A rational approach to e-cigarettes: challenging ERS policy on tobacco harm reduction

To the Editor:

The respiratory community is united in its desire to reduce and eliminate the harm caused by tobacco smoking, which is at present on course to kill one billion people in the 21st century. The stated policy of the European Respiratory Society is to strive "constantly to promote strong and evidence-based policies to reduce the burden of tobacco related diseases". In our view, the recent ERS Tobacco Control Committee statement on tobacco harm reduction [1], though well-intentioned, appears to be based on a number of false premises and draws its conclusions from a partial account of available data. It also presents a false dichotomy between the provision of "conventional" tobacco control and harm reduction approaches. We therefore respond, in turn, to the seven arguments presented against the adoption of harm reduction in the Committee's statement.

Argument 1: The tobacco harm reduction strategy is based on incorrect claims that smokers cannot or will not quit smoking. The strategy is in fact based on the need for additional measures to help the estimated 100 million smokers in the European Union who still *have not* quit. Europe has the highest smoking prevalence of all the WHO regions [2] and business as usual has, so far, failed to help these individuals. Smoking rates are significantly associated with economic disadvantage and ongoing failure to address this is a huge driver of health inequality.

Argument 2: The tobacco harm reduction strategy is based on undocumented assumptions that alternative nicotine delivery products are highly effective as a smoking cessation aid. When smokers use a nicotine replacement product to substitute for cigarettes, even in the absence of intention to quit, they are approximately twice as likely to proceed to quit smoking completely [3]. It would be astonishing if nicotine delivered *via* e-cigarettes was uniquely ineffective in helping people to quit smoking. In fact, in a definitive head-to-head randomised controlled clinical trial, e-cigarettes proved to be twice as effective as combination nicotine replacement therapy (NRT) when delivered as part of an evidence-based smoking cessation intervention [4], and in a recently published smaller New Zealand trial, four times more effective than nicotine patches alone [5]. Whether e-cigarettes are "highly effective" is a question of definition, but it is not an "undocumented assertion" to observe that they are certainly at least as effective as medicinal NRT [4, 5].

Argument 3: The tobacco harm reduction strategy is based on incorrect assumptions that smokers will replace conventional cigarettes with alternative nicotine delivery products. Harm reduction strategies do not assume that all smokers will completely switch from tobacco cigarettes to alternative products, any more than does the medicinally licensed strategy of using nicotine replacement therapy to cut down on smoking. The strategy is instead based on an initial expectation, subsequently supported by clear empirical evidence [6, 7], that an appreciable proportion will switch.

Argument 4: The tobacco harm reduction strategy is based on undocumented assumptions that alternative nicotine delivery products are generally harmless. No credible commentator has argued that reduced harm products are harmless. By definition, harm reduction strategies are based on *reducing* rather than *eliminating* harm and the likelihood that there is some risk from their long-term use is explicitly acknowledged in statements on the subject [8–11]. However, the fact that many of the elements found in

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tobacco smoke that are known to cause toxicity are either absent from e-cigarette vapour or present at much lower levels [12] does support a substantial reduction in this risk. Supportive clinical data in smokers who switch to vaping include rapid improvement in vascular endothelial function [13], profound falls in systemic carcinogen levels to ones equivalent to ex-smokers using NRT [14], and improvement in respiratory symptoms [4]. Understandable concerns over safety arising from the 2019 outbreak of vaping-related lung injury in the USA have been alleviated by evidence it was caused by vaping illicit products, in particular tetrahydrocannabinol (THC) cut with vitamin E acetate [15].

