition to smoking, due to the greater ease and lower health risks of consuming nicotine through an e-cigarette. However, this has not been supported by any research findings.

Early research into e-cigarette use has indicated a range of short-term health impacts in addition to those associated predominantly with nicotine. For instance, in one study, e-cigarette use for only five minutes by otherwise healthy smokers was found to temporarily increase airway resistance (blocking the air getting into and out of the lungs) and local oxidative stress (a natural response by the lungs for dealing with unwanted inhaled material, which causes inflammation).[30] There is a possibility that the latter might lead to long term obstructive lung damage – this is an area in need of further research.

A recent study also found that e-cigarette use among young people may 'worsen acute respiratory diseases, including asthma and bronchitis'.[31] There is little other research into the health risks of e-cigarettes for people with lung disease, despite smoking cessation being recognised as one of the most effective treatments for respiratory conditions – this is another area in need of research.

Concerns have been raised over the safety of the e-cigarette vapour. The US Food & Drug Administration (FDA) reported detectable levels of known carcinogens and toxic chemicals including diethylene glycol (a toxic constituent of anti-freeze) and nitrosamines (known cancer-causing tobacco constituents) in two different brands of e-cigarettes.[32] A range of studies found various toxins in e-cigarette vapour.[33,34,35,36] Although research has suggested the quantity of toxins are unlikely to represent a significant health risk[37,38,39], with the combination of ingredients having been found to vary so significantly (even between supposedly identical liquids)[40,41], concerns persist over the safety controls around production of vaporising liquids. It has been argued that greater regulatory oversight, as recommended in section 1, would help ease those concerns.

There have been several reported incidents of e-cigarettes over-heating and exploding or starting fires. Although occurrences remain very rare compared to the breadth of e-cigarette use, they have been a source of considerable concern within the media. Little research has been conducted into the relative safety of various brands when subjected to real life conditions, and their use simultaneous to use of therapies such as oxygen.

Although early research suggests a potential link with the long-term development of obstructive respiratory diseases[26], there is no indication that the risks are anywhere near those of smoking, and have yet to be conclusively substantiated. Overall, there is little research published into the long-

term health impact of e-cigarettes, although research in this area is underway and is expected to be published within the next year.

E-cigarette use is not advised during pregnancy.

3.4: Health impact of second-hand exposure to e-cigarette vapour

Research suggests second-hand exposure to e-cigarette vapour may result in involuntary inhalation of nicotine, but not of toxic tobacco-specific combustion products common in second-hand smoke.[42] Testing on animals suggests any health risks associated with second-hand vapour exposure are unlikely to extend beyond irritation of the throat, if at all.[19] The impact of second-hand nicotine exposure is not fully understood.

3.5: Conclusion and recommendations

The harm reduction potential of cigarettes as an alternative to smoking is widely acknowledged as immense, and there is no evidence that e-cigarette use represents anywhere near the same health risk as smoking. Although evidence varies as to the value of e-cigarettes as an aid to smoking cessation – some studies observing considerable improvements over over-the-counter NRP, some observing no noticeable affect - it has been speculated that this may relate to the huge variation between brands, particularly with regard to nicotine delivery. Although the Cochrane review of evidence concluded that e-cigarettes were more effective than patches as a smoking cessation aid, the authors commented that the quality of the evidence currently available to support this is relatively low. This is therefore an area in need of urgent research.

The main reason to still recommend NRPs over e-cigarettes relates to certainty over the safety profile. In the short term, there is some evidence that e-cigarette use can cause adverse side-effects in some people: continued use of the same brand by these people would not be recommended. Greater testing of various products with regard to their propensity for combustion would also be useful, although the relatively low incidence of e-cigarette explosions makes this less urgent. More wide-spread concerns arise from uncertainty over the long-term health impact, and the use of e-cigarettes by people with pre-existing lung conditions (for whom smoking cessation represents one of the most cost-effective interventions). In both these applications, more research is urgently required (only in the former is it currently being widely conducted). The establishment of long-term patient cohorts will facilitate research into these areas, though it may take many years to confirm their results.