Argument 5: Alternative nicotine delivery products can have a negative impact on public health even if "stick-by-stick" they turn out to be less harmful than conventional cigarettes. The argument this statement introduces is that e-cigarettes are driving increasing numbers of young people to become nicotine addicted and to go on to become smokers. In fact, experimentation with e-cigarettes occurs predominantly among young people who have already started smoking or are at increased risk of smoking [16, 17], thus representing a rational choice over the far more hazardous tobacco product. Most importantly, smoking rates among teenagers in the USA and UK are falling [18–22]. The same is true of adult smoking, which is falling in both countries [23, 24], and particularly rapidly in the UK as increasing numbers of adult smokers switch to e-cigarettes [24]. Moreover, parental smoking is one of the main drivers of child smoking uptake [22], so as e-cigarette use enables more adults to quit so fewer children will have smoking parents as role models and more children will be protected from *in utero* and passive smoke exposure.

Argument 6: Smokers see alternative nicotine delivery products as a viable alternative to the use of evidence-based smoking cessation services and smoking cessation pharmacotherapy. Smokers are correct to view e-cigarettes as a viable, evidence-based and proven option to aid smoking cessation [4, 5], and the development of novel approaches for people who have tried conventional pharmacotherapy unsuccessfully should be welcomed. It is also incorrect to regard e-cigarettes as an *alternative* to engaging with smoking cessation services, given the compelling evidence that combining psychological support with nicotine replacement increases quit rates. It is precisely the exclusion of people who are choosing to try to quit smoking using e-cigarettes that is likely to reduce these individuals' chances of success. Most importantly, although the statement argues that smoking cessation services "exist", in practice provision of smoking cessation services is limited [25, 26], more so given political choices to pursue austerity policies which reduce public health funding. Access to such services may therefore be difficult, especially for the most disadvantaged people and those with disorganised lives. Rejection of harm reduction strategies is thus likely to worsen health inequalities.

Argument 7: The tobacco harm reduction strategy is based on incorrect claims that we cannot curb the tobacco epidemic. Harm reduction complements conventional tobacco control strategies, it does not replace them. The UK leads Europe in implementing tobacco control policies, including the exclusion of the tobacco industry from influence on policy making [27] and smoking rates there have declined faster than the rest of Europe as a result [28]. Combined with a rational and regulated approach to e-cigarettes (table 1) the UK is

TABLE 1 Key messages for a rational approach to vaping and e-cigarettes

1. People smoke tobacco because of nicotine addiction, but the major harms come not from the nicotine but from toxic substances in the smoke
2. Pharmacotherapy (*e.g.* dual nicotine replacement therapy or varenicline) combined with psychological support should be made available to all smokers to help them to quit and should be considered as the first line approach
3. E-cigarettes are an effective means to deliver nicotine, with a much lower risk of harm than continuing to smoke
4. People who choose to use e-cigarettes to cut down or quit smoking should be offered psychological support and access to smoking cessation services
5. People who choose to use e-cigarettes should be advised that they need to switch *completely* in order to derive substantial health benefits
6. People using e-cigarettes should be advised to try to quit them in the long term, but not at the risk of relapsing to smoking
7. Never-smokers should avoid e-cigarettes
8. E-cigarettes should continue to be subject to restrictions on age of sale, on advertising and on the strength of e-liquids, as set out in the EU Tobacco Products Directive
9. Respiratory clinicians must continue to campaign for the full implementation of the WHO MPOWER strategy [30] designed to assist implementation of the Framework Convention on Tobacco Control, as this is the most powerful tool to deliver a smokefree generation
   - Monitor tobacco use and prevention policies
   - Protect people from tobacco smoke
   - Offer help to quit tobacco use
   - Warn about the dangers of tobacco use
   - Enforce bans on tobacco advertising, promotion and sponsorship
   - Raise taxes on tobacco

now experiencing rates of decline in smoking prevalence, from 20.2% in 2011 to 14.7% in 2018; this decline is faster than it has been for decades [24], and in England the ambition is to reduce smoking prevalence to below 5% across all groups by 2030. European countries in general, and the ERS in particular, should take heed of this evidence, rather than ignore it.

We believe that blanket opposition to e-cigarettes is misguided and will lead to a number of important consequences that are adverse to health. First, smokers who would otherwise have quit smoking by switching to a lower risk product will continue to smoke, and die prematurely from cancer, cardiovascular and respiratory disease. Second, people who have successfully switched to vaping may relapse to smoking if they come to believe that there is no health benefit from vaping, and thus increase their risk of avoidable morbidity and premature death. Third, the pursuit of arguments that vaping cannot help people to quit smoking, in the face of clear evidence that it does, risks undermining public trust in science.

We wholeheartedly support the call for increased efforts to deliver "what we know works". Electronic cigarette use is an epiphenomenon of smoking and current smoking levels are a consequence of past failures and delays in the implementation of tobacco control measures, including effective and accessible treatment, tax increases, smokefree legislation, advertising bans and public health campaigns [29]. We respectfully suggest that the Society reconsiders its position, so that we can focus on our shared goal to make smoking history.

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From the authors:

We wish to thank J. Britton and co-workers for responding to our editorial and giving us an opportunity to clarify our position as well as correct a few misunderstandings. We definitely share the same goal, which is to relieve Europe and the rest of the world from the terrible results of the tobacco epidemic. We also do not "blankly oppose e-cigarettes"; however, we strongly advocate against a harm reduction strategy including e-cigarettes as well as heated tobacco products [1]. As clinicians we all see reluctant smokers where e-cigarettes can be tried as a last resort for getting off cigarette smoking, but that is of little relevance for a general harm reduction strategy. We also agree that the UK has achieved a lot in the area of smoking cessation but would argue that this has been achieved by impressive tobacco control, not by the use of e-cigarettes, and that a country such as Australia, which has banned nicotine-containing e-cigarettes, has achieved similar results.

J. Britton and co-workers commented on our seven responses to what we consider flawed arguments for e-cigarettes as part of harm reduction in public health. Below is our rebuttal.

Argument 1: The tobacco harm reduction strategy is based on incorrect claims that smokers cannot or will not quit smoking. We entirely agree that more efforts are needed in tobacco control; however, smoking prevalence has been declining for decades in most European countries. Proper access to smoking cessation advice, approved free cessation drugs and nicotine replacement therapy (NRT) should be made available to the majority of smokers who want to quit their nicotine addiction, which will have a major impact on the prevalence of smoking. We may as a community have failed in pointing this out to politicians as investment in tobacco control seems to be fading [2]. Excellence in this area could easily be achieved for a fraction of what is currently being spent on marketing and advertising for e-cigarettes and other

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Regarding the use of alternative nicotine delivery systems, ERS argues that including e-cigarettes in a harm reduction strategy is not evidence-based and may result in harm. Instead, we should support access to evidence-based smoking cessation methods. http://bit.ly/2TpUCYG

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alternative nicotine delivery systems. We too find, that it is a great public challenge that the burden of smoking-related disease is higher among disadvantaged groups. However, evidence of the effect of e-cigarette use to reduce health inequalities is lacking; recent studies show the opposite effect [3].

Argument 2: The tobacco harm reduction strategy is based on undocumented assumptions that alternative nicotine delivery products are highly effective as a smoking cessation aid. None of the alternative nicotine delivery products have been approved as tools for smoking cessation. In the trial mentioned [4] it is correct that quit rates were twice as high in the e-cigarette group than in the standard NRT group. However, most participants in the e-cigarette group continued to use e-cigarettes, thereby exposing their lungs to harmful substances, and many ended up with dual use (using both cigarettes and e-cigarettes). Furthermore, large real-world studies strongly indicate that use of e-cigarettes undermines, not promotes, abstinence from smoking [5, 6].

Argument 3: The tobacco harm reduction strategy is based on incorrect assumptions that smokers will replace conventional cigarettes with alternative nicotine delivery products. We agree with J. Britton and co-workers that harm reduction strategies do not assume that all smokers will completely switch from tobacco cigarettes to alternative products and we have not claimed that. We cannot, however, ignore the fact that most individuals use alternative nicotine delivery products as a supplement to conventional cigarettes (without reducing number of cigarettes substantially), not as an alternative to smoking [7]. Therefore, there will be no health benefit for most smokers.