Overall, current smokers should be advised that while there is uncertainty over the long-term health implications of e-cigarette use, vaping can help with smoking cessation if they have not enjoyed success with NRPs or smoking cessation services alone. They should also be advised that there is considerable variation between brands, and that if one brand doesn't work for them, another might prove successful. As with NRPs, however, they should be advised that e-cigarettes, of any single brand or combination thereof, should not be considered a long-term substitute for smoking. Guidelines should be produce to help healthcare professionals advise patients on the use of e-cigarettes (this may need to be actioned by the Department of Health given restrictions on the products NICE is able to issue guidelines on).

Due to the uncertainty over the long-term health risks and the more general inadvisability of nicotine consumption, e-cigarette use is not recommended for non-smokers. For this reason, e-cigarettes are not recommended for children. Further research would be useful into the gateway effect of vaping: although this it is expected that such research would currently confirm the risk to be relatively low, this may change over time as e-cigarette use becomes more widespread.

Summary of policy recommendations:

- More research is urgently needed into the efficacy of e-cigarettes as an aid to smoking cessation, with particular attention paid to variation between brands and relationship with nicotine delivery efficiency.
- Urgent research is needed (and is being conducted) into the long-term health impact of e-cigarette use, with long-term user cohorts established now

- Urgent research is also needed into the use of e-cigarettes by people with lung disease as a smoking cessation aid
- Smokers should be advised that, although there maybe unidentified long-term health risks, e-cigarettes can be used as a smoking cessation aid if NRPs and smoking cessation services alone have not proven successful. They should be advised that they may find some brands more effective than others.
- Guidelines to help healthcare professionals advise patients on e-cigarette use should be produced, potentially by the Department of Health
- E-cigarette use is not recommended for non-smokers, children or during pregnancy

Section 4: Legal status and regulation

4.1: Legal status, regulation and guidelines within the UK

E-cigarettes are not regulated under smoke-free legislation in the UK. As such, users are free to use them in many public places such as bars and restaurants, although the managers of some premises have prohibited their use.[43]

Legally, e-cigarettes are subject to limited regulation. Manufacturers can choose to license e-cigarettes and other nicotine containing products (NCPs) with the Medicines and Healthcare Products Regulatory Agency (MHRA) as medicines[44], enabling them to make specific health claims if approved. However, to-date, only one brand has licensed as a medicine in the UK.[45] Most e-cigarette brands are instead considered consumer products and thus covered by general product safety legislation.[46] The significant variability in nicotine delivery effectiveness, nicotine content, and e-liquid ingredients - both between and sometimes within product brands – suggests that this legislation is not being enacted as well as is intended.[47]

The Department of Health (DH) has stated that UK regulation of e-cigarettes will be developed in line with European requirements.[48] This will subject e-cigarettes in the UK to the terms of the EU Tobacco Products Directive (TPD), due to come into effect in in mid-2016.

Under the terms of the TPD, e-cigarettes containing more than 20 mg/ml of nicotine will need to be regulated by the MHRA as medical devices. Brands containing less that this quantity of nicotine will come under the terms of the TPD.[49] This has proved controversial, with many researchers suggesting that 20mg/ml threshold (identified as replicating the level of nicotine intake experienced whilst smoking the average cigarette) is too low.[50] The e-cigarette clauses of the TPD are currently being subjected to legal challenge.[51]

Other regulations outlined in the TPD include childproof fastening for e-liquid containers, health warnings on external packaging regarding the nicotine content, full responsibility for manufacturers and importers regarding the quality and safety of the product, prohibition of cross-border advertising, and the ability for EU member states to introduce additional safeguards if desired.[52]

Aside from the e-cigarette clauses, the tobacco control aspects of the TPD have been widely welcomed by tobacco control campaigners and researchers.

NICE has produced guidelines on tobacco harm reduction, which supports the use of licensed nicotine products as an aid to cutting down or quitting smoking.[53] NICE has a policy of not recommending the use of unlicensed nicotine-containing products, which includes the majority of e-cigarette brands.