Argument 4: The tobacco harm reduction strategy is based on undocumented assumptions that alternative nicotine delivery products are generally harmless. In the UK, the National Health Service website on smoking cessation states that e-cigarettes are at least 95% less harmful than cigarettes [8]; this is in our perception in concordance with "generally harmless", as we wrote. Vaping introduces inhalation of compounds that have not been properly tested and risk therefore not assessed. Many studies have shown that the respiratory response to vaping is far more pronounced than "5% of that of cigarettes", in some cases fairly similar [9–11]. Thus, the whole basis for this commonly cited statistic is dubious [12]. We admit that the long-term clinical consequences are unclear, and the uncertainty itself makes these products unsuitable for widespread use.

Regarding the US outbreak of e-cigarette, or vaping, product use-associated lung injury (EVALI), the Center for Disease Control states that "However, evidence is not sufficient to rule out the contribution of other chemicals of concern, including chemicals in either THC or non-THC products, in some of the reported EVALI cases" [13]. In European cases reported, neither tetrahydrocannabinol (THC) nor vitamin E seems to have played a major role.

Argument 5: Alternative nicotine delivery products can have a negative impact on public health even if "stick-by-stick" they turn out to be less harmful than conventional cigarettes. We are of course happy if e-cigarette use in teenagers in the UK predominantly occurs in those who already smoke although we note that the number of vaping teenagers has tripled in the past 5 years [14] and that a school-based study from UK found that more than half of e-cigarette users had never used tobacco [15]. Among US e-cigarette users aged 18–24 years in 2015, 40.0% had never been regular cigarette smokers [14]. Use of conventional cigarettes has decreased from 9% in 2014 to 6% in 2019 in US high school students, while use of e-cigarettes has risen from 13% to 27.5% in the same period [16]. It is therefore difficult to follow the argument that e-cigarettes divert youth from cigarettes.

Widespread use of vaping in the public space may also "normalise" inhaling of a nicotine product, a sight that was getting increasingly rare in the UK and elsewhere. We can only guess what that means for future health behaviour but we already know that young adult smokers get the same urge to smoke when they see someone vape as when they see someone smoke and this could therefore have a negative impact on smoking cessation rates [17].

Argument 6: Smokers see alternative nicotine delivery products as a viable alternative to the use of evidence-based smoking cessation services and smoking cessation pharmacotherapy. We mislead smokers if we pretend that the evidence base and safety of e-cigarettes is comparable to that of approved tools such as NRT and varenicline. We agree with J. Britton and co-workers that access to combined NRT/varenicline and psychosocial support is insufficient. Where we disagree is that we find it irresponsible to offer e-cigarettes as a tool, as this will only reinforce the perception that the more costly, but highly efficient, cessation methods are unobtainable. Maintaining nicotine addiction through the use of e-cigarettes will likely not reduce social health inequality.

Argument 7: The tobacco harm reduction strategy is based on incorrect claims that we cannot curb the tobacco epidemic. J. Britton and co-workers state that the UK leads Europe in implementing tobacco control policies. We agree and would hope that many European countries will follow many of the

elements of the UK success. These include the exclusion of the tobacco industry from influence on policy making, tobacco display bans, large graphic health warnings on packs, plain packaging, increased tobacco taxes and minimum pack sizes. We would argue that if all the above evidence-based interventions, known to be free of harm and implemented, were implemented across the EU as they have been in the UK, we would be doing the 100 million smokers in the EU a huge favour. Some of us already use the UK as a shining example [18]. However, all these factors likely play a determining role in the decrement in smoking that so many e-cigarette advocates now ascribe to the sensible British use of e-cigarettes. Also, countries like the USA and Australia, with respectively 2.4% and 0.8% vapers, have experienced similar decline in smoking rates as the UK where 6.2% of the population is vaping.

We still agree with J. Britton and co-workers that more is needed to relieve the population in Europe and elsewhere from the perils of cigarette smoking. If e-cigarettes had been tested in randomised controlled trials similar to those required for smoking cessation drugs and were found to be as efficacious, if they were on prescription, and if they came in neutral packages and without all the artificial flavours, we would actually welcome them as an additional smoking cessation tool to the few reluctant smokers. This would be in consistence with the original harm reduction strategy (for *e.g.* drug addicts), aimed at those few we otherwise would give up upon. However, we will maintain that a harm reduction strategy in tobacco control is inappropriate at population level and that the inadequately regulated market for e-cigarettes and other alternative nicotine delivery products pose harm to non-smokers, in particular children and adolescents.

We also maintain that quitting smoking and quitting nicotine should go hand in hand. In the UK, half of vapers are smoking on a daily basis [12]. E-cigarettes will therefore not reduce the craving for nicotine in smokers and may actually stimulate new addiction in those who have never smoked. To us, this seems like an ideal scenario for any tobacco company and likely explains their huge investments in alternative nicotine delivery systems.

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The ERS approach to e-cigarettes is entirely rational

To the Editors:

The call for the European Respiratory Society (ERS) to change their e-cigarette and vaping policy, from honourable people with decades of experience fighting the evils of tobacco, is unfortunately misconceived. The three issues of greatest concern are acute toxicity, chronic toxicity and, most importantly, the effects on children and young people. The efficacy of e-cigarettes as an adjunct to smoking cessation are outwith the expertise of paediatric specialists, but we would ask for assurances that any benefits really do outweigh the risks to children and young people (below). Our comments on these key issues are as follows:

1) *Acute toxicity*: e-cigarette or vaping induced acute lung injury (EVALI) is an increasingly common entity [1] with near- or actual fatalities reported [1, 2]. The mechanism is unclear. Many but not all reported EVALI cases are related to the addition of cannabinoids. The abuse by children and young people of the hardware used for vaping, of itself, also gives rise to important safety concerns. It is wrong to assert that the acute toxicity of e-cigarettes *per se* is less than that of tobacco.
2) *Chronic toxicity*: the absence of tar and carbon monoxide from e-cigarettes is unequivocally to be welcomed [3]. However, *in vitro* data demonstrate that vaping liquids have their own unique toxicities in addition to those that overlap with tobacco [4]. There are now tens of thousands of "legal" fluids on the market containing a myriad of ingredients and the numbers are growing rapidly; for example, 7764 flavour labels were available on websites in 2013–2014; in 2016–2017 it was more than double, at 15 586 [5]. Some products are known to contain substances that are toxic to the respiratory tract and are in breach of European tobacco legislation [6]. Indeed, medium-term toxicities of e-cigarettes are already emerging [7]. It took decades for many of the harmful effects of conventional cigarettes to be elucidated and new concerns continue to arise. The important lesson from cigarette smoking is that it is impossible to make a rational assessment about the long-term risks of e-cigarettes.
3) *The effects on children and young people*: Our biggest concern is the public health emergency of e-cigarette uptake by children and young people. This is a child protection issue that the UK is failing to confront. As argued elsewhere [3], whether e-cigarettes are a gateway to smoking is irrelevant; they are a journey's end for nicotine addiction, with all the adverse effects of that chemical. E-cigarette uptake by children and young people has grown exponentially in the USA [8]. Their highly positive social media profile outstrips warnings against their use [9–11]. E-cigarette manufacturers have been found guilty of deliberately targeting young people by the US Food and Drug Administration [12]. The UK is not the USA, but it would be foolish to ignore what is

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The ERS has the right approach to e-cigarettes https://bit.ly/3ax72oe

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happening there. We welcome the focus of the next World Tobacco Day on preventing children being exposed to all forms of nicotine. If adult physicians continue to advocate for vaping as a means of harm reduction in adults, there must also be a coherent policy in place for protecting children.

The ERS policy aligns with those of the Federation of International Respiratory Societies [13], the American Academy of Paediatrics [14] and many other bodies. We believe its current statements are absolutely correct and should not be changed.

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