In 2014, in an amendment to the UK Parliament's Children and Families Bill, a ban on the sale of e-cigarettes to under-18s was approved (initially applying to England only)[54]. The Scottish Government has raised the possibility of introducing an age limit of 18 on purchasing e-cigarettes, following statements by Public Health Minister Michael Matheson MSP (SNP).[55] He has further raised concerns around marketing and the potential use of e-cigarettes as a "trojan horse" by tobacco companies.[56]

During a series of Legislative Content Motions (LCMs) on the Children & Families Bill, Welsh Assembly Members voted to allow provisions of the Bill to apply in Wales. One of these LCMs included banning the sale of e-cigarettes to under-18s. In addition, under proposals outlined in a Public Health White paper (currently out for consultation), a ban on using e-cigarettes in enclosed public spaces has been proposed, effectively placing the devices under smoke-free premises legislation.[57]

It has been widely argued by e-cigarette supporters that the costs involved in tighter regulation, including routine regulation as medicinal products, would stifle e-cigarette development (including of safer and more effective varieties). The relatively gradual development and uptake of NRPs over the last five decades has been given as an example of this. However, even if limited availability and profit margins resultant from greater regulation are likely to act as a disincentive to product improvement, the comparison with the slow development of NRPs does not stand up to scrutiny given this occurred during periods of far lower public awareness regarding the dangers of smoking, meaning demand was always likely to be lower.

Overall, given variation in nicotine delivery systems is a possible factor in the efficacy of e-cigarettes, and the fact that more recent e-cigarette brands are less likely to relate to or resemble cigarettes, e-cigarette development is to be encouraged.

4.2: Legal status abroad

The TPD will apply across the EU. Across the rest of the world, regulation of e-cigarettes varies, with Brazil, Egypt, Australia, New Zealand, Canada and Singapore all banning or regulating the sale, import and marketing of e-cigarettes.[58]

4.3: Use in public places

E-cigarettes are not currently included within the terms of the 2007 smoke-free legislation, although many venues such as bars, restaurants and museums have independently chosen to ban their use. There has been little research into whether there is still significant-enough association between smoking and vaping for e-cigarette use to be considered a risk to the denormalisation of smoking occasioned by the smoking ban. Such research would be useful to determine whether e-cigarette use is advisable in the presence of children. Given that perceptions of e-cigarettes are likely to evolve as their use becomes more widespread, such research will need to be regularly updated.

4.4: Marketing and advertising

In October 2014, the Committee of Advertising Practice (CAP) in the UK advised that e-cigarettes could be advertised on TV and elsewhere in the media, providing they are not targeted at under-18s, do not encourage non-smokers to use e-cigarettes, do not claim e-cigarettes are healthier or safer than smoking tobacco (or make any health claims without MHRA approval), and do not depict tobacco in a positive light. The regulations also restrict marketing targeted at young people through the use of social media and celebrity endorsement.[59] This guidance is due to be reviewed again in October 2015, with particular attention paid to the renormalisation of tobacco.

It has been suggested that domestic regulations on advertising is ineffective in the age of cross-border social media, and that efforts should be sought to achieve international agreement on e-cigarette advertising standards. Some research in this area is currently being undertaken by the University of Stirling, and is due for publication in 2015.

With regard to marketing techniques, research has found that older brands of e-cigarette have traditionally tended to highlight the advantages of their use over conventional cigarettes (these brands are more likely to be 'cigalikes' – brands that resemble the appearance of cigarettes).[8,60] Newer brands tend to emphasise more consumer choice with regards to flavours and product versatility, and less likely to compare themselves to cigarettes in marketing activity.[8] However, the current leading brands have all marketed the relative health benefits if used instead of cigarettes.

Claims made on the use of e-cigarettes as a smoking cessation aid are generally supported by testimonials rather than research evidence; many brands include disclaimers on their efficacy in this regard.

4.5: Labelling and packaging

E-liquids with a nicotine level greater than 5mg per ml must be supplied with appropriate toxic warnings and hazard symbols as required under the Chemical (Hazard Information and Packaging for Supply) Regulations 2009 (CHIP 4).

4.6: Conclusion and recommendations

The BLF recommends the tighter enforcement of consumer protection legislation around e-cigarettes, with regards to nicotine content and other ingredients. This should prove one of several advantages of the EU Tobacco Products Directive (TPD) when it comes into effect in 2016. If it is more tightly enforced than existing consumer protection regulations, it should will help minimise the inclusion of potentially harmful ingredients in e-liquids, and give users greater confidence in the accuracy of labelling relating to ingredients and nicotine content. By making manufacturers and importers responsible for the quality and safety of the product, it will also increase incentives to guard against malfunction, fire hazard and tampering by children. Labelling regulations would help guard against poisoning in children.

That said, the BLF does have concerns that some of the e-cigarette clauses within the TPD currently lack an evidence-base. In particular, the clause limiting e-liquid nicotine concentration to 20mg/ml before the product should be regulated as a medicine, seems overly restrictive: a higher limit, that would deliver nicotine at a rate similar to a regular cigarette, should be considered.

With regards to other regulations, the BLF supports the government's decision to ban the sale of e-cigarettes to under-18s, as part of the Children and Families Bill. The BLF also supports the regulations around advertising recently introduced by the CAP, providing it is rigorously enforced and promises for a review after a year of use are kept. Research should be conducted into whether such advertising restrictions are effective in the age of cross-border social media, particularly among young audiences. This should be used to inform future regulation development and potentially the seeking of international cooperation on advertising regulations.

The smoke-free legislation was introduced with the primary intention of limiting second-hand smoke exposure. With the risks of second-hand vapour exposure relatively minor (see section 3.4), the BLF does not recommend the extension of the smoke-free legislation to incorporate e-cigarettes. However, research is required into any potential renormalisation impact of e-cigarettes on tobacco use, particularly with regard to perceptions among children. The smoke-free legislation may require amending in light of this research. The BLF also supports the right of any individual institution to prohibit e-cigarette use on their premises, and believes that this may even be a wise precaution in child-friendly venues such as museums and school-grounds until such time as research allays any concerns over the renormalisation of tobacco.

Summary of policy recommendations:

- The EU Tobacco Products Directive is an important piece of tobacco control legislation that could also help improve e-cigarette safety and labelling accuracy. However, some of the clauses relating to e-cigarettes (such as the nicotine concentration permitted before an e-cigarette is regulated as a medicinal rather than consumer product) lack a sufficiently robust evidence base, and should be considered for updating
- The BLF also supports the regulation of e-cigarette advertising as outlined by the Committee on Advertising Practice, providing it is rigorously enforced
- Research should be conducted into whether such advertising restrictions are effective among young audiences more likely to come across advertising online and through social media. This should inform future regulations and efforts for international cooperation
- Research should be conducted into the tobacco renormalisation impact (if any) of public – cigarette use, particularly among children

- Although e-cigarettes should not be regulated under the terms of the 2007 smoke-free legislation, the BLF supports the right of individual premises, particularly those with a high child footfall, to prohibit e-cigarette use on their grounds until such time as the research base renders it unnecessary

Section 5: Research

5.1: Current e-cigarette research and the BLF's role within the research sector

Although a number of calls for new research have been made for further e-cigarette research throughout this paper, consultation with leading UK tobacco control experts suggests that much of this research is already planned and receiving appropriate funding.
One notable exception might be the health impacts of e-cigarette use amongst people with lung disease – this should be considered for potential funding as part of the BLF's research strategy, pending more thorough assessment of the current e-cigarette research spectrum.

5.2: Conclusion and recommendations

As detailed throughout this document, there are a number of recommendations for further e-cigarette research, most of which appear to already be receiving funding. It is imperative that this funding continue. More general research into lung disease, by contrast, receives relatively little funding compared to other disease areas, meaning that the BLF is likely to have a great impact on the lung health of the nation by focusing research investment in these areas rather than e-cigarettes. A possible exception may lie where these areas cross: e-cigarette use by individuals with pre-existing lung conditions. The BLF will therefore monitor whether this seemingly underfunded area of research might represent a valuable area for investment.

Summary of policy recommendations:
- The BLF welcomes the level of investment e-cigarette research is currently receiving, and recommends adequate funding for all research areas outlined in this paper
- The BLF will consider the value of research into e-cigarette use by people with lung disease as part of its overall research strategy

Section 6: Overview of policy positions held by selected other organisations

6.1. British Medical Association

The British Medical Association have called for e-cigarettes to be regulated as medicinal products.[61] They also voted in 2014 to call for the inclusion of e-cigarettes in the smoke-free legislation. They have advised doctors to inform patients that e-cigarettes are a lower-risk option than continuing to smoke, whilst also explaining the BMAs view on the lack of certainty over their safety and efficacy.

6.2. World Health Organisation and World Lung Foundation

The World Health Organisation (WHO) has called for stiff regulation of e-cigarettes, including bans on use in enclosed public places, advertising, sale to children.[62] They have also recommended a ban on fruit, candy, and alcoholic drink flavoured varieties This was supported by concerns over the involvement of the tobacco industry in their manufacture and sale, and an in-house review that found a lack of evidence for their efficacy, considerable health risks associated with their use (for both vapers and bystanders), and a potential gateway relationship with smoking.

The WHO's stance has been supported by the World Lung Foundation.[63]

In response to the WHO's statement, and open letter signed by more than 50 researchers and public health specialists (including BLF Honorary Medical Adviser Professor John Britton) was sent to the

organisations Director General, rebuking their recommendations and calling for a full revision.[64] A full critique and proposed revision of the WHO statement was published in the journal Addiction in October 2014.[65]

6.4 European Respiratory Society and European Lung Foundation

The European Respiratory Society (ERS) and European Lung Foundation (ELF) have both called for greater regulation in order ensure greater quality control, greater confidence among smokers, greater certainty over the nicotine content and other ingredients, and to help smokers choose between e-cigarettes and other smoking cessation aids. [66,67] The ERS support their position by stating that "as a Society grounded in scientific principles, ERS believes that the precautionary principle should be applied when scientific evidence is inconclusive and insufficient".

6.5. Royal College of Physicians

The Royal College of Physicians (RCP) have called for the regulation of e-cigarettes as medicines, to ensure effective nicotine delivery, and prevent the promotion of e-cigarettes to children and non-smokers.[68] The RCP also call for close monitoring of e-cigarette use in the UK.

6.6. Royal Pharmaceutical Society

The Royal Pharmaceutical Society (RCP) support the use of e-cigarettes as an option for smokers looking to reduce or quit smoking.[69] The RCP recommend against the regulation of e-cigarettes as medicinal products, and instead call for the implementation of the regulations as outlined in the EU Tobacco Products Directive. They believe that advertising and sales should be restricted in line with tobacco products, and that e-cigarettes should be included in the smoke-free legislation.

6.6. Cancer Research UK

Cancer Research UK (CRUK) call for greater regulaton of e-cigarettes (including restrictions on the ir sale to minors), but not to the extent that development of the market and access of the products by smokers is stifled.[70] CRUK support the EU Tobacco Products Directive as a way of ensuring safer, more effective products.

6.7 Action on Smoking Health

ASH support enhanced regulation to ensure the safety and reliability of electronic cigarettes and to prevent their promotion to non-smokers and children.[71] ASH is against the inclusion of e-cigarettes in the smoke-free legislation, and have welcomed the EU Tobacco Products Directive.

References

[1] 'Electronic Cigarettes (e-Cigarettes)' – US Food and Drug Administration: www.fda.gov/NewsEvents/PublicHealthFocus/ucm172906.htm

[2] 'E-cigarettes in public places and workplaces' - A briefing from the BMA Occupational Medicine Committee and the Board of Science (March 2012)

[3] 'Use of electronic cigarettes in Great Britain' – Action on Smoking and Health Factsheet, April 2014: http://www.ash.org.uk/files/documents/ASH_891.pdf

[4] Grana, R; Benowitz, N; Glantz, SA (13 May 2014). "E-cigarettes: a scientific review." - Circulation 129 (19): 1972–86. http://www.ncbi.nlm.nih.gov/pubmed/24821826

[5] 'Electronic cigarettes' - Action on Smoking and Health (ASH) briefing, March 2014: http://ash.org.uk/files/documents/ASH_715.pdf

[6] 'Electronic cigarettes' - Action on Smoking and Health (ASH) briefing, March 2014: http://ash.org.uk/files/documents/ASH_715.pdf

[7] "Consistency of Labeled Nicotine Content in Electronic Cigarettes: Regulatory Challenges, Roswell Cancer Park Institute, Goniewicz (February 2014)

[8] Shu-Hong Zhu, Sun J, Bonnevie E, Cummins S, Gamst A, Lu Yin. Madeleine LeeFour hundred and sixty brands of e-cigarettes and counting: implications for product regulation. *Tob Control* 2014;**23**:iii3-iii9 doi:10.1136/tobaccocontrol-2014-051670 http://tobaccocontrol.bmj.com/content/23/suppl_3/iii3.full

[9] Durmowicz, E. The impact of electronic cigarettes on the paediatric population. *Tob Control* 2014;**23**:ii41-ii46 doi:10.1136/tobaccocontrol-2013-051468 http://tobaccocontrol.bmj.com/content/23/suppl_2/ii41.full

[10] http://www.intelligig.com/blog (January 2015)

[11] Chittock M (2014). Focus on e-cigarettes: A touch of the vapours. *The Grocer*, February 15th: 51-52, 54

[12] The Pharmaceutical Journal (2014). *Boots and Lloyds Pharmacy join the vaping fold by selling e-cigarettes*. February 13 292:154 http://www.pjonline.com/news/boots_and_lloyds_join_the_vaping_fold_by_selling_ecigarettes

[13] 'Use of electronic cigarettes in Great Britain' – Action on Smoking and Health Factsheet, April 2014: http://www.ash.org.uk/files/documents/ASH_891.pdf

[14] West, R. Electronic cigarettes in England: latest trends. Smoking Toolkit Study. 8 April 2014. http://www.smokinginengland.info/latest-statistics/

[15] Exposure to secondhand smoke in cars and e-cigarette use among 10-11 year old children in Wales. Welsh Government Statistics and Research. http://wales.gov.uk/statistics-and-research/exposure-secondhand-smoke-cars-ecigarette-use-among-children/?lang=en November 2014

[16] Ayers JW, Ribisl KM, Brownstein JS. Tracking the rise in popularity of Electronic Nicotine Delivery Systems (electronic cigarettes) using search query surveillance. Am J Prev Med 2011; 40: 448–53

[17] Nicotine Science and Policy website http://nicotinepolicy.net/n-s-p/1753-who-needs-to-see-ecigs-as-part-of-a-solution

[18] 'Electronic cigarettes' - Action on Smoking and Health (ASH) briefing, March 2014: http://ash.org.uk/files/documents/ASH_715.pdf

[19] Brown, J. et al. Real-world effectiveness of e-cigarettes when used to aid smoking cessation: a cross-sectional population study. Addiction DOI: 10.1111/add.12623. http://onlinelibrary.wiley.com/doi/10.1111/add.12623/abstract

[20] Grana R et al. A Longitudinal Analysis of Electronic Cigarette Use and Smoking Cessation *AMA Intern Med.* 2014;174(5):812-813. doi:10.1001/jamainternmed.2014.187. http://archinte.jamanetwork.com/article.aspx?articleid=1846627

[21] McRobbie H et al. Can electronic cigarettes help people stop smoking or reduce the amount they smoke, and are they safe to use for this purpose? The Cochrane Collaboration 2014 http://summaries.cochrane.org/CD010216/TOBACCO_can-electronic-cigarettes-help-people-stop-smoking-or-reduce-the-amount-they-smoke-and-are-they-safe-to-use-for-this-purpose#sthash.nWXsbMQj.dpuf

[22] 'The Renormalization of Smoking? E-Cigarettes and the Tobacco "Endgame"' - Amy L. Fairchild, Ph.D., M.P.H., Ronald Bayer, Ph.D., and James Colgrove, Ph.D., M.P.H. N Engl J Med 2014; 370:293-295, January 2014

[23] Vansickel AR, Cobb CO, Weaver MF, Eissenberg TE. A clinical laboratory model for evaluating the acute effects of electronic 'cigarettes': nicotine delivery profile and cardiovascular and subjective effects. Cancer Epidemiol Biomarkers Prev 2010; 19: 1945–53

[24] Robertson OH, Loosli CG, Puck TT et al. Tests for the chronic toxicity of propylene glycol and triethylene glycol on monkeys and rats by vapour inhalation and oral administration. J Pharmacol Exp Ther 1947; 91: 52–76.

[25] Bullen C, McRobie H, Thornley S, et al. Effect of an electronic cigarette on desire to smoke and withdrawal, user preferences and nicotine delivery: randomized cross-over trial. Tobacco Control 2010; 19: 98–103

[26] 'Electronic Cigarettes and Conventional Cigarette Use Among US Adolescents: A Cross-sectional Study', UCSF Center for Tobacco Control Research and Education. Lauren M. Dutra, ScD; Stanton A. Glantz, PhD, JAMA Pediatrics (March 2014)
[27] Goniewicz M et al. Rise in Electronic Cigarette Use Among Adolescents in Poland. Journal of Adolescent Health, 2014. DOI: http://dx.doi.org/10.1016/j.jadohealth.2014.07.015

[28] CDC. National Youth Tobacco Survey. Atlanta, GA: US Department of Health and Human Services, CDC; 2013.
[29] Mills E et al. Adverse events associated with nicotine replacement therapy for smoking cessation A systematic review and meta-analysis of 120 studies involving 177,390 individuals. Tobacco Induced Diseases 2010; **8**: 8 http://www.ncbi.nlm.nih.gov/pubmed/20626883
[30] Vardavas C et al. Short-term pulmonary effects of using an electronic cigarette. Chest 2012; **141**: 1400-06
[31] 'Electronic cigarettes may cause, worsen respiratory diseases, among youth, study finds', RTI International, April 2014
[32] US Food & Drug Administration. Summary of results: laboratory analysis of electronic cigarettes conducted by FDA. www.fda.gov/NewsEvents/PublicHealthFocus/ucm173146.htm
[33] Laugesen M. Safety report on the Ruyan® e-cigarette and cartridge. 2008
[34] Williams M, Villarreal A, Bozhilov K, Lin S, Talbot P. Metal and silicate particles including nanoparticles are present in ECcartomizer fluid and aerosol. PloS one 2013;8(3):e57987.
[35] Goniewicz ML, Knysak J, Gawron M, et al. Levels of selected carcinogens and toxicants in vapour from electronic cigarettes. Tob Control 2013;23(2):133–9.
[36] Kim HJ, Shin HS. Determination of tobacco-specific nitrosamines in replacement liquids of electronic cigarettes by liquid chromatography-tandem mass spectrometry. Journal of Chromatography A 2013;1291:48–55
[37] Siegel M. Metals in ECVapor are Below USP Standards for Metals in Inhalation Medications.
[38] Burstyn I. Peering through the mist: systematic review of what the chemistry of contaminants in electronic cigarettes tells us about health risks. BMC Public Health 2014;14(1):18.
[39] Cahn Z, Siegel M. Electronic cigarettes as a harm reduction strategy for tobacco control: a step forward or a repeat of past mistakes? J Public Health Policy 2011;32(1):16–31.
[40] 'Electronic cigarettes' - Action on Smoking and Health (ASH) briefing, March 2014: http://ash.org.uk/files/documents/ASH_715.pdf
[41] 'Electronic cigarettes' - Action on Smoking and Health (ASH) briefing, March 2014: http://ash.org.uk/files/documents/ASH_715.pdf
[42] Czogala J et al. econdhand Exposure to Vapors From Electronic Cigarettes. Nicotine Tob Res (2013) doi: 10.1093/ntr/ntt203 http://ntr.oxfordjournals.org/content/early/2013/12/10/ntr.ntt203.short
[43] 'Electronic Cigarettes' - Houses of Parliament Parliamentary Office of Science and Technology (POST), Number 455 January 2014
[44] 'Licensing Procedure for Electronic Cigarettes and Other Nicotine Containing Products (NCPs) as Medicines' Medicines and Healthcare Products Regulatory Agency, 2013
[45] 'BMA calls for stronger regulation of e-cigarettes', A briefing from the Board of Science and the Occupational Medicine Committee, January 2013
[46] 'E-cigarettes to be regulated as medicines', NHS Choices website, June 2013
[47] 'Electronic cigarettes' - Action on Smoking and Health (ASH) briefing, March 2014: http://ash.org.uk/files/documents/ASH_715.pdf
[48] Health Questions, Electronic Cigarettes, Hansard, Written Answer to Stephen McPartland by The Parliamentary Under-Secretary of State for Health, 12 Feb 2014
[49] 'Electronic cigarettes' - Action on Smoking and Health (ASH) briefing, March 2014: http://ash.org.uk/files/documents/ASH_715.pdf
[50] Etter at al. Scientific Errors in the Tobacco Products Directive. Open letter to the European Union. http://www.ecigarette-research.com/web/index.php/2013-04-07-09-50-07/149-tpd-errors
[51] Totally Wicked website. http://www.totallywicked-eliquid.co.uk/news/2014/august/totally-wicked-formally-challenges.html (last accessed January 2015)
[52] Legal framework governing medicinal products for human use in the EU. European Commission, Accessed May 2014, European Commission
[53] Tobacco – Harm reduction (PH45): Public Health Guidance, National Institute for Health and Care Excellence (NICE), June 2013
[54] Lords Amendments to the Children and Families Bill, February 2014: http://www.publications.parliament.uk/pa/bills/cbill/2013-2014/0171/14171.pdf
[55] 'E-cigarettes: Minister raises concerns about spread of devices', Scottish Government, February 2014: http://news.scotland.gov.uk/News/E-cigarettes-9d4.aspx
[56] E-cigarettes (Availability and Marketing), Portfolio Question Time, Health and Wellbeing, The Scottish Parliament, 12 March 2014
[57] ASH Wales – Electronic cigarettes, Health Issues and Debates: http://www.ashwales.org.uk/electronic-cigarettes/

[58] 'Electronic Cigarettes' - Houses of Parliament Parliamentary Office of Science and Technology (POST), Number 455 January 2014
[59] Committee on Advertising Practice website: http://www.cap.org.uk/Advice-Training-on-the-rules/Advice-Online-Database/Electronic-cigarettes.aspx#.VFu4sctyaM8
[60] 'Electronic cigarettes' - Action on Smoking and Health (ASH) briefing, March 2014: http://ash.org.uk/files/documents/ASH_715.pdf
[61] Briefing from the BMA's Board of Science and Occupational Medicine Committee. November 2014. http://bma.org.uk/working-for-change/improving-and-protecting-health/tobacco/e-cigarettes
[62] World Health Organisation. Electronice Nicotine Delivery Systems: Report by WHO. 2014. http://apps.who.int/gb/fctc/PDF/cop6/FCTC_COP6_10-en.pdf?ua=1
[63] World Lung Foundation website. August 2014. http://www.worldlungfoundation.org/ht/d/ReleaseDetails/i/32757
[64] Abrams D et al. Statement from specialists in nicotine science and public health policy. May 2014. http://nicotinepolicy.net/documents/letters/MargaretChan.pdf
[65] McNeill A et al. A critique of a World Health Organization-commissioned report and associated paper on electronic cigarette. Addiction Volume 109, Issue 12, pages 2128–2134, December 2014. http://onlinelibrary.wiley.com/doi/10.1111/add.12730/abstract
[66] European Lung Foundation website. http://www.europeanlung.org/en/news-and-events/media-centre/press-releases/e-cigarettes-studies-presented-at-the-ers-congress .
[67] European Respiratory Society website. http://ersnet.org/index.php?option=com_user&view=login&return=YToyOntzOjI6ImlkIjtpOjQ0OTQ7czozOiJjaWQiO2k6MDt9
[68] Royal College of Physicians. RCP Statement of E-cigarettes. June 2014. https://www.rcplondon.ac.uk/press-releases/rcp-statement-e-cigarettes
[69] Royal Pharmaceutical Society. Policy statement: e-cigarettes. http://www.rpharms.com/policy-pdfs/e-cigarettes---ps---201402.pdf (last accessed Jan 2015)
[70] Cancer Research UK Briefing: Electronic Cigarettes May 2014. CRUK website. http://www.cancerresearchuk.org/sites/default/files/policy_may2014_e-cigarette_briefing.pdf
[71] ASH Briefing: Electronic cigarettes. ASH website 2014. http://www.ash.org.uk/files/documents/ASH_715.pdf